September 24, 2020

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
Swedish Match USA, Inc.
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
Phone: 804-787-5100
e-mail: Gerry.Roerty@swedishmatch.com

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: RESPONSE TO DEFICIENCY LETTER for PM0000593 – PM0000612

Dear Sir or Madam:

We received your correspondence dated July 24, 2020 (the "Deficiency Letter"), included as **Attachment A**, relating to the Agency's review of certain PMTAs that Swedish Match USA, Inc. ("Swedish Match", "we", "us" or "our") had previously submitted on March 4, 2020 for the following products (collectively, the "PM Reports):

- PM0000593: ZYN Cool Mint 3 mg
- PM0000594: ZYN Cool Mint 6 mg
- PM0000595: ZYN Peppermint 3 mg
- PM0000596: ZYN Peppermint 6 mg
- PM0000597: ZYN Spearmint 3 mg
- PM0000598: ZYN Spearmint 6 mg
- PM0000599: ZYN Wintergreen 3 mg
- PM0000600: ZYN Wintergreen 6 mg
- PM0000601: ZYN Citrus 3 mg
- PM0000602: ZYN Citrus 6 mg
- PM0000603: ZYN Coffee 3 mg
- PM0000604: ZYN Coffee 6 mg
- PM0000605: ZYN Cinnamon 3 mg
- PM0000606: ZYN Cinnamon 6 mg
- PM0000607: ZYN Smooth 3 mg

- PM0000608: ZYN Smooth 6 mg
- PM0000609: ZYN Chill 3 mg
- PM0000610: ZYN Chill 6 mg
- PM0000611: ZYN Fresh 3 mg
- PM0000612: ZYN Fresh 6 mg

As part of our reply to the Agency's request for additional information, we set forth below our Response to each request enumerated in the Deficiency Letter. This Response and its associated reference and attachments have been constructed as directed by FDA in the Deficiency Letter. Where appropriate, we have included any previously submitted information, as well as direct FDA to the section(s), page(s), and line number(s) of our prior PM Reports, including amendments, where this information can also be found.

Swedish Match submits that this Response and the information we are supplying in connection with this Response are trade secret, proprietary information that is protected under state and federal law from public disclosure. This information should therefore be handled in accordance with the security procedures adopted by FDA, in connection with enforcement of the FDCA.

We appreciate your consideration and evaluation of this Response concerning our PMTAs identified above. If you should have any questions, please let me know. (b) (6)

Sincerely yours,

(b) (6) [redacted]

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary

Document Attachments (List)

Attachment A – 20200924: CTP Deficiency Letter (STN) PM0000593 – PM0000612 Dated July 24, 2020
Attachment 1A – 20200924: Standard Test Method for Percent Dispersibility
Attachment 1B – 20200924: Dispersibility Results for Individual Products PM0000593-PM0000612
Attachment 1C – 20200924: ZYN Materials Before/After Solubility Measurement
Attachment 1Ca. – 20200924 Birch Water Solubility
Attachment 1D – 20200924: Solubility Results for Individual Products PM0000593-PM0000612
Attachment 1E – 20200924: Neff 1967 Thesis
Attachment 1F – 20200924: Water Solubility OECD-en
Attachment 2A – 20200924: PRD 201 SOP Z Measurement of Dimensions of ZYN Pouches
Attachment 2B – 20200924: Raw Data for Pouch Measurements
Attachment 4A – 20200924: Particle Size Distribution Measurement
Attachment 4B – 20200924: Particle Size Distribution Parameters for PM0000593-PM0000612
Attachment 5A – 20200924: Digard H *et al* Nicotine & Tobacco Res, Volume 15 (1), Jan 2013
Attachment 5B – 20200924: Maessen et al 2020
Attachment 6a.1 – 20200924: Manufacturing Equipment Type and Settings
Attachment 6a.2 – 20200924: Operation of the Fluid Bed SOP – Final Granulate

Attachment 6b.1 – 20200924: QAD 302 SOP A COA Review of Incoming Ingredients and Materials
Attachment 6b.2 – 20200924: Certificate of Analysis Celanese Sunett Acesulfame K Sweetener
Attachment 6d.1 – 20200924: Summary Validation Start-up 2019 Owe
Attachment 6e.1 – 20200924: 7.5.1.1.321 SOP C Performing Quality Checks in ZYN Pouch Formation
Attachment 6e.2 – 20200924: 7.5.1.1.323 SOP C ZYN Packing Defects-Detection and Correction
Attachment 7A – 20200924: ZYN Omnibus Flavor Study
Attachment 7B – 20200924: California Tobacco Facts and Figures 2019
Attachment 7C – 20200924: Article "Flavored e-cigarette use: Characterizing youth, young adult and adult users"
Attachment 8A – 20200924: SM18-01_Supplement_post-hoc_report_final_v1.0_02SEP2020
Attachment 8B – 20200924: ZYN 20 products_final_11SEP2020
Attachment 8C – 20200924: Data analysis 20 ZYN products (*NOTE - Excel Attachment)
Attachment 9A – 20200924: ZYN Post-Hoc Flavor Analysis

Environmental Assessment (EA) Attachments (List)

Attachment EA-A-20200924: (ZYN Chill 3 mg) Environmental Assessment
Attachment EA-B-20200924: (ZYN Chill 6 mg) Environmental Assessment
Attachment EA-C-20200924: (ZYN Cinnamon 3 mg) Environmental Assessment
Attachment EA-D-20200924: (ZYN Cinnamon 6 mg) Environmental Assessment
Attachment EA-E-20200924: (ZYN Citrus 3 mg) Environmental Assessment
Attachment EA-F-20200924: (ZYN Citrus 6 mg) Environmental Assessment
Attachment EA-G-20200924: (ZYN Coffee 3 mg) Environmental Assessment
Attachment EA-H-20200924: (ZYN Coffee 6 mg) Environmental Assessment
Attachment EA-I-20200924: (ZYN Cool Mint 3 mg) Environmental Assessment
Attachment EA-J-20200924: (ZYN Cool Mint 6 mg) Environmental Assessment
Attachment EA-K-20200924: (ZYN Fresh 3 mg) Environmental Assessment
Attachment EA-L-20200924: (ZYN Fresh 6 mg) Environmental Assessment
Attachment EA-M-20200924: (ZYN Peppermint 3 mg) Environmental Assessment
Attachment EA-N-20200924: (ZYN Peppermint 6 mg) Environmental Assessment
Attachment EA-O-20200924: (ZYN Smooth 3 mg) Environmental Assessment
Attachment EA-P-20200924: (ZYN Smooth 6 mg) Environmental Assessment
Attachment EA-Q-20200924: (ZYN Spearmint 3 mg) Environmental Assessment
Attachment EA-R-20200924: (ZYN Spearmint 3 mg) Environmental Assessment
Attachment EA-S-20200924: (ZYN Wintergreen 3 mg) Environmental Assessment
Attachment EA-T-20200924: (ZYN Wintergreen 6 mg) Environmental Assessment

Confidential Appendix (CA) Attachments (List)

Attachment CA-A-20200924: (ZYN Chill 3 mg) Confidential Appendix
Attachment CA-B-20200924: (ZYN Chill 6 mg) Confidential Appendix
Attachment CA-C-20200924: (ZYN Cinnamon 3 mg) Confidential Appendix
Attachment CA-D-20200924: (ZYN Cinnamon 6 mg) Confidential Appendix
Attachment CA-E-20200924: (ZYN Citrus 3 mg) Confidential Appendix
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Attachment CA-H-20200924: (ZYN Coffee 6 mg) Confidential Appendix
Attachment CA-I-20200924: (ZYN Cool Mint 3 mg) Confidential Appendix
Attachment CA-J-20200924: (ZYN Cool Mint 6 mg) Confidential Appendix
Attachment CA-K-20200924: (ZYN Fresh 3 mg) Confidential Appendix

Attachment CA-L-20200924: (ZYN Fresh 6 mg) Confidential Appendix
Attachment CA-M-20200924: (ZYN Peppermint 3 mg) Confidential Appendix
Attachment CA-N-20200924: (ZYN Peppermint 6 mg) Confidential Appendix
Attachment CA-O-20200924: (ZYN Smooth 3 mg) Confidential Appendix
Attachment CA-P-20200924: (ZYN Smooth 6 mg) Confidential Appendix
Attachment CA-Q-20200924: (ZYN Spearmint 3 mg) Confidential Appendix
Attachment CA-R-20200924: (ZYN Spearmint 3 mg) Confidential Appendix
Attachment CA-S-20200924: (ZYN Wintergreen 3 mg) Confidential Appendix
Attachment CA-T-20200924: (ZYN Wintergreen 6 mg) Confidential Appendix

Each request for additional information ("Deficiency") identified by number in the Deficiency Letter is reproduced below in bold type followed by Swedish Match's Response.

<u>Deficiency Question #1</u>. - All of your PMTAs provide information on the design parameters for the new tobacco products. However, your PMTAs do not include all of the design parameters necessary to fully characterize the new tobacco products. In order to adequately characterize the tobacco products, it is necessary to evaluate key design parameters. Powder granulation may improve the rapid dispersion and dissolution of powders introduced to liquids, referred to as instantization, through fluid bed processing to apply coating/binder or control the particle size, shape, surface area, and porosity2. Thus, the solubility and dispersibility of the new tobacco products are necessary to evaluate the instantization properties and the burst release rate of constituents. Provide the manufacturing data sheet specifications (MDSS) or the target specifications, upper and lower range limits, and complete test data for both of the following design parameters for each new tobacco product, for all PMTAs:

a. Powder granulate solubility

b. Powder granulate dispersibility

For each set of range limits, identify if the range limits correspond to process control parameters or product control parameters, as appropriate.

<u>Swedish Match Response to Deficiency Question #1</u>

Instantization is used to aid the wetting of powders which have a high amount of protein and therefore a tendency to form a gel layer preventing wetting of the powders (e.g protein isolates). Instantization is also used to aid the wetting of powders which are hydrophobic in character, such as powders with a high amount of free fat on the surface of the particles (e.g. whole milk powder). In many cases a surface-active ingredient is used to aid wettability and dispersibility of such powders.

ZYN granulate comprises no proteins and the content of hydrophobic components is limited to flavor components, which constitute a small fraction of the recipe. ZYN granulate comprises no surface-active ingredients.

ZYN granulate consists of a number of components, of which the vast majority are hydrophilic in character and easily dispersed and dissolved in water. Although micro crystalline cellulose (MCC) is insoluble in water, it is hydrophilic and easily dispersed in water. There are minor variations in the proportions of components between the different products (PM0000593-PM0000612) due to different flavors and nicotine strengths.

The granulation process when producing ZYN granulate aims to ensure a homogeneous granulate with a uniform pH and nicotine content. Furthermore, it aims to ensure a readily packable product which does not produce dust or contains particles that can leak through the pouch material. It does not aim to affect the solubility and dispersibility of the granulate.

In order to assess whether the granulation process, or the minor variations in the proportions of components, have an effect or not, the solubilities and dispersibilities were determined for the granulates of each of the product (PM0000593-PM0000612), as well as for the corresponding ungranulated ZYN materials. As demonstrated below, the granulation process performed when producing ZYN granulate does not have any meaningful effect on the solubility or the dispersibility of the ZYN granulates. Note that the ungranulated ZYN materials were made without the addition of hydroxypropylcellulose (HPC), which constitutes approximately (b) (4) of the granulate. The HPC constitutes approximately (b) (4) of the ungranulated ZYN materials, and the remainder is added during the granulation process.

The dispersibility of ZYN materials, before and after granulation, was measured with a method ***(See Attachment 1A – 20200924: Standard Test Method for Percent Dispersibility)*** according to ASTM 1945-02 "Standard Test Method for Percent Dispersibility". The average difference in dispersibility for ungranulated and granulated material, for PM0000593-PM0000612, is shown in Table 1. Results for the individual products PM0000593-PM0000612 are shown in ***Attachment 1B – 20200924: Dispersibility Results for Individual Products PM0000593 – PM0000612.***

Table 1. Average dispersibility (%) of ZYN materials before and after granulation.

(b) (4)

[redacted]

The results demonstrate that the ungranulated material already is easily dispersible before granulation, and further that the values are practically unchanged between granulated and ungranulated ZYN materials. The magnitude of the difference, approximately (b) (4) percentage points, is very small. As a comparison, in a study on the dispersibility of non-fat dried milk powder, a change of dispersibility from approximately (b) (4) to (b) (4) ((b) (4) [redacted] is described as a "small" decrease ***(See Attachment 1E - 20200924, page 83, Neff 1967)***.

The solubility of ZYN materials, before and after granulation, was measured with the method shown in ***Attachment 1C – 20200924: ZYN Materials Before/After Solubility Measurement***, based on the flask method in OECD Guideline 105 **(*See Attachment 1F – 20200924: Water Solubility OECD-en)***. The average difference in solubility for ungranulated and granulated material, for PM0000593-PM0000612, is shown in Table 2. Results for the individual products PM0000593-PM0000612 are shown in ***Attachment 1D – 20200924: Solubility Results for Individual Products PM0000593 – PM0000612***. The insoluble fraction is approximately (b) (4) corresponding to the amount of insoluble MCC in the granulate (approximately (b) (4)). As expected, the absence of approximately (b) (4) water-soluble HPC results in slightly lower solubility for the ungranulated ZYN material.

Table 2. Average solubility (%) of ZYN materials before and after granulation.

(b) (4)

[redacted]

The product control parameter acceptance criteria (average ± 3 standard deviations) presented in **Table 3** were determined based on the results in **Table 1**. and **Table 2**.

Table 3. Acceptance criteria for Powder Granulate Solubility and Dispersibility.

(b) (4)

[redacted]

Swedish Match considers annual testing sufficient due to the consistent values for dispersibility and solubility between the different products (PM0000593-PM0000612), as well as the lack of a substantial effect from the granulation process.

<u>Deficiency Question #2.</u> *- All of your PMTAs include design parameter specifications, but do not include data confirming that specifications are met. Complete test data is used to confirm that design parameter specifications have been met and that the product can be manufactured consistently. In order to confirm the target specifications are met, provide the test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for all of the following design parameters for each new product, for all PMTAs:*

a. Portion length
b. Portion width
c. Portion thickness

For each of the above parameters, provide the necessary data on a per unit of measurement of product basis (e.g., portion length should be reported in mm per pouch).
Additionally, for the design parameters that were tested according to national or international Standards, identify the standards and state what deviations, if any, from the standards occurred. Provide a justification for the sampling protocol used to obtain the test data and state why the data is representative of the final finished product.

<u>Swedish Match Response to Deficiency Question #2</u>

For test protocols: see ***Attachment 2A-20200924: PRD 201 SOP Z Measurement of Dimensions of ZYN Pouches*** of this response.

For quantitative acceptance criteria, data sets, and a summary of the results for all PMTAs see ***Attachment 2B-20200924: Raw Data for Pouch Measurements,*** of this response.

Swedish Match provided quantitative acceptance criteria and justification for specification for the parameters portion length, width and thickness in the original application at:

Section Path	**H. SCIENTIFIC STUDIES AND ANALYSES\H.1 Product Analysis and Manufacturing\H.1.2 Properties\H.1.2.3 Final Product\H.1.2.3.5 Justification of Specification**
Document Title	Final Product, Justification of Specification, Justification of Release Specification and Characterization Testing
Location in Document	Page 12 of 19, section 2.1.15 Pouch Dimensions
Document file name	File Name; h-1-2-3-5-fnl-pdt-release-specs-charact-testing.pdf

Swedish Match relies on pouch weight, pouch material width, and equipment settings/design to control pouch dimensions. We perform routine quality checks for the purpose of monitoring or controlling pouch length, width, and thickness. Line operators monitor pouch formation and document findings in Swedish Match (b) (4) [redacted].

When off-line measurements are made to describe these dimensions, simple (un-calibrated/non-standardized) tools such as rulers for width and length and calipers for thickness are used. Swedish Match does not have a standardized or validated test protocol for the measurement of these dimensions and does not consider these dimensions to be release criteria due to the fixed nature of the processing equipment and materials, which is described in more detail in the following paragraphs. ***Attachment 2A-20200924*** explains how length, width, and thickness are measured for ZYN finished pouches.

The pouch material width and length seam overlay (lengthwise seal) and the filling equipment's dosing tube dictate the width of the pouch. The dosing tube is a fixed size (diameter). The pouch material has a fixed width and wraps around the dosing tube. The pouch material overlaps around the tube where heating bars press the pouch material against the dosing tube to form a lengthwise seal. Swedish Match reasonably does not monitor this fixed condition or consider it to be a release criterion.

The length of the pouch is dictated by an equipment set point. A mechanic sets the desired stroke length on the equipment. Once set, the equipment pulls the desired length of pouch material down the length of the dosing tube. Sealing equipment with a set length seals one end and then the other as the pouch material advances. Once the mechanic sets stroke length during machine set up, it remains fixed as filling of pouches and packaging of products begins. Pouch lengths are checked every 15 minutes by using the Pouch length gauge. The pouch is placed into one of the gauge's pre-determined acceptable length slots. If the pouch does not fit, then settings are adjusted until the correct length is obtained and previous unverified pouches are discarded.

The thickness of the pouch is dictated by desired pouch weight and the other two dimensions, i.e., width and length. The pouch weight will define how full the pouch is and the other dimensions work to restrict the possible thickness. Given the physical constraints of the processing equipment itself, it is reasonable to assume that it is not necessary to measure these pouch specifications (length, width, and thickness) as part of batch analysis. Summary results in ***Attachment 2B-20200924*** demonstrates the consistency amongst batches and SKUs for these pouch measurements.

<u>Deficiency Question #3.</u> - All of your PMTAs provide information on instructions for product use including breaking the perforation of the side label. However, you do not provide any information on tamper-resistant packaging, such as whether the perforated side label is intended as an indicator for tampering, or how consumers are instructed to check for product tampering. Breakable perforations that are not necessary to open the package, are inadvertently broken while twisting the lid without attempting to break the perforation, or are readily broken during shipping and handling may not be noticeable indicators for tampering. Tamper resistance may provide evidence to consumers that tampering has occurred and mitigate the health hazards associated with exposure, especially to infants and children. Therefore, explain what product components, if any, are intended for tamper-resistance, provide a rationale for how those components provide adequate tamper-resistance, and explain how consumers are instructed to check for product tampering.

<u>Swedish Match Response to Deficiency Question #3</u>

Swedish Match is not sure what information within its PMTA application has given rise to this question. Indeed, among more than 100 million cans of ZYN sold, (b) (4) [redacted] Both cases were resolved to the consumers' satisfaction.

In addition, ZYN cans' tamper-resistance features are consistent with other similar cans within the moist snuff and snus categories. The side label of the can has a perforation and is intended to provide consumers with evidence of tampering. Specifically, there are instructions for use on the side label of the can that begin with "Break perforation on side label". A can in which the perforation of the side label has been broken, other than by the consumer, is intended to indicate tampering. The perforation is necessary in order to access the child resistant feature of the can and the material of the label. Other products in similar categories such as moist snuff and snus use nearly identical side labels to indicate potential tampering. It is commonly understood among consumers in these categories that the can has potentially been tampered if the perforation has been broken.

<u>Deficiency Question #4.</u> - All of your PMTAs provide the target specifications, upper and lower range limits, and test data for particle size distribution measured by dry sieve analysis. However, for this new product type, which is composed of powder granulates, you have not demonstrated that dry sieve analysis is a sufficient method to characterize the particle size distribution of the new tobacco products during normal use, since your granulation process may affect fluid interactions of the dry powder granulates. Specifically, the granulation process for the new tobacco products may affect the dispersion, dissolution, wettability, and bulk density of the powder material such that the particle size distributions of the new tobacco products measured under dry conditions may not sufficiently describe their characteristics, function, and interaction with fluids during normal use, including their instantization properties and burst release rate of constituents. For example, the presence of saliva may rapidly solubilize the granulated materials, in which case the measured particle size distribution of the dry granulates would have no bearing on the rate of dissolution and nicotine release. Particle size distributions describe the particle surface area and the accessibility of saliva to interact with the surface of the product, and are necessary to evaluate product instantization and dissolution characteristics such as burst release and overall rates of constituents released during actual use. Therefore, provide a rationale for why dry sieve

analysis would adequately characterize the particle size distribution of the new tobacco products under actual use conditions. Alternatively, for all of your PMTAs, you may provide the particle size distribution target specifications, range limits, and test data of the new tobacco products dispersed in fluid.

Swedish Match Response to Deficiency Question #4

Dry sieve analysis of ZYN granulate is used to monitor the process consistency and to ensure a packable granulate, as too small or too large particles could cause problems during pouch packing. Dry sieve analysis is not used to assess final product quality or release properties.

Stated another way, particle size distribution (PSD) measured by dry sieve analysis is not meant to characterize the particle size distribution of the new tobacco products during normal use.

For all the PMTAs, we now provide the particle size distribution target specifications, range limits, and test data of the new tobacco products dispersed in fluid.

The particle size distribution for the PMTA products dispersed in fluid was measured before and after granulation using the method shown in ***Attachment 4A – 20200924: Particle Size Distribution Measurement***. As shown Table 4, there was only slight differences in the PSDs, demonstrating that the granulation process does not substantially affect the PSD of the PMTA products dispersed in fluid. Results for the individual products PM0000593-PM0000612 are shown in ***Attachment 4B – 20200924: Particle Size Distribution Parameters for PM0000593-PM0000612***.

Table 4. Particle size distribution parameters (µm) in dispersion.

(b) (4)

[redacted]

The particle size distribution target specifications and range limits presented in Table 5, for the new tobacco products dispersed in fluid, were determined based upon results shown in Table 4 and **Attachment 4B - 20200924**.

Table 5. Acceptance criteria for PSD parameters.

(b) (4)

[redacted]

Swedish Match considers annual testing of PSD in dispersion sufficient due to consistence in PSD in dispersion results between the different products (PM0000593-PM0000612).

<u>Deficiency Question #5.</u> - All of your PMTAs identify potential for product failure and misuse, including small pouch dimensions that may increase the risk of swallowing the pouches, consumer use studies that identify 6.3% of users that cut the pouches open and use the pouch contents, and consumer complaint reports that identify 91% of contacts related to manufacturing and potential adverse events involve broken pouches or nicotine residue in container and on pouches and 2.4% involve swallowing the pouch. However, you do not discuss human factors for the new tobacco products nor provide information on mitigating manufacturing defects, foreseeable hazards, or potential for misuse. Manufacturing defects involving broken pouches or nicotine residue outside of the pouches, as well as product misuse involving opening the pouches, may increase the potential for exposure to non-intended users as well as increase any health effects of skin contact, while foreseeable hazards involving ingesting the pouch contents or swallowing the intact pouch may increase the potential for associated health effects. Therefore, provide a rationale for why the identified foreseeable hazards, potential for misuse, and product manufacturing defects do not pose health hazards to users and non-users.

<u>Swedish Match Response to Deficiency Question #5</u>

In G.6., Section 7.8 of the ZYN PMTAs, Swedish Match demonstrated that any product failure or misuse would not have a health impact upon the consumer and Section 8 addressed that there are no possible impacts on non-users. Specifically, a consumer would have to consume the equivalent of 44-89 six milligram ZYN pouches to reach a lethal level and would experience severe nausea well before reaching such a level. We are unaware of a single instance of this occurring with a Swedish Match product, including ZYN. And, while some consumers have raised questions about potentially swallowing a pouch or its contents (either by emptying the contents or due to a pouch breaking), neither of these situations could give rise to an adverse event.

In the event a pouch was cut open and the consumer used the pouch content in loose form, there is no health risk differentiation to the profile of the product. Disbursement of the pouch content does not alter the health risk profile per se, as the pouch material is intended as a carrier during storage, but not a filter during use. In a similar way, consumption of loose Swedish snus is not considered different from pouched Swedish snus when it comes to health risks. It has been shown that the pharmacokinetic profile does not differ between loose snus (10.8mg nicotine) and pouched snus (10.7 mg nicotine). Both products were shown to have the same C_{max} and t_{max} values and similar $AUC_{0\text{-}120\ mn}$ (Digard H *et al* Nicotine & Tobacco Res, Volume 15 (1), Jan 2013 – ***See Attachment 5A - 20200924***)

Table 3. Pharmacokinetic Parameters of Plasma Nicotine Following Single Use of Different Tobacco Products and a Nicotine Gum

	Product (nicotine content) $N = 20$					
	Cigarette (14.6 mg)	Loose snus (10.8 mg)	Loose snus (27.1 mg)	Pouched snus (10.7 mg)	Pouched snus (14.7 mg)	Nicotine gum (4.2 mg)
AUC_{0-120} ng.h/ml						
Geometric mean*	14.8	16.0[a]	26.9[b]	16.8[a]	20.4[c]	13.1
Geometric coefficient of variation %	30.4	31.2	23.8	39.6	37.6	28.3
C_{max} ng/ml						
Geometric mean*	12.8	10.8[a]	17.9[b]	10.8[a]	13.4[a]	9.1
Geometric coefficient of variation %	41.3	34.4	22.8	41.4	39	28.6
t_{max} h						
Median	0.117	1.00	1.00	1.00	1.00	0.75
Range: minimum–maximum	0.083–0.517	0.75–1.50	0.75–1.50	0.33–1.50	0.75–1.50	0.33–1.50

Note. *Means with different letters are significantly different according to Tukey's multiple comparison test ($p < .05$).

If swallowed, the nicotine and other food-grade (or higher) ingredients found in ZYN are not harmful to adults. According to the Center for Disease Control, an average adult would need to consume at least 50 to 60 mg of nicotine to develop serious overdose symptoms. Based on a study of case reports of nicotine intoxication by e-cigarette liquids, the lethal dose is assumed to be 4.4 to 8.9-fold higher (Maessen et al 2020 – ***See Attachment 5B - 20200924***). As noted above, this is somewhere between 44 and 89 ZYN six milligram pouches and such an exposure would result in nausea and vomiting well before the entire dose is absorbed. This circumstance may help to explain why no lethal snus intoxication has ever been reported to the Swedish Poisons Information Center, despite the widespread use of snus in Sweden for over more than a century, with about one-million current users.

The potential risk of any health effects on skin contact is judged as low. ZYN products do not contain any ingredients, including nicotine and flavors, in concentrations together with the calculated exposure would lead to any unacceptable risk when it comes to acute toxicity as well as irritation or sensitization Continuous production quality improvements have reduced the number of consumer complaints.

The production facilities for ZYN have a weight check system in place to ensure each can of ZYN has exactly 15 pouches and the contents weigh 6g. On the production line, each can is weighed to ensure a tolerance of no more than 10%. Any variance to this weight tolerance caused by an underfilled or smaller pouch will be rejected.

(b) (4)

[redacted]

(b) (4)

[redacted]

<u>Deficiency Question #6.</u> - All of your PMTAs include a description of manufacturing steps and manufacturing process flow charts. However, the information provided does not include all the necessary information for the processes and equipment used, including process control methods and parameters, performance criteria tolerance limits, and test data and methodology related to semi-finished or finished products. Without this information, it is unclear whether the manufacturing processes and quality controls you use assure that the new tobacco products can be manufactured consistently. For each step of the finished powder granulate manufacturing and packing processes, provide the information below:

a. Equipment type and settings, including sieve settings

b. Procedures to ensure that the incoming materials meet your specifications or requirements (e.g., procedures to verify the component mixing specifications) and corresponding test data

c. Storage conditions such as temperature and humidity for materials and components and corresponding test or monitoring data

d. In-process specifications or expected performance and tolerance values and associated test data for the bulk finished powder granulates

e. In-process specification or criteria and corresponding test data for pouch samples for the parameters listed in Section G.1.5.1.2: weight, appearance, and seal integrity

Additionally, for any quality control tests that were tested according to national or international standards, identify the standards and state what deviations, if any, from the standards occurred.

<u>Swedish Match Response to Deficiency Question #6</u>

Collectively the information provided in section *<u>H.1.2.3.4 Batch Analysis</u>* which scrutinizes particle size, characterizing results and routine release results should provide enough evidence that manufacturing processes and quality controls in use assure that the new tobacco products are manufactured consistently. Out of an abundance of caution, Swedish Match provides additional requested information below.

<u>Swedish Match Response to Deficiency 6a.</u>

Equipment type and settings, including sieve settings ***(See Attachment 6a.1 – 20200924: Manufacturing Equipment Type and Settings)***. Settings of the fluid bed were optimized during the validation process of the fluid bed. Because of the automation used in the process, operators do not adjust any settings during the manufacturing of finished powder granulate. ***(Attachment 6a.2 – 20200924: Operation of the Fluid Bed SOP – Final Granulate).***

Note that Swedish Match is providing an updated Fluid Bed Operation SOP for the Owensboro factory, which is intended to replace and supersede any previous versions of this SOP. See ***Attachment 6a.2 - 20200924.***

Swedish Match Response to Deficiency 6b.

Procedures to ensure that the incoming materials meet specifications or requirements was provided in original PMTA application at Section *H.1.4.3 Swedish Match Corporate Applicable Procedures*. However, the reference in section *G.3 Product Manufacturing and Controls Summary* was unfortunately omitted, why its enclosure might have been overlooked.

Document Titles	Document file names
Incoming Materials Controls SOP (Owensboro, KY)	h-1-4-3-sm-ky-sop-incoming-materialscontrols.pdf
Incoming Materials Controls SOP (Kungälv, SE)	h-1-4-3-sm-se-sop-incoming-materialscontrols.pdf

Swedish Match is providing an updated Incoming Materials Controls SOP for the Owensboro factory, which is harmonious with the corresponding SOP for the Kungälv factory and is intended to replace and supersede any previous versions of this SOP **(See *Attachment 6b.1 – 20200924: QAD 302 SOP A COA Review of Incoming Ingredients and Materials).***

As described in the SOP, when a ZYN ingredient or material is received at Swedish Match, the manufacturer's Certificate of Analysis (COAs) is reviewed to ensure that specifications are met. The material is visually inspected to verify that it is correct and free of defects.

Swedish Match is providing a sample Certificate of Analysis for a ZYN ingredient ***(See Attachment 6b.2 – 20200924: Certificate of Analysis Celanese Sunett Acesulfame K Sweetener)***.

Swedish Match Response to Deficiency 6c.

Swedish Match stores all materials and components for ZYN manufacturing according to the manufacturer's recommendations. Table 6c.1, below, provides the storage information for the ZYN materials.

Table 6c.1, Storage Conditions for ZYN Ingredients

ZYN Ingredients			
Manufacturer's Recommended Storage Conditions			
Part #	**Item Name**	**Temperature Range**	**Humidity Range**
410-8100	Nicotine Bitartrate Dihydrate (Nicotine Salt)	<25 degrees C, ensure good ventilation/exhaustion at the workplace	keep sealed

410-8150	Sodium Bicarbonate	Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Incompatible Materials: Strong acids, strong bases, strong oxidizers. Water. Lime. Storage Temperature: < 65 °C (< 150 °F)	keep sealed
410-8200	Sodium Carbonate Light	Keep in an area equipped with alkali resistant flooring. Store in original container. Keep tightly closed in a dry and cool place. Avoid moisture. Product is hygroscopic. Do not store near acids. Keep away from food, drink and animal feeding stuffs	n/a
410-8250	HPC	Keep container tightly closed in a dry and well-ventilated place.	n/a
410-8300	Maltidex	Take measures to prevent the build up of electrostatic charge. Avoid dust formation. Keep away from heat and sources of ignition. Potential dust explosion hazard. Keep tightly closed in a dry and cool place. Keep in a dry, cool place. Keep away from direct sunlight. Incompatible products: oxidizing agents	n/a
410-8350	MCC Avicel	<25 degrees C	keep sealed
410-8400	Ace-K Pharma Grade Type C	Take measures to prevent the build up of electrostatic charge. Avoid dust formation. Keep away from heat and sources of ignition. Potential dust explosion hazard. Keep tightly closed in a dry and cool place. Keep in a dry, cool place. Keep away from direct sunlight. Incompatible products: oxidizing agents	n/a
410-8450	Ethyl Alcohol 95% 190 Proof (Ethanol)	Keep away from heat, sparks and open flame. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Store in a cool, dry place out of direct sunlight. Store in tightly closed container. Store in a well-ventilated place. Keep in an area equipped with sprinklers. The product is stable and non-reactive under normal conditions of use, storage and transport.	n/a
410-8500	Menthol Flavor	18-20 degrees C, keep container tightly closed in a dry and well-ventilated place.	<70% rel humidity
410-8550	Peppermint Flavor	18-20 degrees C, keep container tightly closed in a dry and well-ventilated place.	<70% rel humidity
410-8600	Spearmint Flavor	18-20 degrees C, keep container tightly closed in a dry and well-ventilated place.	<70% rel humidity
410-8650	Wintergreen Flavor	18-20 degrees C, keep container tightly closed in a dry and well-ventilated place.	<70% rel humidity
410-8700	Coffee Flavor	18-20 degrees C, keep container tightly closed in a dry and well-ventilated place.	<70% rel humidity
410-8750	Cinnamon Flavor	18-20 degrees C, keep container tightly closed in a dry and well-ventilated place.	<70% rel humidity
410-8800	WS3	n/a	n/a
410-8850	Lemon Flavor	Ambient / 10-30°C (50-85°F). Keep container tightly closed in a dry and well-ventilated place.	n/a
410-8900	Eucalyptus Flavor	Ambient / 10-30°C (50-85°F). Keep container tightly closed in a dry and well-ventilated place.	n/a

Swedish Match Response to Deficiency 6d.

Swedish Match has validated the manufacturing processes in order to assure that the new tobacco products can be manufactured consistently. The expected performance and tolerance

values and associated test data for the bulk finished powder granulates can be found in the validation report for the granulation process ***(See Attachment 6d.1 – 20200924: Summary Validation Start-up 2019 Owe)***.

Final Product Routine Release Specifications for moisture, pH and total nicotine demonstrate products are consistently manufactured. Final Product Specifications can be found in section H.1.2.3.1 Routine Release Specification and Characterization Requirements.

Final Product Characterization test data can be found in sections H.1.2.3.4.1 Final Product Characterization 3mg and H.1.2.3.4.2 Final Product Characterization 6mg. Test methods are available in section H.1.2.3.2 Analytical Procedures; the applicable file names are: h-1-2-3-2-analytical-procedures-moisture.pdf, h-1-2-3-2-analytical-procedures-ph.pdf, h-1-2-3-2-analytical-procedures-alkaloids.pdf.

Final Product Routine Release Results, Certificates of Analysis can be found in sections H.1.2.3.4.1 Final Product Routine Release Results, Certificates of Analysis 3mg and H.1.2.3.4.2 Final Product Routine Release Results, Certificates of Analysis 6mg. Test methods are available in section H.1.2.3.2 Analytical Procedures; the applicable file names are: h-1-2-3-2-analy-proced-halogen-moisture-owensboro.pdf, h-1-2-3-2-analytical-procedures-ph-owensboro.pdf and h-1-2-3-2-analytical-procedures-nicotine-owensboro.pdf.

Swedish Match Response to Deficiency 6e.

As mentioned in Section *G.1.5.1.2*, pouches are checked at set intervals by the operators during production. This is done to ensure that the process is running effectively and that the pouches are being formed as expected.

As mentioned in Swedish Match's response to deficiency 6.a above, this in process step is used to verify that the MERZ pouch machine is operating properly to produce pouches within specification. These results are recorded by operators into Swedish Match's ERP system.

See ***Attachment 6e.1 – 20200924: 7.5.1.1.321 SOP C Performing Quality Checks in ZYN Pouch Formation*** for a complete description of this process and ***Attachment 6e.2 – 20200924: 7.5.1.1.323 SOP C ZYN Packing Defects-Detection and Correction*** for the complete instructions on how operators respond if the pouches fail the test for weight, appearance, and seal integrity at this step of the process.

Note that Swedish Match is providing updated Quality Checks in ZYN Pouch Formation SOP for the Owensboro factory, which is intended to replace and supersede any previous versions of this SOP.

Deficiency Question #7. - All of your PMTAs provide data on intentions to use and product appeal for the "cool mint" variety, but you did not provide information on your other flavors nor did you provide scientific justification for extrapolating findings from the cool mint flavor to the remaining nine flavors. In particular, you provided no data or information on the potential impact of different flavor profiles such as coffee, citrus, and cinnamon. Further, you

reported that you have "chosen flavors for ZYN that appeal more toward adult consumers and avoid appealing to youth;" however, you present no data to support this statement. Additionally, we note that you have developed the marketing messages in response to findings from "consumer marketing research" though findings from these studies were not included. These research studies may have information about appeal and/or likelihood of use of these flavors and nicotine strength varieties. Scientific research has indicated that that flavored tobacco products are appealing, particularly to youth, and flavored tobacco products pose a risk to youth initiation and use. You did not provide a scientific rationale for extending findings from young adults to youth. Because of this, these PMTAs raise concerns about these products from a social science perspective. FDA needs information on the appropriateness of including young adults as a proxy for youth in these studies and information on the appropriateness of using cool mint in this study as a proxy for the other ZYN flavors and nicotine strength.

Swedish Match Response to Deficiency Question #7

For purposes of organization, we are breaking down our reply into several parts.

In the first part, Swedish Match addresses: ***"All of your PMTAs provide data on intentions to use and product appeal for the "cool mint" variety, but you did not provide information on your other flavors nor did you provide scientific justification for extrapolating findings from the cool mint flavor to the remaining nine flavors. In particular, you provided no data or information on the potential impact of different flavor profiles such as coffee, citrus, and cinnamon".***

The PMTAs provided consumer data in the form of a Likelihood of Use Study ([redacted]) and a Prospective Study ([redacted]). This question pertains to [redacted] and Swedish Match assumes that question 9 pertains to [redacted]. To the extent that our responses to question 9 are relevant to this question 7, we incorporate the question 9 responses by reference. [redacted] explored the question: "How does exposure to the ZYN description and packaging label (referred to as 'stimuli' going forward) affect intentions, behaviors, and perceptions of Tobacco/Nicotine Product (TNP) users and TNP non-users, when compared pre- to post-exposure?" For purposes of the survey, the participants were informed that ZYN® comes in 2 strengths (3 and 6 mg) and six varieties "Cool Mint", "Peppermint", "Spearmint", "Wintergreen", "Cinnamon", "Coffee") ([redacted]). [redacted] therefore does apply to more than just Cool Mint ZYN.

However, to further investigate the impact of flavors, including Citrus, Swedish Match commissioned an Omnibus Survey including [redacted] based on tobacco use and five age strata. ***(See Attachment 7A – 20200924: ZYN Omnibus Flavor Study)*** Key conclusions of this Omnibus Survey were:

- There is little variation in likelihood to buy ZYN across the variety of offerings. Patterns of flavor preference are similar within each cohort and within each age group.
- Never smokers have the lowest interest in buying ZYN and current smokers have moderate interest, but there is little difference among flavors.
- Regarding age, older adults 55-64 have the lowest levels of interest in buying ZYN, followed by those age 21-24, again with little difference by flavor.
- There is little variation in likelihood to buy ZYN across the various flavor offerings. Patterns of flavor preference are similar within each cohort and within each age group.

- Sales data demonstrate that the mint and wintergreen flavors remain the preferred choice from year to year, and that the majority of consumers prefers the 6 mg strength.
- Data from consumer research (b) (4) [redacted] demonstrates that ZYN has very limited appeal to never- and former tobacco users regardless of flavor. Sales data shows that the mint and wintergreen flavors and the 6 mg strength have the greatest consumer appeal. Expansion of available flavor varieties will not increase the consumer likelihood to buy ZYN nicotine pouches.

In the second part, Swedish Match addresses***: "Further, you reported that you have "chosen flavors for ZYN that appeal more toward adult consumers and avoid appealing to youth;" however, you present no data to support this statement. Additionally, we note that you have developed the marketing messages in response to findings from "consumer marketing research" though findings from these studies were not included. These research studies may have information about appeal and/or likelihood of use of these flavors and nicotine strength varieties. Scientific research has indicated that that flavored tobacco products are appealing, particularly to youth, and flavored tobacco products pose a risk to youth initiation and use.***

In selecting flavor options for ZYN one key piece of guidance for Swedish Match was the Center for Tobacco Product's TPL review for our General Snus PMTAs. The following was stated in the TPL "The proposed products are reported to have flavors such as mint, wintergreen, or tobacco character with citrus. These proposed flavors are consistent with traditionally available [smokeless tobacco] flavors and are not novel flavors that likely increase appeal to youth." In other words, simply because a tobacco product comes in certain flavors does not mean the product appeals to youth or contributes to youth use or initiation.

As an example, youth usage rates for smokeless tobacco products (which as discussed below primarily come in flavors in the mint family) are low. In California, one of the largest markets for ZYN, according to the California Department of Public Health's California Tobacco Fact and Figures 2019 only .8% of California teens have tried smokeless tobacco, even one time in a period of 30 days. ***(See Attachment 7B – 20200924: California Tobacco Facts and Figures 2019)***

Further, youth usage rates for smokeless tobacco have been trending downwards. According to the 2019 Youth Tobacco Survey, from 2011 to 2019, current use of smokeless tobacco went down among middle and high school students:

- Nearly 2 of every 100 middle school students (1.8%) reported in 2019 that they had used smokeless tobacco in the past 30 days—a decrease from 2.2% in 2011.
- Nearly 5 of every 100 high school students (4.8%) reported in 2019 that they had used smokeless tobacco in the past 30 days—a decrease from 7.9% in 2011.

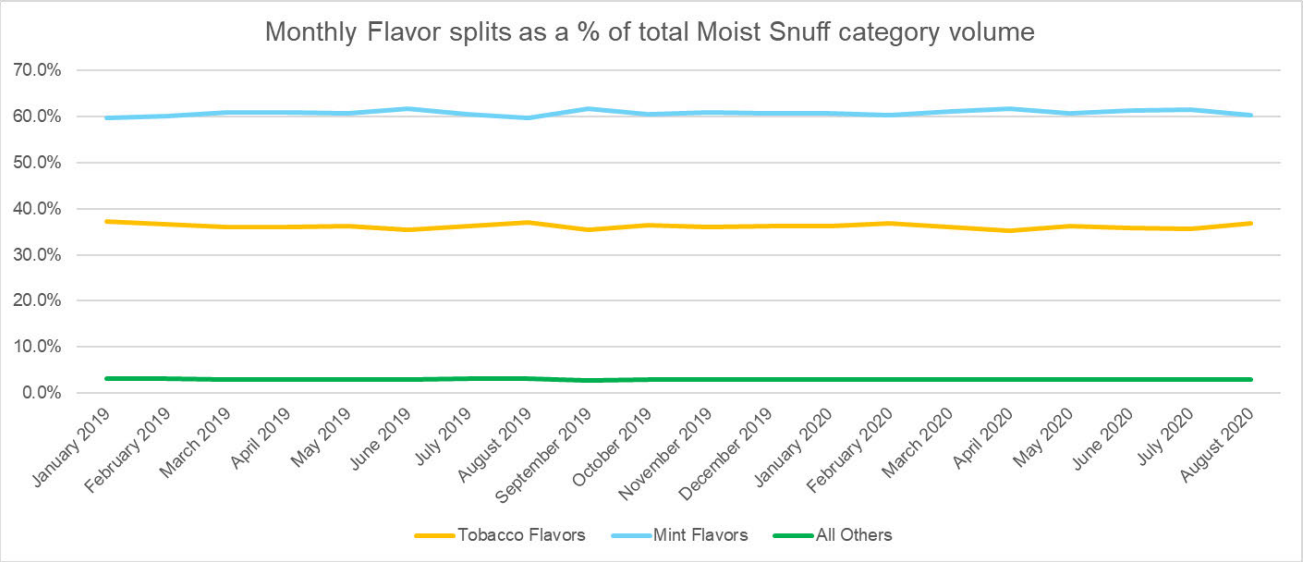
There is no evidence that the ZYN flavors would be likely to appeal to youth, while there is an abundance of evidence that youth usage rates for smokeless tobacco products are low and trending downwards. Should ZYN be granted a PMTA marketing order Swedish Match would be subject to annual reporting/post market surveillance requirements. Should any of these conditions change the Center for Tobacco Products would have the ability to revoke the marketing order.

What follows is additional information relevant to this second part of Question 7.

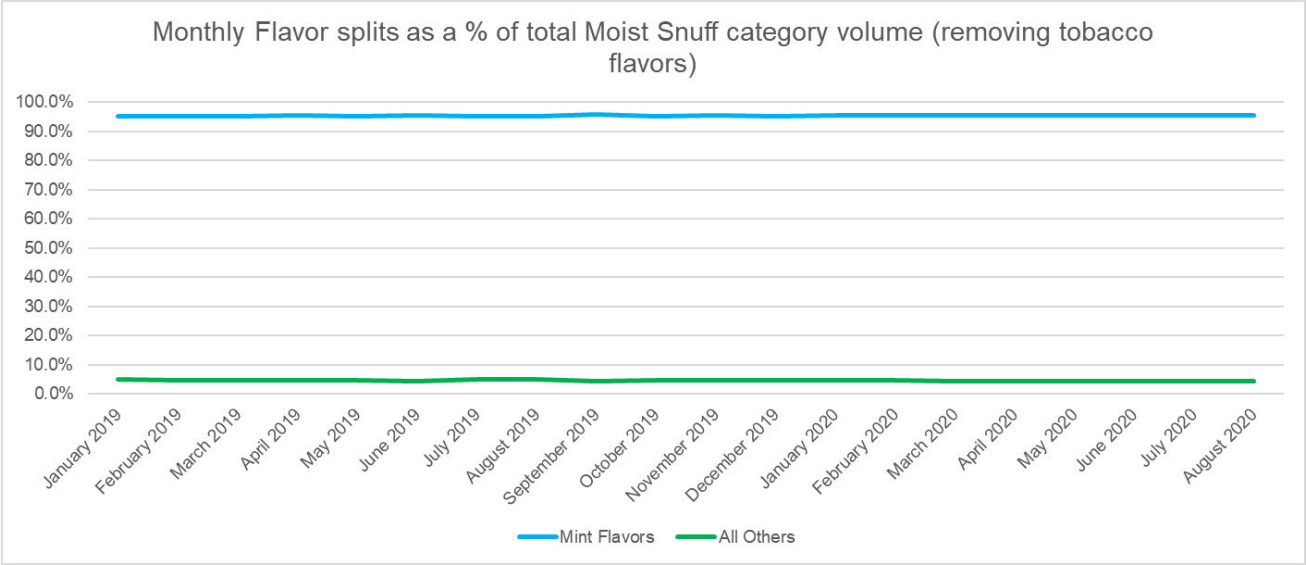
Flavor Development:

- ZYN flavors were initially developed to emulate either what was currently available as a moist snuff flavor or focused on a flavor that is considered to reach an adult audience.
- Wintergreen, Cool Mint, Spearmint and Peppermint all fall within the mint family which represents 95% of the flavored moist snuff category.
- Citrus is also a flavor that has been available in moist snuff.
- Coffee is a flavor that is largely considered to reach an adult audience and cinnamon was chosen due to its spicy profile, a profile that is not widely considered to be attractive to youth. (see, https://www.sciencedirect.com/science/article/pii/S2211335516301346) ***– (See Attachment 7C – 20200924: Article "Flavored e-cigarette use: Characterizing youth, young adult and adult users")***
- Chill and Smooth are unflavored varieties to emulate roughly 36% of the moist snuff category that has no characterizing flavor.

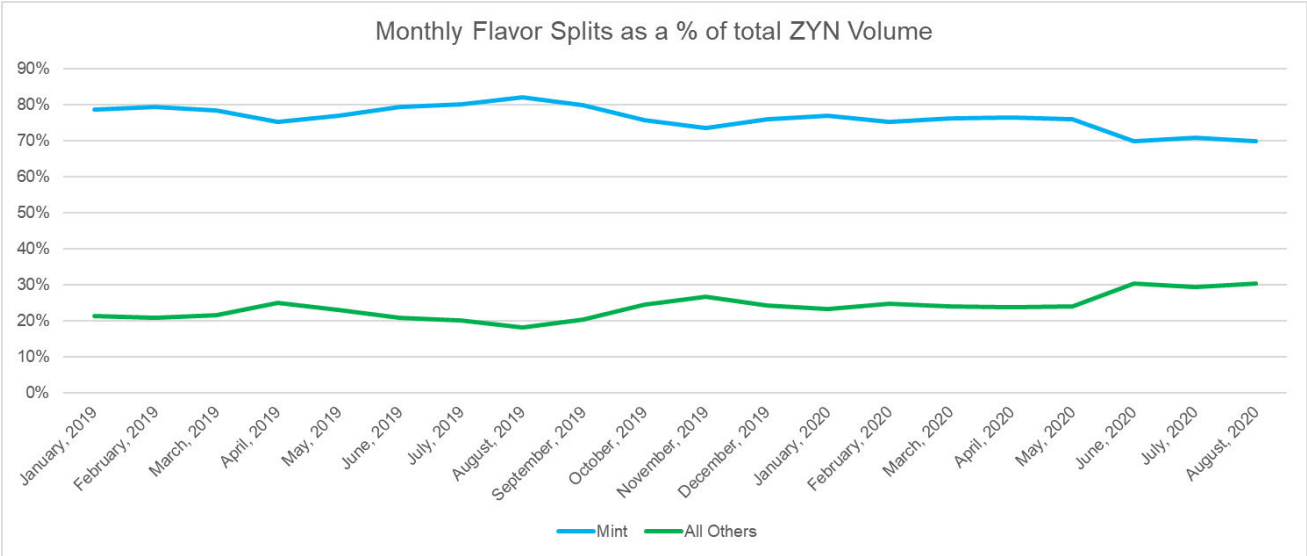
The charts below show the close correlation between the sales of smokeless products and ZYN products.



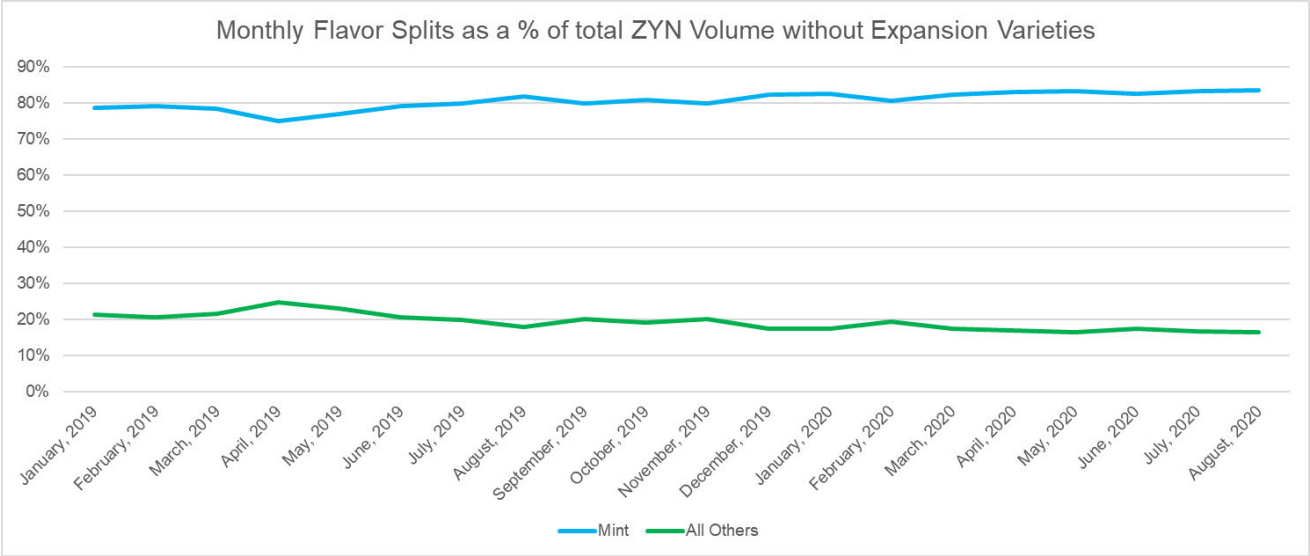
Source: MSA distributor shipments, all moist snuff brands
Tobacco Flavors include: Classic, Natural, Straight
Mint Flavors include: Cool Spearmint, Mint, Peppermint, Smooth Wintergreen, Spearmint, Wintergreen, Wintergreen Chill
All Others include: Apple, Berry, Cherry, Citrus, Grape, Peach



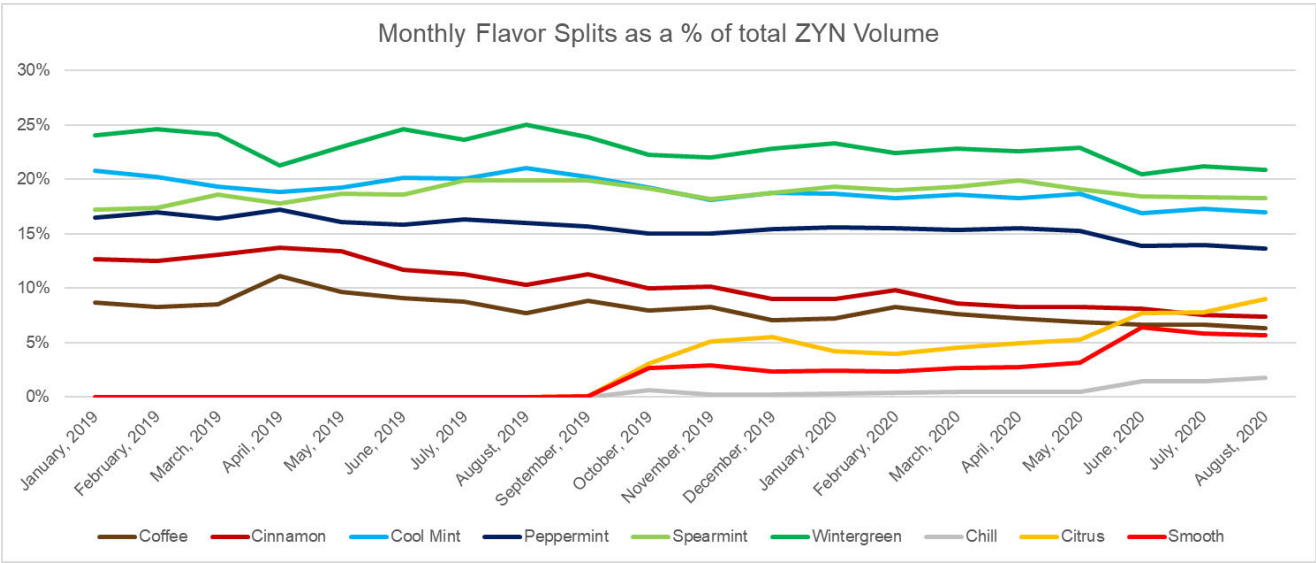
Source: MSA distributor shipments, all moist snuff brands
Tobacco Flavors include: Classic, Natural, Straight
Mint Flavors include: Cool Spearmint, Mint, Peppermint, Smooth Wintergreen, Spearmint, Wintergreen, Wintergreen Chill



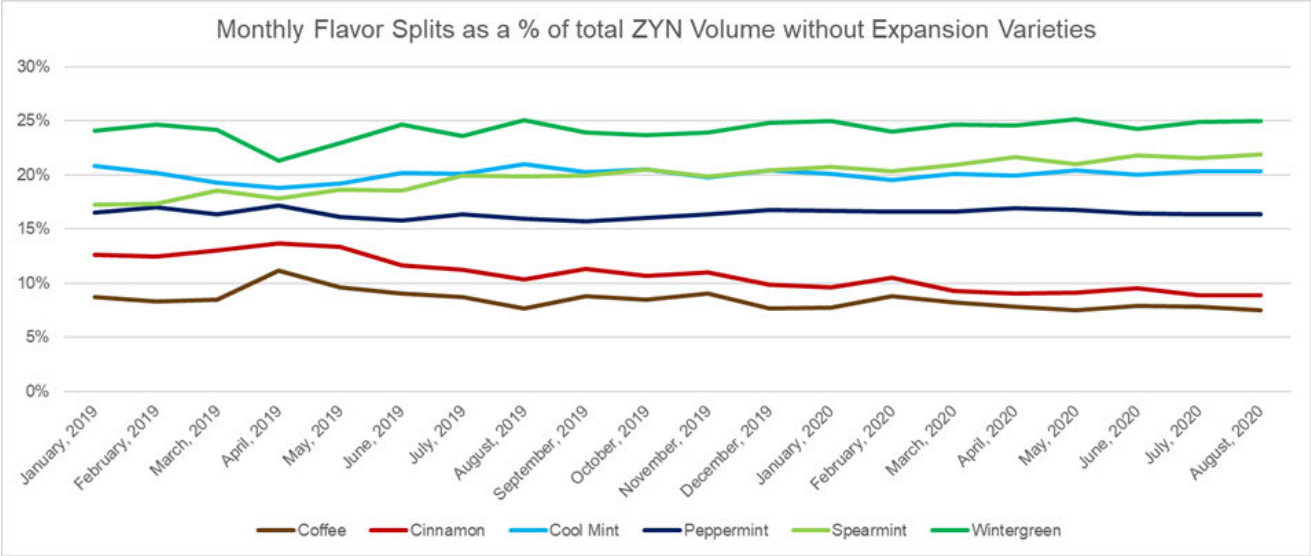
Source: Swedish Match direct shipments
Mint Flavors include: Cool Mint, Peppermint, Spearmint, Wintergreen
All Others include: Coffee, Cinnamon, Chill, Citrus, Smooth (last 3 expanded distribution during time period)



Source: Swedish Match direct shipments
Mint Flavors include: Cool Mint, Peppermint, Spearmint, Wintergreen
All Others include: Coffee, Cinnamon (only flavors that have consistent distribution during time period)



Source: Swedish Match direct shipments



Source: Swedish Match direct shipments

Here we address, this part of the CTP's question 7: ***Additionally, we note that you have developed the marketing messages in response to findings from "consumer marketing research" though findings from these studies were not included.***

Response:

While the ZYN concept, brand and messaging were being developed, observational research was conducted among tobacco consumers.

The objective of this research was to determine if a nicotine pouch product would be of interest to existing adult tobacco consumers, and if so, how should the new product be introduced to consumers.

This research was conversational in nature, aimed at giving general guidance. Therefore, data or definitive findings were not produced.

Approach to Consumer Research:

- A 10-week prospective study (b) (4) [redacted] was conducted among ZYN consumer in preparation for the PMTA.
- This study remains the most reliable for predicting consumer behavior and demographics for several reasons:
    - A consumer must have purchased a specially marked can of ZYN to be eligible for the study creating a very reliable group of verified consumers.
    - This study was conducted roughly 1.5 years after the product being introduced into market (11 states).

- With an April 2019 expansion to the rest of the country, most of the US population falls within the expansion states that now have had the product for approximately 1.5 years – roughly the time in market as when the study was done.
- The trend of flavors during the entire time period in market has had remained relatively constant.

In this final section, Swedish Match addresses -- ***You did not provide a scientific rationale for extending findings from young adults to youth. Because of this, these PMTAs raise concerns about these products from a social science perspective. FDA needs information on the appropriateness of including young adults as a proxy for youth in these studies and information on the appropriateness of using cool mint in this study as a proxy for the other ZYN flavors and nicotine strength.***

Surveying youth for new tobacco/nicotine products brings up a complex legal dilemma as tobacco manufacturers need to be cautious regarding promoting their products to youth.

According to the FDA proposed rule on Premarket Tobacco Product Applications and Recordkeeping Requirements, studies using minors should have a narrow research scope and be as focused as possible given sensitivities around the conduct of research in youth populations. Specifically, research priorities for youth should be focused on key questions relating to use (e.g., prevalence of use, characteristics of users, and patterns of use), risk perception, and intention to use/ susceptibility among non-users. **Studies conducted among youth should avoid exposing youth to advertisements or marketing material for tobacco products**. Study design and methodology for these ZYN PMTA studies utilized marketing information that would have informed youth regarding the ZYN product, thus Swedish Match and (b) (4) determined it not appropriate to include them in this research.

Another consideration in the decision to exclude youth was that the product ZYN most resembles, snus and moist snuff, has very low youth utilization and the suggestion by FDA that inferences regarding youth may potentially be extrapolated from young adults, as well as derived from existing sources of data, reviews of published scientific literature, and/or bridging information; (84 Fed. Reg. 50,566, 50,606 (Sep. 25, 2019) [4].

Per CDC, smokeless tobacco use among youth is far lower than use of cigarettes and ENDS products.

- From 2011 to 2019, current use of smokeless tobacco went down among middle and high school students:[1,2,3]
- Nearly 2 of every 100 middle school students (1.8%) reported in 2019 that they had used smokeless tobacco in the past 30 days—a decrease from 2.2% in 2011.
- Nearly 5 of every 100 high school students (4.8%) reported in 2019 that they had used smokeless tobacco in the past 30 days—a decrease from 7.9% in 2011

In order to minimize the exposure of marketing materials to youth, Swedish Match oversampled the young adult population (age 18-24 prior to the legal age of purchase changing to 21 (b) (4) and 1(b) (4) and 21-24 afterwards (Omnibus Survey)) to be a proxy for youth. And, among young adults surveyed who were non-users, there was little to no interest in ZYN, irrespective of the flavor/variety or strength.

1. Gentzke AS, Creamer M, Cullen KA, et al. *Vital Signs*: Tobacco Product Use Among Middle and High School Students—United States, 2011–2018. Morbidity and Mortality Weekly Report 2019;68:157–164.
2. Wang TW, Gentzke AS, Creamer MR et al. Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019. Morbidity and Mortality Weekly Report, 2019;68(12) [accessed 2019 Dec 6].

3. Centers for Disease Control and Prevention. Tobacco Product Use Among Middle and High School Students – United States, 2011 and 2012. Morbidity and Mortality Weekly Report, 2013;62(45):893-7 [accessed 2019 Feb 28].
4. Federal Register, 84 Fed. Reg. 50,566, 50,606 (Sep. 25, 2019). https://www.federalregister.gov/documents/2019/11/26/2019-25675/premarket-tobacco-product-applications-and-recordkeeping-requirements-reopening-of-the-comment

Deficiency Question #8. ***- You included limited abuse liability information for some ZYN Smooth, Peppermint, Spearmint, and Wintergreen products (PM0000607, PM0000608, PM0000595, PM0000597, PM0000599) and did not submit clinical studies or bridging information to peer-reviewed literature to address the abuse liability of the other flavors (i.e., Chill, Cinnamon, Citrus, Coffee, Cool Mint, and Fresh; PM0000593, PM0000594,PM0000601-PM0000606, PM0000609-PM0000612) and nicotine contents. Because significant differences in nicotine PK emerged between ZYN Smooth 6 mg (4.5 mg measured) and ZYN Wintergreen 6 mg (4.5 mg measured) products, flavors may influence nicotine exposure. Based on the limited bridging information, the extent to which flavors may impact nicotine exposure and abuse liability across nicotine content and flavor combinations relative to General Snus or other smokeless tobacco products is unclear. In order to present a robust abuse liability profile of ZYN products, provide evidence, such as clinical study data or data from peer-reviewed literature with appropriate bridging information, demonstrating the relative abuse liability (e.g., subjective effect ratings of product liking, relative reinforcement) of the PMTA products to adequately describe the abuse liability profiles, or the impact of flavors and nicotine content on abuse liability for PM0000593, PM0000594, PM0000596, PM0000598, PM0000600-PM0000606, PM0000609-PM0000612.***

Swedish Match Response to Deficiency Question #8

To our knowledge none of the flavor components in PM0000593, PM0000594, PM0000596, PM0000598, PM0000600-PM0000606, PM0000609-PM0000612 has been demonstrated to influence nicotine uptake.
We specifically tested the impact of the Wintergreen flavor on nicotine pharmacokinetics as it has been hypothesized that methyl salicylate might enhance nicotine uptake by increasing the mucosal permeability. In contrast the study SM18-01 showed a small, but statistically significant negative effect of Wintergreen on in C_{max} and $AUC_{0\text{-}120\ min}$. C_{max} was found to be approximately 10% lower, and $AUC_{0\text{-}120\ min}$ was approximately 8% lower compared to Smooth. However, these differences are not considered clinically meaningful.

The 90% confidence interval for the ratio of C_{max} was 0.840–0.986, and for $AUC_{0\text{-}120\ min}$ it was 0.867–0.971 ***(Attachment 8A – 20200924: SM18-01_Supplement_post-hoc_report_final_v1.0_02SEP2020)***. These intervals are completely contained in the range 0.80–1.25, and therefore fulfill the criteria that FDA establishes in the guidance for industry entitled *Statistical Approaches to Establishing Bioequivalence* issued in January 2001. Consequently, we consider ZYN Smooth and ZYN Wintergreen to be bioequivalent with respect to nicotine exposure.

To further evaluate the impact of flavor on nicotine releases an *in vitro* dissolution test comparing the nicotine extraction profile between PM0000593, PM0000594, PM0000596, PM0000598, PM0000600-PM0000606, PM0000609-PM0000612, and PM0000607 (ZYN Smooth 3 mg) and PM0000608 (ZYN Smooth 6 mg), respectively, was conducted. The dissolution test showed that the nicotine release profiles for the various flavored products were highly similar to the profiles for the unflavored ZYN

Smooth products ***(See Attachments 8B – 20200924: ZYN 20 products_final_11SEP2020 and 8C – 20200924: Data analysis 20 ZYN products (raw data excel file))***.

To conclude, the data submitted as part of Swedish Match PMTA application on March 4, 2020 does not indicate that flavors influence the nicotine exposure. The difference seen in C_{max} and $AUC_{0\text{-}120\ min}$ between ZYN Smooth 6 mg (4.5 mg measured) and ZYN Wintergreen 6 mg (4.5 mg measured) is small and within the bioequivalent range. Additional *in vitro* dissolution data show no impact on nicotine extraction by flavor.

> ***Deficiency Question #9.*** ***- All of your PMTAs provide data on ZYN flavors and switching from cigarettes to ZYN products overall from a prospective study. This study showed that 24% of ZYN users completely substituted ZYN in place of other tobacco and nicotine products (i.e., switching), including cigarettes. This study also provided the overall percentage of ZYN flavors used each week during the 10-week prospective study. However, although you collected data on the flavored products used in the study, you did not provide any information about ZYN product use or uptake by flavor. Flavors play an important role in tobacco use behavior, and, in the absence of data on patterns of ZYN use by flavor, FDA is unable to provide a complete assessment of these PMTAs from the epidemiology perspective. In order to address this concern, provide analyses of ZYN patterns of use by flavor from your prospective study of product switching.***

Swedish Match Response to Deficiency Question #9

This question relates to (b) (4) [redacted], the data and analysis of which was provided in the original PMTAs. In order to address whether flavors have an impact on ZYN consumers' behavior, Swedish Match commissioned the Omnibus Study described in our response to Deficiency Question #7. Key results of the Omnibus Study were:

- There is little variation in likelihood to buy ZYN across the variety of offerings. Patterns of flavor preference are similar within each of the 5 cohorts and within each age group.
- Never smokers have the lowest interest in buying ZYN and current smokers have moderate interest, but there is little difference among flavors.
- Regarding age, older adults 55-64 have the lowest levels of interest in buying ZYN, followed by those age 21-24, again with little difference by flavor.

In addition, Swedish Match requested that (b) (4) [redacted], which conducted the (b) (4) [redacted], to provide a report that further organizes the study data by flavor. For purposes of this response, Swedish Match will refer to this report as the Post Hoc Flavor Analysis. A copy of this report is attached. **(See Attachment 9A)** The Post Hoc Flavor Analysis yielded results similar to the Omnibus Study showing little variation due to flavor. Specifically, among the 24% of ZYN users who completely substituted ZYN in place of other tobacco and nicotine products, the highest percentage of complete substitution occurred among coffee and spearmint users (34.8% and 31.3% respectively). The percentage of complete substitution for the remaining SKUs was fairly similar (between 19.8% and 25.3%).

> ***Deficiency Question #10. - We note that the descriptor "tobacco-free" is used in proposed advertising and labeling for ZYN. However, in your submission for ZYN, you claim that ZYN***

contains nicotine that is derived from tobacco leaves. Under section 201(rr) of the FD&C Act, a tobacco product is defined as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." Therefore, ZYN meets the definition of a tobacco product because it is made or derived from tobacco, and it would be false or misleading to imply or suggest through labeling and/or advertising that ZYN is "tobacco-free" when it is not. Additionally, under sections 903(a)(1) and 903(a)(7)(A) of the FD&C Act, a tobacco product shall be deemed to be misbranded if its labeling and/or advertising is false or misleading in any particular. We recommend that you review and revise your proposed labels, labeling, and advertising and ensure that they are not false or misleading in any particular, and comply with other applicable provisions under the FD&C Act.

Swedish Match Response to Deficiency Question #10

(b) (4)

[redacted]

(b) (4)

[redacted]

Information Request #11. ***- You submitted a single combined EA document for 20 individual PMTA products. However, a separate EA is required for each PMTA product. Revise and submit a separate EA for each STN with relevant information for the specific PMTA product. Consult all updated guidance documents found at https://www.fda.gov/tobacco-products/products-guidance-regulations, the 2018 public meeting found at https://www.fda.gov/tobacco-products/ctp-newsroom/tobaccoproduct application-review-public-meeting, and the 2019 public meeting found at https://www.fda.gov/tobacco-products/ctp-newsroom/deemed-tobacco-product-applicationspublic meeting-10282019-10292019. Also, in the revised EAs include the dates that you prepare the revised EAs. Separate EAs are used to assess the potential environmental impact of each of the PMTA products.***

Swedish Match Response to Information Request #11

Per FDA's request in Information Request #11, Swedish Match revised the single combined EA document from our initial March 4, 2020, application into 20 separate EA documents, one for each of the PMTA products at issue in this Deficiency letter:

- PM0000593: ZYN Cool Mint 3 mg
- PM0000594: ZYN Cool Mint 6 mg
- PM0000595: ZYN Peppermint 3 mg
- PM0000596: ZYN Peppermint 6 mg
- PM0000597: ZYN Spearmint 3 mg
- PM0000598: ZYN Spearmint 6 mg
- PM0000599: ZYN Wintergreen 3 mg
- PM0000600: ZYN Wintergreen 6 mg
- PM0000601: ZYN Citrus 3 mg
- PM0000602: ZYN Citrus 6 mg
- PM0000603: ZYN Coffee 3 mg
- PM0000604: ZYN Coffee 6 mg
- PM0000605: ZYN Cinnamon 3 mg
- PM0000606: ZYN Cinnamon 6 mg
- PM0000607: ZYN Smooth 3 mg
- PM0000608: ZYN Smooth 6 mg
- PM0000609: ZYN Chill 3 mg
- PM0000610: ZYN Chill 6 mg
- PM0000611: ZYN Fresh 3 mg
- PM0000612: ZYN Fresh 6 mg

Further, in the revised EAs, we included the dates on which we prepared the revised EA documents.

Information Request #12. ***- Your submitted EA includes portions marked confidential (Section II.B. Description of the products; lines 81-115), however, the EA is a public document. 21 CFR 25.51 (a) states that "Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in the portion of environmental documents that is made public. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner shall submit such data***

and information separately in a confidential section and shall summarize the confidential data and information in the EA to the extent possible." Submit revised EAs that are not confidential and, as applicable, summarize confidential data and information in accordance with 21 CFR 25.51(a). Include all the relevant detailed confidential information in a confidential appendix.

Swedish Match Response to Information Request #12

Per FDA's request in Information Request #12, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We summarized confidential data and information in accordance with 21 CFR 25. 51(a) and included all the relevant detailed confidential information in a Confidential Appendix to the Environmental Assessment.

Information Request #13. - Your submitted EA lacks alternatives to the proposed action. This information is needed to evaluate the environmental impacts of manufacturing, use, and disposal of the new products under any alternatives, compared to the environmental impacts of the proposed action. According to 21 CFR 25.40(a), an "EA shall include, at a minimum, a brief discussion of the need for the proposed action, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives and a listing of the agencies and persons consulted." Provide alternatives to the proposed action in your EAs, for example, the no-action alternative (FDA does not issue a marketing order for the new products) and discuss the environmental impacts of manufacturing, use, and disposal of the PMTA products under any stated alternatives.

Swedish Match Response to Information Request #13

Per FDA's request in Information Request #13, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We provided alternatives to the proposed action in our EAs and discussed the environmental impacts of manufacturing, use, and disposal of the PMTA products under any stated alternatives. The alternative to the proposed action is found in **Section III.D.**

Information Request #14. - The Proposed Operating Permit for the Owensboro, KY facility as required by Kentucky Title V expired on 4/13/2020 per information provided in the Confidential Appendix CA.3 of your EA (line 726). In your revised EAs, provide the updated operating permits per Kentucky Title V requirements for the Owensboro, KY facility.

Swedish Match Response to Information Request #14

Per FDA's request in Information Request #14, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We provided updated operating permits per Kentucky Title V requirements for the Owensboro, KY, facility. This update is located in **Section C** of the Confidential Appendix to the Environmental Assessment.

Information Request #15. - Your EA does not include information related to the current conditions of the environmental effects of the facility. Such information can be found in U.S.

Environmental Protection Agency's Toxic Release Inventory (TRI)4. In your revised EAs, include the TRI reports for the Owensboro, KY facility.

Swedish Match Response to Information Request #15

Per FDA's request Information Request #15, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product, providing information related to the current conditions of the environmental effects of the facility. **Section IV.A.1.** discusses how the Owensboro, KY, facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Information Request #16. - Your submitted EA includes assessments on the impacts to endangered species and critical habitats, for three bat species enlisted in ESA. However, U.S. Fish and Wildlife Service's Environmental Conservation Online System indicates 13 enlisted species for Daviess Co., KY, comprising multiple taxonomic groups5. In your revised EAs discuss the impacts on all the enlisted species in Daviess Co., KY from manufacturing, use and disposal of the new PMTA products.

Swedish Match Response to Information Request #16

Per FDA's request in Information Request #16, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We provided information related to the impacts on all the enlisted species in Daviess Co., KY, from manufacturing, use and disposal of the new PMTA products. **Section IV.A.1.** discusses this impact in more detail.

Information Request #17. - Your submitted EA does not completely address whether the marketing of the PMTA product is likely to have a disproportionately high and adverse human health or environmental effects on low-income, minority including native or indigenous tribes, or vulnerable populations. In your revised EAs, address whether the exposure to, use and disposal of the PMTA products is likely to have a disproportionately high and adverse human health or environmental effects on environmental justice populations (low-income, minority or native/indigenous populations). Include any relevant data, analysis, or scientific literature on demographic patterns of use of PMTA products to demonstrate that environmental justice populations will not be disproportionately affected from the proposed actions. If applicable, propose mitigation strategies if impacts are found to environmental justice populations. For more information on environmental justice considerations see: https://www.epa.gov/environmentaljustice/environmental-justice-and-national-environmentalpolicy- act. Information regarding impacts on environmental justice populations is a required component of the EA used to assess the potential environmental impacts of the PMTA products.

Swedish Match Response to Information Request #17

Per FDA's request in Information Request #17, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We demonstrate for each EA that exposure to (e.g., exposure to marketing materials), manufacturing of, use of, and disposal of the new product would not be expected to have a disproportionately high and adverse human health or environmental effect

on environmental justice populations. This conclusion extends to Native American/Alaska Natives, a specific environmental justice population cited by FDA in Information Request #17. Support for these conclusions is found in **Section IV.A.1.** for each EA.

> ***Information Request #18.*** ***- Your submitted EA does not include estimated municipal solid waste loads for packaging materials. In your revised EAs, provide the waste load estimates in metric tonnes for individual packaging material components (Can base, Can lid etc.) and overall total values, given the projected market volumes for the PMTA products.***

Swedish Match Response to Information Request #18

Per FDA's request in Information Request #18, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We included estimates for municipal solid waste loads for packaging materials in metric tonnes for individual packaging material components and overall total values (given the projected market volumes for the PMTA product). This information is presented in **Section CA.2** of the Confidential Appendix to the Environmental Assessment.

> ***Information Request #19.*** ***- Your submitted EA did not include assessment of the environmental impacts from use and disposal of the chemical ingredients in the PMTA products. Evaluate these environmental impacts by including a list of ingredients in the PMTA products, addressing their ecotoxicity potential, and expected environmental introduction concentration of substances from the PMTA products due to excretion after use 8. Additionally, remove portions in sections IV. B (lines 553-596) discussing disposal impacts that pertain to combusted tobacco products or electronic devices as they are not relevant for the PMTA tobacco products.***

Swedish Match Response to Information Request #19

FDA recommends in Information Request #19 that Swedish Match include a list of ingredients in the EA, assessing the environmental impacts from use and disposal of the chemical ingredients in the new product. Specifically, FDA recommends we evaluate the ecotoxic potential of each ingredient and the expected environmental introduction due to excretion after use.

In response, Swedish Match is providing information which we consider appropriate and sufficient for an evaluation of ecotoxicity potential and environmental introduction. Swedish Match deems that inclusion of a complete proprietary list of ingredients unnecessary to do this. Instead, we want to put forward the ingredients' potential for excretion into the environment after use based on their functional properties. For the purposes of this discussion, we assume 100% excretion of water soluble ingredients, or which may otherwise be taken up into the body. Likewise, those ingredients that are insoluble, and otherwise not taken up by the body, we assume 0% excretion.

- (1) Microcrystalline cellulose ("MCC") and (2) Pouch material are components of the product that are not soluble in water and should not be taken up by the body. MCC comprises a range of (b) (4) of the new products. Pouch material comprises a range of (b) (4) of the new products.
- (3) Nicotine is 0.75% for the 3 mg new products and 1.50% for the 6 mg new products.
- The balance of components consists of (4) fillers, (5) flavors, (6) pH adjustors, (7) stabilizers, (8) processing aids and (9) sweeteners. The potential for biological, chemical or physical stressors

1103 to affect ecosystems is of low level of concern for these ingredients given their extreme
1104 commonality for use in foodstuffs and their generally recognized as safe (GRAS) status in food.[1]
1105
1106 Users of ZYN, which is intended as a spit-free smokeless tobacco product, would not be expected to
1107 expectorate the new product into the environment. Any urinary and bowel excretions would be
1108 processed through local municipal waste systems. Reasonably, the ability of these municipal waste
1109 systems to process these historically common ingredients (e.g., ingredients commonly found in
1110 smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern. We included
1111 appropriate language to that effect in the EA in **Section IV.A.1.**
1112
1113 Swedish Match has examined ecotoxicity potential according to GHS criteria and calculated an Expected
1114 Introduction Concentration ("EIC") for each ingredient, in accordance with FDA's recommendation.
1115 Seven substances among the PMTA products,[1] including the dissociation product nicotine, are indeed
1116 classified as harmful or toxic to aquatic life with long-lasting effects according to GHS criteria.

1117 However, each of these seven substances have an Expected Introduction Concentration ("EIC") less than
1118 1% of the lowest respective No Observed Effect Concentration ("NOEC") or ErC50. Therefore, when
1119 considering that the waste predominantly will pass through local municipal waste systems, and
1120 observing that the EICs[2] are substantially lower than any concentrations with observable effects on
1121 aquatic life (including microorganisms in wastewater treatment), it is evident that the waste produced is
1122 unlikely to entail any significant impact on the Publicly Owned Treatment Works ("POTWs") or to the
1123 natural environment. Accordingly, the substances in the PMTA products all would be expected to have a
1124 negligible or minor impact on the environment by means of product use and disposal.
1125
1126 Finally, per FDA's request in Information Request #19, we revised the EA document included in our
1127 initial March 4, 2020, application for each PMTA product. We revised the portions in Section IV.B which
1128 FDA interprets as not being relevant for a discussion of the PMTA tobacco products (i.e., sections
1129 discussing the disposal impacts of combusted tobacco products and electronic devices). We included in
1130 Section III.D a discussion how the no-action alternative would not change trends in nationwide use of
1131 combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends
1132 in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging
1133 disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of

[1] Swedish Match is aware of FDA's reluctance of applying a discussion of GRAS status to a tobacco product. The commonality of the new product's ingredients in foodstuffs, and their lack of ecotoxic potential, is, however, important for the purposes of evaluating this application.
[1] EIC has been calculated for all ingredient substances and relevant dissociation products using the following formula (presented in the Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications) available from: https://www.fda.gov/downloads/Drugs/Guidances/ucm070561.pdf. Regarding ecotoxicity potential, it has been evaluated following the criteria of United Nations Globally Harmonized System of Classification and Labelling (GHS) eighth revised edition Available from https://www.unece.org/trans/danger/publi/ghs/ghs_rev08/08files_e.html. Data has been collected from suppliers' Safety Data Sheets (SDSs) and the European Chemicals Agency's (ECHA's) database between August 17 and August 28, 2020. The presented data is considered valid and reliable.
[2] EIC has been calculated for all ingredient substances and relevant dissociation products using the following formula (presented in the Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications) available from: https://www.fda.gov/downloads/Drugs/Guidances/ucm070561.pdf. Regarding ecotoxicity potential, it has been evaluated following the criteria of United Nations Globally Harmonized System of Classification and Labelling (GHS) eighth revised edition Available from https://www.unece.org/trans/danger/publi/ghs/ghs_rev08/08files_e.html. Data has been collected from suppliers' Safety Data Sheets (SDSs) and the European Chemicals Agency's (ECHA's) database between August 17 and August 28, 2020. The presented data is considered valid and reliable.

1134 toxic substances into aquatic environments and soil would remain unchanged in the no-action
1135 alternative. These effects were summarized as follows (Novotny et al., 2015).
1136
1137 > Cigarette butts are the most commonly discarded piece of waste globally and are
1138 > the most frequent item of litter picked up on beaches and water edges worldwide . .
1139 > . The non-biodegradable cellulose acetate filter attached to most manufactured
1140 > cigarettes is the main component of cigarette butt waste . . . Hazardous substances
1141 > have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl
1142 > phenol. These substances are leached from discarded butts into aquatic
1143 > environments and soil.[3]

1144 Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been
1145 estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations
1146 (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were
1147 littered. (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the
1148 overall level of cigarette butt litter in the United States.
1149

1150 ***<u>Information Request #20.</u> - Your submitted EA contains out-of-date MSW information of the***
1151 ***Advancing Sustainable Materials Management: Facts and Figures Report from 2009.***
1152 ***Currently, the most up-to-date data for MSW is 20179. In your revised EAs, update all MSW***
1153 ***tables and data. The purpose of this is to provide the most up-to-date and verifiable***
1154 ***information to the public.***
1155

1156 **<u>Swedish Match Response to Information Request #20</u>**
1157 Per FDA's request in Information Request #20, Swedish Match revised the EA document included in our
1158 initial March 4, 2020, application for each PMTA product. We included the most up-to-date MSW
1159 information from the 2017 Advancing Sustainable Materials Management document.
1160
1161

1162 ***<u>Information Request #21.</u> - Your submitted EA discusses sustainability strategies followed by***
1163 ***Swedish Match. Sustainability is not a required component of an EA because it is not a***
1164 ***relevant environmental issue described in 21 CFR 25.40. However, if you find such information***
1165 ***is to be included in the EA, provide the evidence in your revised EAs for its relevance for***
1166 ***environmental impacts associated with the PMTA products. If you find such information is***
1167 ***irrelevant or lacks supporting evidence of your sustainability related statements, do not***
1168 ***include statements related to your sustainability practices in the revised EAs; specifically***
1169 ***remove lines 154-168; 262-300 and repeated information on lines 437-446 of your EA.***
1170
1171
1172
1173
1174

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. www.kab.org/

Swedish Match Response to Information Request #21

Per FDA's request in Information Request #21, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We removed the language cited in Information Request #21.

Information Request #22. ***- Your submitted EA includes the following statements pertaining to consumer tobacco product use behavior and likelihood of PMTA product use:***

> ***283 – 287 "Based upon likelihood of use research, we find a high likelihood that the new products' production material and waste would not be additions to the environment, but likely partial replacements for products made from other tobacco companies, like cigarettes. This consumer use behavior would be expected to result in a net decrease in any comparable compounds that would have been emitted by the manufacture of the discontinued or substituted products made by a competitor."***
>
> ***288 – 291 "This consumer use behavior would also be expected to result in a net decrease in any comparable compounds that would have been emitted by the manufacture of the discontinued or substituted products made by Swedish Match."***
>
> ***380 – 386 "It is reasonable to conclude that, though there is a minor expansion of the manufacturing facility to accommodate production of the new products, this expansion would result in the overall transition of more tobacco users away from the tobacco products situated on the most harmful end of the continuum of risk. These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new products, resulting in no significant environmental impact and reinforcing the new product's appropriateness for the protection of the public health."***

These statements suggest that the PMTA products' use would result in overall reductions in environmental impacts due to consumers switching from other combusted tobacco products, and hence are also appropriate for the protection of the public health. Your submitted EA included a confidential appendix summarizing the consumer research results (Confidential Appendix F. CA.6; lines 878-922). However, review of the consumer research indicates that it does not provide evidence that the PMTA products would be differentially effective in promoting complete switching among smokers, thereby potentially benefiting the environment by reductions in environmental impacts due to switching. Particularly, the submitted EA fails to quantitatively or qualitatively evaluate potential reductions in environmental impacts due to the purported switching. In your revised EAs, justify these statements by including relevant data, analysis or evidence from scientific literature on consumer tobacco product use behavior and likelihood of PMTA product use for each specific PMTA product and examine the associated potential positive or negative environmental impacts.

Swedish Match Response to Information Request #22

Per FDA's request in Information Request #22, Swedish Match revised the EA document and the Confidential Appendix to the EA included in our initial March 4, 2020, application for each PMTA

product. Given FDA's interpretation of the consumer perceptions research, we removed the language cited in Information Request #22.

*****In addition, while alternative formats may be used, the following changes to your EA would assist completeness of the EAs and promote efficiency in the review process:***

Change Request #23. - Your submitted EA lacks details on qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing the environmental assessment. In the revised EAs, include all relevant qualifications of individuals primarily responsible for EA preparation and review in accordance with 40 CFR 1502.17.

Swedish Match Response to Change Request #23

Per FDA's request in Change Request #23, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We included the requested qualifications. This information is located in **Section VII.**

Change Request #24. - Your submitted EA includes statements related to FONSI (lines 26-31; lines 495-498). The purpose of the EA is for an evaluation to determine if a FONSI or an environmental impact statement is needed for marketing authorizations. The inclusion of statements of FONSI is incorrect. In your revised EAs, do not include any statements related to FONSI.

Swedish Match Response to Change Request #24

Per FDA's request in Change Request #24, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We removed any statements referencing FONSI.

Change Request #25. - Your submitted EA lacks a certification that the information in the EA is true, accurate, and complete to the best of your knowledge. Include a certification that contains a signed and dated statement as follows:

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of [the company name].

_____

(Date)

_____

(Signature of responsible official)

_____

(Name and title of responsible official, printed)"

Swedish Match Response to Change Request #25

Per FDA's request in Change Request #25, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We included the requested signed and dated statement. This signature is located at the conclusion of the document.

Change Request #26. ***- Your submitted EA includes information not relevant or appropriate for environmental assessments. In the revised EAs, remove all textual references to food use as they are not relevant to the proposed action. Additionally, remove statements such as 'we would like to remind FDA' as the EA is a document aimed at the public.***

Swedish Match Response to Change Request #26

Per FDA's request in Change Request #26, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We removed all textual references to food use and statements such as "we would like to remind FDA."

Change Request #27. ***- Your submitted EA includes errors in the cover page and other typographical errors. In the revised EAs, remove any text in language other than English and document versions in the cover page, and other typographical errors (line 204).***

Swedish Match Response to Change Request #27

Per FDA's request in Change Request #27, Swedish Match revised the EA document included in our initial March 4, 2020, application for each PMTA product. We revised the cover letter, removing text in languages other than English, removing document versions, and correcting other typographical errors.

ATTACHMENTS – RESPONSE DOCUMENTS

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

July 24, 2020 **DEFICIENCY**

Swedish Match USA, Inc.
Attention: Gerard J. Roerty, Jr., Vice President, General Counsel & Secretary
1021 East Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Numbers (STNs): PM0000593-PM0000612

Dear Mr. Roerty:

We reviewed your March 4, 2020, PMTAs[1] and concluded that additional information is needed for FDA to make a determination for the tobacco products identified in Appendix A.

We request that within 14 calendar days from the date of this letter you inform us of how much time you need to provide a complete response to all deficiencies.

This letter does not reflect a final decision on the information reviewed. We will evaluate the information in your timely response to this letter prior to finalizing our review of your applications.

The following information is necessary for FDA to make a scientific determination:

1. All of your PMTAs provide information on the design parameters for the new tobacco products. However, your PMTAs do not include all of the design parameters necessary to fully characterize the new tobacco products. In order to adequately characterize the tobacco products, it is necessary to evaluate key design parameters. Powder granulation may improve the rapid dispersion and dissolution of powders introduced to liquids, referred to as instantization, through fluid bed processing to apply coating/binder or control the particle size, shape, surface area, and porosity[2]. Thus, the solubility and dispersibility of the new tobacco products are necessary to evaluate the instantization properties and the burst release rate of constituents. Provide the manufacturing data sheet specifications (MDSS) or the target specifications, upper and lower range limits, and complete test data for *both* of the following design parameters for each new tobacco product, for all PMTAs:

    a. Powder granulate solubility
    b. Powder granulate dispersibility

    For each set of range limits, identify if the range limits correspond to process control parameters or product control parameters, as appropriate.

[1] Premarket Tobacco Product Applications (PMTAs) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and received on March 4, 2020
[2] Du, Thomas. Binders in pharmaceutical granulation. *In Handbook of Pharmaceutical Granulation Technology*, pp. 94-113. CRC Press, 2016.

2. All of your PMTAs include design parameter specifications, but do not include data confirming that specifications are met. Complete test data is used to confirm that design parameter specifications have been met and that the product can be manufactured consistently. In order to confirm the target specifications are met, provide the test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for *all* of the following design parameters for each new product, for all PMTAs:

   a. Portion length
   b. Portion width
   c. Portion thickness

   For each of the above parameters, provide the necessary data on a per unit of measurement of product basis (e.g., portion length should be reported in mm per pouch).

   Additionally, for the design parameters that were tested according to national or international standards, identify the standards and state what deviations, if any, from the standards occurred. Provide a justification for the sampling protocol used to obtain the test data and state why the data is representative of the final finished product.

3. All of your PMTAs provide information on instructions for product use including breaking the perforation of the side label. However, you do not provide any information on tamper-resistant packaging, such as whether the perforated side label is intended as an indicator for tampering, or how consumers are instructed to check for product tampering. Breakable perforations that are not necessary to open the package, are inadvertently broken while twisting the lid without attempting to break the perforation, or are readily broken during shipping and handling may not be noticeable indicators for tampering. Tamper resistance may provide evidence to consumers that tampering has occurred and mitigate the health hazards associated with exposure, especially to infants and children. Therefore, explain what product components, if any, are intended for tamper-resistance, provide a rationale for how those components provide adequate tamper-resistance, and explain how consumers are instructed to check for product tampering.

4. All of your PMTAs provide the target specifications, upper and lower range limits, and test data for particle size distribution measured by dry sieve analysis. However, for this new product type, which is composed of powder granulates, you have not demonstrated that dry sieve analysis is a sufficient method to characterize the particle size distribution of the new tobacco products during normal use, since your granulation process may affect fluid interactions of the dry powder granulates. Specifically, the granulation process for the new tobacco products may affect the dispersion, dissolution, wettability, and bulk density of the powder material[2] such that the particle size distributions of the new tobacco products measured under dry conditions may not sufficiently describe their characteristics, function, and interaction with fluids during normal use, including their instantization properties and burst release rate of constituents. For example, the presence of saliva may rapidly solubilize the granulated materials, in which case the measured particle size distribution of the dry granulates would have no bearing on the rate of dissolution and nicotine release. Particle size distributions describe the particle surface area

and the accessibility of saliva to interact with the surface of the product,[3] and are necessary to evaluate product instantization and dissolution characteristics such as burst release and overall rates of constituents released during actual use. Therefore, provide a rationale for why dry sieve analysis would adequately characterize the particle size distribution of the new tobacco products under actual use conditions. Alternatively, for all of your PMTAs, you may provide the particle size distribution target specifications, range limits, and test data of the new tobacco products dispersed in fluid.

5. All of your PMTAs identify potential for product failure and misuse, including small pouch dimensions that may increase the risk of swallowing the pouches, consumer use studies that identify 6.3% of users that cut the pouches open and use the pouch contents, and consumer complaint reports that identify 91% of contacts related to manufacturing and potential adverse events involve broken pouches or nicotine residue in container and on pouches and 2.4% involve swallowing the pouch. However, you do not discuss human factors for the new tobacco products nor provide information on mitigating manufacturing defects, foreseeable hazards, or potential for misuse. Manufacturing defects involving broken pouches or nicotine residue outside of the pouches, as well as product misuse involving opening the pouches, may increase the potential for exposure to non-intended users as well as increase any health effects of skin contact, while foreseeable hazards involving ingesting the pouch contents or swallowing the intact pouch may increase the potential for associated health effects. Therefore, provide a rationale for why the identified foreseeable hazards, potential for misuse, and product manufacturing defects do not pose health hazards to users and non-users.

6. All of your PMTAs include a description of manufacturing steps and manufacturing process flow charts. However, the information provided does not include all the necessary information for the processes and equipment used, including process control methods and parameters, performance criteria tolerance limits, and test data and methodology related to semi-finished or finished products. Without this information, it is unclear whether the manufacturing processes and quality controls you use assure that the new tobacco products can be manufactured consistently. For each step of the finished powder granulate manufacturing and packing processes, provide the information below:

    a. Equipment type and settings, including sieve settings
    b. Procedures to ensure that the incoming materials meet your specifications or requirements (e.g., procedures to verify the component mixing specifications) and corresponding test data
    c. Storage conditions such as temperature and humidity for materials and components and corresponding test or monitoring data
    d. In-process specifications or expected performance and tolerance values and associated test data for the bulk finished powder granulates
    e. In-process specification or criteria and corresponding test data for pouch samples for the parameters listed in Section G.1.5.1.2: weight, appearance, and seal integrity

    Additionally, for any quality control tests that were tested according to national or international standards, identify the standards and state what deviations, if any, from the standards occurred.

[3] Dash S, Murthy PN, Nath L, Chowdhury P. Kinetic modeling on drug release from controlled drug delivery systems. *Acta Poloniae Pharmaceutica – Drug Research*. 2010;67(3):217-223.

7. All of your PMTAs provide data on intentions to use and product appeal for the "cool mint" variety, but you did not provide information on your other flavors nor did you provide scientific justification for extrapolating findings from the cool mint flavor to the remaining nine flavors. In particular, you provided no data or information on the potential impact of different flavor profiles such as coffee, citrus, and cinnamon. Further, you reported that you have "chosen flavors for ZYN that appeal more toward adult consumers and avoid appealing to youth;" however, you present no data to support this statement. Additionally, we note that you have developed the marketing messages in response to findings from "consumer marketing research" though findings from these studies were not included. These research studies may have information about appeal and/or likelihood of use of these flavors and nicotine strength varieties. Scientific research has indicated that that flavored tobacco products are appealing, particularly to youth, and flavored tobacco products pose a risk to youth initiation and use. You did not provide a scientific rationale for extending findings from young adults to youth. Because of this, these PMTAs raise concerns about these products from a social science perspective. FDA needs information on the appropriateness of including young adults as a proxy for youth in these studies and information on the appropriateness of using cool mint in this study as a proxy for the other ZYN flavors and nicotine strength.

8. You included limited abuse liability information for some ZYN Smooth, Peppermint, Spearmint, and Wintergreen products (PM0000607, PM0000608, PM0000595, PM0000597, PM0000599) and did not submit clinical studies or bridging information to peer-reviewed literature to address the abuse liability of the other flavors (i.e., Chill, Cinnamon, Citrus, Coffee, Cool Mint, and Fresh; PM0000593, PM0000594,PM0000601-PM0000606, PM0000609-PM0000612) and nicotine contents. Because significant differences in nicotine PK emerged between ZYN Smooth 6 mg (4.5 mg measured) and ZYN Wintergreen 6 mg (4.5 mg measured) products, flavors may influence nicotine exposure. Based on the limited bridging information, the extent to which flavors may impact nicotine exposure and abuse liability across nicotine content and flavor combinations relative to General Snus or other smokeless tobacco products is unclear. In order to present a robust abuse liability profile of ZYN products, provide evidence, such as clinical study data or data from peer-reviewed literature with appropriate bridging information, demonstrating the relative abuse liability (e.g., subjective effect ratings of product liking, relative reinforcement) of the PMTA products to adequately describe the abuse liability profiles, or the impact of flavors and nicotine content on abuse liability for PM0000593, PM0000594, PM0000596, PM0000598, PM0000600-PM0000606, PM0000609-PM0000612.

9. All of your PMTAs provide data on ZYN flavors and switching from cigarettes to ZYN products overall from a prospective study. This study showed that 24% of ZYN users completely substituted ZYN in place of other tobacco and nicotine products (i.e., switching), including cigarettes. This study also provided the overall percentage of ZYN flavors used each week during the 10-week prospective study. However, although you collected data on the flavored products used in the study, you did not provide any information about ZYN product use or uptake by flavor. Flavors play an important role in tobacco use behavior, and, in the absence of data on patterns of ZYN use by flavor, FDA is unable to provide a complete assessment of these PMTAs from the epidemiology perspective. In order to address this concern, provide analyses of ZYN patterns of use by flavor from your prospective study of product switching.

10. We note that the descriptor "tobacco-free" is used in proposed advertising and labeling for ZYN. However, in your submission for ZYN, you claim that ZYN contains nicotine that is derived from

tobacco leaves. Under section 201(rr) of the FD&C Act, a tobacco product is defined as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." Therefore, ZYN meets the definition of a tobacco product because it is made or derived from tobacco, and it would be false or misleading to imply or suggest through labeling and/or advertising that ZYN is "tobacco-free" when it is not. Additionally, under sections 903(a)(1) and 903(a)(7)(A) of the FD&C Act, a tobacco product shall be deemed to be misbranded if its labeling and/or advertising is false or misleading in any particular. We recommend that you review and revise your proposed labels, labeling, and advertising and ensure that they are not false or misleading in any particular, and comply with other applicable provisions under the FD&C Act.

In addition to the deficiencies listed above, we request the following information to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI). The information requested is not required for a scientific determination to receive marketing authorization; however, we are precluded from issuing orders until the below items are resolved. Information requested in this section is not necessary for a complete response to this letter:

11. You submitted a single combined EA document for 20 individual PMTA products. However, a separate EA is required for each PMTA product. Revise and submit a separate EA for each STN with relevant information for the specific PMTA product. Consult all updated guidance documents found at https://www.fda.gov/tobacco-products/products-guidance-regulations, the 2018 public meeting found at https://www.fda.gov/tobacco-products/ctp-newsroom/tobacco-product-application-review-public-meeting, and the 2019 public meeting found at https://www.fda.gov/tobacco-products/ctp-newsroom/deemed-tobacco-product-applications-public-meeting-10282019-10292019. Also, in the revised EAs include the dates that you prepare the revised EAs. Separate EAs are used to assess the potential environmental impact of each of the PMTA products.

12. Your submitted EA includes portions marked confidential (Section II.B. Description of the products; lines 81-115), however, the EA is a public document. 21 CFR 25.51 (a) states that "Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in the portion of environmental documents that is made public. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner shall submit such data and information separately in a confidential section and shall summarize the confidential data and information in the EA to the extent possible." Submit revised EAs that are not confidential and, as applicable, summarize confidential data and information in accordance with 21 CFR 25.51(a). Include all the relevant detailed confidential information in a confidential appendix.

13. Your submitted EA lacks alternatives to the proposed action. This information is needed to evaluate the environmental impacts of manufacturing, use, and disposal of the new products under any alternatives, compared to the environmental impacts of the proposed action. According to 21 CFR 25.40(a), an "EA shall include, at a minimum, a brief discussion of the need for the proposed action, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives and a listing of the agencies and persons consulted." Provide alternatives to the proposed action in your EAs, for example, the no-action alternative (FDA does not issue a marketing order for the new products) and discuss

the environmental impacts of manufacturing, use, and disposal of the PMTA products under any stated alternatives.

14. The Proposed Operating Permit for the Owensboro, KY facility as required by Kentucky Title V expired on 4/13/2020 per information provided in the Confidential Appendix CA.3 of your EA (line 726). In your revised EAs, provide the updated operating permits per Kentucky Title V requirements for the Owensboro, KY facility.

15. Your EA does not include information related to the current conditions of the environmental effects of the facility. Such information can be found in U.S. Environmental Protection Agency's Toxic Release Inventory (TRI)[4]. In your revised EAs, include the TRI reports for the Owensboro, KY facility.

16. Your submitted EA includes assessments on the impacts to endangered species and critical habitats, for three bat species enlisted in ESA. However, U.S. Fish and Wildlife Service's Environmental Conservation Online System indicates 13 enlisted species for Daviess Co., KY, comprising multiple taxonomic groups[5]. In your revised EAs discuss the impacts on all the enlisted species in Daviess Co., KY from manufacturing, use and disposal of the new PMTA products.

17. Your submitted EA does not completely address whether the marketing of the PMTA product is likely to have a disproportionately high and adverse human health or environmental effects on low-income, minority including native or indigenous tribes, or vulnerable populations . In your revised EAs, address whether the exposure to, use and disposal of the PMTA products is likely to have a disproportionately high and adverse human health or environmental effects on environmental justice populations (low-income, minority or native/indigenous populations). Include any relevant data, analysis, or scientific literature on demographic patterns of use[6,7] of PMTA products to demonstrate that environmental justice populations will not be disproportionately affected from the proposed actions. If applicable, propose mitigation strategies if impacts are found to environmental justice populations. For more information on environmental justice considerations see: https://www.epa.gov/environmentaljustice/environmental-justice-and-national-environmental-policy-act. Information regarding impacts on environmental justice populations is a required component of the EA used to assess the potential environmental impacts of the PMTA products.

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[4] https://www.epa.gov/toxics-release-inventory-tri-program.

[5] https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=21059.

[6] Odani, S., Armour, B. S., Graffunder, C. M., Garrett, B. E., & Agaku, I. T. (2017). Prevalence and disparities in tobacco product use among American Indians/Alaska Natives—United States, 2010–2015. MMWR. Morbidity and mortality weekly report, 66(50), 1374.

[7] Hoffman, L., Ganz, O., Delahanty, J., Jones, C., Homsi, G., & Nonnemaker, J. (2019). Tobacco Product Use Health Equity Among Non-Hispanic American Indian Alaska Native Youth in 29 States, 2007–2013. American journal of preventive medicine, 57(2), e43-e50.

18. Your submitted EA does not include estimated municipal solid waste loads for packaging materials. In your revised EAs, provide the waste load estimates in metric tonnes for individual packaging material components (Can base, Can lid etc.) and overall total values, given the projected market volumes for the PMTA products.

19. Your submitted EA did not include assessment of the environmental impacts from use and disposal of the chemical ingredients in the PMTA products. Evaluate these environmental impacts by including a list of ingredients in the PMTA products, addressing their ecotoxicity potential, and expected environmental introduction concentration of substances from the PMTA products due to excretion after use[8]. Additionally, remove portions in sections IV. B (lines 553-596) discussing disposal impacts that pertain to combusted tobacco products or electronic devices as they are not relevant for the PMTA tobacco products.

20. Your submitted EA contains out-of-date MSW information of the Advancing Sustainable Materials Management: Facts and Figures Report from 2009. Currently, the most up-to-date data for MSW is 2017[9]. In your revised EAs, update all MSW tables and data. The purpose of this is to provide the most up-to-date and verifiable information to the public.

21. Your submitted EA discusses sustainability strategies followed by Swedish Match. Sustainability is not a required component of an EA because it is not a relevant environmental issue described in 21 CFR 25.40. However, if you find such information is to be included in the EA, provide the evidence in your revised EAs for its relevance for environmental impacts associated with the PMTA products. If you find such information is irrelevant or lacks supporting evidence of your sustainability related statements, do not include statements related to your sustainability practices in the revised EAs; specifically remove lines 154-168; 262-300 and repeated information on lines 437-446 of your EA.

22. Your submitted EA includes the following statements pertaining to consumer tobacco product use behavior and likelihood of PMTA product use:

    > 283 – 287 "Based upon likelihood of use research, we find a high likelihood that the new products' production material and waste would not be additions to the environment, but likely partial replacements for products made from other tobacco companies, like cigarettes. This consumer use behavior would be expected to result in a net decrease in any comparable compounds that would have been emitted by the manufacture of the discontinued or substituted products made by a competitor."
    >
    > 288 – 291 "This consumer use behavior would also be expected to result in a net decrease in any comparable compounds that would have been emitted by the manufacture of the discontinued or substituted products made by Swedish Match."

---

[8] Environmental introduction concentration for specific chemical ingredients may be calculated based on the equation and assumptions provided in U.S. Food & Drug Administration. (1998). "Guidance for Industry: Environmental Assessment of Drug and Biologics Applications." U.S. Department of Health and Human Services, Food & Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), July 1998, CMC6, Revision 1. Available from: https://www.fda.gov/downloads/Drugs/Guidances/ucm070561.pdf

[9] https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/advancing-sustainable-materials-management

> 380 – 386 "It is reasonable to conclude that, though there is a minor expansion of the manufacturing facility to accommodate production of the new products, this expansion would result in the overall transition of more tobacco users away from the tobacco products situated on the most harmful end of the continuum of risk. These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new products, resulting in no significant environmental impact and reinforcing the new product's appropriateness for the protection of the public health."

These statements suggest that the PMTA products' use would result in overall reductions in environmental impacts due to consumers switching from other combusted tobacco products, and hence are also appropriate for the protection of the public health. Your submitted EA included a confidential appendix summarizing the consumer research results (Confidential Appendix F. CA.6; lines 878-922). However, review of the consumer research indicates that it does not provide evidence that the PMTA products would be differentially effective in promoting complete switching among smokers, thereby potentially benefiting the environment by reductions in environmental impacts due to switching. Particularly, the submitted EA fails to quantitatively or qualitatively evaluate potential reductions in environmental impacts due to the purported switching. In your revised EAs, justify these statements by including relevant data, analysis or evidence from scientific literature on consumer tobacco product use behavior and likelihood of PMTA product use for each specific PMTA product and examine the associated potential positive or negative environmental impacts.

In addition, while alternative formats may be used, the following changes to your EA would assist completeness of the EAs and promote efficiency in the review process:

23. Your submitted EA lacks details on qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing the environmental assessment. In the revised EAs, include all relevant qualifications of individuals primarily responsible for EA preparation and review in accordance with 40 CFR 1502.17.

24. Your submitted EA includes statements related to FONSI (lines 26-31; lines 495-498). The purpose of the EA is for an evaluation to determine if a FONSI or an environmental impact statement is needed for marketing authorizations. The inclusion of statements of FONSI is incorrect. In your revised EAs, do not include any statements related to FONSI.

25. Your submitted EA lacks a certification that the information in the EA is true, accurate, and complete to the best of your knowledge. Include a certification that contains a signed and dated statement as follows:

    "The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of [the company name].

    _____
    (Date)

    _____
    (Signature of responsible official)

    _____
    (Name and title of responsible official, printed)"

(b) (4)

[redacted]

When responding to this letter, you should send an amendment with a cover letter that includes the following text in your subject line: "**RESPONSE TO DEFICIENCY LETTER for PM0000593-PM0000612**." Refer to Appendix B for best practices in submitting a response to a Deficiency letter.

If you intend to respond to these deficiencies, clearly state (by STN) that you have responded to each numerated deficiency above. Please be advised that an inadequate resolution of the deficiencies described above will likely result in marketing denial orders.

Amendments, which contain a substantial amount of new information (e.g., detailed new analyses of previously submitted data, new manufacturing information), may extend the time required for review. FDA generally does not intend to review unsolicited amendments that would require significant review time by the agency. In the circumstance that the time required for review is extended, FDA will notify you by letter.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[10,11] using eSubmitter.[12] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[13]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

[10] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[11] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[12] For more information about eSubmitter, see http://www.fda.gov/ForIndustry/FDAeSubmitter
[13] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

If you have any questions, please contact Elizabeth Eydelman, MPH, Regulatory Health Project Manager, at (301) 796-5071 or elizabeth.eydelman@fda.hhs.gov.

Sincerely,

Digitally signed by Mayo J. Wright -S
Date: 2020.07.24 13:02:46 -04'00'

Mayo J. Wright, Ph.D.
Branch Chief, Division of Nonclinical Science
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New Tobacco Products Subject of This Letter
Appendix B – Best Practices for Submitting a Response to a Deficiency Letter

Appendix A

New Tobacco Products Subject of This Letter

- PM0000593: ZYN Cool Mint 3 mg
- PM0000594: ZYN Cool Mint 6 mg
- PM0000595: ZYN Peppermint 3 mg
- PM0000596: ZYN Peppermint 6 mg
- PM0000597: ZYN Spearmint 3 mg
- PM0000598: ZYN Spearmint 6 mg
- PM0000599: ZYN Wintergreen 3 mg
- PM0000600: ZYN Wintergreen 6 mg
- PM0000601: ZYN Citrus 3 mg
- PM0000602: ZYN Citrus 6 mg
- PM0000603: ZYN Coffee 3 mg
- PM0000604: ZYN Coffee 6 mg
- PM0000605: ZYN Cinnamon 3 mg
- PM0000606: ZYN Cinnamon 6 mg
- PM0000607: ZYN Smooth 3 mg
- PM0000608: ZYN Smooth 6 mg
- PM0000609: ZYN Chill 3 mg
- PM0000610: ZYN Chill 6 mg
- PM0000611: ZYN Fresh 3 mg
- PM0000612: ZYN Fresh 6 mg

Appendix B

Best Practices for Submitting a Response to a Deficiency Letter

We recommend that your submission include consecutively numbered pages and be organized as follows:

- List each number and full deficiency text as stated in this letter, and provide your response immediately following the deficiency.
    - Your response should address all STNs identified in a deficiency; if different information/data is being submitted for different STNs in your response to a given deficiency, the response should clearly correlate information/data to the applicable STNs.
    - If your response applies to a subset of STNs (e.g., 5 out of 10) and you would like us to start scientific review upon receipt of your response, provide a statement to that effect in your cover letter.
    - Submit data as an appendix or appendices and reference the appropriate appendix/appendices in your response.
    - Submit publications as an appendix or appendices and reference the appropriate appendix/appendices in your response.
- If resubmitting information (e.g., tables) to correct earlier omissions/errors, clearly identify what information has been revised. FDA will consider that new information to supersede the information provided in the original submission, except for measured values (e.g., test data, HPHC data). For measured values, applicants should provide rationale for why the updated data are appropriate for consideration. If rationale is not provided, measured values will be combined with previous measured values for evaluation.
- If you have already submitted any of the information requested in the deficiency, identify the date of the prior submission, page numbers, and line numbers where the requested information is located.

Swedish Match.

Attachment 1A 20200924

Introduction

A method for measurement of dispersibility according to **ASTM E1945-02**, "Standard Test Method for Percent Dispersibility".

Material:

250 ml mixing cylinder
Vacuum apparatus
Weighing boat
Weighing dish
Balloon whisk
Analytical balance
Deionized water, MilliQ
Para film, approx. 8x8 cm
Oven set at 50 °C, UNE 400
Timer

Method:

1. Ungranulated material (aka Charge Powder) is homogenized by stirring with a balloon whisk during 5 minutes at 150 rpm. Granulated material is not stirred since this would cause the granules to disintegrate.
2. Tare an analytical balance and weigh a 2,5 g sample into a weighing boat. Record the weight with an accuracy of ± 0,001g = S1.
3. Fill a 250 ml mixing cylinder to volume with deionized water and equilibrate to 20 ± 2 °C.
4. Transfer the material in the weighing boat to the mixing cylinder. Weigh the empty weighing boat with an accuracy of ± 0,001g = S2. The weight W1 = S1 – S2.
5. Place a sheet of parafilm over the top of the mixing cylinder and invert the cylinder 30 times in 2 minutes.
6. Let the mixing cylinder stand for 1 minute.
7. Remove 225 ml from the mixing cylinder using the vacuum apparatus. Ensure that the tip of the suction tube remains slightly below the liquid surface while removing the 225 ml. Take care not to disturb the bottom 25 ml.
8. Record the tare weigh of the weighing dish to an accuracy of ± 0,001g. Record the weight as = M1 with an accuracy of ± 0,001g.
9. Gently swirl the remaining suspension to loosen the hard-packed material. Transfer quantitatively to the weighing dish. Rinse the cylinder with additional water if necessary.
10. Dry the weighing dish containing the residue from 9. in an oven set at 50 °C, to a constant weight. Record the weight with an accuracy of ± 0,001g = M2. The weight W2 is defined as: W2 = M2 – M1

Calculation:

Calculate % dispersibility of the material as follows:

$$\%\ Dispersibility = \frac{10}{9} \times \frac{(W_1 - W_2) \times 100}{W_1}$$

Precision and bias:

Repeatability – Two results obtained by the same analyst should be considered suspect if they differ more than 2% absolute.

Reproducibility – Two results obtained by analysts in different laboratories should be considered suspect if they differ by more than 5% absolute.

Swedish Match.

Attachment 1B 20200924

The average dispersibility and standard deviation for products PM0000593-PM0000612 are shown in Table 1B.1, together with the corresponding results for the ungranulated powder.

Table 1B.1. Dispersibility (%) of ZYN materials before and after granulation.

Product	Ungranulated	Granulated	Difference
ZYN Cool Mint 3mg	(b) (4) [redacted]		
ZYN Cool Mint 6mg			
ZYN Peppermint 3mg			
ZYN Peppermint 6mg			
ZYN Spearmint 3mg			
ZYN Spearmint 6mg			
ZYN Wintergreen 3mg			
ZYN Wintergreen 6mg			
ZYN Citrus 3mg			
ZYN Citrus 6mg			
ZYN Coffee 3mg			
ZYN Coffee 6mg			
ZYN Cinnamon 3mg			
ZYN Cinnamon 6mg			
ZYN Smooth 3mg			
ZYN Smooth 6mg			
ZYN Chill 3mg			
ZYN Chill 6mg			
ZYN Fresh 3mg			
ZYN Fresh 6mg			
Average			
Standard deviation			

eurofins

2020-08-31

Method for the measurement of solubility of ZYN-materials.

Introduction

Ungranulated and granulated ZYN materials consist of a mixture of components. The only component that is completely insoluble in water is microcrystalline cellulose, MCC, and there is also a small amount of flavor components that are only partially soluble in water.

While there are standard methods to measure the water solubility of individual substances, no standardized methods exist for multi-component materials. However, if a major part of the material is readily soluble in water, more than 1 mg per liter, it is recommended to use the "shake flask" method [Determining the water solubility of difficult-to-test substances: A tutorial review; H. Birch et al., Analytica Chimica Acta 1086 (2019) 16-28]. In our case the solubility, excluding MCC, is larger than 1 mg per liter.

(See Attachment 1Ca. - 20200924: Birch Water Solubility)

The method was designed by Eurofins in Lidköping, Sweden and is based on the shake flask method.

Equipment

Erlenmeyer flask
Milli-Q water
Funnel
Filter paper, Ahlström 00H, diameter 90 mm
Desiccator
Oven set at 103 °C
Waterbath with shaking mechanism

Method

1. Dry the filter paper over night at 103 °C.
2. Let the filter paper cool down in a desiccator. The paper should be stored in the desiccator until use.
3. Weigh a 1 g sample into an Erlenmeyer-flask and record the sample weight.
4. Add 100 ml Milli-Q water, tempered to 35 °C, to the flask.
5. Shake the sample and place it in a waterbath with shaking mechanism for two hours. The waterbath should have a temperature of 35 ± 2 °C.
6. Remove the sample from the waterbath and let cool down to 20 ± 2 °C.
7. Weigh a filter paper from step 2.
8. Filter the sample from step 6 through the filter paper and rinse the Erlenmeyer-flask with at least two rounds of 20 ml Milli-Q water, at 20 ± 2 °C, in order to remove all insoluble material from the flask.
9. Dry the filter paper in an oven at 103 °C overnight (16 hours).
10. Weigh the filter paper and calculate the residue weight.
11. The solubility is calculated as $100 * (1 - \frac{\text{Weigh of dry residue from step 10}}{\text{Sample weight from step 3}})$

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Tutorial

Determining the water solubility of difficult-to-test substances: A tutorial review

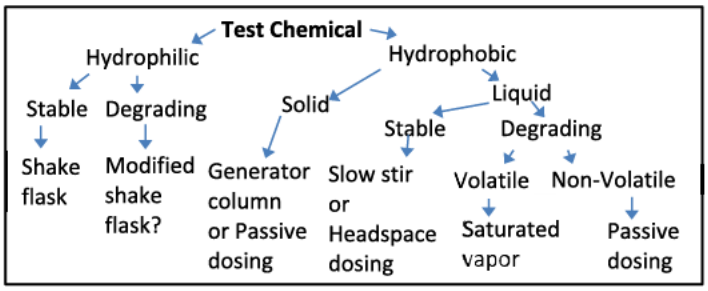
Heidi Birch [a,*], Aaron D. Redman [b], Daniel J. Letinski [c], Delina Y. Lyon [d], Philipp Mayer [a]

[a] Department of Environmental Engineering, Technical University of Denmark, 2800, Kgs. Lyngby, Denmark
[b] ExxonMobil Petroleum and Chemical, Hermeslaan 2, 1831, Machelen, Belgium
[c] ExxonMobil Biomedical Sciences, Inc, 1545 US Highway 22 East, Annandale, NJ, 08801-3059, USA
[d] Shell Health Americas, 150 N. Dairy Ashford, Houston, TX, 77079, USA

HIGHLIGHTS

- Solubility measurement methods for difficult to test chemicals.
- Avoiding microcrystals/droplets in solubility testing of highly hydrophobic chemicals.
- Rapid methods to saturate water with fast degrading chemicals.
- Solubility and critical micelle concentrations of surfactants.
- Concepts and strategies to measure solubility parameters for mixtures.

GRAPHICAL ABSTRACT



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ABSTRACT

Water solubility is one of the most important and frequently used physical-chemical properties of chemicals. It is crucial within several industrial sectors, in research and in the regulatory sector e.g. for the risk and hazard assessment of chemicals. The most recent OECD guideline (Test No. 105) for measuring solubility is from 1995 and limited to mono-constituent, stable and non-volatile substances. This OECD guideline and the described methods are not suited for several groups of difficult-to-test substances, such as highly hydrophobic chemicals, volatile chemicals, surfactants and mixtures. The aim of this paper is to review solubility measurement methods for difficult-to-test substances on a technical, analytical and scientific level. Methods to handle highly hydrophobic chemicals and volatile chemicals, and methods to rapidly saturate water with fast degrading chemicals are reviewed. A decision tree is presented outlining the preferred choice of method for each chemical group. This review also includes measurement methods for critical micelle concentrations that set the upper concentration limit for freely dissolved surfactants. Finally, concepts and strategies to measure solubility parameters for mixtures, including multi-constituent substances and chemical substances of unknown or variable composition, are discussed.

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Abbreviations: UVCB, Chemical Substances of Unknown or Variable Composition,Complex Reaction Products and Biological Materials; OECD, Organization for Economic Cooperation and Development; QSAR, Quantitative Structure-Activity Relationship; NAPL, non-aqueous phase liquid.

* Corresponding author.
E-mail addresses: hbir@env.dtu.dk (H. Birch), aaron.d.redman@exxonmobil.com (A.D. Redman), daniel.j.letinski@exxonmobil.com (D.J. Letinski), Delina.Lyon@shell.com (D.Y. Lyon), philm@env.dtu.dk (P. Mayer).

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1. Introduction

Water solubility can be defined as "the saturation mass concentration of the substance in water at a given temperature" [1]. Water solubility is one of the key physical-chemical properties of organic chemicals in environmental chemistry, analytical chemistry, environmental toxicology and many other fields of research and testing. The water solubility sets the upper limit for freely dissolved concentrations in aqueous solutions and thus for the exposure of aquatic organisms to chemicals in toxicity testing and the environment [2]. The water solubility sets the maximum concentration gradient that drives the diffusive uptake and bioconcentration in aquatic organisms [3]. While bound forms of the chemical can also contribute to the mass transfer and uptake kinetics of hydrophobic chemicals under dynamic conditions [4,5], the dissolved concentration, which is limited by the water solubility, is still the main governing parameter. Solubility is also important for the human uptake of chemicals since solubility can limit the uptake of drugs from the digestive tract to the blood. It is therefore an essential parameter in discovery and development of oral drugs [6,7].

The aqueous solubility is critical for the mobility, distribution and behavior of organic chemicals within experiments, analytical systems and our environment. Water solubility is for instance closely linked to the release and partition processes determining the transport and distribution of chemicals in the environment. Water solubility is therefore also a fundamental parameter in the risk assessment of chemicals, where it is used as input to exposure and fate models [8].

A number of models have been developed for estimating rather than measuring water solubility [9–15]. The uncertainty of such prediction models is currently approaching the uncertainty found in experimental and analytical solubility determinations [10,14]. Such prediction models are based on and calibrated with experimental data, and they therefore rely on sound experimental methods, accurate and precise analytical methods and carefully measured solubility values for a sufficient number of chemicals. It is essential to note that the models are limited to the chemical domain included when constructing and calibrating the models, and therefore it is important that experimental methods are suited for the solubility determinations within a very wide chemical space.

Solubility experiments are conceptually quite simple and consist typically of two steps: (1) preparation of saturated water and (2) measurement of the chemical concentration in the saturated water. The OECD guideline No. 105 for solubility testing dates back to 1995 and is limited to mono-constituent, stable and non-volatile substances [1]. Fortunately, laboratory and analytical techniques have greatly improved during the last decades. Some of the new technical and analytical techniques may provide solutions to the limitations and challenges of the traditional methods.

The aim of this paper is therefore to review the current status regarding solubility testing and measurements of difficult-to-test substances (chemicals with low water solubility, volatile chemicals, fast degrading chemicals, surfactants, and multi-constituent substances [2]) on a technical, analytical and scientific level. The section on technical challenges deals with the preparation of saturated water, i.e. the first step of solubility experiments. This part focuses on methods to avoid micro-droplets or crystals of pure chemical in the water phase, on volatile chemicals and on reducing the saturation time in order to handle chemicals which are not stable in water over longer time-frames. The section on analytical challenges deals with the measurement of highly hydrophobic chemicals in saturated water, i.e. the second step of a solubility experiment. The section on scientific challenges focuses on the concept of solubility for surfactants and mixtures including nonpolar hydrophobic UVCBs.

2. Determining water solubility

Two basic principles can be used when determining water solubility experimentally. One group of methods determines solubility by establishing equilibrium between an excess amount of test chemical and its dissolved form in pure water. These methods have been termed 'variable composition' [16] 'excess solid' [17] or 'thermodynamic' methods [6,18,19]. Another group of methods are termed 'apparent', 'excess solvent' or 'kinetic' solubility methods

[6]. They determine solubility using a fixed amount of test chemical and varying factors such as temperature or volume of water to reach the solubility point or 'cloud point' from undersaturation, oversaturation or a combination of these [6,16]. By doing this, the solubility of the fastest precipitating crystal structure is measured, and these methods are therefore likely to overpredict the thermodynamic solubility [6,18]. They are also much more sensitive to impurities [17] and more prone to supersaturation artefacts than thermodynamic methods [20,21]. They are widely used in drug discovery because they can be set up as high-throughput methods requiring a minimal amount of solute [6], however they cannot substitute for careful thermodynamic solubility determinations [7]. The focus of this review will therefore be on the thermodynamic methods.

Important factors to ensure high quality solubility determinations include high purity of the test chemical, high purity of water, stability of the test chemical during equilibration, temperature control of the experiment, sufficient agitation, sufficient time for the water to reach saturation, and complete separation of the soluble fraction from the pure phase [16,22].

The current OECD guideline for water solubility testing recommends two approaches for saturating water by equilibrium partitioning with test substance; the shake-flask method for chemicals with a solubility above 0.01 g L^{-1} and the column elution method for chemicals with solubilities below this limit [1]. The shake-flask method consists of mixing solute and water at the desired temperature until equilibrium is reached (see Fig. 1), and then separating the non-dissolved test substance from the water phase by either filtration or temperature controlled centrifugation [1]. The column elution method consists of pumping water through a column containing an inert support material (e.g. glass beads) coated with the solid chemical (Fig. 1). The flow rate can be adjusted to ensure full saturation of the water passing through the column or the water can be recirculated through the column until equilibrium is reached, as defined by five successive samples that do not differ by more than ±30% in concentration in a random fashion [1]. For both methods, the concentration in the water is subsequently measured with an appropriate analytical technique [1]. An adaptation of this method, the generator column method [23], is included in the United States Environmental Protection Agency water solubility guidelines [24]. It is closely related to the column elution method as it uses the same saturation principle. However, the generator column method includes automated extraction and analytical procedures for the water exiting the saturation column [23,25,26].

The ability to experimentally establish equilibrium between phases is important not only for solubility determinations. Experiments to determine the octanol-water partition ratio of organic chemicals requires equilibrium of a chemical between a water phase and an octanol phase. For this purpose, a slow-stir method has been developed and adopted into the OECD guidelines [27–29]. The method has subsequently been used for solubility determinations by various groups [30–33]. It consists of saturating water with a low density liquid test chemical through carefully controlled magnetic slow stirring (no vortex) in order to avoid emulsion of the chemical and water (Fig. 1). The equilibrated water is collected from the bottom of the test system for analysis. The same principles can be used for solubility determinations of low density liquids, when the magnetic stirrer at the bottom is replaced by another stirring mechanism operating from the top of the bottle. However no examples of this have been found in the literature.

In aquatic toxicity testing, a range of passive dosing methods has been developed to control the aqueous concentration of hydrophobic organics at their solubility limit and at defined concentrations below solubility [34–39]. Passive dosing applies a polymer pre-loaded with the test substance for establishing and controlling constant aqueous concentrations by equilibrium partitioning between polymer and water [40]. Systems are designed with dimensions (polymer/water/headspace ratios) allowing the polymer to dominate the partitioning of the test chemical in order to control the freely dissolved test chemical or chemical activity in the system (Fig. 1). The polymer needs to be loaded to the saturation level when applying passive dosing for solubility determinations. For solids, two different principles have been used: (1) Saturated methanol suspensions with solid hydrophobic chemicals were prepared and then used to saturate the silicone polymer. After cleaning of the polymer to remove methanol and remaining crystals, water was added and saturated by equilibrium partitioning with the saturated silicone [35]. (2) Crystals of solid hydrophobic chemicals have been cast into silicone polymer and after curing and cleaning the silicone, water was added and saturated by partitioning from the loaded polymer [41]. For liquid test chemicals, the silicone polymer can be saturated by direct immersion of the polymer in the pure liquid chemical. After carefully cleaning the polymer surface, the saturated polymer can be used as partitioning donor to saturate water [42]. Volatile liquid substances can even by themselves serve as partitioning donor to saturate water. Such a headspace passive dosing method has recently been developed for toxicity testing, where water was saturated directly from the pure liquid through the headspace [43] (Fig. 1).

Methods have also been developed for solubility testing of volatile liquid chemicals. Sanemasa et al. designed a saturated vapor method [44], which was later simplified by Dohányosová et al. [45]. The water was saturated by bubbling an inert gas through the liquid test substance and then through the water (Fig. 1).

3. Technical challenges

3.1. Ensuring full separation of undissolved and dissolved chemical

A crucial aspect of determining water solubility is the ability to avoid or remove non-dissolved chemical from the solution after the equilibration phase. This means ensuring that there is no particulate phase, microcrystals, emulsions or micro-droplets in the water sample that is extracted for analysis. Loftsson [19] found that chemicals with low solubility are more prone to overestimation of solubility due to formation of nano-sized aggregates than chemicals with high solubility. This challenge therefore mainly relates to hydrophobic chemicals. The practical challenges are slightly different for chemicals which are in the solid state than for chemicals which are in the liquid state at the desired temperature. However, three main approaches have been used in order to overcome the challenges (1) efficient removal of microcrystals/droplets after equilibration, (2) reducing agitation in order to eliminate formation of microcrystals/droplets and (3) avoiding direct contact between the pure chemical and the water during equilibration.

The presence or absence of micro and nano-sized droplets in the saturated water can, if necessary, be investigated using methods such as laser particle counting [46], dynamic light scattering, or other light scattering methods used for the determination of the critical micelle concentration of surfactants (see section 5.1).

3.1.1. Solid hydrophobic chemicals

The shake-flask method is prone to formation of microcrystals because of the high agitation during equilibration, and for this reason the shake flask method is not recommended for hydrophobic chemicals [1]. Methods to improve efficiency in removal of microcrystals include dialysis and ultrafiltration, which have been used when measuring the solubility of nanomaterials [47].

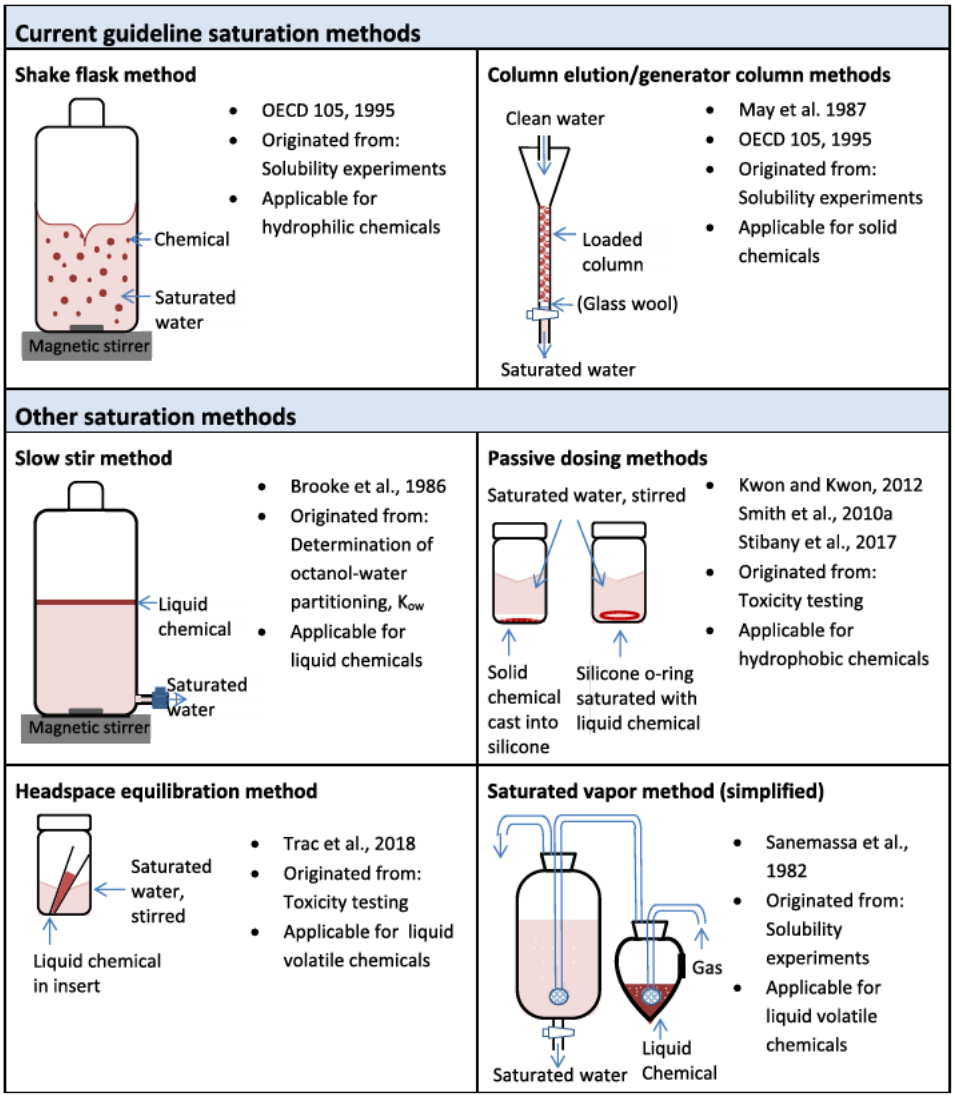

Fig. 1. Conceptual drawing of selected methods for equilibrium based saturation of water. Temperature control measures, sample withdrawal and analysis are not included.

However, even these are not considered sufficiently reliable to fully remove nano-sized particles from solution [47].

The generator column and column elution methods, based on passing water through a column with a high surface area support materials coated with the test chemical, were developed in order to reduce the formation of microcrystals in the saturated solutions by reducing the agitation during equilibration of solid chemicals with water [23]. Some studies have observed higher initial concentrations in the water produced by the generator column, likely due to loose crystals detaching from the column [41,48]. The concentrations, however, decreased with recirculation of the water through the column, during which, the detached crystals were most likely retained in the column. The generator column method was found to produce lower and more reliable solubilities than the shake-flask method for the hydrophobic polycyclic aromatic hydrocarbons (PAHs) because of the reduction in formation of microcrystals [48].

Methods have also been designed to avoid contact between the pure chemical crystals and the water [41,49,50]. Akiyoshi et al. proposed a vapor generator method using saturated solvent vapor to transfer the chemical to the water [49]. However, the solubility of the substance can change in the presence of another solvent, so this method may bias the solubility determination [41]. The use of water vapors to transfer the chemical was also tested, but the equilibration times increased substantially [50]. The method has not gained considerable use. Considering that most solid state hydrophobic chemicals are more lipophilic than volatile, it seems more promising to use passive dosing methods. Kwon and Kwon [41] casted an excess amount of crystals (five PAHs) into silicone (polydimethylsiloxane, PDMS) in order to saturate the silicone while leaving a crystal layer beneath the PDMS at the bottom of the vial. Water was then equilibrated with crystals through the saturated PDMS producing similar results as the column elution method. This way they reduced the direct contact between the water and the crystals, decreasing the risk of crystals detaching from the column. This method is thus promising for solid lipophilic chemicals.

3.1.2. *Liquid hydrophobic chemicals*

The vigorous agitation used in the shake flask method is challenging for liquid hydrophobic chemicals as well as for solid hydrophobic chemicals. Peake and Hodgson [51] found that shaking water and alkanes produced concentrations above water solubility which depended on the subsequent filtration pore size. This could be due to the formation of micelles in solution [51].

The generator column method [26] may reduce the formation of micro-droplets in the water because it reduces the agitation compared to the shake-flask method [52]. However, this method is not reliable for liquid test chemicals as there is a possibility for the liquid test chemical to slough off the support material during equilibration [1]. In an extreme effort to avoid formation of micro-droplets, Coates et al. equilibrated alkanes in a static system where diffusion was the only transfer process between the water and the liquid solute. They found equilibration times in the range of 90 days [53]. These high equilibration times are of course not practical, and a compromise is to use the slow-stirring method (see Fig. 1). The slow stir method has been preferred to avoid emulsion problems when determining solubilities for hydrophobic liquid chemicals such as phthalates [30], hydrocarbons [32,33] and alcohols and diesters [31]. The slow stir method has been argued to be more accurate than other methods: The solubility of di(2-ethylhexyl) adipate determined by the slow stir method was consistent with values predicted from molecular structure (using the physico-chemical calculator SPARC) but over two orders of magnitude lower than the shake-flask method [54]. Furthermore, molecular dynamic simulations used to estimate water solubilities of n-alkanes agreed well with results using the slow-stir method, but not with results from the shake-flask method [11]. The disadvantage of the slow stir method is the long equilibration times. Equilibration times of one-two weeks [31,32,54] or three days [33] have been reported in different studies. However, the slow stir method is a robust method to determine solubility of liquid hydrophobic chemicals.

For liquid chemicals, methods have also been proposed to separate the pure chemical from the water phase in order to avoid formation of micro droplets. For semi-volatile and volatile chemicals, equilibration through the headspace has been used. Sutton and Calder [55] used half-filled 1 l flasks with an insert containing liquid alkylbenzenes. The alkylbenzenes equilibrated with the water through the headspace within 35 h [55]. Equilibration through headspace was also evaluated by Tolls et al. [33]. Without details of the test system dimensions, they reported equilibration times of 3 weeks for decane, making them decide to use the slow-stir method instead. Trac et al. [43] recently described a headspace passive dosing setup for toxicity testing at saturation with dimensions allowing equilibrium of water from a pure phase liquid within 24 h (Fig. 1). Compared to the prior test set-ups, the surface area to volume ratio of the water phase was increased to increase transfer kinetics. The headspace passive dosing systems require tight temperature control in order to avoid condensation of the pure chemical in the test system. Apart from this the test systems are quite simple.

Passive dosing of liquid chemicals from a silicone polymer is another possibility to separate the pure phase chemical from the water. A passive dosing method, where silicone was saturated by immersion in the pure liquid chemical and subsequently used to saturate an aqueous medium, worked well with silicone o-rings [42]. Another method is to dose through liquid filled tubes. This method has been demonstrated using two oils and stirring of either the water phase [56] or stirring of the oil filled silicone tubing tied to the stir bar at 300 rpm [57]. The method is however vulnerable to production of micro-emulsions [42] and leakage from the ends of the tubing [46]. From current experiences, if using passive dosing of liquid chemical at saturation, special attention is necessary regarding careful closing of liquid filled tubes, careful physical cleaning of saturated polymers and appropriate shaking/stirring of the systems in order to avoid emulsion formation.

3.2. Reducing equilibration times

The strongest driver for developing fast methods to determine solubility is the practical aspect which is closely linked to costs. Miniaturized methods for thermodynamic solubility determinations have therefore been developed for high-throughput in drug discovery [6]. Since 87% of marketed drugs in a 1997 study had turbidimetric solubilities above 65 mg L^{-1} [7], the focus of solubility testing in drug discovery is the mg L^{-1} range [7,58], and the shake flask method is used as a basis for high-throughput methods. A review by Alsenz and Kansy [6] describes automation developed for powder dispensing in microtiter plates, automation for dispensing of solvents with low or high viscosity, mixing in small systems, filtration of the solutes, pH determinations, and characterization of solid state properties in high throughput screening. One example of an automated setup, is a 2 mL test system (Whatman UniPrep filter chamber) equilibrated for 24 h after which a plunger with a filtration membrane is pressed into the chamber to filter out the crystals from the medium before HPLC measurements [20,59]. In this system, equilibration kinetics are not determined, and the full saturation therefore not proven.

Solid chemicals may have different crystalline forms, where metastable forms have a higher solubility than the stable form. While solubility can be measured for any crystalline form as long as the structure do not change during the measurement, it can be important to characterize the solid state properties after the measurements [6]. In some cases it is crucial to determine the solubility of the most stable polymorph [6], which can be produced by solvent mediated polymorphic transformation. The choice of solvent for this is important for the transformation rate [60]. A modified shake-flask method was adopted by Loftsson and Hreinsdottir [61] in order to shorten equilibration times for solid chemicals while measuring the solubility of the most stable polymorph. An excess amount of solute was added to water, which was supersaturated by heating to 121 °C for 20 min followed by cooling. Then the water was seeded with the stable crystalline compound and equilibrated for 3–7 days during which the supersaturated material precipitated. The seeding ensured that the most stable crystalline chemical form was produced during precipitation.

A rapid method, called CheqSol, has also been developed for establishing equilibrium in solubility determinations of ionizable compounds. The CheqSol approach is an automated titration method where pH is adjusted in small steps and the direction of precipitation/dissolution determined by the direction of the subsequent pH change. The point of equilibrium is thus found by changing the concentration of the neutral form of the solute by the pH change [21]. The method works down to solubilities of 1 mg L^{-1}, and is therefore not useful for hydrophobic chemicals.

The high-throughput methods described above were developed in order to save time in the laboratory, and not in order to expand solubility determination methods towards difficult-to-test substances. These methods are therefore not designed to be appropriate for hydrophobic chemicals, volatile chemicals or fast degrading chemicals.

3.2.1. Fast degrading chemicals

Some may argue that a solubility determination has limited environmental relevance for fast degrading chemicals. However, there are scenarios where the volume of chemical present would still warrant a thorough hazard assessment. Furthermore, since solubility is a fundamental physical-chemical property, it is part of the characterization of the chemical even though it may in some cases not be important for the fate of the chemical.

Test chemicals can be subject to abiotic degradation processes during solubility testing such as photolysis, oxidation and hydrolysis. Most solubility test systems can be adapted to avoid photolysis during equilibration. Amber glass bottles can be used for shake flask experiments, the test system can be shielded from light by the

temperature controlling water jacket around the system or by aluminum foil, and in the case of slow stir methods, bottles can simply be placed in incubators [32] in the dark.

Chemicals prone to oxidation are easier to handle in solubility testing compared to toxicity testing [62], because oxygen saturated water is not necessary for the successful determination of water solubility. Test water should then be kept anaerobic by flushing with nitrogen gas, and tests conducted using a reduced or eliminated headspace as has been done when testing volatile chemicals with the slow stir method [32].

Chemicals for which hydrolysis can occur are more problematic. As already mentioned reaching equilibrium between pure substances and water may require long equilibration times. For fast degrading chemicals it is therefore crucial to shorten saturation times in order to be able to determine the solubility of these chemicals with a reasonable accuracy.

Two methods have been proposed where equilibrium of the chemical with the water can be obtained within minutes. The first method with potential for very fast equilibration kinetics is the passive dosing method. Equilibration kinetics in passive dosing increases with increasing donor surface area to medium volume ratio and also with increasing degree of stirring of the system. It is therefore possible to optimize passive dosing systems for fast equilibration. The system dimensions in the study by Stibany et al. [42], were not optimized for very fast equilibration times, and 11 h were needed to establish equilibrium with algal medium containing 20% methanol. Equilibration times less than 10 min have been demonstrated for passive dosing of hydrocarbons to water in an optimized design [63,64]. The concentrations in this study were below solubility, but very similar equilibration times are expected also for equilibration at the solubility limit. For solid and unstable chemicals, an accelerated passive dosing system seems to be the best option, as this method worked well at the solubility point [41].

For liquid test chemicals, initial experiments have revealed that passive dosing at the solubility limit can be vulnerable to the condensation of chemical and the subsequent droplet formation. Loading the silicone to 90% of the saturation level resulted in more reproducible results (unpublished data). The most efficient and practical way to avoid micro droplets would then be to load the polymer just below saturation. Running such experiments at several loadings below saturation (e.g. 50, 70, 90 and 100%) might be the best way to approach the solubility level from below, while generating the necessary measurements to detect and discern any micro droplet formation artefacts.

The second method with potential for very fast equilibration kinetics is the saturated vapor method for liquid test chemicals. This method ensures a high agitation while keeping the solute phase and the water phase separate (avoiding droplet formation). The equilibrium time was 3 min [44]. However, also this method is vulnerable to condensation of the chemical in the water reservoir. Therefore, it was better at producing reproducible concentrations when the temperature of the solute reservoir was lower than that of the water i.e. when the water was slightly under-saturated, and poor precision was observed when the temperatures were equal, exactly at the solubility point [44].

Even though there are drawbacks for the two methods for liquid chemicals (saturated vapor and passive dosing), the methods provide sufficiently short equilibration times for fast degrading chemicals.

4. Analytical challenges

As stated in the introduction, solubility experiments consist of (1) preparation of saturated water and (2) measurement of the chemical concentration in the saturated water. As with the first step, the measurement of chemicals is subject to challenges dependent on the test substance.

4.1. Volatile chemicals

A high volatility can be used as an advantage when testing the solubility of chemicals, but it can also be a challenge. For volatile chemicals, headspace passive dosing methods can be used to saturate water via the headspace, while avoiding a direct contact between test substance and water and thus avoiding non-dissolved test chemical entering the water phase (Fig. 1). However, volatile chemicals are also more prone to losses during extraction and analysis of the water sample after equilibration. It is therefore important to minimize or even eliminate the steps between equilibration and analysis, which can be done by a close alignment between the experiment and the instrumental analysis. Much can be done with careful handling of the water, using gas-tight syringes, avoiding headspace etc. Letinski et al. (2016) successfully determined solubility for highly volatile hydrocarbons by using gas-tight syringes for sampling the saturated water, adding the samples to headspace vials and performing analysis using headspace solid phase micro-extraction coupled to GC-MS without storage. Tolls et al. [33] also used gas-tight syringes and a closed purge and trap system and were careful not to lose chemicals by evaporation.

Multiple headspace extraction gas chromatography is a method specifically developed for volatile organic chemicals, which aligns the solubility experiment with the analysis [65]. Technically it is a kinetic method, where water with an excess amount of solute is used, and then multiple headspace extractions remove solute from the headspace while measuring the concentration in the headspace using GC analysis. As long as there is excess pure phase chemical in the water phase, the concentration in the headspace will be buffered by the pure phase chemical, however, when there is not any more pure phase left in the system, headspace concentrations will decrease fast [65]. Care should be taken with this method to ensure that agitation and equilibration time is sufficient and that sorptive losses to septum and other surfaces or impurities do not interfere with the measurements.

4.2. Highly hydrophobic chemicals

The aqueous solubility of highly hydrophobic chemicals is very low. One of the challenges for this group of chemicals is therefore related to analytical detection of very low concentrations [66]. Developments in analytical chemistry within the last 20 years have ensured that concentrations in the ng L^{-1} range can be measured for almost all organic chemicals using liquid-liquid extraction or solid phase extraction and GC-MS or LC-MS. Tolls et al. [33] used for instance headspace SPME on 25–500 μL samples (quantitative extraction) for alkanes (μg L^{-1} range) and purge and trap analysis for alkanes with even lower solubilities (ng L^{-1} range) where the SPME method did not provide sufficient sensitivity. Lower concentrations, in the pg L^{-1} range or lower, is however still challenging to quantify.

Careful sample handling is particularly important for highly hydrophobic chemicals in water samples. Avoiding pure phase micro-droplets and ensuring that there is no dissolved organic carbon or dust contamination of the water, which would lead to overestimation of solubilities, can be quite challenging, and is preferably handled during the equilibration step. However, highly hydrophobic chemicals have a high potential for sorptive losses during the analytical work, which then can lead to an underestimation of the solubility. The immediate addition of non-polar solvents to aqueous samples for liquid-liquid extraction before GC measurements as well as the immediate addition of more polar

solvents to aqueous samples before HPLC measurements can reduce such losses. If available, ^{13}C-labeled substances can be added via the solvent, which then can be used to correct for losses and incomplete extractions.

Background contamination of the test chemical can be of crucial importance for highly hydrophobic chemicals, especially when solvents are used for extraction. During the equilibration step, the pure phase chemical is handled in the laboratory. In the subsequent step, concentrations >10 orders of magnitude lower have to be handled without any contamination. High care must therefore be taken regarding the solvents and equipment used in sample handling steps to avoid contamination with the test chemical in order to avoid overestimation of the solubility. A clear separation between equipment used in the two phases of the solubility measurements is recommended. Background contamination stemming from a wide use of the test chemical in equipment used in the laboratory or its surroundings is harder or may be even impossible to get rid of.

5. Scientific challenges

5.1. Surfactants

Surface active compounds, or surfactants, are molecules with a polar head and a nonpolar tail. Technically these compounds are highly miscible with water. However, above a certain concentration in water, the critical micelle concentration (CMC), the surfactants cluster into micelles, and are thus not freely dissolved anymore. This can be viewed as equivalent to the formation of micro-droplets or emulsions of hydrophobic chemicals in water. The difference is that the formation of the micelles cannot be avoided by eliminating agitation, and the micelles are uniformly distributed within the water phase. This also means that even given quiescent conditions and long time-frames, the micelles will not separate from the water phase to form a pure phase at the top or bottom of the water.

Since the critical micelle concentration sets the upper limit for freely dissolved molecules, it is sometimes used as a surrogate for the solubility of surfactants [67]. The OECD guidance document recommends that exposure concentration in toxicity testing are expressed as nominal concentrations but that toxic effect concentrations are compared to the dispersibility limit or the critical micelle concentration instead of the solubility limit [62].

Most methods for determination of the CMC are indirect methods. This means that the equilibrium concentration of the freely dissolved molecules in water is not measured. Instead, physical or chemical properties are measured over a concentration range, and the CMC is inferred from a change in their trend. The most common physical methods are surface tension [68–70], electrical conductivity [71,72] and spectroscopic methods [73].

The surface tension method works by the principle that below the CMC the surface tension decreases as surfactant concentration increases, whereas above the CMC this increase levels off since additional surfactant molecules form micelles. However, surface tension methods have the drawback that the detected changes do not refer directly to the bulk phase of the solution but to phenomena at the surface. Data may therefore be challenging to interpret, and in some cases erroneous results are found. These errors can occur if the surface interface is saturated with molecules at concentrations below the CMC [68] or an efficient packing structure of the chemicals at the interface leads to increased capacity of the interface for surfactant molecules above the CMC [74].

The electrical conductivity method consists of measuring the specific conductivity of surfactant solutions and is limited to ionic surfactants [75]. In most cases a sharp break will be seen in the conductivity at the CMC, and the data are easy to interpret. In cases where a weak curvature is seen in the region around the CMC, a number of different mathematical procedures can be used for the analysis of the experimental data [75,76] or dielectric constants can be measured instead [77].

If surfactants have aromatic fragments in their structure, the CMC can be measured by non-invasive spectroscopic methods, where the CMC is measured in a solution containing only the surfactant and water using absorbance or fluorescence spectroscopy [78–80]. Otherwise, invasive spectroscopic methods can be used, where a tracer is added to the solutions before measurement. Examples of tracers used for spectroscopic methods are summarized in Supplementary material S1.

Several other methods have been developed for CMC determinations. Non-invasive physical methods include capillary electrophoresis [81–83], speed of sound measurements [84,85], resonance Rayleigh scattering [86], static and dynamic light scattering [74,87,88], potentiometry [89], nuclear magnetic resonance, NMR [90,91], diffusion ordered spectroscopy NMR [92,93], ultrasonic spectroscopy [94], fiber-optical measurements [95], induction current [96], chemiluminescence [97] and chiroptical spectroscopic methods [98].

Partitioning of hydrophobic chemicals to the micelles can also be used to determine CMC by measuring the solubility enhancement of solvent solutions [64,99], and recently a method was suggested where the partitioning of toluene between headspace and solution was used for automated CMC measurements [100].

All of the above mentioned methods are vulnerable to loss processes because nominal concentrations are used to infer the CMC and the concentrations of the surfactants in solution are not measured. This would mainly affect measurements of surfactants with a low CMC and high affinity for partitioning to interfaces. A method where the dissolved concentrations in the water is measured to determine solubility of surfactants was described by Haftka et al. [67]. They used solid phase microextraction fibers to measure the concentration of the freely dissolved surfactant in order to determine the CMC for a range of neutral, zwitterionic, anionic and cationic surfactants. The method is limited to surfactants with CMCs below the aqueous concentration corresponding to the binding capacity of the fiber [67]. Ultrafiltration combined with centrifugation has also been used to separate the freely dissolved molecules from the micelles for CMC measurements [101–103].

5.2. Multi-constituent substances

Water solubility is first of all an intrinsic property of pure chemicals. However, use and emissions of chemicals often occur as mixtures. For mixtures with one dominant component and a minor impurity, solubility determinations should target the solubility of the main component, which requires dedicated analytical techniques to separate and quantify the main component in the presence of the impurity. The next level of complexity is multi-constituent substances, which include mixtures of chemicals, congeners, isomers and enantiomers. Saturated aqueous solutions of multi-constituent substances do not provide a real “solubility” in the strict sense. However, they are still highly relevant for the fate, exposure and toxicity of multi-constituents substances.

The simplest mixtures contain a limited number of pure chemicals. The concentrations of the mixture components in water equilibrated with an excess amount of such mixtures depend on whether the chemicals are in the liquid state or solid state and how the components in the mixture interact (within the mixture and in the water) [104].

If the activity coefficients of all *i*th components in a mixture, $\gamma_{i,mix}$, approximates 1, then the mixture is called an ideal mixture

[104]. This means that the intermolecular interactions between a molecule of the *i*th component and other components in the mixture are approximately similar to the intermolecular interactions between two molecules of the *i*th component [105].

When the mole fraction does not change much during equilibration in the test system, e.g. at high loadings, the following relationships applies for dissolved concentrations of mixture components. For ideal liquid mixtures, the equilibrium water concentration of the *i*th component, C_i, is related to the water solubility of the pure form of the *i*th component, S_i, by the mole fraction of the component in the mixture, $x_{i,mix}$ as shown in equation (1) (Raoult's law) [104,105].

$$C_i = x_{i,mix} \cdot S_i \tag{1}$$

For ideal solid mixtures, the equilibrium water concentration of each component is however independent of the composition of the mixture (equation (2)) [104,106,107].

$$C_i = S_i \tag{2}$$

Ideal mixtures may also comprise of a mix of chemicals, which are liquid and solid in their pure form. If the liquid components dissolve the solid components, the mixture will behave as a liquid mixture, and the equilibrium concentration depend on the mole fraction of each component in the mixture. However, for the solid components, the equilibrium will not be a fraction of the solubility of the solid pure form, but of the subcooled liquid solubility of the chemical, which is higher than the solid solubility (equation (3)) [104].

$$C_i = x_{i,mix} \cdot S_{i,subcooled\ liquid} \tag{3}$$

If the amount of solids in the mixture exceeds what can be dissolved in the liquids, they will crystalize and behave according to equation (2) [104].

The saturation concentrations in water from non-ideal mixtures are not as straight-forward to predict. Mixtures of hydrophobic and hydrophilic components are non-ideal mixtures. When these mixtures are equilibrated with water, two factors affect the equilibrium concentrations: 1) A significant amount of water can partition into the mixture and thereby increase the activity coefficient of the hydrophobic chemical in the mixture, and 2) a significant amount of the hydrophilic components can partition into the water and thereby reduce the activity coefficient of hydrophobic component in the water, the co-solvent effect. The equilibrium concentration of the hydrophobic component will then be increased compared to the expectations from equation (1). The activity coefficients of the component in the mixture, $\gamma_{i,mix}$, and in the water $\gamma_{i,water}$, can be predicted from group contribution structure-property relationships (the UNIFAC method [108], UNIFAC appears to have comparable performance relative to other physicochemical property models [109]), and the equilibrium concentration in water can be described by equation (4),

$$C_i = \frac{x_{i,mix} \cdot \gamma_{i,mix} \cdot \gamma^p_{i,water} \cdot S_i}{\gamma_{i,water}} \tag{4}$$

where $\gamma^p_{i,water}$, is the activity coefficient in the water of the pure chemical [104].

In non-ideal solid mixtures, constituents interact and e.g. form solid solution [106] or eutectic structures [110]. For interacting solid mixtures, the composition of the solid solution will influence the solubility of the components [106,110], and the resulting equilibrium concentration in water will most often be somewhere in between what would be expected from ideal liquids (equation (3)) and ideal solids (equation (2)).

Special attention is needed for analytical determination of the solubility of multi-constituent substances. In principle, the methods for solubility determination of single chemicals can still be used for multi-constituent substances. However, it is then crucial to use a sufficiently high mixture to water ratio to ensure that the mixture composition is not significantly changed during equilibration.

5.3. UVCBs

While it may be complicated to define and determine the "solubility" of multi-constituent substances of known compositions, an even more complicated matter is to characterize and predict saturated solutions of Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB's). In a specific mixture of known composition, the saturated concentration of each constituent can be predicted as described above. However, for UVCB's, the composition is not fully known and variable. A meaningful parameter could then be the total dissolved concentration of the UVCB components in pure water in equilibrium, while ensuring that none of the components are depleted during equilibration. Two focus points are therefore especially important when characterizing saturated solutions of UVCB's: 1) determination of aqueous concentrations of mixtures which are not fully characterized and 2) ensuring a constant mixture composition during the equilibration (avoiding depletion of single constituents).

The water:mixture volume ratio necessary to avoid depletion of mixture components, depends on the partition ratio of the constituents between the mixture and the water. It can be estimated if the mixture-water partition ratio of the least hydrophobic constituent is known. For petroleum mixtures, the minimum octanol-water partition ratio of components in the mixture, $K_{ow,min}$, can be used to estimate this ratio if partitioning between the mixture and water phase is assumed to roughly follow octanol-water partitioning. If partitioning to headspace is also neglected, then based on mass balance calculations, a minimum water:mixture ratio, $R_{w:m,min}$, to ensure less than 5% depletion of the mixture can be found by $R_{w:m,min} = 0.05^{*}K_{ow,min}$. These rough mass balance calculations are in line with observations reported in the literature. Of eight investigated compounds in a diesel fuel (benzene, alkylbenzenes, and PAHs), only benzene was seen to deplete from the diesel (by 10%) when using a water:diesel ratio of 20 [111]. Shiu et al. [112] found that a water:oil ratio of 20:1 or 10:1 was sufficient to avoid depletion for three crude oils and a gasoline, however, for fuel oil no. 2, which contained a large fraction of pentane and lighter constituents, a low water:oil ratio of 5:1 was not even sufficient [112].

Saturated solutions of liquid UVCB's have been generated using the same approaches as for the pure liquid chemicals including shake flask [113], slow stir [111,112], generator column [114], passive dosing methods [56,57], and modeling [115].

Experimental methods to prepare saturated solutions of UVCB's face the same challenges as for pure substances regarding avoiding micro-droplets and emulsions of hydrophobic liquid chemicals and losses of volatile chemicals. The slow-stirring method is therefore often preferred for petroleum products [111,116]. Equilibration times of 1–2 days were seen in one study, but it was pointed out that for viscous UVCBs, transport of the solute to the water can become rate limited by slow mass transfer through the viscous UVCB [111].

Saturated solutions of UVCB's are of special concern when evaluating the leaching potential from non-aqueous phase liquids (NAPLs) in soil. Mao et al. [114] investigated the saturated solutions of 13 mixtures of petroleum hydrocarbons using a column

generator type of set-up, where petroleum spiked sand was added to a column and water pumped through to generate saturated solutions. Analysis was done using HPLC-GCxGC, in order to identify 79 hydrocarbon fractions. Indicator compounds and their solubility were assigned to each fraction, and Raoult's law used to calculate total saturated concentrations for each petroleum product, which corresponded within a factor of 3 to the experimental solubilities. Deviations were assigned to non-ideality of the chemicals in the mixtures and losses during sample extraction and analysis [114].

The total saturated concentration of UVCBs in water is a challenging subject because it is determined by the sum of solubilities of the individual constituents. The variable physicochemical properties of the constituents can result in variable fate of chemicals in test systems, and the environment. For example, volatile constituents will partition to air phases, soluble constituents will remain in water, and insoluble constituents will remain in the UVCB, and all of the constituents exist along a spectrum of volatility and solubility. UVCB concentration will also change over time because of the 'weathering' of the mixture, where the constituents of highest solubility and volatility are depleted from the mixture. Depletion of constituents over time (>20 d) was noted in oiled gravel studies resulting in time variable exposures [117,118].

In modeling approaches relevant descriptors of the UVCB mixture are crucial. A number of UVCB's such as gasolines, diesel fuels and coal tars have been shown to reveal near-ideal behavior [114,115,119–122]. These UVCB's can be characterized by block methods or structure oriented lumping methods, where constituents are lumped into groups based on their structure and/or size [123,124]. Representative water solubilities can then be assigned to each block based on relevant measurements or solubility models. For near-ideal mixtures, saturated concentrations in water for block components can be modeled using the equations for ideal mixtures (Raoult's law) based on representative structures in the mixtures [46,125]. For polar components such as phenols, anilines and benzotriazoles in nonpolar fuels, descriptors for polar molecular interactions has to be included in the models in order to produce reliable solubility predictions [113]. Dissolution of constituents from a UVCB is generally controlled by the mole fraction of the constituents in the UVCB phase. However, volatile or soluble constituents can partition to the aqueous or air phase and alter the mole fraction of the parent oil. Therefore, a mass balance model is needed to account for the depletion. Application of a mole fraction-based mass balance solubility model has been successfully applied to petroleum substances [46,57,126]. This modeling framework can describe the solubility of constituents with a wide range of physicochemical properties, and also accounts for depletion of the test substance at low substance loadings. This approach is an extension of the hydrocarbon block method [127], which define a petroleum substances into blocks by chemical class and carbon number. The physicochemical properties are generally estimated by QSARs. However, advances in data analysis of GCxGC analytical results provide an opportunity to refine predictions of saturated concentrations by providing methods to assign properties to individual peaks instead of aggregated blocks.

6. Recommendations for solubility determination of difficult-to-test substances

Based on this literature review, the authors suggest a decision tree for solubility determinations of difficult-to-test chemicals as shown in Fig. 2. As described in section 5.1, surfactants represent special challenges for solubility measurements, which are not covered in this decision tree. Readers are referred to section 5.1 for methods to determine CMC. Mixtures are also not included in Fig. 2. When determining solubilities of mixtures, the same issues regarding stability, hydrophobicity and volatility apply as for pure chemicals. Therefore, analytical methods can be chosen based on the chemical properties of the major fraction of components in the mixtures. The decision tree includes criteria for categorization of chemicals in each group: hydrophilic/hydrophobic/very hydrophobic, solid/liquid, stable in water/not stable in water, and volatile/non-volatile. The cutoff between the hydrophilic/hydrophobic group is based on the literature data presented by Ferguson et al. [11]. It showed that solubility data for alkanes of chain length up to heptane had little variability, data for octane to decane had some variability, and data for alkanes with a chain length longer than decane had high variability. These solubility data mainly stemmed from measurements using the shake flask method. Even though the current OECD guideline [1] recommends a solubility cut-off of 10 mg L^{-1} for the shake-flask method, we therefore assess the method to be applicable down to solubilities of at least 1 mg L^{-1}. The expected solubility of the test chemical can be estimated prior to experiments using QSAR relationships [128] in order to select the appropriate test method using the decision tree. However, it should be noted that uncertainty in the order of a couple of magnitudes can be associated with such estimations [9]. Experimental Log K_{ow} values can be used instead of estimated solubility values. For chemicals with high molecular weight, solubility estimations are however more appropriate to use, since large chemicals tend to have lower solubilities in both octanol and water. Also, for chemicals with a high melting point the grouping between hydrophilic, hydrophobic and very hydrophobic will be somewhat different when based on Log K_{ow} compared to water solubility. The reason for this is that water solubility not only depends on the hydrophobicity (i.e. activity coefficient in water), but also on the enthalpy required to transfer the solid chemical to a liquid state (i.e. melting enthalpy directly related to melting point) [129].

Stability of the chemical relates primarily to degradation processes that are difficult to eliminate by controlling the oxygen, light or sterility of the test system. Hydrolysis is the most important degradation process that is hard to eliminate, but biological degradation can also be difficult to avoid when the testing requires prolonged equilibration times. No specific methods were found in the literature describing solubility testing of chemicals that hydrolyzes rapidly. However, acid and base catalyzed hydrolysis can often be reduced by adjusting to the pH at which the test substance is most stable. For the purpose of using the flowchart, an estimated half-life based on these non-controllable degradation processes would assist in choosing the appropriate testing methodology. Hydrolysis half-lives can be determined experimentally using an OECD guideline or estimated based on QSAR relationships [128]. The cutoff for stability in water varies depending on the equilibrium times of the recommended methods, since shake-flask and column elution methods usually equilibrate in the time-range of day(s), whereas the slow-stir method equilibrate for week(s).

The methods suggested for the chemical groups vary in how well established they are in the literature. The two groups of chemicals covered within the 1995 OECD guidelines are the stable hydrophilic chemicals and stable solid hydrophobic chemicals (methods indicated in green). For the rest of the chemical groups, the methods are divided into methods, which are well described in literature and have been demonstrated to work for the designated chemical group (purple), and methods which are suggested based on literature descriptions using other chemicals or used for other purposes than solubility determinations (orange). It is therefore the expectation that the methods indicated by purple can be used without much alteration, whereas the methods indicated by orange require further developments and testing. The suggested methods for solubility determinations do not differ for the hydrophobic and very hydrophobic chemicals. However, the degree to which some of

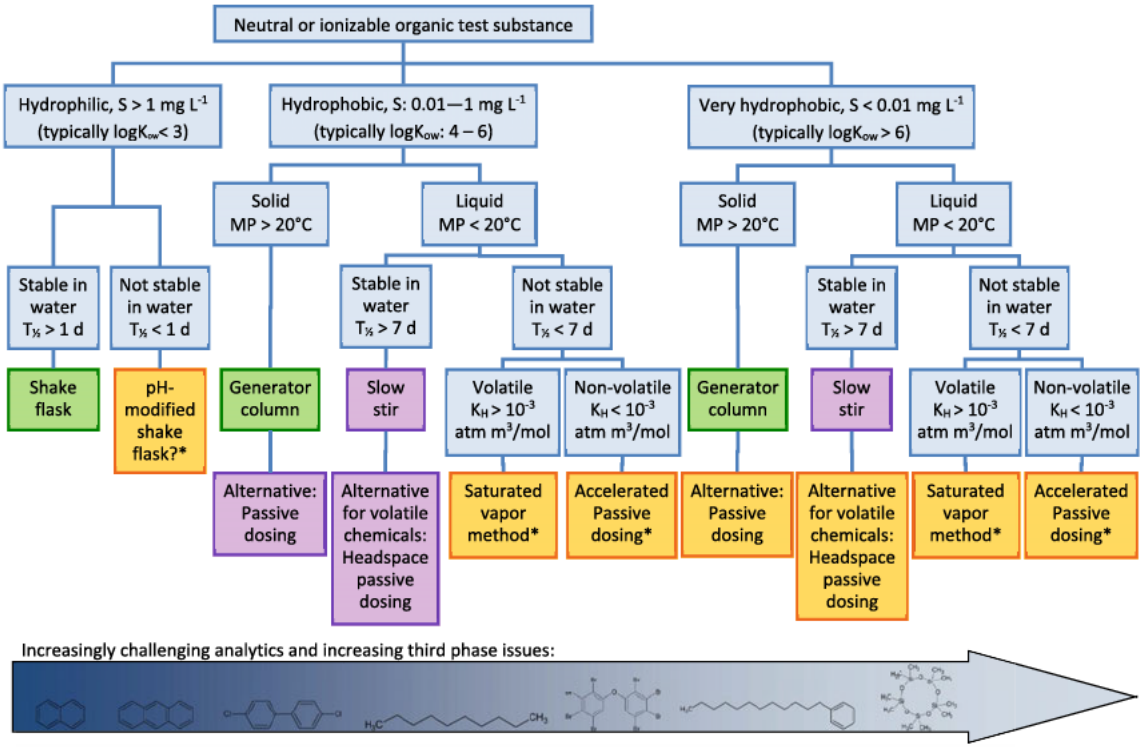

Fig. 2. Decision tree for choice of solubility determination methods. Green indicates methods in the OECD guideline from 1995, purple indicates methods demonstrated in current literature for the designated chemical group, orange indicates methods with a potential to improve determinations for the chemical group, however not demonstrated for the designated chemical group in current literature. Criteria for the groups are indicated in italics where S is the expected solubility, $\log K_{ow}$ is the octanol water partition ratio, MP is the melting point, $T_{½}$ is the half-life in water, and K_H is the Henry's laws constant. Mixtures are not included, but methods can be chosen based on their major constituents. *If the absence of stability stems from hydrolysis which is acid or base catalyzed, test should be performed at pH at which test substance is most stable. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

the methods have been demonstrated decreases for the very hydrophobic chemicals, and the degree of analytical challenges and third phase issues increase.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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Heidi Birch: Dr. Heidi Birch is an environmental engineer with a Master's degree (2007) and doctorate (2012) from the Technical University of Denmark (DTU). She worked three years as a consultant engineer in Alectia A/S before returning to DTU for a Postdoc and Researcher position. Her research focus is within environmental fate and exposure of organic chemicals. This includes passive dosing and sampling techniques, biodegradation testing, and adaptation of laboratory testing methods for volatile and hydrophobic chemicals. Heidi introduced “analytical passive dosing” in 2010 and is presently working on the CEFIC project: “Cross-validation for improving determinations of water solubility for difficult-to-test substances”.

Aaron Redman: Dr. Aaron Redman is a Senior Environmental Scientist with ExxonMobil. He has 20 years of experience in research and assessment of petroleum substances and other chemicals. He was lead developer of the PETROTOX and PETRORISK spreadsheet models that adapt classical risk assessment approaches to the physical chemical properties of complex petroleum substances. He has published more than 40 papers and chapters in the refereed literature and presents frequently at international conferences. Specific expertise includes research on the bioavailability of organics in oil sand process waters, PBT assessments of hydrocarbons, and hazard and risk assessment of petroleum substances and crude oil, which include development of methods for measuring and estimating physicochemical properties including water solubility measurements.

Daniel Letinski: Daniel Letinski is a Senior Scientific Associate with ExxonMobil Biomedical Sciences, Inc. He has over 30 years of experience developing trace analytical methods and passive dosing techniques associated with laboratory ecotoxicity testing of petrochemical substances. He is one of the developers of biomimetic passive sampling using solid phase extraction as an analytical technique for predicting the aquatic toxicity of complex petroleum substances. He has contributed to the development of the OECD fish dietary biomagnification test guideline and the slow-stir water solubility method. He has co-authored 20 papers on water solubility determinations and the environmental fate and effects of petrochemical products.

Delina Lyon: Dr. Delina Lyon is an Ecotoxicologist for the Shell Oil Company where she specializes in chemical risk assessment of difficult-to-test substances. She has spoken at multiple international conferences and is involved in several task forces on risk assessment of poorly soluble UVCBs with emphasis on the need for greater analytical characterization. Del has a Master's in Microbiology from the University of Georgia and obtained her doctorate in Environmental Engineering from Rice University in 2008. Prior to Shell, she was an academic researcher spanning a broad range of topics from bioremediation of explosives to microbial metagenomics to fate and transport of nanoparticles.

Philipp Mayer: Professor Philipp Mayer studied at the Technical University of Denmark (M.Sc, 1995), the University of Wisconsin, Milwaukee (Fullbright, 1994–1995) and the University of Utrecht (Ph.D., 2000). He was then Study Director (GLP) and Product Manager for Environmental Toxicology at TNO (NL, 2001–2002), before he moved back to Denmark for a position at the National Environmental Research Institute (2001–2013). Since 2013, Philipp Mayer is Professor for Applied Environmental Chemistry at the Technical University of Denmark, Lyngby, Denmark. The research focus of his group is on partitioning based analytical technology and the fate, exposure and effects of organic contaminants in the environment.

Swedish Match.

Attachment 1D 20200924

The average solubility and standard deviation for products PM0000593-PM0000612 are shown in Table 1D.1, together with the corresponding results for the ungranulated powder.

Table 1D.1. Solubility (%) for ZYN materials, before and after granulation.

Product	Ungranulated	Granulated	Difference
ZYN Cool Mint 3mg	(b) (4) [redacted]		
ZYN Cool Mint 6mg			
ZYN Peppermint 3mg			
ZYN Peppermint 6mg			
ZYN Spearmint 3mg			
ZYN Spearmint 6mg			
ZYN Wintergreen 3mg			
ZYN Wintergreen 6mg			
ZYN Citrus 3mg			
ZYN Citrus 6mg			
ZYN Coffee 3mg			
ZYN Coffee 6mg			
ZYN Cinnamon 3mg			
ZYN Cinnamon 6mg			
ZYN Smooth 3mg			
ZYN Smooth 6mg			
ZYN Chill 3mg			
ZYN Chill 6mg			
ZYN Fresh 3mg			
ZYN Fresh 6mg			
Average			
Standard Deviation			

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RECONSTITUTION CHARACTERISTICS OF FOOD POWDERS AND GRANULES WITH EMPHASIS ON NON FAT DRIED MILK

A Thesis presented in partial fulfilment of the requirements for the Degree of Master of Food Technology in Food Processing at Massey University, Palmerston North, N.Z.

Edward Neff

July, 1967.

"When you know a thing, to hold
that you know it; and when you
do not know a thing, to allow
that you do not know it;
this is knowledge".

CONFUCIUS

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EDWARD NEFF

ABSTRACT

Reconstitution characteristics of food powders form a major determinant of consumer acceptance, particularly with the trend to instant foods. A working theory has been proposed to explain the mechanism of dispersion of any soluble food powder.

A study was made of methods which may be employed to modify reconstitution characteristics. No significant improvement in the dispersibility of Non Fat Dried Milk (NFDM) could be achieved by a compression/repowdering process even though the particle density and porosity of the powder could be increased by this technique. When applied to spray dried instant coffee such process of compression, up to 150 psi, resulted in a small improvement in dispersibility while at the same time achieving a marked increase in the bulk density of the powder. The significance of this observation with regard to potential saving in packaging volume has been discussed.

The most significant improvements in reconstitution characteristics of NFDM were achieved by a rewetting/redrying process. A granulation technique is described which has been successfully employed to simulate commercial instantising of powders. By means of this granulation technique it has been shown that by far the most important factors in agglomeration influencing the properties of the resultant "granules" are :

1. Rewetting moisture content at which granulation is achieved prior to redrying;

2. Particle or granule size of the final product.

Optimum conditions for NFDM have been determined to be 11-12% rewetting moisture and a mean particle size of 200/u. This granulation technique has also been employed to study the effect of additives at agglomeration upon reconstitution properties of NFDM.

Several commercial processes are in use, and are covered in patents, for the purpose of instantising NFDM and other food powders. Despite this, however, no study has previously demonstrated the critical nature of certain variables in this process as clearly as has been done in this study.

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I. INTRODUCTION

It cannot be disputed that the trend today is towards instant and convenience foods. At the same time there has been considerable expansion in the spray drying of food powders; in particular, in the dairying industry the last few years has seen the installation of a large number of high capacity spray drying plants both in Australia and New Zealand. One of the problems, however, is that many of these conventionally spray dried powders among them Non Fat Dried Milk (NFDM) possess poor reconstitution or dispersibility characteristics. This has prevented widespread acceptance of such powders as a household item and has restricted the development of new markets. As an example it may be pointed out that by far the major portion of the market for milk powders still relies on industrial recombining and reconstitution facilities and sale of the liquid products. This obvious market prejudice against powders must be, at least in part, due to poor dispersibility characteristics. It is the aim of this study to examine more closely factors associated with dispersibility or reconstitution properties of powders.

Taking again spray dried NFDM as an example it must be emphasised that this possesses excellent ultimate solubility. For example, A.D.M.I. standards for Extra Grade NFDM require a solubility index of not greater than 1.25 ml. This is equivalent to a solubility of greater than 96%. The problem, therefore, lies not with ultimate solubility but with its instant solubility or dispersibility, as would be encountered by a consumer attempting to

reconstitute NFDM with water. Admittedly, the dispersibility of NFDM is not the prime consideration when referring to reconstitution on a large scale as is the case in commercial recombining plants in operation in South East Asia. But, dispersibility of a food powder still remains a major quality attribute where reconstitution is to be performed by the consumer immediately before use. In view of the trend towards instant foods, therefore, a better understanding of dispersion of food powders is paramount to technological progress in this field.

Evidence suggests that the dispersibility characteristics of a powder are associated mainly with physical properties. This is suggested by the fact that a conventionally spray dried NFDM of poor dispersibility can be converted to an "instant" powder by an agglomeration process involving rewetting and redrying to produce a powder of increased particle size.

Research on reconstitution characteristics of food powders has been examined in three sections :

(1) Characterisation of Typical Food Powders

This includes the development of test methods to allow characterisation of powders culminating in the postulation of a working theory of the mechanism of dispersion of any food powder.

(2) Effect of Non-Rewetting Processes Upon Dispersibility

This examines possible techniques which may be employed to modify reconstitution characteristics without requiring a rewetting operation.

(3) Effect of Rewetting Processes Upon Dispersibility

This examines a rewetting process, as in commercial instantising, employed to improve the dispersibility of NFDM.

II. METHODS OF ANALYSIS

A. LITERATURE REVIEW

Analytical techniques were required for the determination of dispersibility charactersitics of a powder and also physical properties such as density, particle size, etc. Comparatively little difficulty was encountered in the selection of techniques for the measurement of physical properties. However, the evaluation of dispersibility characteristics proved to be a more elusive task.

The difficulty in designing an objective test of dispersibility, or ease of reconstitution, is best illustrated by reference to a review by King (1966), wherein scores of tests are described which have been employed for such evaluation of milk powders. King (1966) categorises these tests as :

(a) Determination of wettability;

(b) Determination of self-dispersion and of dispersion at low energy stirring;

(c) Determination of sinkability.

These divisions seem rather artificial since sinkability will be influenced by wettability, as will self-dispersion. It was, therefore, decided to examine the tests in perspective to consumer requirements for a powder. It was soon appreciated that no one test

would fully evaluate ease of reconstitution as judged by a consumer. Resigned to the fact that at least two test methods would be required it was decided that the two most important factors in evaluating ease of dispersion are :

(i) Sinkability

i.e. disappearance of powder from an unagitated water surface;

(ii) Dispersibility

i.e. ability of powder to disperse when mixed with water in a manner comparable to reconstitution by consumer.

In searching for a suitable sinkability test a technique was desired which would give a measure of the ability of a powder to disappear from a quiescent water surface. Reports of such tests include Kleinert (1950); Ashworth and Gunthardt (1954); Mather and Hollender (1955); Baker and Bertok (1959); Bullock and Winder (1960); and Radema and van Dijk (1962). These workers all describe tests involving the spreading of varying amounts of milk powder on the surface of water and measuring the solids passing into "solution" at varying intervals either by direct sampling and solids determination or by photometric measurement. Muers and House (1962) describe a method of spreading a sample of milk powder on a quiescent water surface and measuring the time for complete wetting. Mol and de Vries (1962) describe a technique for continually feeding a stream of milk powder onto a stream of water and measuring the reflection from the surface of a light beam to give an index of wettability.

Many of these tests appeared cumbersome and the major

problem appeared to be in achieving a uniform distribution of powder onto a quiescent water surface. For this reason a sinkability test was developed for the purpose of this research.

The problem of designing a suitable dispersibility test to evaluate the ability of a powder to redisperse to a fluid milk has been well discussed by Stone (1955). He describes the development of a dispersibility test wherein 52gm of powder are mixed with 400ml of water in a Hobart kitchen mixer. In this instance, rotation of the agitator was controlled at 135 rpm and continued for varying periods of 10-40 seconds. Upon completion of stirring, the reconstituted milk was drained from the bottom of the mixing bowl and passed through a 210/u screen before determination of total solids of an aliquot.

Moats et al (1959) modified this test by varying the speed of rotation and reducing mixing time to 5 seconds, claiming that this gave better sensitivity. They also employed a hydrometric method to determine the solids dispersal.

The American Dry Milk Institute (A.D.M.I.) adapted the dispersibility method of Stone et al (1954), to the testing of instant Non Fat Dried Milk (NFDM). A.D.M.I. specify the mixing of 52gm of powder with 400ml of water at 75°F for a period of 20 seconds, using a speed of rotation of 192 rpm. It was decided to adapt this test for dispersibility evaluation in this research. Since a Hobart kitchen mixer was not available, some modifications were necessary to the A.D.M.I. procedure.

B. PROCEDURES

(i) Sinkability Index (Original Method)

As mentioned previously, the major problem with all reported methods (variously called sinkability, self-dispersion, or wettability) involved the placing of a sample of powder uniformly onto a quiescent water surface. The procedure here adopted may best be described by reference to Figure 1.

A sintered glass funnel is rigidly mounted on a stand and a disc of filter paper is cut to 6cm diameter (28.2cm^2 area), so as to just fit on the sintered glass plate of the funnel. A known weight of powder is then placed onto the filter paper and carefully spread to a uniform layer by means of a fine brush. The filter paper is next held down onto the sintered plate by means of two wire clips. Water, at 75°F, from a thermostatically controlled elevated tank is then carefully allowed through the bottom of the funnel by opening the pinch clamp on a connecting rubber tubing. This allows the powder sample to be floated on the surface of the water without causing any disturbance of the surface, while maintaining a uniform distribution of powder on the surface. The time required for all the powder to disappear from the surface is measured; whether this be by self-dispersion or sinking without dispersion.

This technique, therefore, makes possible the determination of the time required for a weight of powder to disappear from a water surface. This information alone is not sufficient to compare different powders since there will not be a linear relationship

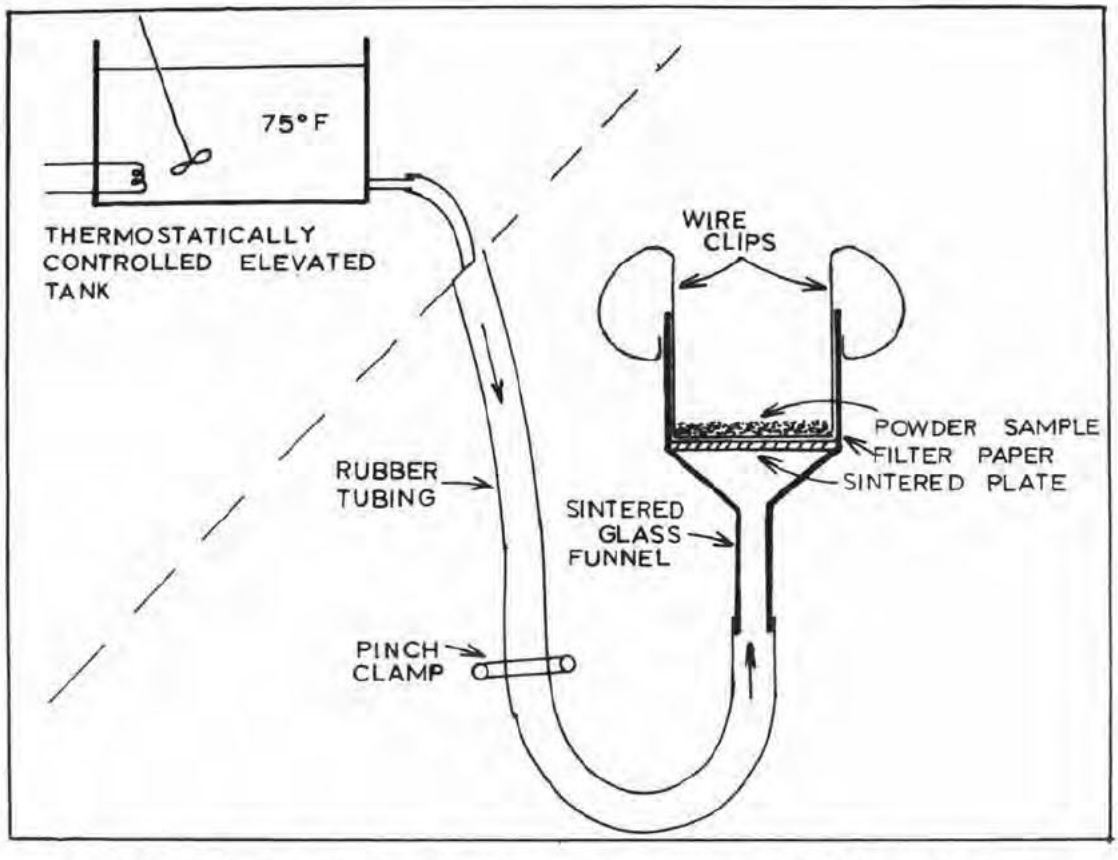

FIG. 1 APPARATUS FOR SINKABILITY INDEX DETERMINATION

between the loading of the water surface and time for complete disappearance. Therefore, times for sinking are measured for different weights of powder so as to allow the plotting of results as in Figure 2. Then, in order to compare different powders the weight sinking in 20 minutes is interpolated from the graph and the sinkability index is expressed as mg of powder sinking per minute per square cm of area, (i.e. $mg/min.cm^2$).

Typical plots obtained for several powders are shown in Figure 2. It may be noted that this method is applicable to any food powder, not necessarily milk powder.

(ii) Dispersibility (Modification of A.D.M.I. Method)

It was decided to adapt the A.D.M.I. technique for the determination of dispersibility of Instant NFDM as closely as possible using apparatus available locally.

Since a Hobart mixer was not available, the mixer chosen was a Kenwood "Chefette". Tests were first carried out with different shaped bowls and beakers, different mixing speeds and different mixing times. The A.D.M.I. method requires the mixer to be hinged so as to allow the beaters to be lowered into the bowl. It was first thought that the Kenwood mixer could be manually raised and lowered vertically on a laboratory stand. Another factor concerned the use of one or two beaters in mixing. The A.D.M.I. method employs one large whisker-type beater. However, the Kenwood mixer possesses two smaller beaters which may be used singly or

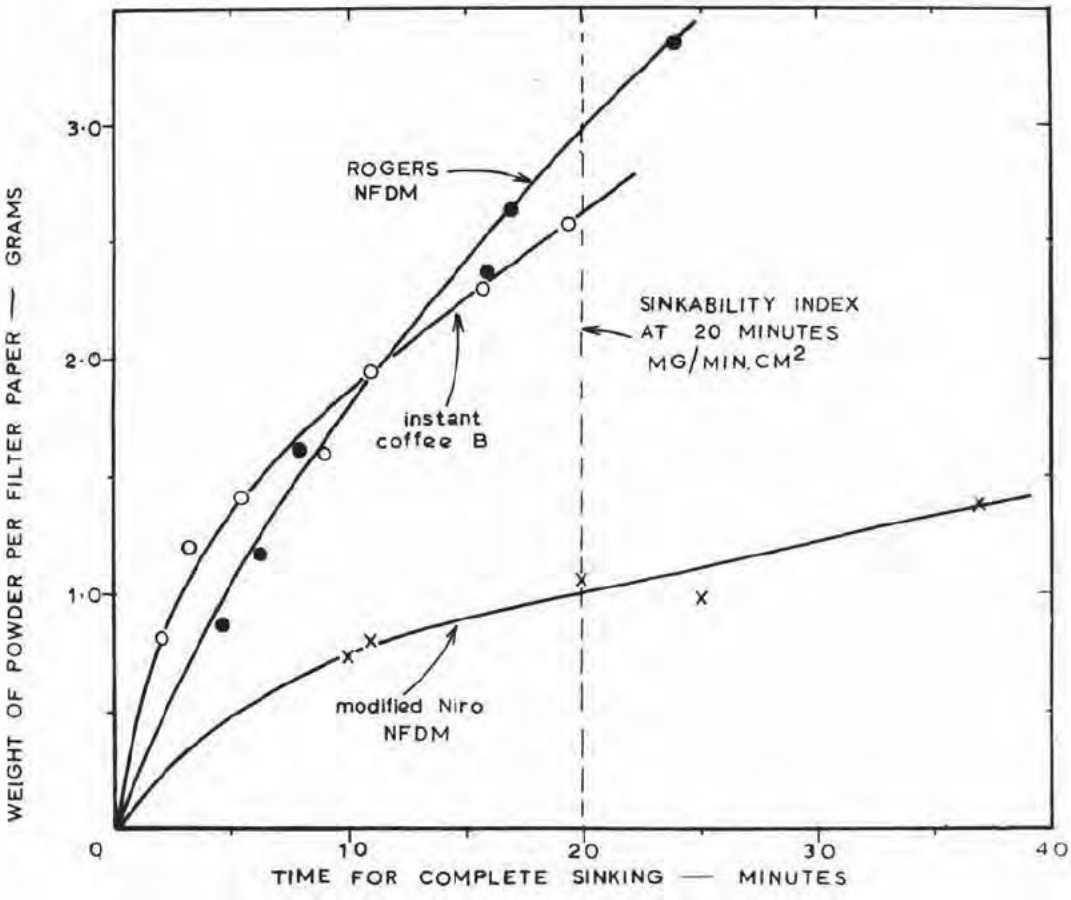

FIG. 2 TYPICAL SINKABILITY CURVES

together. These factors had to be determined and reproducibility tests were carried out as each technique was improved. Reproducibility was determined by carrying out 10 dispersibility determinations on the same sample of Niro NFDM. These results are best presented in tabular form in Table 1 :

TABLE 1

Reproducibility of Dispersibility Test

Details of Procedure	No.of Tests	Mean Value	Standard Deviation
1. Using 1 beater, manually raising and lowering mixer vertically, mixing 350 rpm/ 20 seconds.	10	41.1%	11.3
2. Using 2 beaters, mixer hinged for raising and lowering, mixing 175 rpm/20 seconds.	10	32.5%	1.9
3. Using 2 beaters,etc. as for 2, bowl more rigidly fixed and operation streamlined.	10	35.0%	1.8

As can be seen the variation in the test was eventually reduced to a standard deviation of 1.8 which was considered satisfactory. The procedure employed may be described by reference to Figure 3.

The Kenwood mixer is clamped in position using a laboratory clamp and stand in such a way that it can be raised and lowered about a fulcrum as shown. A stop is provided to allow the mixer to be lowered to the same position consistently. Two beaters are fitted to the mixer and these are adjusted to rotate at 175 rpm by means of

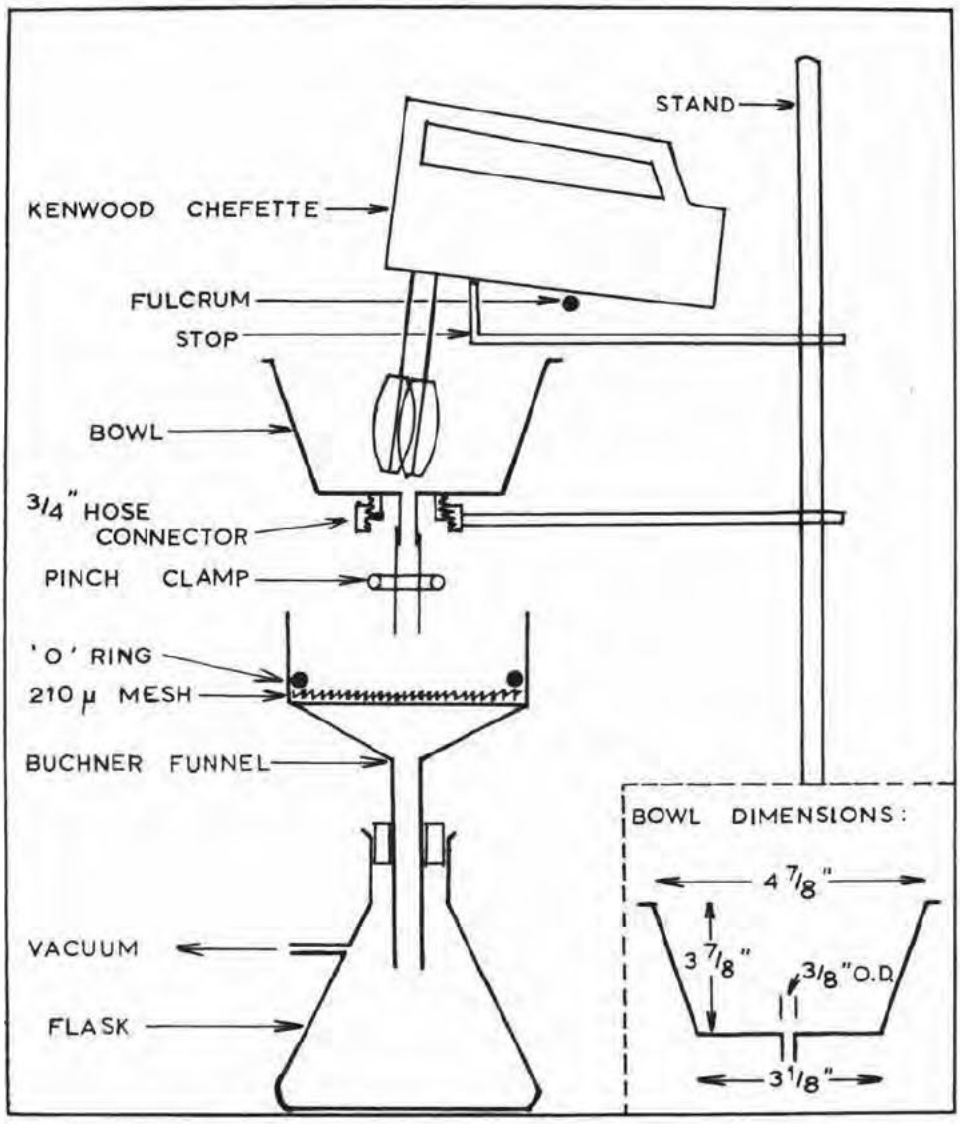

FIG. 3 APPARATUS FOR DISPERSIBILITY TEST

a "variac" variable voltage control, in the power supply to the mixer. Adjustment is made by means of a tachometer and it was found necessary to adjust the setting immediately before each test. The mixing bowl* is placed in position and can easily be removed and replaced to the same position by means of a ¾" hose connector assembly, one part of which is brazed to the bowl, the other being held in position by a connecting arm to stand. The bowl is fitted with a ⅜" O.D. outlet tube which can be closed off by means of a pinch clamp over rubber tubing. Below the bowl is arranged a Buchner funnel and flask as shown. A disc of 210/u screen (70 mesh) is held in the funnel by means of a rubber "O" ring.

In the testing of powder samples a procedure similar to that of A.D.M.I. is followed. Three hundred ml of water at 75°F is placed into the bowl and 39gm of powder is transferred to the surface of the water. (This is in the same proportions to the A.D.M.I. method where 400ml and 52gm, respectively, are employed). The mixer is then turned on, rotation being 175 rpm, and lowered into the bowl. Agitation is continued for 20 seconds, after which the beaters are left in their position in the bowl. The pinch clamp on the outlet of the bowl is then opened to release the contents onto the 70 mesh screen. The screened liquid is collected in the filter flask and diluted to 500ml. Two 10ml portions are then transferred to two weighed aluminium dishes, evaporated to dryness on a steam bath and dried at 102°C/3 hours. This allows the weight of solids dispersed to be calculated. This is expressed as percent dispersibility.

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* A "Dissco", size 5, stainless steel bowl was employed, manufactured by Dunedin Stainless Steel Co.Ltd, 33 Creswell Street, Dunedin, N.Z.

It was found, after testing many samples, that this method is in fact more sensitive than the A.D.M.I. method. Reports in the literature, Tamsma et al (1965), Hanrahan and Kontson (1965) suggest that the A.D.M.I. method continually gives a dispersibility figure of above 90% for instant milk powders. This makes it very difficult to attach any significance to changes in dispersibility between 90 and 100 percent. This modified method, however, would appear to be more sensitive in this respect since the highest dispersibility figure obtained with a commercial instant NFDM was 69%.

(iii) Solubility Index (Standard Method)

Although many objections have been raised at the A.D.M.I. method of solubility index determination, Steen (1962); van Kreveld and Verhoog (1963), it still remains the most widely accepted method today. Therefore, it seemed reasonable to follow this method as closely as possible.

The only variation necessary to the A.D.M.I. method was with regard to the special mixer which was not available locally. This was overcome by employing the liquidiser attachment together with a Kenwood "Chefette" mixer. Steen (1962) describes the A.D.M.I. mixer as having an impeller speed of 3,400 rpm. The Kenwood mixer was adjusted to this speed by means of a "variac", variable voltage control, in the power supply to the motor. Due to the dimensions of the liquidiser attachment, it was more convenient to mix 20gm of NFDM (or 26gm of Full Cream Dried Milk (FCDM)) with 200ml of water. The A.D.M.I. method specifies 10gm of NFDM (or 13gm of FCDM) with

100ml of water.

In all other respects the A.D.M.I. method was adhered to. The solubility index is expressed as ml of sediment.

(iv) Moisture Content (Standard Methods)

For the section of experimental work dealing with the characterisation of food powders, moisture determinations were carried out by the Toluene Distillation method as specified by A.D.M.I. Care was taken to extend the distillation time until the reading in the moisture trap remained constant. This precaution will be appreciated by reference to Choi et al (1948) who show that water of crystallisation requires an extended distillation time if it is to be desorbed.

For the section of work dealing with rewetting processes, an oven drying moisture determination was employed. Weighed samples were dried in a fan assisted air oven at 102-103°C/3 hours.

All moisture contents are expressed on a "wet weight" basis.

(v) Bulk Density, Particle Density, Porosity

King (1954),(1965) reviews fully the physical structure of dried milk, including references to methods of determination.

Briefly, particle density of a powder will be a finite value representing the density of particles excluding voids between particles. Bulk density and porosity on the other hand, will be a function of packing of the powder mass. It is common, therefore, to

evaluate bulk density as :

1. Tapped Bulk Density

   i.e. powder mass is subjected to a standard compaction treatment;

2. Loose Bulk Density

   i.e. powder mass not compacted.

Tapped bulk density was determined by weighing approximately 70ml of powder into a 100ml measuring cylinder and giving this five sharp taps before reading the volume of powder. Tapped bulk density is expressed as gm per cc.

Particle density, loose bulk density and porosity (loose), were determined by the method of Beckett et al (1962). This method is a liquid displacement method employing hexane as a low specific gravity, inert liquid. The method is easily applied to NFDM and powders other than NFDM providing their particle density is above 0.8gm/cc. In the case of less dense powders the method could still be employed for determining particle density by use of a wire gauze disc soldered to a piece of wire which could be used to submerge all particles in the hexane. It should be noted that Beckett et al (1962) do not give details of porosity evaluation. However, it is soon realised that porosity can be obtained from this method since :

Percentage Porosity = 100 - Percentage of Bulk Volume Occupied by Powder Particles

Porosity is expressed as cc of void per cc of bulk powder (loose).

(vi) Particle Size

Methods which may be used for particle size measurement are well discussed by Irani and Clayton (1963). For spray dried powders such as NFDM sieving techniques present difficulties; other alternatives being sedimentation techniques and microscopy.

The method finally adopted is based on a microscopic technique as described by Janzen et al (1953). 0.2gm of powder is mixed with 5ml of paraffin oil and a drop of this is placed on a microscope slide and covered with a cover slip. Measurement is made with an ocular disc calibrated against a stage micrometer and 100-200 particles are measured. A modification found successful was to use a projection microscope; measurement being made on the glass luminescent scope which had been calibrated against a stage micrometer. This technique greatly eased the tedium of particle size measurement.

In the measurement of spray dried coffee particles it was found that suspension in oil and covering of a slide with a cover slip caused fragmentation of particles. This would lead to erroneous results for measurement of particle size. In this case measurement was made by sprinkling a small sample of powder onto a slide and measuring particles before too much moisture sorption had occurred.

The expression and calculation of results is best illustrated by reference to Figure 4, showing typical results for several powders. The results of microscopic measurement are grouped into the various size ranges observed. The percentage of particles falling into each size range are then expressed on a

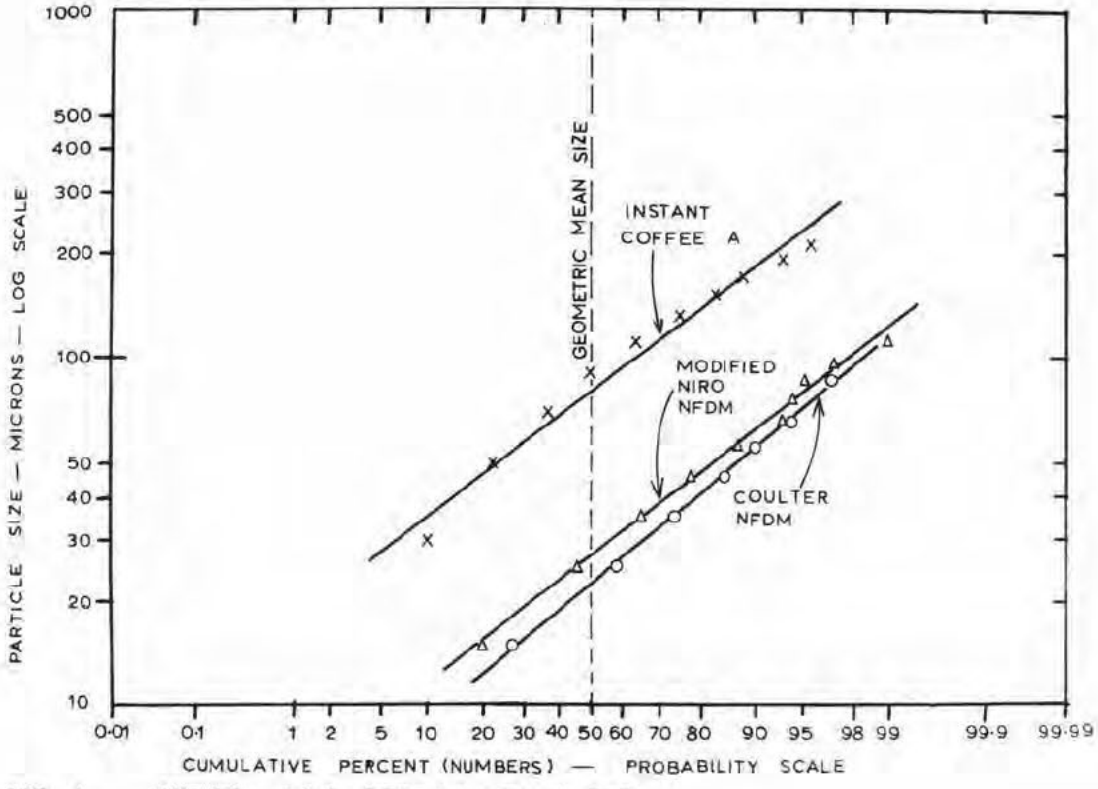


FIG. 4 TYPICAL LOG-PROBABILITY PLOTS FOR PARTICLE SIZE ANALYSIS

cumulative basis with increasing size of particles. This allows plotting of results as shown in Figure 4, on log/probability paper.

All samples examined approximated closely a straight line relationship on such a log/probability plot. Under such conditions the following population characteristics can be defined :

1. Geometric mean particle size (based on numbers) is represented by the interpolation of size at 50% cumulative;

2. Geometric Standard Deviation (Based on numbers) $= \frac{\text{Size at 85\% Cumulative}}{\text{Size at 50\% Cumulative}}$

This method of presentation and calculation of population characteristics is described by Zenz and Othmer (1960).

(vii) Photomicrographs

Photomicrographs were obtained by use of a Leitz Photomicrograph Unit. Samples were mounted on a microscope slide as described in Particle Size Analysis.

(viii) Determination of Crystalline Lactose

The state of lactose in a powder can be readily determined by means of polarised light microscopy as described by King (1948). Upon total extinction of light, using a polariser attachment, lactose crystals are readily identified as they reflect light.

III. EXPERIMENTAL WORK

SECTION (1) CHARACTERISATION OF TYPICAL FOOD POWDERS

III. EXPERIMENTAL WORK

SECTION (1) - CHARACTERISATION OF TYPICAL FOOD POWDERS

A. INTRODUCTION

A large range of food powders is to be found on the market today. Many of these are readily accepted as "instant" foods while others, such as conventionally spray dried NFDM, are more difficult to disperse on reconstitution. Further, there are several different types of spray driers employed in the manufacture of NFDM resulting, to some extent, in different powder characteristics. Although isolated references are to be found in the literature of different powder characteristics it is impossible to assess these in any comparative manner. It appeared justifiable, therefore, to analyse a range of typical food powders, including different NFDM powders, for dispersibility characteristics and physical properties.

The purpose of such a comparative evaluation is twofold :

1. It allows a comparison in perspective of the range of dispersibilities and physical properties encountered in such powders;
2. It allows a better insight to be gained into the mechanism and physical properties involved in dispersion of a powder, thus allowing postulation of a working theory.

Characterisation of food powders led to research work which may be described under three headings, viz. :

(i) Moisture determination by azeotropic distillation;

(ii) State of lactose in commercial NFDM;

(iii) Working theory of mechanism of dispersion.

B. LITERATURE REVIEW

(i) Moisture Determination by Azeotropic Distillation

Kumetat (1955) discusses the various methods of moisture analysis employed for milk powders. These include an oven method at 102-103°C, a vacuum oven method, a toluene distillation, and a Karl-Fischer titration. It is pointed out that the Karl-Fischer titration method determines all water present including the water of crystallisation of the lactose α hydrate. In NFDM if all lactose were as α hydrate then the Karl-Fischer method would give a reading of 2.5% higher than, say, an oven method. Kumetat states that this fact would only be of significance in the moisture determination of instant powders containing crystalline lactose.

Choi et al (1948) discuss the effect of the presence of crystalline lactose α hydrate upon a toluene distillation. They describe a moisture desorption method capable of estimating the water of crystallisation of α hydrate using a toluene distillation. The method depends on the difference in rates of dehydration of the crystalline α hydrate from other moisture adsorbing constituents. They claim that the rate of dehydration of crystalline α lactose hydrate follows a first order kinetic expression. This means that if the dehydration of a powder sample during toluene distillation is plotted on semi-log paper then dehydration of any α lactose hydrate

present will result in a straight line relationship.

The A.D.M.I. specifies a toluene distillation for moisture determination. The method emphasises, without qualification, that "for some products a 60 minute distillation period is not sufficient". As toluene distillations were employed in the characterisation of typical powders it appeared worthwhile to study the rates at which water was desorbed and to note the effect of crystalline α lactose upon dehydration rates.

(ii) State of Lactose in Commercial NFDM

It is generally accepted that in commercially spray dried and roller dried milk powder the lactose occurs in an amorphous glassy state. This was probably first investigated by Troy and Sharp (1930). Since then many researchers have again confirmed the occurrence of lactose in powders in a glassy state. Such reports are discussed in reviews by King (1954),(1965). It is thought that this glassy lactose constitutes a continuous phase, or hollow shell, in spray dried powder.

It is appreciated that if milk powder is permitted to take up moisture from the atmosphere then lactose crystallisation will occur; Troy and Sharp (1930); Bushill et al (1965). It is also realised that lactose will occur in a crystalline state to a variable extent in some forms of instant NFDM; Bergsoe (1957). King (1954), (1965) reports a paper by Mohr and Koenen (1951) stating that crystalline lactose had been observed in freshly made powder. In this particular instance it is inferred that this is as a result of

faulty manufacture. Apart from this isolated report in 1951 it has always been accepted that lactose in milk powder occurs as an amorphous glass.

(iii) Working Theory of Mechanism of Dispersion

Pyne (1961) has undoubtedly made the most significant contributions towards an understanding of the mechanism of dispersion of food powders, even though he studied milk powders only. Pyne states : "A basic physical concept of the process of reconstitution has never been established although many studies of the reconstitution phenomena have been made".

Pyne's hypothesis is that reconstitution is governed by capillary movement of the reconstituting liquid into the interspaces of the powder mass. Capillary movement of water into the mass allows separation of particles from the mass and hence allows easy reconstitution of those particles.

In order to prove this hypothesis, Pyne first showed that the interspaces of milk powders could act as capillaries in a predictable manner when employing non-solvating liquids. The equilibrium height of rise of a liquid in packed columns of powder was shown to be a function of pore size and could be predicted by a constant, 0.232, times the average particle radius. Further, the capillary properties of a powder could be represented by a variable termed the hydraulic radius. The hydraulic radius relates the surface contacted by liquid to the volume of liquid associated with it. The larger the particle size, the larger the hydraulic radius,

and the more rapid is the movement of liquid in the capillary. Pyne showed that there exists a linear relationship between the square of the hydraulic radius and the rate of reconstitution of a powder.

Pyne admits that his hypothesis cannot account for powders having a particle density less than 1gm/cc since in this case a particle does not separate from the powder mass since it is less dense than water. Reconstitution must occur at the powder/water interface.

Other workers have attempted to elucidate the mechanism of dispersion, or to explain factors responsible for the greater dispersibility of instant milk powders as compared with original base powder. No other work would appear to be as conclusive as that of Pyne (1961).

Bockian et al (1957) attempted to explain the greater dispersibility of instant NFDM. They found that instantised powders contained crystalline lactose although this appeared to have little significance. They found little difference in the protein nitrogen distribution between all dried milks studied. There was a large difference in size between instant and ordinary NFDM. This was considered to have a significant effect on dispersibility. Using a successive washing technique these workers were able to show that in instantising of NFDM there occurred a re-orientation of components with the highly soluble components such as salts and lactose being concentrated towards the surface. This factor was also considered to contribute towards the higher dispersibility of NFDM.

Holsinger et al (1964) modified the washing technique of

Bockian et al (1957) and also employed the technique to study orientation of components in powders made by different drying techniques. Their results were not in complete agreement with Bockian et al (1957) but they did show that instantising tended to increase the concentration of osmotically active material at the surface.

Harper et al (1963) studied the instant solubility of milk powder particles from the point of view of concentration of milk solids in the vicinity of the powder particle. The lower the bulk density of a powder, the higher the porosity, and hence the lower will be the milk solids concentration in the vicinity of each particle during reconstitution. This effect was studied by dispersing milk powders in varying amounts of sand and measuring instant solubility by a washing technique. It was shown that as the proportion of sand was increased, that is, the effective bulk density is decreased, then the instant solubility increased. The authors concluded that the bulk density of a powder must be one of the quality limiting factors in producing a self-dispersing milk powder. They set an upper limit of 0.4gm/cc for the bulk density of a self-dispersing dried milk.

Mori and Hedrick (1965) studied the effect of processing factors during instantising upon dispersibility and bulk density of the resultant powder. The most significant change of dispersibility occurred with increasing fat content in the powder.

Tamsma et al (1965) studied a range of NFDMs produced by different drying techniques for their dispersibility, sinkability, bulk

density and particle density. Some general trends are suggested but no firm conclusions are made.

From such a literature review it appeared desirable to develop a more general working theory of the mechanism of dispersion of any food powder.

C. RESULTS AND DISCUSSION

(i) Moisture Determination by Azeotropic Distillation

Powder samples were analysed for moisture content by means of toluene distillations. Rates of water desorption were noted by reading the quantity of water collected in the distillation trap at regular intervals. The distillations were continued at a uniform rate until no further water was desorbed. Results were expressed as percent moisture remaining in powder at any particular time and these were plotted on semi-log paper. The graphs obtained for several powders are shown in Figure 5.

Nearly all samples behaved in a manner similar to the "Gray-Jensen NFDM". (This represents NFDM spray dried in a Gray-Jensen drier). That is, nearly all samples showed no further water desorption after approximately 40 minutes of distillation time. However, two samples in particular, the spray dried tomato powder and the Modified Niro NFDM showed much slower rates of moisture desorption (Figure 5).

Microscopic examination, using polarised light, revealed that the Modified Niro NFDM contained crystalline lactose while the

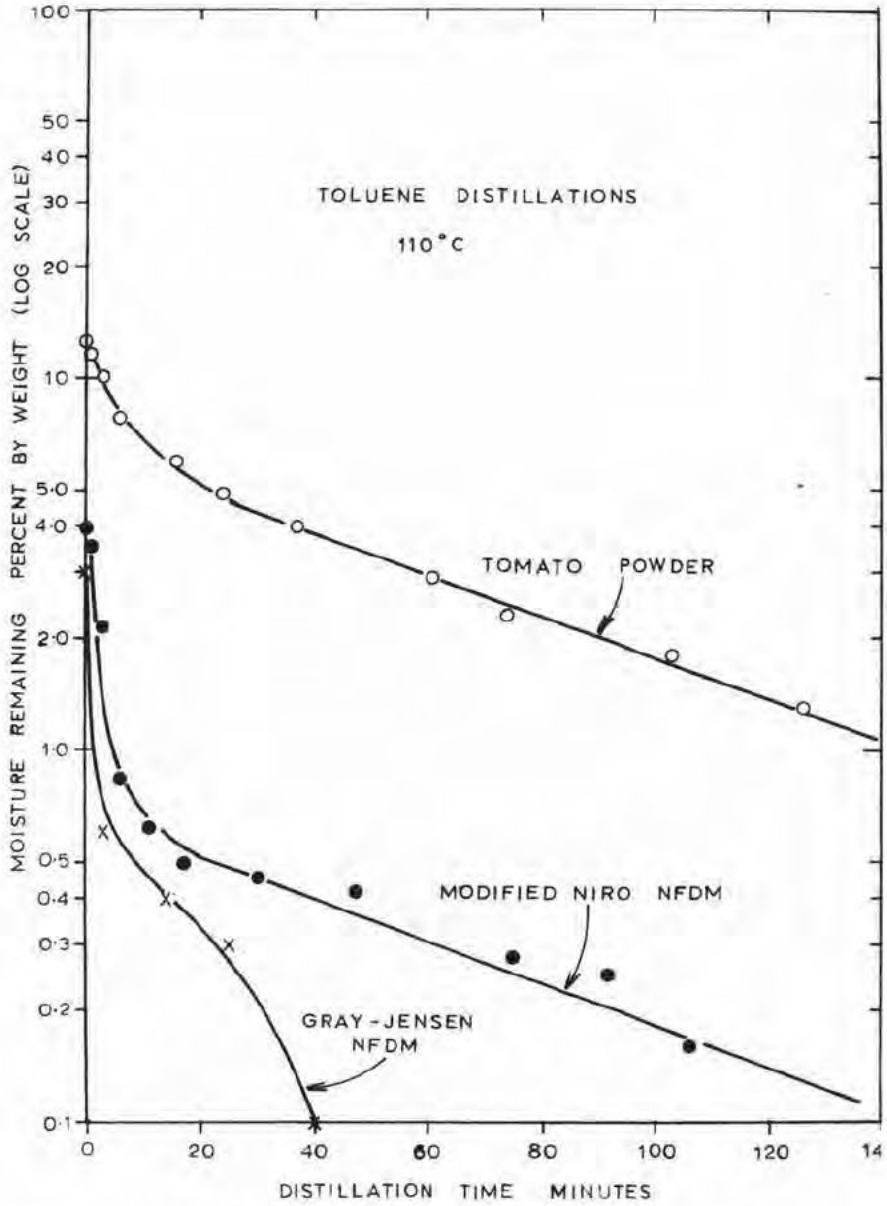


FIG. 5 REPRESENTATIVE DISTILLATION CURVES

tomato powder possibly contained other crystalline sugars. (Free sugars account for approximately 60% by weight of tomato solids, consisting mainly of D-fructose and D-glucose and a small amount of sucrose; Williams and Bevenue (1954)). All other samples were free of crystalline sugar, including two samples of instant NFDM.

In order to demonstrate the effect of the state of lactose in a milk powder upon azeotropic distillation rates, another approach was also used. A sample of Gray-Jensen NFDM was equilibrated at 55% R.H. for a period of several weeks so as to allow substantial lactose crystallisation. Equilibration was achieved over a saturated sodium dichromate solution. Toluene distillations were then performed upon the 55% R.H. NFDM and the control NFDM containing no crystalline lactose. The results are shown in Figure 6.

It is seen that with a toluene distillation the control NFDM containing no crystalline lactose showed complete moisture desorption within 40 minutes; whereas the NFDM with crystalline lactose required 70 minutes to reach the same stage.

However, this differential desorption rate was emphasised further by the use of a lower boiling point azeotropic boiling liquid. Benzene was used for this purpose, having a B.P. of 80°C, compared with toluene having a B.P. of 110°C. As can be seen from Figure 6 , using benzene distillation, the control NFDM required 60 minutes for moisture desorption whereas the 55% R.H. NFDM required approximately 130 minutes. Despite the longer distillation time required for benzene, the moisture content obtained for both samples corresponded with the toluene

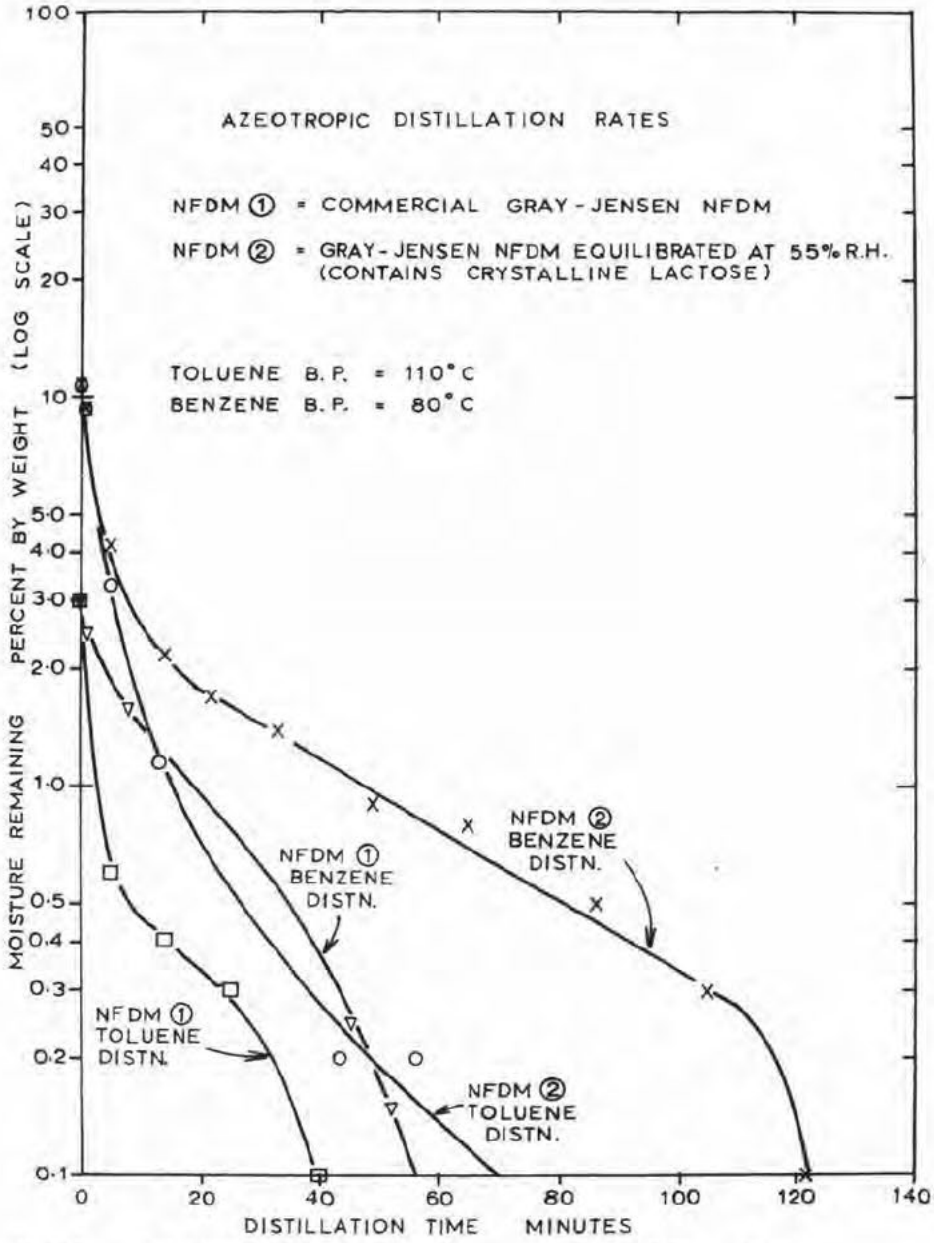


FIG. 6 EFFECT OF CRYSTALLINE LACTOSE UPON AZEOTROPIC DISTILLATION RATES

distillation result.

A theoretical explanation of these results is afforded by Choi et al (1948). They claim that the rate of dehydration of crystalline lactose hydrate follows a first order kinetic expression resulting in a straight line relationship when plotted on semi-log paper as in Figures 5 and 6. This bears out well with the dehydration rate curves obtained for samples containing crystalline lactose in this study. In every case where crystalline lactose was present in a sample a significantly longer distillation time was necessary in order to achieve complete desorption. It is reasonable to suggest that this technique may be useful as an index of the presence of crystalline lactose in NFDM. Since routine toluene distillation on NFDM are carried out in many laboratories then the presence of crystalline lactose would be suspected where an unusually long distillation time is required to achieve a constant reading.

In the case of the tomato powder interpretation of this observation is not as straightforward. Admittedly a semi-log plot of dehydration results in a definite straight line portion in the latter stages. This may be due to :

1. Desorption of water of hydration from sugars present at a rate determined by a first order kinetic expression; or
2. Caramelisation or browning of the sample to produce water. The curve obtained would suggest that such caramelisation follows a first order reaction. If this were the case, it

would be possible to extrapolate the straight line portion of the curve back to zero distillation time and find the quantity of free water originally present in the sample; as was shown by Choi et al (1948) for the case of lactose hydrate.

Further research in this field would appear worthwhile.

(ii) State of Lactose in Commercial NFDM

A quantity of Niro NFDM was obtained from a commercial factory for the purpose of research into the effect of rewetting processes upon the dispersibility of NFDM. In the course of this work it was desired to determine at which stage in remoistening lactose appeared in a crystalline state. Examination of samples revealed that, in fact, lactose occurred in a crystalline state in the original control powder obtained from the factory. This at first seemed rather surprising and it was originally thought that this may have been due to moisture pickup by the powder at some stage so as to allow crystal formation. This observation was, therefore, followed up by the examination of further samples from the factory; this time with a detailed summary of manufacturing conditions.

Samples of powder were obtained direct from the cyclone separator after drying and in this way could be matched up directly with a particular skim milk concentrate fed to the dryer previously.

Typical operating conditions at the factory were found to be concentration of the skim milk to approximately 48% total solids; the

temperature of the concentrate leaving the final effect of the evaporator being approximately 106°F. In addition, it was noted that the capacity of the evaporator is a little above that of the dryer, with the result that skim milk concentrate slowly accumulates over a period of several hours until the concentrate storage capacity of approximately 300gals is filled, when the evaporator is run on water for a time so as to allow the dryer to catch up.

It was found that powders produced under such typical operating conditions, consistently showed the occurrence of small lactose crystals. Powders produced from concentrate of lower total solids (e.g. 44%) and dried immediately without holding showed a much reduced incidence of crystalline lactose. Even at the high concentration to 48-49% total solids it was found that increased concentrate holding time had a marked effect upon increased incidence of lactose crystals, and upon their size.

A further observation was made which suggested that crystals were occurring in the powder as a result of self-nucleation of lactose in the skim milk concentrate. This was, that many small crystals were observed under the polarised light microscope to occur as separate identities, that is, not within a milk powder particle. In comparison, if a sample of milk powder which has been equilibrated at 55% R.H. for some weeks is examined, it will be found that considerable lactose crystallisation has occurred but in this case all crystals are contained within the skim milk powder particle.

An attempt was also made to examine the skim milk concentrate

directly for occurrence of crystalline lactose. It will be appreciated that this poses severe problems since any cooling of the concentrate or prolonged holding will favour self-nucleation and crystal growth and thereby introduce experimental artefacts. Unless a heated stage were employed on the microscope, some cooling could not be avoided. The way in which this was attempted, therefore, was to cool a weighed sample of concentrate of known total solids while simultaneously adding water to the concentrate so as to maintain the concentration of lactose in water at a point just slightly above the equilibrium solubility value for lactose at the corresponding temperature. This means that the concentrate is continually diluted while cooling so as to keep it only marginally supersaturated. When the concentrate reaches room temperature it can then be examined under the polarised light microscope for occurrence of crystalline lactose. Using this technique, lactose crystals were detected in concentrate of high total solids, but it is felt that more experimentation with this method would be desirable.

Theoretical considerations of the occurrence of crystalline lactose in a skim milk concentrate may best be explained by reference to Figure 7. (Lactose solubility figures from Whittier (1944)). Figure 7 relates the final or equilibrium solubility of lactose in water as a function of temperature. For example, at 110°F the final solubility is 36gm lactose per 100gm water. In addition a super-solubility curve is shown indicating the degree of supersaturation which may be achieved in a pure lactose/water system. Above this supersolubility value, self-nucleation would occur and crystal growth

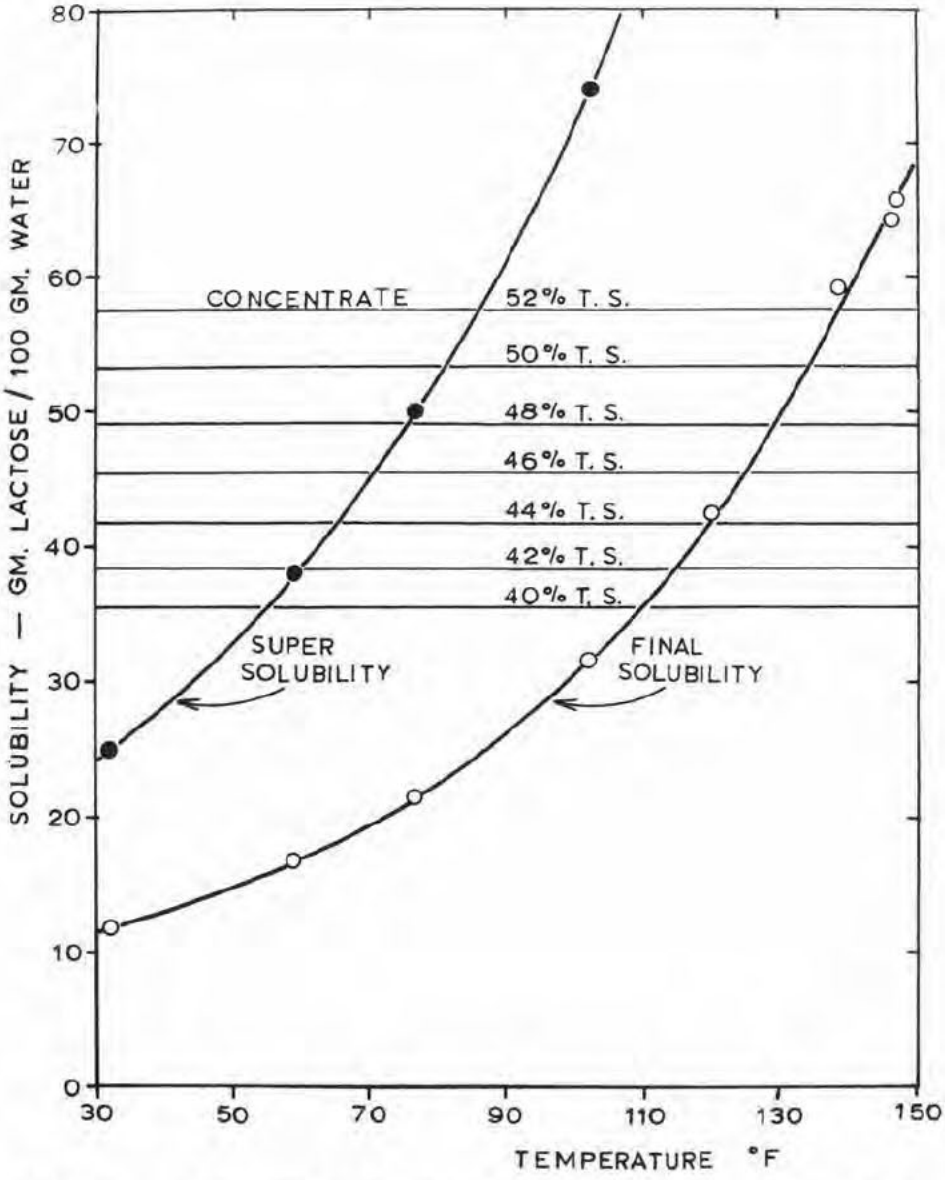


FIG. 7 SOLUBILITY OF LACTOSE AS A FUNCTION OF TEMPERATURE DATA OF WHITTIER (1944)

would continue until the final solubility value is reached corresponding to the temperature of the solution. Horizontal lines are also shown on Figure 7, representing the concentration of lactose in skim milk concentrates of varying total solids content, (assuming lactose to make up 53.2% of skim milk solids).

Therefore, taking a skim milk concentrate of, say 48% total solids, emerging from the last effect of the evaporator at 106°F, it will be seen from Figure 7 that the 48% concentrate will have a lactose concentration of 49gm per 100gm water. At this temperature the final solubility of lactose in water is seen to be 34gm per 100gm water. This means that the lactose in the concentrate is well into the supersaturated range. Hence, from a theoretical point of view it appears feasible that self-nucleation may be occurring, or that crystal growth is occurring around foreign nuclei such as clusters of casein micelles.

With recent advances in milk concentration, in particular the development of multiple effect falling film evaporators, concentration of skim milk to the range of 45-50% total solids is not uncommon. Also such concentrate is removed from the evaporator at relatively low temperatures, e.g. below 110°F. Both these factors, as can be seen from Figure 7, increase the probability of lactose crystallisation in the concentrate. It is believed that a stage has been reached where the occurrence of crystalline lactose in spray dried skim milk is no longer uncommon.

It is felt that the occurrence of crystalline lactose in

skim milk concentrate, without seeding offers several avenues for research. Among these may be listed :

1. Effect of crystalline lactose upon hygroscopic nature of NFDM. Sharp (1955) holds a patent employing the seeding of concentrate to produce this effect, claiming a less hygroscopic, more soluble and more dense powder. This principle is also employed in the drying of whey;
2. Effect of crystalline lactose upon the dispersibility of NFDM;
3. Effect of crystalline lactose upon particle characteristics; in view of the fact that the continuous lactose phase may be disrupted.

These observations of the occurrence of crystalline lactose in commercial NFDM have been reported fully in a paper by Morris, Neff, and Latimer (1967).

(iii) Working Theory of Mechanism of Dispersion

Eleven samples of food powders were analysed for dispersion and physical characteristics. These samples consisted of :

4 samples of spray dried NFDM

1 sample of spray dried Full Cream Dried Milk (FCDM)

2 samples of commercial instant NFDM

1 sample of roller dried NFDM

2 samples of spray dried instant coffee

1 sample of spray dried tomato powder

The results of these analyses are presented in Table 2. The type of drier employed for the milk powders is indicated in the results. "Modified Niro" represents a Niro spray drier modified to include fines recirculation into the atomising zone in an attempt to produce a "single stage instant".

Figure 8 shows microphotographs of several powders representing typical shapes and sizes encountered in such powders.

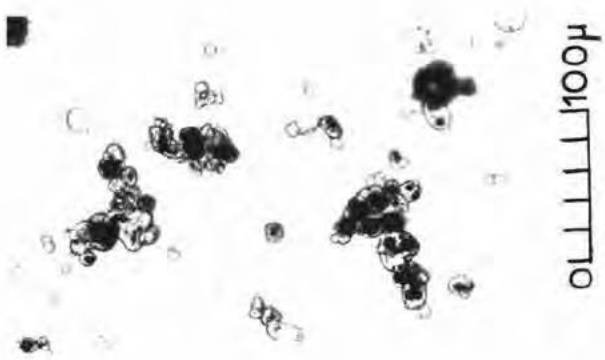
These results place in perspective the dispersibility characteristics and physical properties of such powders. Several interesting points are worth noting :

1. The samples of instant NFDM showed the highest dispersibility and sinkability properties and highest porosities;
2. The roller dried NFDM showed a moderate dispersibility and a high sinkability despite its low solubility (i.e. high solubility index). This can be attributed to the irregular shape of particles (as seen in Figure 8) and the high particle density;
3. The Coulter NFDM showed the best dispersion characteristics of all the spray dried NFDMs. This powder is produced by a special drier employing a venturi-atomiser for the dispersion of feed into the drying air stream; Townley and Coulter (1954); Bradford and Briggs (1963). As can be seen from Figure 8 this produces an agglomerated type product which may be termed a "single stage instant";

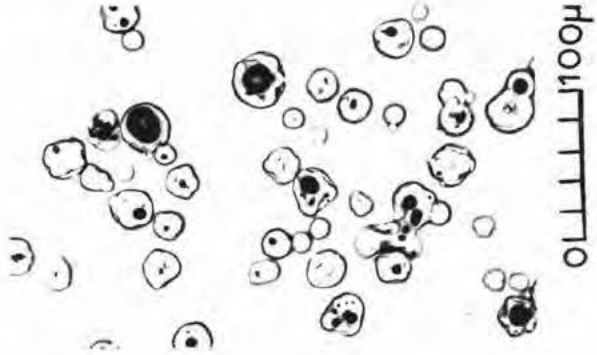
TABLE 2

Characterisation of Typical Food Powders

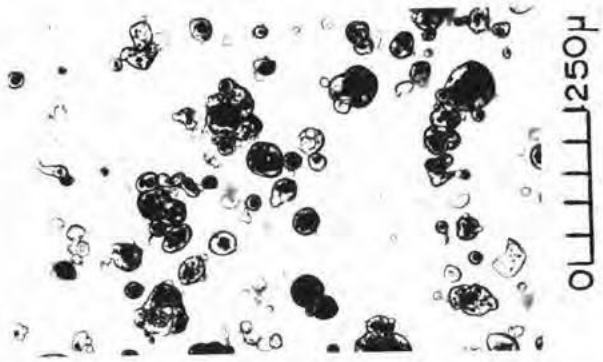
Sample	Moisture	Sinkability Index	Dispersibility	Solubility Index	HEXANE METHOD			Bulk Density (Tapped)	Geom. Mean Particle Size	Geom. Standard Deviation	Mean Aggregate Size	Lactose Crystallisation
					Bulk Density	Particle Density	Porosity (Loose)					
Modified Niro NFDM	3.98%	1.78mg/min.cm^2	28.5%	0.15ml	0.406gm/cc	0.85gm/cc	0.523cc/cc	0.498gm/cc	26 μ	1.96	-	+
Gray-Jensen NFDM	3.0	3.45	16.1	1.3	0.64	1.32	0.515	0.695	14	1.66	-	-
Rogers NFDM	3.6	5.2	16.4	0.1	0.58	1.25	0.535	0.62	<10	3.4	-	-
Coulter NFDM	4.3	5.5	39.1	2.2	0.59	1.21	0.510	0.715	22.5	2.05	-	-
Modified Niro FCDM	3.2	<0.20	11.2	4.5	0.448	0.88	0.490	0.435	21	-	-	-
Instant NFDM A (Base = Buflovak NFDM)	7.42	20.7	62.6	1.0	0.396	1.225	0.678	0.497	19	2.0	100 μ	-
Instant NFDM B (Base = Buflovak NFDM)	5.87	-	59.1	2.0	0.382	1.16	0.672	0.443	24	2.17	80	-
Roller Dried NFDM	3.45	12.0	31.5	13.5	0.503	1.46	0.655	0.64	22	3.3	-	-
Spray Dried Instant Coffee A	3.35	5.2	44.3	0.05	-	0.614	-	0.264	80	1.93	-	-
Spray Dried Instant Coffee B	2.32	4.6	28.7	<0.05	-	0.72	-	0.274	38	2.1	-	-
Spray Dried Tomato Powder	12.7	∞	-	-	0.67	1.43	0.535	0.68	54	1.66	180	-



Instant NFDM B
(Magnification x 250)

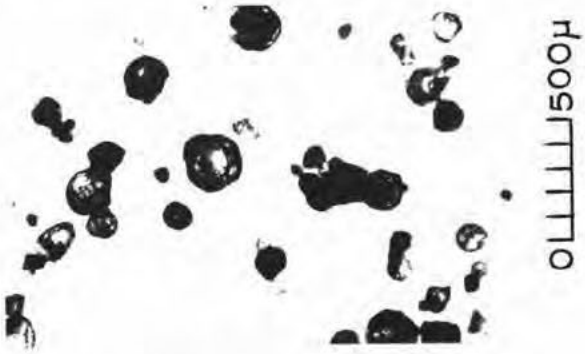


Gray-Jensen NFDM
(Magnification x 250)



Coulter NFDM
(Magnification x 100)

Roller Dried NFDM
(Magnification x 100)



Spray Dried Instant Coffee A
(Magnification x 40)

FIGURE 8 Microphotographs of Some Typical Powders

4. The Modified Niro FCDM showed an extremely low dispersibility and virtually zero sinkability. This can be attributed to the poor wettability resulting from the presence of fat. The effect of fat upon wettability and reconstitution is comprehensively dealt with by Pyne (1961);

5. The samples of instant coffee showed only moderate dispersibility and sinkability properties, in fact, in the same range as many spray dried NFDMs. Yet, instant coffee is generally looked on as a good example of an instant food powder. One reason for this is that in the reconstitution of a cup of instant coffee the average consumer would reconstitute to only a little above 1% solids whereas milk powder would be required to be reconstituted to approximately 12% solids. The dispersibility test mixes components at an equivalent of 11.5% solids;

6. In the case of the four samples of spray dried NFDM, the influence of particle density upon sinkability can be seen. The Modified Niro NFDM having a particle density of less than 1gm/cc showed a very low sinkability since dispersion would need to occur at the powder/water interface;

7. The instant coffee samples possess a very low particle density (0.6-0.7gm/cc) and yet showed moderate dispersibility and sinkability. Even though dispersion must occur at the powder/water interface, the moderate dispersibility can be attributed to the higher rate of solution of instant coffee

as compared to NFDM;

8. Subjective assessment of the tomato powder indicated excellent reconstitution properties. Due to the high viscosity of the reconstituted product the dispersibility test, as such, could not be employed.

As can be seen a broad range of food powders have been examined. While the results do not make possible direct correlations of factors responsible for dispersion upon reconstitution they, nevertheless, allow a better appreciation of the mechanism of dispersion. This, together with a literature review has made possible the formulation of a general working theory or hypothesis of the mechanism of dispersion. Pyne (1961) put forward a hypothesis of the importance of capillary movement of liquid in reconstitution, and then went on to supply experimental evidence in support of this hypothesis. His theory applied only to certain types of milk powder. It is intended here to give a more general hypothesis applicable to the reconstitution of any food powder.

It is postulated that the mechanisms of reconstitution can best be considered in terms of three major factors :

1. The Wettability-Capillarity of the Powder

This is obviously the first step since a particle must be wetted before it can be reconstituted.

For example, FCDM shows poor dispersion due, no doubt, to poor wetting of the particle surface. Tomato powder on the other hand

possesses infinite sinkability indicating a high wettability.

However, the shape or aggregation of particles will also have an influence on wettability-capillarity characteristics. This fact is illustrated in the case of instant NFDM where the dispersibility and sinkability of a powder is markedly increased by a process of agglomeration. This improvement in reconstitution is due, in part anyway, to a capillarity effect upon contact with water. Such improvement in wettability-capillarity is also noted in the case of roller dried NFDM.

Particle size appears to have a marked effect upon wettability-capillarity. Pyne (1961) showed that below a minimum particle size (9 μ in the case of NFDM) no wetting of a powder surface occurred. Later work in this research also illustrates the very marked effect of granule or "particle" size upon both sinkability and dispersibility. To some extent this can be explained by the effect of particle size upon the surface area to mass ratio (or upon hydraulic radius). As particle size is increased, the surface area per unit mass to be wetted is decreased thus tending to improve the wettability characteristics.

2. The Particle Density of the Powder

Particle density may influence reconstitution in two ways. Firstly, a high particle density will tend to increase the wettability of a particle. In other words, the ability of a particle to be wetted when placed at the surface of a liquid will be a function of its surface area, its inherent wettability (chemical composition) and

its density.

Secondly, particle density will influence reconstitution by determining the ability of a particle to separate or sink from the surface when wetted. If a wetted particle possesses a density greater than that of water, 1gm/cc, then it will separate from the unwetted powder mass. This must be considered desirable since dispersion is more easily effected when particles are distributed throughout the volume of water. This fact was demonstrated by Harper et al (1963) when they studied the effect of concentration of milk solids in the vicinity of the particle upon its instant solubility.

Where a powder possesses a particle density less than that of the reconstituting liquid then dispersion must occur at the powder/liquid interface. This tends to promote caking of the powder mass, reconstitution then being dependent on the rate of solution at the interface. This particular situation is well illustrated by instant coffee.

3. Rate of Solution of Substance

The last phase in reconstitution will be the rehydration or "solution" of the particles. The rate at which this final state is achieved will influence the dispersibility of the powder.

A high rate of solution can impart reasonable dispersibility to a powder having poor wettability or limiting particle density. This is illustrated by the case of instant coffee, where all dispersion must occur at the water/powder interface but due to a high rate of

solution, a reasonable dispersibility is achieved.

It is interesting to note that rate of solution will be directly proportional to the surface area to mass ratio, whereas wettability is inversely proportional.

Rationalising the mechanism of dispersion in terms of these three major factors, wettability-capillarity, particle density and rate of solution, it is possible to construct certain models in order to represent any food powder.

Examples of such models are represented diagramatically in Figure 9.

Model 1

Low Wettability-Capillarity, Low Particle Density, Medium Rate of Solution

Here the first stage in dispersion, viz. wetting of the particles, will be a limiting factor. Even when a particle is wetted its low density will prevent separation from the interface. Dispersibility and sinkability of such a substance will, therefore, be poor; being dependent on the rate of solution from the interface.

Certain milk powders would appear to fall into this category in particular spray dried FCDM and some NFDMs.

Model 2

Low Wettability-Capillarity, High Particle Density, Medium Rate of Solution

This illustrates the effect of a higher particle density in allowing separation from the interface once a particle is wetted. Dispersibility of such a system will be greater than Model 1. Low

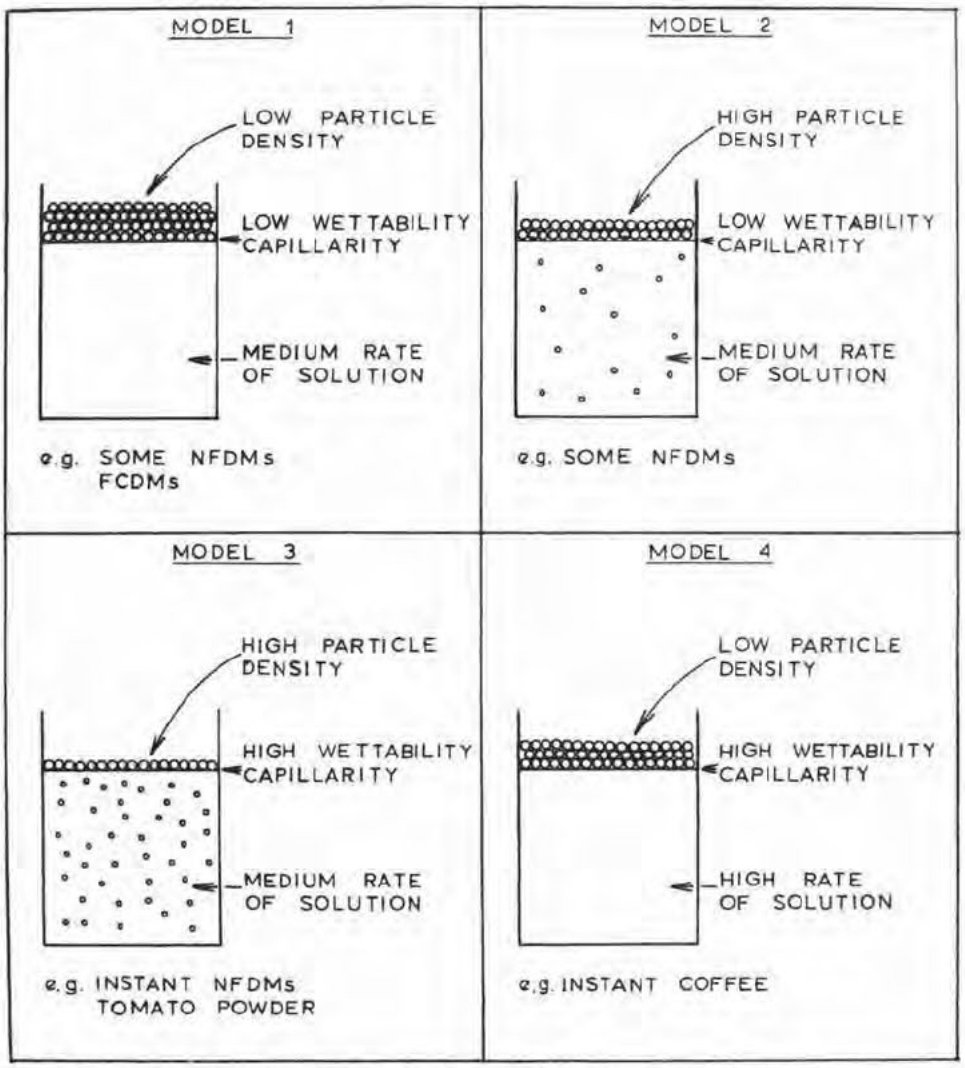


FIG. 9 MODEL REPRESENTATION OF MECHANISM OF DISPERSION OF A POWDER

wettability-capillarity is still a limiting factor.

Certain spray dried NFDMs would fall into this category.

Model 3

High Wettability-Capillarity, High Particle Density, Medium Rate of Solution

Such a system would show marked improvement in dispersibility over Models 1 and 2. The only limiting factor would be the rate of solution of the substance.

Into this category could be classed instant NFDMs and tomato powder.

Model 4

High Wettability-Capillarity, Low Particle Density, High Rate of Solution

This example shows the limiting effect of a low particle density. The particles cannot separate into the liquid and dispersion must take place at the interface. Dispersibility is then dependent on the rate of solution.

Spray dried instant coffee would fall into this category.

Obviously, other combinations are possible, and further models may be constructed. However, these four models serve to illustrate the manner in which a powder can be categorised so as to elucidate the mechanism of dispersion.

It is believed that such illustration considerably simplifies an understanding of the mechanism of dispersion of a powder. In this way it is now possible to extend such principles in an effort to improve the dispersibility of typical powders.

D. PRINCIPAL RESEARCH FINDINGS

1. It has been demonstrated that the presence of crystalline lactose in a milk powder will influence the rate of moisture desorption upon azeotropic distillation. For example, a toluene distillation time in excess of 60 minutes is required for complete moisture removal from a sample containing lactose in a crystalline state; such observation may well be employed as an index of state of lactose during routine analysis;
2. It has been found that lactose may exist in a crystalline state in commercial spray dried NFDM, such observation having been correlated with manufacturing conditions;
3. Theoretical considerations of lactose solubility data as compared with lactose concentrations in skim milk concentrates reveal the strong probability of lactose crystal nucleation and growth occurring in such concentrate, particularly in view of the high solids concentrations and low holding temperatures employed today;
4. A working theory has been proposed to explain the mechanism of dispersion of a food powder. This theory takes into account the wettability-capillarity characteristics, the particle density, and the rate of solution of the powder;
5. It is shown how by means of this working theory it is possible to construct models to represent the mechanism of dispersion of any food powders.

III. EXPERIMENTAL WORK

SECTION (2) EFFECT OF NON-REWETTING PROCESSES UPON DISPERSIBILITY

SECTION (2) - EFFECT OF NON-REWETTING PROCESSES UPON DISPERSIBILITY

A. INTRODUCTION

It is appreciated that considerable improvements in the dispersibility of a powder are to be achieved by such techniques as instantising of NFDM. However, instantising type processes involve the rewetting of a base powder to achieve agglomeration of particles, followed by redrying; such operations adding considerably to the complexity and cost of manufacture. It was, therefore, decided to investigate the possibilities of improving dispersion characteristics of a food powder by non-rewetting processes.

In addition, it was desired to relate and explain any changes observed in reconstitution characteristics of powders in terms of the working theory of dispersion already developed.

Keeping in mind that this was to be an attempt to improve reconstitution by non-rewetting processes it was decided to study the effect of compression of powders. Such a study appeared justified on referring to the working theory of dispersion and noting the following points :

1. The importance of capillary characteristics of a powder. It appeared feasible that compression could promote aggregation of particles which would result in more rapid capillary penetration of liquid upon reconstitution;
2. The importance of particle density. Remembering that many spray dried particles contain entrapped gases it would seem reasonable that the particle density of a powder could be

increased by compression. The effect of this upon dispersibility was worthy of investigation.

The description and presentation of research dealing with non-rewetting processes is best classified into three headings, viz. :

(i) Compression of powders;

(ii) Temperature of water for reconstitution;

(iii) Addition of free flow agents.

B. LITERATURE REVIEW

(i) Compression of Powders

Many workers have reported on the effect of compression of milk powders upon bulk density and residual oxygen content, but seldom is there any mention of the effect upon reconstitution characteristics. Webb and Hufnagel (1943) reported on the saving in shipping space which could be achieved by compression. They related pressures, volume reduction and packing densities for NFDM and FCDM. Similar work is reported by Miller (1945). Lea et al (1943) and Thiel (1945) extended this work by studying the effect of compression upon the residual oxygen content of FCDM. It was hoped that the milk powder could be compressed sufficiently to expel oxygen responsible for oxidative deterioration thus eliminating the need for inert gas or vacuum packing of FCDM. Although residual oxygen contents could be reduced to levels comparable to those achieved by gas packing this technique has never been accepted commercially.

Brochner (1962) and Arbatskaya (1962) report on the

manufacture of dried milk tablets employing compression of constituents.

Wagner et al (1964) report a compression technique employed for foam mat dried orange and grapefruit juice powders involving heating/compression of the powder in a modified double drum drier. This technique produced a more acceptable powder of increased bulk density although it is reported that reconstitution time suffered slightly.

Hanrahan and Kontson (1965) studied the effect of compressing NFDM into cake form upon bulk density of the cake and upon bulk density and dispersibility of the repowdered sample. These studies were made on commercial spray dried NFDM, instant NFDM, and foam spray dried NFDM. It was found that compression adversely affected the dispersibility of the repowdered samples in all cases except at very low pressures (up to 600 psi) in the case of foam spray dried NFDM. This work is the only report in the literature of the effect of compression upon dispersibility. It appeared warranted to extend this work in order to study the effect of compression upon particle density and porosity of the powder; also to apply the technique to two different classes of spray dried food powders.

Further support, suggesting the use of compression as a means of achieving agglomeration comes from a study of practice in the pharmaceutical industry and powder compaction in other industries; Peck (1958); Train and Lewis (1962); Gregory (1962); Little and Mitchell (1949). Granulation is a size enlargement operation employed for example in the pharmaceutical industry, in the fertiliser industry, and in metallurgy. One method of granulation sometimes employed in

the pharmaceutical industry is termed "dry granulation" or"slugging". This involves the "slugging" or compression of the base powder to form oversize tablets, followed by size reduction to the desired granule size. The overall result is one of size enlargement or agglomeration by compaction.

(ii) Temperature of Water for Reconstitution

It is appreciated that the temperature of the water of reconstitution will influence the rate of dispersion of food powders. However, optimum temperatures of reconstitution have seldom been determined. Instructions for reconstitution found accompanying food powders will often recommend the use of cold water with little justification.

Work is reported on the effect of water temperature in the reconstitution of milk powders. King (1966) reviews much of this work. Ashworth and Bendixen (1947) report that there exists an optimum temperature for reconstitution of milk powders but fail to give an actual value. Aldrich and Downs (1959) used a manual stirring dispersibility test to determine the effect of reconstitution temperatures in the range 50°C to 100°C upon dispersibility. They tested instant NFDMs, spray dried NFDMs and FCDMs, and found in all cases that increasing water temperature above 50°C decreased dispersibility. Gibson and Raithby (1954) found that optimum temperature for wettability (equivalent to sinkability in present work) was 50°C for NFDM. Above 50°C there occurred a sharp decrease in the wettability of the powder.

The decrease in dispersion or wettability at higher temperatures is generally attributed to a denaturation of casein. This corresponds well with work of Howat and Wright (1933). They determined the percentage of insoluble protein in milk powders (NFDM and FCDM) after reconstitution at different temperatures. For roller dried samples it was found that a minimum percentage of insoluble protein was obtained at approximately 45°C. This effect was not obtained for spray dried powders.

Although work is reported on the effect of temperature of reconstitution upon rate of reconstitution of milk powders there appears to be some confusion as to optimum temperatures. This fact is evidenced in a review by Gibson (1952) describing industrial methods for reconstitution. Methods show great variation in water temperature employed ranging from 45-120°F. It appeared desirable, therefore, to study the effect of water temperatures, at least for NFDM.

(iii) Addition of Free Flow Agents

Interest in free flow agents with regard to this study can be said to be twofold :

1. It is noted that instant milk powders possess improved flow properties as a result of increased particle size. The question arises, therefore, whether some of the improvement in dispersibility of instant powders is due to improved flow properties?

2. It is noted that the flow properties of food powders can be improved by chemical agents. It is desired to determine the effect of such agents upon the dispersibility of the powders.

Good reviews of flow properties of powders and methods of measurement are given by Carr (1965) and Burak (1966).

Burak (1966) states that flow difficulties become acute at particle sizes below about 100/u. This, of course, includes spray dried NFDM and many other food powders. However, flow characteristics can be greatly improved by the addition of certain chemicals loosely termed free flow agents and anticaking agents. The mode of action of such free flow agents can be put into two main groups :

1. Chemical agent which physically separates powder particles to prevent bridging. Such an agent may act as a lubricant between particles to improve powder flow;
2. Chemical agent which selectively absorbs moisture in the environment to prevent caking. Such an agent is truly an anticaking agent.

Many free flow agents combine both these modes of action.

Watson (1957) describes the use of anticaking agents in the conditioning of table salt. Sjollema (1963) reports on some investigations of the free flow properties of milk powders and use of free flow agents. Linton-Smith (1961) and Linton-Smith and Hansen (1963) report on the use of free flow agents in improving the flow

properties of milk powder for use in hot drink dispensing machines. These agents also serve in reducing the packing volume of powders.

Free flow agents which have been used or proposed for powders include synthetic silicas, silicates, and metallic oxides, carbonates and phosphates. Flow-conditioning agents or lubricants are also employed in the pharmaceutical industry to assist tabletting; common agents being talc and magnesium stearate. In general, the flow-conditioning agent should have a particle size very much below that of the host powder.

It should be remembered that improved flow properties in a powder will, of itself, be a desirable quality attribute quite apart from any effect an additive may have on other powder properties, such as dispersibility.

C. PROCEDURE FOR COMPRESSION

Compression of powders was achieved by means of a hydraulic press and a simple punch and die set. The hydraulic press was operated by compressed air, fed into a pressure chamber having a bore diameter of 12 inches, (113 inches^2 area). This means that for every 1 psi of air pressure in the pressure chamber, there will be a downward force of 113lb.

It was realised in the course of experimentation that the downward force, as calculated from the air pressure admitted to the chamber, did not correspond with the downward force shown by the punch. This is due to an upward force exerted by an internal spring acting to

retract the piston of the press when air pressure is released, i.e.

$$\begin{matrix}\text{(Downward Force)}\\ \text{(of Punch (lb))}\end{matrix} = \begin{matrix}\text{(Pressure in)}\\ \text{(Chamber psi)}\end{matrix} \times 113 - \begin{matrix}\text{(Upward Force of)}\\ \text{(Spring (lb))}\end{matrix}$$

Since the force exerted by a spring is a function of its compression or elongation, this factor will be variable depending upon the distance of travel of the piston, i.e. Hooke's Law.

Therefore, this necessitated the calibration of the retracting spring, as a function of distance of travel of the press piston. This was done by :

1. Calculating total downward force from air pressure in chamber;
2. Measuring the net downward force on punch by means of a spring balance attached to a beam above the hydraulic press;
3. Measuring the distance of projection of the piston;
4. Calculating the upward force of the spring as per formula shown.

This then allowed plotting of a calibration curve shown in Figure 10. As can be seen, Hooke's Law is demonstrated from the straight line plot obtained. Using Figure 10 it was possible to determine the net downward force on the compression punch from the air pressure admitted to the chamber and the distance of projection of the piston. The net force on the punch is converted to psi from a knowledge of the punch face area. Two punch and die sets were employed having punch face areas of 2.0 inches^2 and 3.73 inches^2.

The procedure adopted for the compression of NFDM powder and instant coffee powder was as follows :

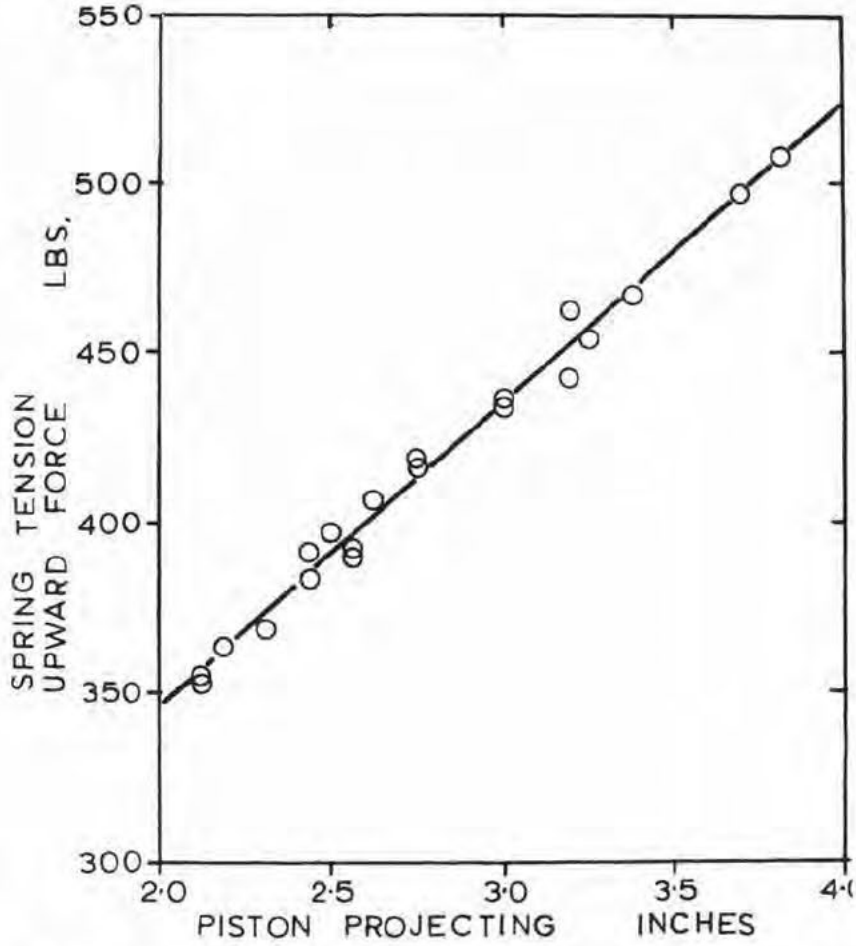


FIG. 10 CALIBRATION OF HYDRAULIC PRESS

1. The 2.0 inches^2 area punch and die set was used for NFDM samples while the 3.73 inches^2 area set was used for instant coffee samples. In both cases loose powder depth of fill in the dies was approximately $\frac{7}{8}$ inches. Samples were compressed at varying pressures, pressures being calculated as described above. Compressed sample was immediately transferred to a closed jar, each operation being repeated until sufficient sample for test was obtained;
2. The samples at each compression pressure were transferred to a "Moulin" manual kitchen grinder. This served to break up samples by forcing particles through a perforated plate. In all work the smallest plate having 1,400/u holes was employed;
3. For the sake of uniformity, samples were next screened through a single standard sieve. For NFDM, a 36 mesh B.S. sieve (420/u) was employed while for the instant coffee an 18 mesh B.S. sieve (850/u) was used;
4. Since all the powders employed are extremely hygroscopic, care was taken throughout to minimise moisture uptake. Moisture checks revealed that the complete compression and regrinding operations resulted in a moisture uptake from 3.6% to 5.0% for NFDM and from 2.8% to 3.6% for instant coffee. This minimal moisture uptake was considered acceptable.

D. RESULTS AND DISCUSSION

(i) Compression of Powders

(a) Non-Fat Dried Milk (NFDM)

Samples of Niro NFDM were prepared by a process of compression and regrinding as described under PROCEDURE. Pressures of treatment varied from 0-6,000 psi. In addition to commercial Niro NFDM, the study was also repeated with Niro NFDM + 2% Magnesium Stearate powder added in the dry state. Magnesium Stearate is commonly employed as a lubricant and free flow agent and as an aid in compression in the pharmaceutical industry. Treated samples were then analysed for dispersibility, sinkability, particle density, bulk density and porosity. Microscopical examination was also carried out.

The results are best presented in graphical form and are shown in Figure 11. The following points are noted from the results :

1. No significant improvement in dispersibility can be achieved in NFDM by compression. Beyond 1,500 psi the dispersibility of the reground powder shows a steady decrease; whereas up to 1,500 psi there is little effect upon dispersibility;
2. The sinkability of the Niro NFDM shows a slight increase on compression but not until the particle density of the powder had exceeded approximately 1.18gm/cc;
3. It is clearly demonstrated that the particle density of spray dried NFDM can be increased by compression. This is due to the unique nature of spray dried powders. Since particles contain entrapped gas cells it is possible to decrease

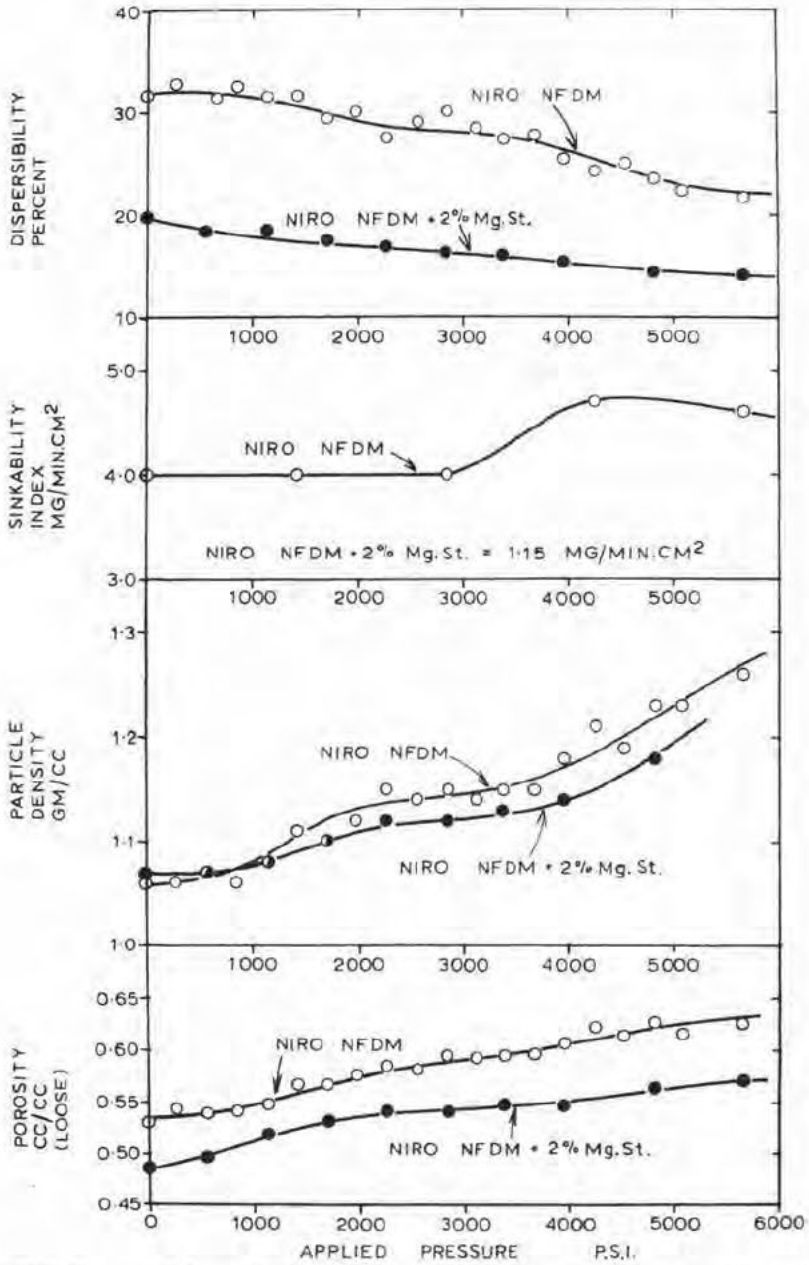


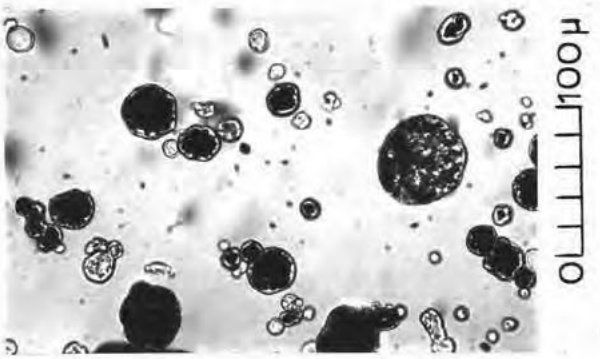
FIG. 11 COMPRESSION OF NIRO NFDM (REPOWDERED)

particle volume by compression;

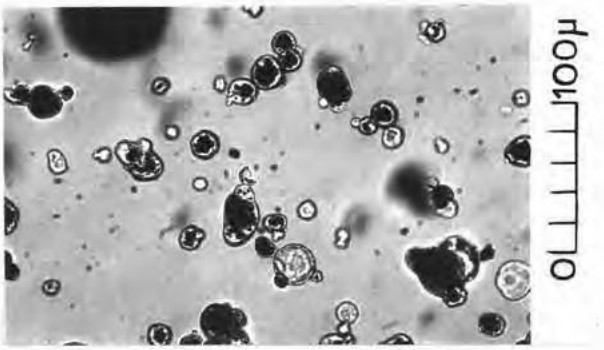
4. An interesting effect of compression is the increase in porosity which can be achieved. Porosity is expressed as cc of voids per cc of loose powder. This increase in porosity could be achieved either by a tendency of particles to aggregate or by fragmentation to form irregular particles. Microscopic examination revealed that, in fact, both effects were occurring. At low pressures considerable tendency for particle aggregation was evidenced. However, the effect of higher pressures was merely to increase fragmentation of particles. This effect of compression is well illustrated by the microphotographs in Figure 12;

5. The bulk densities (loose) of the regound powders showed little change and have not been plotted. Bulk densities of the Niro NFDM ranged only from 0.50-0.47gm/cc for the pressure range 0-6,000 psi. Correspondingly, the bulk densities with 2% Magnesium Stearate added ranged from 0.55 to 0.50gm/cc. It should be noted that bulk densities can be calculated from the particle density and porosity figures which have been plotted;

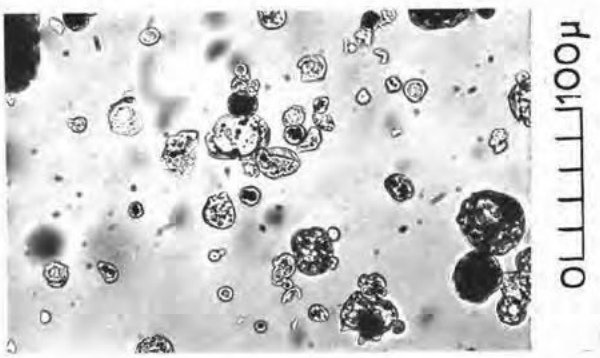
6. The effect of Magnesium Stearate addition upon compression of NFDM provides an interesting comparison. Firstly, it must be mentioned that, subjectively, NFDM with 2% Magnesium Stearate appeared far superior in free flow properties and general handling characteristics. The compression, re-grinding, and sieving operations were all facilitated with this additive.



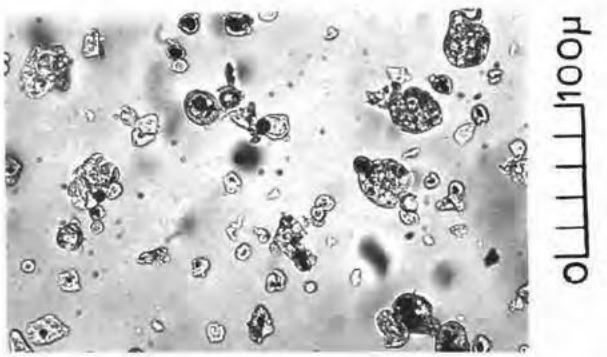
Control : 0 psi



Compression : 570 psi



Compression : 2550 psi



Compression : 5090 psi

FIGURE 12 Microphotographs Showing Effect of Compression/Repowdering Treatment upon Niro NFDM (Magnification x 250)

However, the effect upon dispersibility was far from beneficial. This can be explained by the hydrophobic properties of the Stearate which in effect has given the NFDM particles a coating as for FCDM. This is reflected in the low sinkability value with Stearate addition, reducing sinkability index from 4.0 to 1.15mg/min cm^2 at 0 psi;

7. The lubricating effect of Stearate during compression is evidenced in the plot of particle density versus applied pressure. As can be seen in Figure 11, at any particular applied pressure the sample with Stearate added will have undergone a smaller increase in particle density than the straight Niro NFDM. This is attributed to the lubricating effect of the Stearate in allowing better dissipation of compression energy;

8. The role of Stearate as a flow-conditioner is seen in the porosity measurements. Reground samples with this additive consistently show a lower porosity indicating greater packing of the powder;

9. The highest particle density achieved in this study is 1.26 gm/cc at 5,650 psi. At 0 psi the control NFDM possesses a particle density of 1.06gm/cc. Buma (1965) discusses and reviews work on the determination of the true density of dairy products. He arrives at a value of 1.52gm/cc for the true density of NFDM solids. Accepting this figure it is seen that compression has effected 43.5% of the maximum

theoretically possible increase in particle density.

From these results it is concluded that no significant improvement in the dispersibility of spray dried NFDM can be achieved by compression. In itself, this conclusion is no different to that obtained by Hanrahan and Kontson (1965) except that in the present study no adverse effect on dispersibility was noted below 1,500 psi, whereas Hanrahan and Kontson found an adverse effect at lower pressures. This observation gives added feasibility to the suggestion that powders may be compressed for packaging and distribution in order to reduce packaging, storage and transport costs. As mentioned earlier, this has been suggested by many workers in the past but never with any reference of the effect of compression upon reconstitution characteristics.

However, these results and conclusions extend beyond those of Hanrahan and Kontson (1965) in so far as they have included measurements of particle density and porosity. When the results are examined with regard to the working the ry of dispersion previously developed some interesting observations are possible.

Firstly, the influence of particle density upon sinkability of the powder has been clearly demonstrated. It is seen that an increase in sinkability is achieved beyond a particle density of 1.18gm/cc.

Secondly, it has been shown that the porosity of the powder can be increased by compression. This porosity increase may be effected by :

1. Aggregation of particles as a result of particle/particle adhesion;

and/or

2. Fragmentation of particles to form irregular shaped units.

Microscopic examination suggests that both effects are occurring although fragmentation appears predominant at higher pressures, (e.g. Figure 12). It would be expected that since the porosity of the powder is increased the dispersibility should be improved due to increased wettability-capillarity, and yet this was not the case. This can be attributed to the decrease in particle size associated with fragmentation. Pyne (1961) illustrated the importance of particle size upon the wettability of particles. Later work in this thesis also emphasises the importance of particle size upon reconstitution characteristics.

(b) Instant Spray Dried Coffee (Brand A)

The study of effect of compression upon dispersibility of a food powder was extended to the case of Spray Dried Instant Coffee A. The main interest in this study is due to the low particle density of instant coffee, e.g. 0.65gm/cc. Characteristically, instant spray dried coffee particles contain a large volume of entrapped air, being virtually a hollow shell. Dispersion of such a powder must occur by solution at the powder/water interface, (Model 4). It appeared feasible, therefore, that compression could be employed to increase particle density so as to allow sinking of wetted particles from the surface and so facilitate reconstitution (Model 3).

Samples of Instant Coffee A were prepared by compression and regrinding as described under PROCEDURE. Pressures of treatment varied from 0-1,700 psi. Samples were analysed for dispersibility, sinkability, particle density, bulk density and porosity. Microscopical examination was also carried out.

Results are presented in graphical form in Figure 13. Before discussing these results it may be said that the immediate result which caught the eye was the slight, but significant, increase in dispersibility possible at relatively low compression pressures. This led to the repeating of the experimental procedure and analyses, but this time with greater emphasis on the range of compression from 0-350 psi. The results at this lower range of pressures are presented in Figure 14. The results are presented separately since a different batch of instant coffee A was used in this repeat trial.

The following points are noted from the results in Figures 13 and 14 :

1. A slight improvement in the dispersibility of this brand of spray dried coffee is achieved by compression below approximately 250 psi. Certainly, there is no adverse effect on dispersibility by such treatment, below 250 psi;
2. The effect of compression on sinkability is quite an interesting one. Initially, there occurs a decrease in the sinkability index until, at above approximately 350 psi, a gradual increase in sinkability is achieved. It is interesting to note that the sinkability does not show an

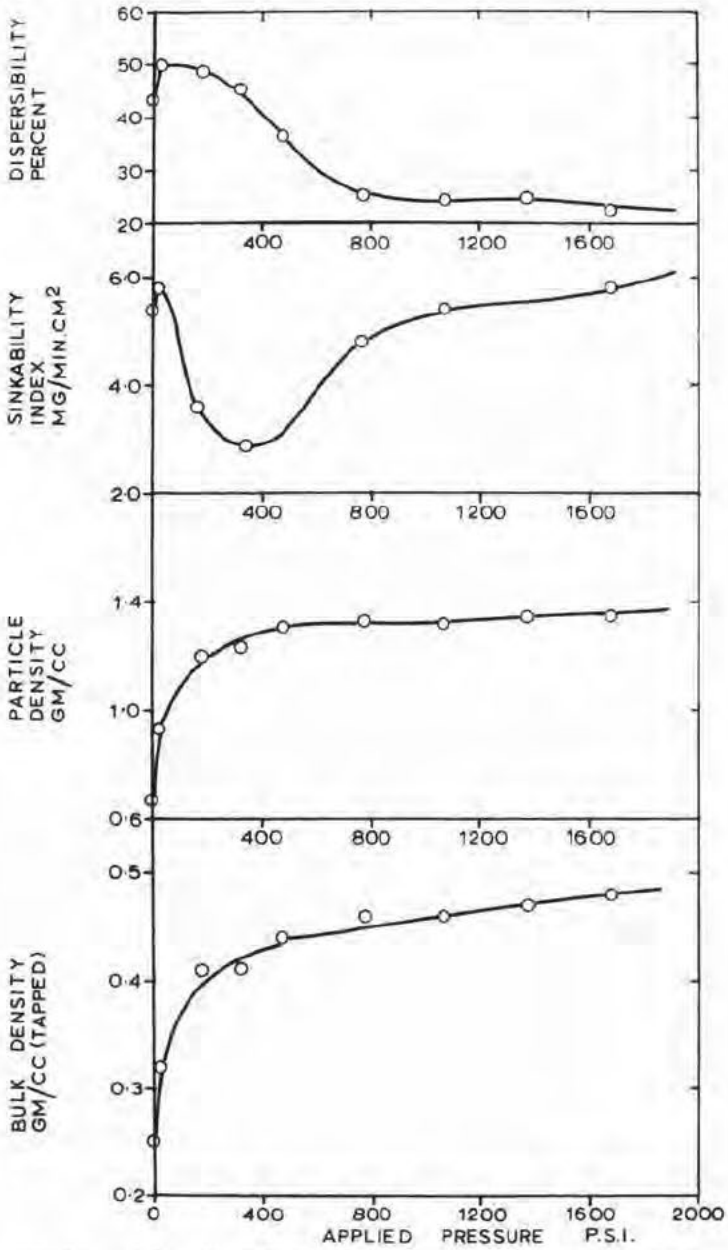


FIG.13 COMPRESSION OF INSTANT COFFEE A
RANGE 0 - 2000 P.S.I. (REPOWDERED)

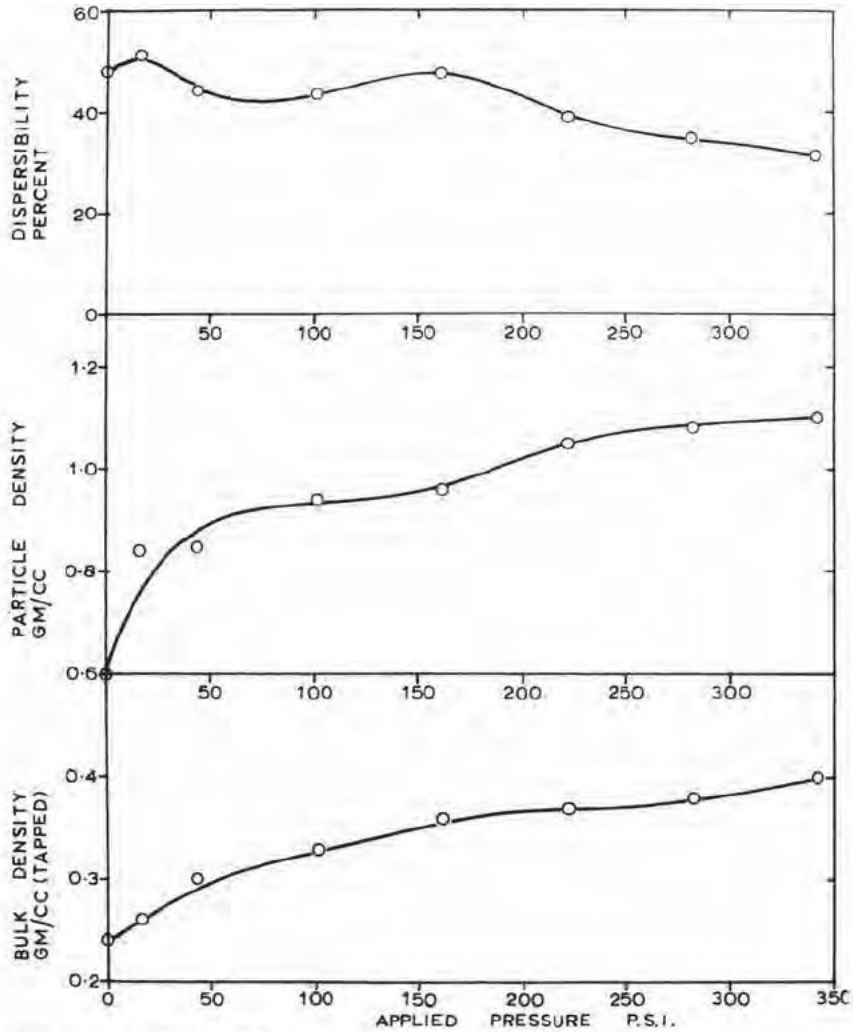


FIG. 14 COMPRESSION OF INSTANT COFFEE A
RANGE 0 - 350 P.S.I. (REPOWDERED)

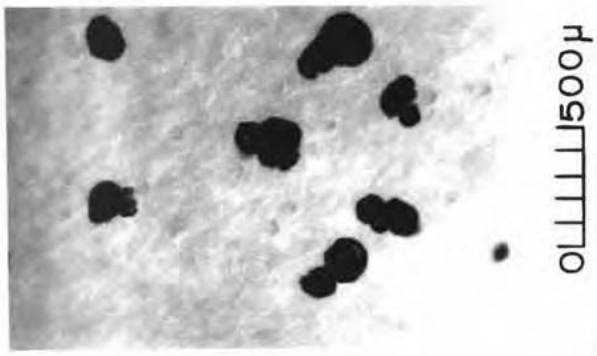
increase until the average particle density of the powder has reached 1.2gm/cc; this was also the case with NFDM;

3. With spray dried coffee the effect of compression upon particle density is much more marked than with NFDM. In fact, even at 600 psi, the particle density has almost doubled from 0.67 to 1.32gm/cc;

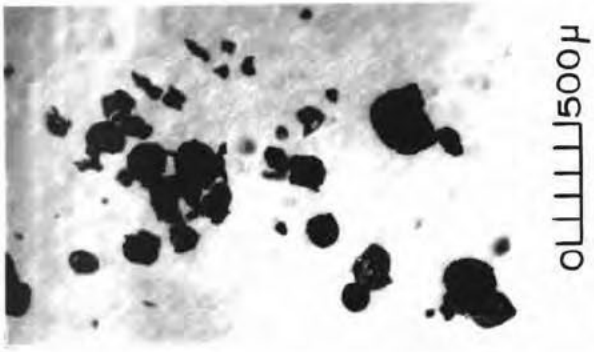
4. Microscopic examination revealed quite plainly that the effect of compression was to cause successive fragmentation of the originally hollow spray dried spheres. This can be seen in the microphotographs shown in Figure 15;

5. Another interesting effect of compression relates to the bulk density of the reground powder. It is well appreciated that commercial instant coffee possesses an extremely low bulk density, e.g. 0.24gm/cc in this instance. Any increase in the bulk density of such a powder would represent savings in packaging, storage and transport costs. Now, it is seen from Figure 14 that at, say, 150 psi compression treatment there is no adverse effect on the dispersibility of the powder, and yet bulk density of the reground powder has increased from 0.24 to 0.35gm/cc. This represents a potential saving in the packaging volume of the present product of 31%. Such a saving speaks for itself;

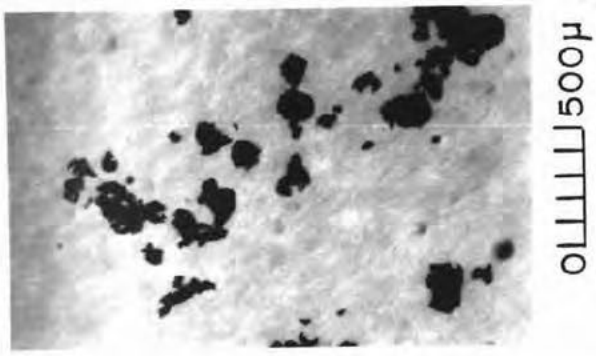
6. It should be mentioned that at a compression treatment of 50 psi no compaction effect (lumping) is evident and the compressed product is still truly a powder. At 150 psi some compaction is just evident but any lumps present break



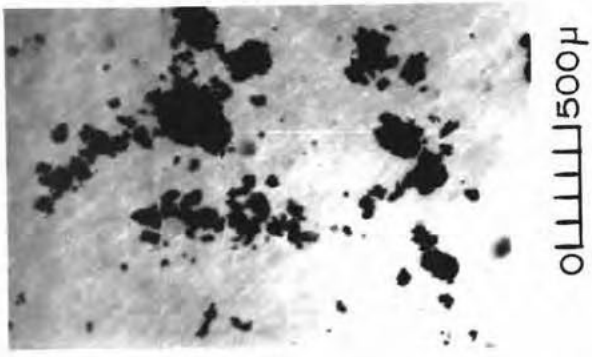
Control : 0 psi



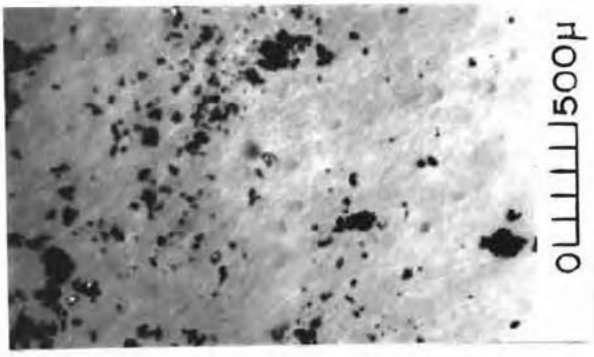
Compression : 16 psi



Compression : 102 psi



Compression : 282 psi



Compression : 1370 psi

FIGURE 15 Microphotographs Showing Effect of Compression/Repowdering Treatment upon Spray Dried Instant Coffee A (Magnification x 40)

up most readily;

7. Porosities of the reground powders are not shown in this case as they showed little variation, increasing only slightly on compression from approximately 0.63-0.67cc of voids per cc of loose powder. Porosities can be calculated from the particle densities and bulk densities shown in the graphs.

Some explanation of the phenomena observed can be made in terms of the working theory of dispersion :

The increase in dispersibility of powders compressed at low pressures can be attributed to an increase in the average particle density leading to a greater tendency for particles to separate from the powder/water interface once wetted. Eventually, however, higher pressures lead to a decrease in dispersibility which may be attributed to the high degree of fragmentation which has produced, virtually, a powder of much smaller particle size. As mentioned earlier, powders of finer particle size exhibit lower wettability and dispersibility characteristics.

Sinkability characteristics of the compressed powder are somewhat different from dispersibility. Initially there is evident a slight increase in sinkability which may be attributed to the increase in average particle density. However, until a pressure of approximately 350 psi is applied, average particle density is below 1.2gm/cc and it may be presumed that dispersion still occurs mainly at the powder/water interface. At the same time compression has the

effect of increasing the bulk density of the powder and this in itself may have the effect of decreasing sinkability while dispersion must occur from the interface. The influence of bulk density upon dispersion is supported by Harper et al (1963). They support and present evidence for the theory that concentration of solids in the vicinity of powder particles will have a marked influence on dispersibility. The bulk density of the powder will directly influence the concentration of solids in the vicinity of each particle upon reconstitution. Beyond 350 psi the sinkability of the powder again increases. By this stage the particle density has been increased beyond 1.2gm/cc and it may be assumed that dispersion no longer takes place at the interface only (i.e. Model 3). The limiting factor at these higher pressures now becomes the small particle size of the fragments and their resulting lower wettability (Pyne (1961)).

Although these explanations appear to satisfy the observed results they are tendered only from deductions which can be made. The process of reconstitution of a powder is obviously rather complex since many factors interact simultaneously to bring about dispersion. Nevertheless, some explanation has been possible by use of the proposed working theory of dispersion.

However, from a technological point of view, rather than theoretical, these results have more direct implications. The fact that spray dried coffee can be subjected to relatively mild compression without adverse effect on reconstitution characteristics immediately suggests certain commercial applications :

1. Results suggest the possibility of compressing coffee powders at low pressures, e.g. 150 psi, in order to achieve a higher bulk density product without adverse effect on dispersibility. Since little compaction occurs below 150 psi a "regrinding" operation may not be necessary. As pointed out above, treatment of 150 psi would increase bulk density of the repowdered product from 0.24 to 0.35gm/cc;
2. Results also suggest the possibility of compressing coffee powders, using low pressures, and packing the product at compressed volume. Obviously this would achieve even greater savings in packaging volume. Providing no compaction had occurred on storage the "compressed pack" could be transferred to a larger container by the consumer in order to release the repowdered product. Alternatively, the "compressed pack" could contain the exact quantity for a particular reconstitution;
3. Results indicate that compression has been used to modify the particle density and bulk density of spray dried coffee with no adverse effect upon dispersibility characteristics. This suggests the possibility of modifying spray drying conditions so as to produce a powder of higher bulk density and particle density. For example, high inlet air temperatures in spray drying tend to promote ballooning of particles, giving a powder of low particle density and bulk density, similar to spray dried coffee. It may well be that manufacturers have encouraged high inlet air temperatures

believing this to produce an instant coffee of optimum dispersibility. These results, at least, would justify some research on modification of drying technique in view of potential savings in bulk volume.

It is believed that the technological applications of this research show considerable potential and for this reason some follow-up work was done with regard to applications 1 and 2 above. Several points warranted investigation :

1. Since very little compaction occurs below 150 psi it would be interesting to compare dispersibilities of samples merely compressed and then transferred directly for reconstitution, versus samples compressed and then repowdered by use of the Moulin grinder and 850/u sieve as described in PROCEDURE;
2. If powders were to be compressed at low pressures and held at compressed volume a much greater saving in packaging would be possible as compared to repowdering, or "regrinding" before packaging. Determination of compressed bulk densities was warranted. Also, it appeared possible that some deterioration in dispersibility could occur if samples were stored at compressed volume; this warranted elucidation.

In this follow-up work 50gm samples of spray dried coffee A were compressed in standard 8oz cans using a specially made punch, or piston, which just fitted inside the can. With a little care powder could be compressed "in can" to over 150 psi without damage to the can. In two cases it was desired to store samples at compressed volume for four

weeks. This was done by placing a spacer into the remaining headspace of the can and then sealing the can. Coffee samples were given different treatments and then tested for dispersibility as presented in Table 3 below. Compressed bulk densities of coffee powders were determined by measuring the volume occupied by a known weight of powder in the compression die following a particular compression. These results are presented in Figure 16.

TABLE 3

Effect of Different Compression Treatments Upon Dispersibility of Spray Dried Coffee A

Treatment	Dispersibility %
Control Instant Coffee A	48.1
47 psi, not repowdered, not stored	51.3
47 psi, repowdered, not stored	49.9
47 psi, stored four weeks at compressed volume, repowdered	42.9
138 psi, not repowdered, not stored	53.8
138 psi, repowdered, not stored	48.6
138 psi, stored four weeks at compressed volume, repowdered	42.2

The following points are noted from the results :

1. Compression of instant coffee A up to 150 psi followed by repowdering of the product in the standard manner resulted in a slight increase in dispersibility;

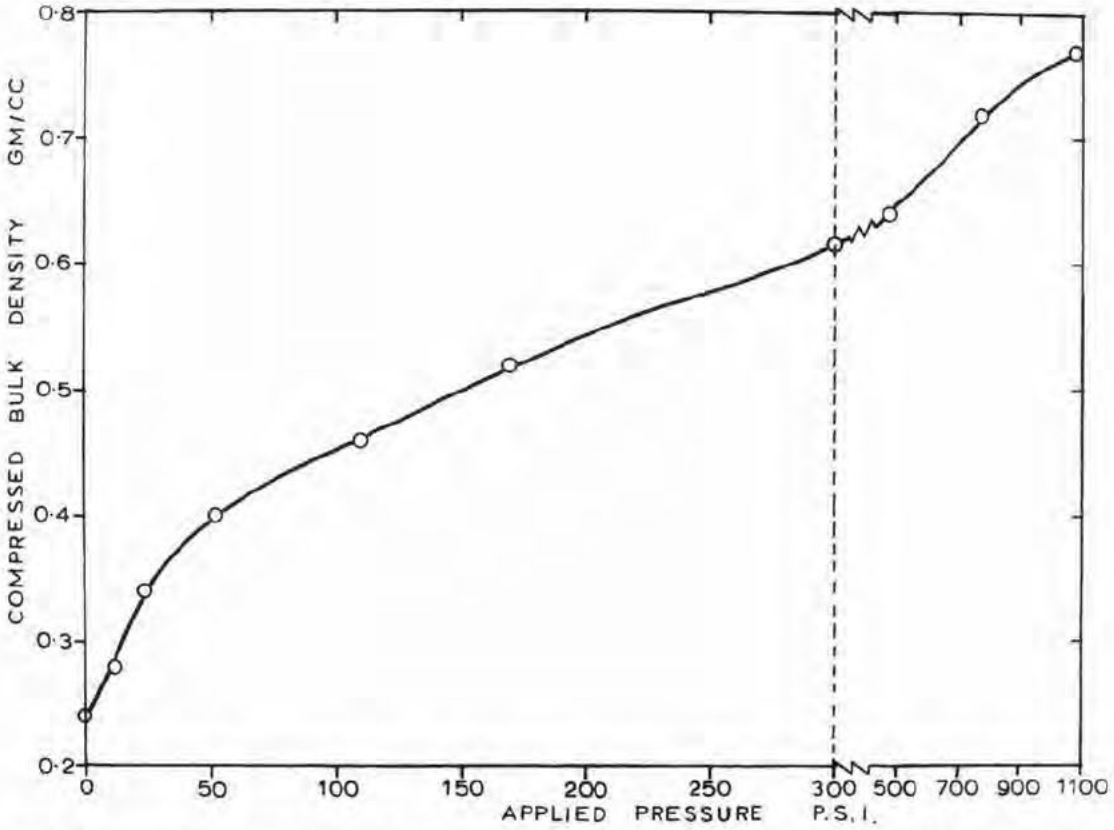


FIG. 16 COMPRESSED BULK DENSITIES OF INSTANT COFFEE A

2. At both pressures studied, 47 psi and 138 psi, insufficient compaction had occurred to affect the dispersibility of compressed powder not reground in the standard manner;
3. When Figure 16 is compared with the bulk densities of the repowdered coffee as shown in Figures 13 and 14 it is seen that an even greater saving in packaging space can be achieved if the powder is kept at compression volume. For example, at 150 psi treatment the compressed bulk density is 0.5gm/cc, representing a 52% saving in packaging volume over the original powder, compared with the 31% saving if repowdered;
4. Storage of treated samples at compressed volume for four weeks results in a slight decrease in the dispersibility of the repowdered coffee. The reason for this is not altogether clear. It may be that on holding at compressed volume, even though pressure is released vertically, internal stresses are retained. Such internal stresses could act in increasing the degree of fragmentation in the powder upon storage as illustrated in Figure 15. This could mean that the effect of storage is ,in fact, similar to the application of a higher pressure initially. More research on this aspect would be desirable before any conclusions are offered.

It is fully realised that the follow-up work which has been done with a view to technological applications of compression of spray dried coffee can serve as little more than a preliminary investigation.

Nevertheless, it is believed that results obtained are conclusive enough to justify further investigation. In addition such techniques of compression could have applications with other spray dried products. For example, sodium caseinate has a tendency to "balloon" considerably during spray drying, as do detergents, resulting in a product of low particle density and bulk density. As in instant coffee, therefore, the possibility exists of increasing bulk density and particle density of such powders with little if any adverse effect on reconstitution characteristics.

(ii) Temperature of Water for Reconstitution

The effect of temperature of reconstitution upon dispersibility of two samples of spray dried NFDM was determined. In all other work the temperature of the water in the dispersibility test is 75°F (23.9°C); in this case the temperature was varied and measured immediately before the placing of powder onto the water surface. Results are shown in Figure 17.

Both the Niro NFDM and the Modified Niro NFDM show a marked increase in dispersibility as the temperature of water for reconstitution is raised to 50°C. Above 50°C the Niro NFDM shows a sharp decrease in dispersibility from a maximum of 54% to approximately 40%. The behaviour of the Modified Niro NFDM is not as straight-forward, showing a decrease in dispersibility on raising temperature from 50°C to 60°C but showing another peak at 70°C. This result is almost identical to that obtained for wettability versus water temperature on a sample of spray dried NFDM by Gibson and Raithby (1954). They do not offer an

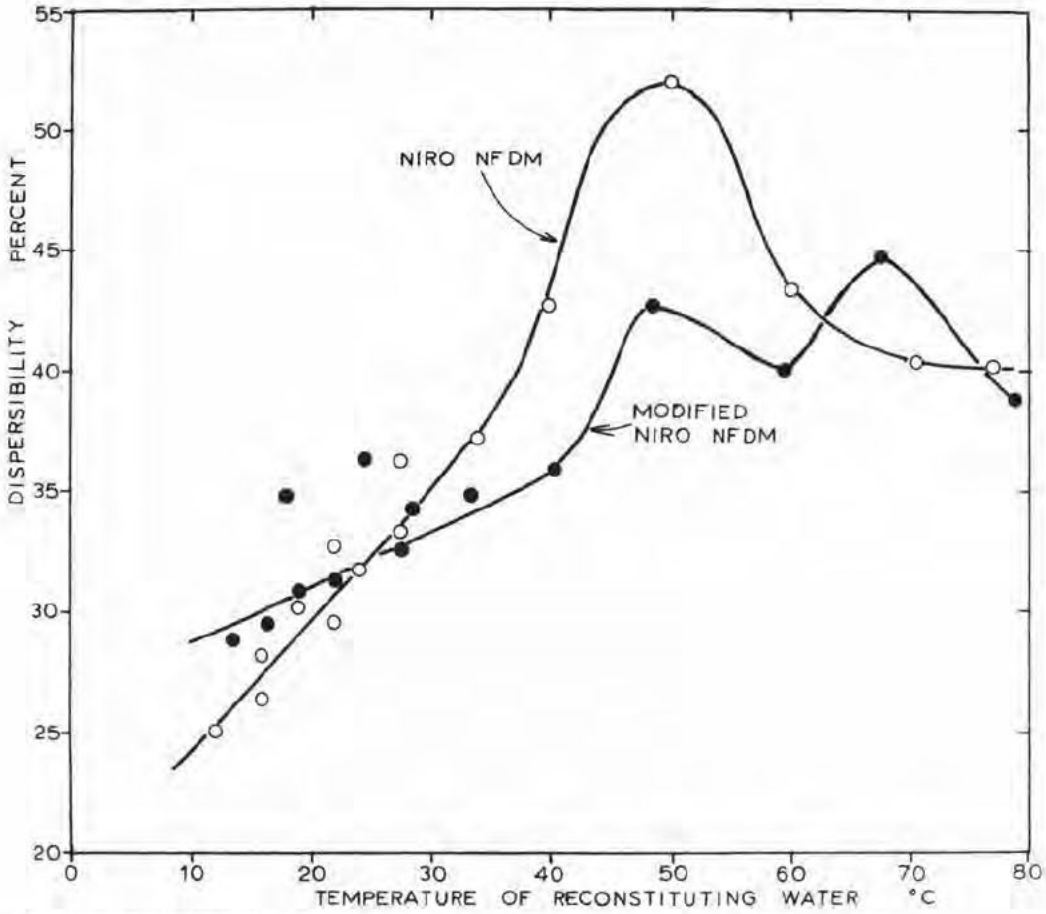


FIG.17 TEMPERATURE EFFECT ON DISPERSIBILITY OF NFDM

explanation for this observation.

As discussed in the literature review, the decrease in dispersibility above 50°C can be attributed to protein denaturation. This corresponds with work of Howat and Wright (1933).

It has been shown, therefore, that improvement in the dispersibility of NFDM can be achieved by a non-rewetting process, namely, by raising thetemperature of water for reconstitution to an optimum value. This optimum appears to be approximately 50°C for NFDM. The technique of determination could be used to determine optimum temperatures for other food powders. The improvement in dispersibility achieved for NFDM is quite considerable, e.g. from 25% at 12°C to 54% at 50°C for the Niro NFDM, particularly when this is compared with dispersibilities of approximately 60% for instant NFDMs at 24°C (Table 2). Results indicate that raising of reconstitution temperature becomes a compromise between an increasing dispersibility as against a decreasing net solubility, due to protein denaturation.

(iii) Addition of Free Flow Agents

The effect of addition of two free flow agents upon the dispersibility of Niro NFDM was studied. The addition of the agents to NFDM was carried out by dry mixing, employing two separate mixing steps, since concentrations of less than 5% were required. For example, free flow agent + NFDM to give a 10% mix was first blended thoroughly. This was then followed by blending of 10% mix and NFDM to give the required concentration of free flow agent in final mix.

Magnesium Stearate was added to Niro NFDM at the 2% level only. This work was done in conjunction with the study of effect of Stearate as a lubricant in compression of NFDM. The effect of Stearate addition upon dispersibility, sinkability index, and bulk density of the powder is summarised in Table 4.

TABLE 4

Effect of Magnesium Stearate Addition Upon Reconstitution of NFDM

Sample	Dispersibility %	Sinkability Index mg/min.cm^2	Bulk Density (Tapped)gm/cc
Niro NFDM	31.7	4.0	0.50
Niro NFDM + 2% Mag. Stearate	19.8	1.15	0.55

The other free flow agent studied was Syloid 244. This is one of a range of synthetic silica gels. Syloid 244 has an average particle size of 3 microns and even then each particle possesses a large internal porous structure. The bulk density of Syloid 244 was measured as 0.059gm/cc. The properties and applications of these synthetic silicas are described in technical literature by Grace (1966).

The effect of addition of Syloid 244 to Niro NFDM at concentrations of 0% to 5% was studied with reference to dispersibility and tapped bulk density. Results are shown graphically in Figure 18.

The following points may be noted from the results :

1. The addition of Magnesium Stearate to NFDM causes considerable

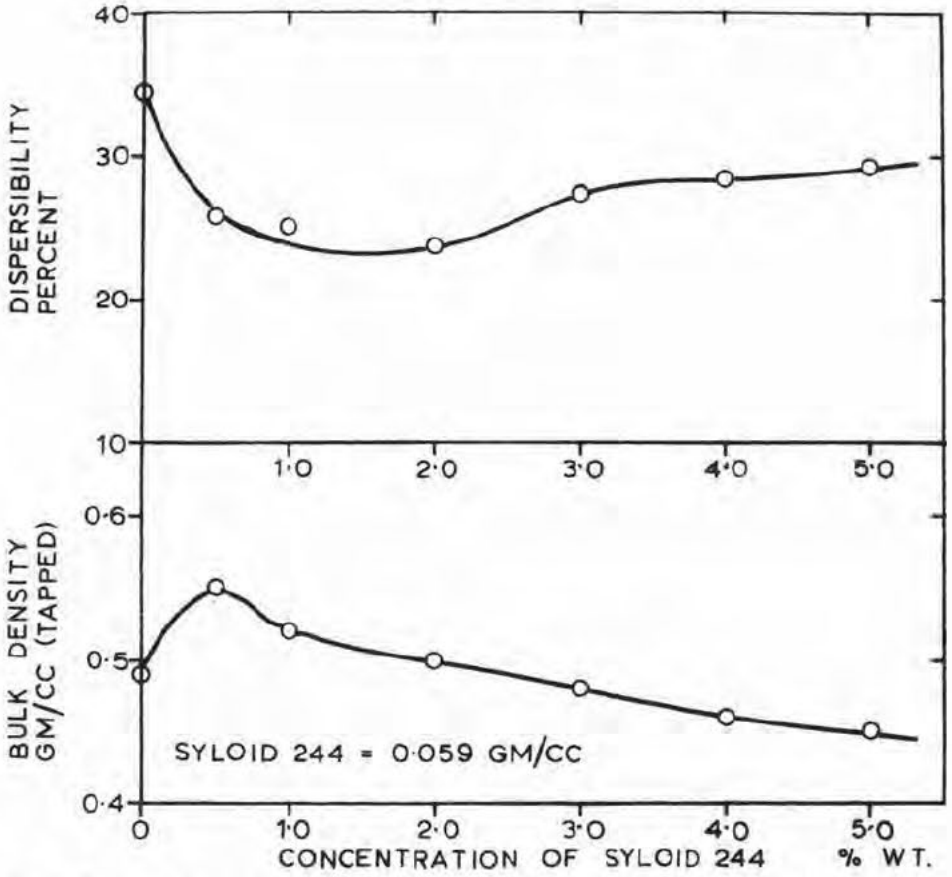


FIG. 18 EFFECT OF SYLOID 244 ADDITION TO NIRO NFDM

reduction in dispersibility. As mentioned previously this can be attributed to the hydrophobic character of Stearate, which in effect coats particles to produce a product similar to FCDM in reconstitution properties. This hydrophobic effect is reflected in the much lower sinkability index upon Stearate addition;

2. Syloid 244 addition causes a small decrease in dispersibility showing a minimum dispersibility at the 2% level, and increasing again on further addition;

3. Both free flow agents are able to increase bulk density of NFDM. Beyond 2% addition of Syloid 244, however, a reduction in bulk density is noted. This is to be expected in view of the extremely low bulk density of this agent (0.06gm/cc). Linton-Smith and Hansen (1963) also noted the reduction in bulk volume which could be achieved with free flow agents;

4. It is most interesting in Figure 18 to compare dispersibility with bulk density of the powder. Low concentrations of Syloid 244 bring about an increase in bulk density of the powder commensurate with a decrease in dispersibility. High concentrations of this agent decrease bulk density below the value of control powder while dispersibility now increases approaching that of the control. This observation therefore, suggests that the effect of Syloid 244 addition upon dispersibility may be largely due to modification of bulk density. This is supported by work of Harper et al

(1963) which demonstrated the effect of bulk density upon instant solubility of milk powders. They suggest that the lower the bulk density of a powder, the lower will be the concentration of milk solids in the vicinity of powder particles on reconstitution and hence the higher its instant solubility.

Both these flow conditioning agents when added to Niro NFDM produce a marked improvement in free flow properties as assessed subjectively. Even at 0.5% Syloid 244 addition the improvement is marked. However, it is shown that, for these two agents at least, this necessitates some sacrifice in the dispersibility of the powder. This may be a satisafactory compromise in some applications as, for example, in the case of milk powder for vending machines as described by Linton-Smith (1961). The hydrophobic nature of Stearate serves to explain the decrease in dispersibility in one case while with the silica some bulk density effect may be involved. However, silica gel also possesses strong water sorption properties suggesting that this agent may not be completely inert in the reconstitution process. It would be interesting to study the effect of a completely inert agent, if such exists, upon dispersibility of NFDM. Sodium aluminium silicate may possibly be such an inert free flow agent but a sample was unprocurable for this study.

E. PRINCIPAL RESEARCH FINDINGS

1. A study has been made of the effect of compression, followed by repowdering, upon physical properties and reconstitution characteristics of NFDM and spray dried instant coffee;
2. It has been shown that no significant increase in the dispersibility of NFDM can be achieved by such compression techniques; beyond a treatment of 1,500 psi there results a gradual decrease in dispersibility;
3. Compression treatment of both powders results in a marked increase in particle density. It is shown that much of this particle density increase can be attributed to fragmentation of the hollow spray dried shell;
4. Compression of both NFDM and instant coffee to particle densities of approximately 1.2gm/cc results in an increase in the sinkability index of the powder, even though such treatment affects adversely the dispersibility;
5. Compression of instant coffee up to 150 psi results in a slight improvement in dispersibility. Therefore, it is shown that, without adverse effect upon dispersibility, a treatment of 150 psi can effect a saving of 31% in packaging volume of the repowdered instant coffee or of 52% if packaged at compressed volume;
6. It is shown that 50°C appears to be the optimum water temperature for dispersion of NFDM. Above 50°C there is evident a net decrease in dispersibility attributable to increased protein denaturation;

7. It was found that addition of free flow agents to NFDM resulted in much improved flow and general handling properties although this improvement necessitates some compromise with dispersibility. Free flow agents may also effect an increase in the bulk density of a powder.

III. EXPERIMENTAL WORK

SECTION (3) EFFECT OF REWETTING PROCESSES UPON DISPERSIBILITY

SECTION (3) - EFFECT OF REWETTING PROCESSES UPON DISPERSIBILITY

A. INTRODUCTION

It is well known that NFDM and other food powders, such as chocolate mix, sugars, starches, etc. may be "instantised" by a rewetting/redrying process. Mori and Hedrick (1965) emphasise the importance of the instantising process in U.S.A. and state that practically all NFDM for home use in that country is now instantised. In 1963 this amounted to 255.3 million lb or 28.5% of total non-governmental use. Hall and Hedrick (1961) describe the manufacture of instant milk powders, while other agglomerated and instantised food powders are dealt with by Moore et al (1964); Claus and Brooks (1965); Miller and Powell (1965); and Lachmann (1966).

What is not so well recognised, however, is that such instantising processes are, in fact, little more than size enlargement or agglomeration operations commonly employed in many other industries. One such operation is that of wet granulation as practised in the pharmaceutical industry and in the fertiliser industry.

Undoubtedly, much work has been done on the agglomeration of food powders, and in particular NFDM, by instantising type processes. Unfortunately, however, very little such work has been published as most instantising processes are tightly controlled by patent rights. Nevertheless, the paucity of published information does suggest that little research has been carried out on the basic factors controlling the agglomeration process; probably due to the difficulty in setting up controlled experiments in commercially

available instantising equipment.

Keeping in mind that the basic steps in commercial instantising processes are no different to the basic steps in wet granulation of powders, it was the aim of this study to simulate an agglomeration process employing the principles of wet granulation. Once a simulated instantising process has been developed it can then be readily employed to study some of the basic factors controlling the process.

Research into rewetting processes is described under four headings, viz. :

(i) Effect of Rewetting Moisture;

(ii) Effect of Granule and Particle Size;

(iii) Uniformity of Moisture Distribution and Effect of Mixing during Granulation;

(iv) Additives in Wet Granulation.

B. LITERATURE REVIEW

(i) Effect of Rewetting Moisture

Mention is made in patents on instantising of milk powders of the range of rewetting moistures to be employed. Rewetting may be either by means of finely atomised water, steam, moist air, or a combination of these. The range of rewetting moistures specified in patents shows great variation and, in fact, forms the basis of discrimination between several patents. At the same time, it is realised in the industry that the extent of rewetting must be a

critical factor in producing a suitable agglomerated product, but no work or research is reported in the literature on this aspect. Probably the amount of rewetting employed in manufacture is a matter of subjective assessment by comparison with the final product.

Bullock (1962) in a review article discusses the manufacture of "Two-Stage" instants. Some of these methods for instantising may be listed :

1. Peebles was granted patents in 1955 and 1958. In this method powder is moistened by finely atomised water and air saturated with steam to a moisture content of 10-20% before redrying. In a description of the process, Peebles (1956) makes no mention of the moisture content of the rewet powder. However, in his patent, Peebles (1958) states an optimum rewetting moisture of 15%. This is not qualified other than by : "introduction of too much moisture results in too high a total moisture content for the material being delivered to the table feeder whereby the material tends to form a doughy mass rather than a fluffy stream of aggregates and cannot be dried to form a satisfactory product. An insufficient amount of moisture also causes the material delivered to be unsatisfactory".
2. The Cherry-Burrell system involves the agglomeration of particles with moist high humidity air moving at high velocity. Bullock (1962) reports a rewetting moisture of 6-10% for this system. Yet Carlson et al (1956) in

describing this process mention a rewetting moisture of 10-20%;

3. Louder and Hodson (1958) were granted a patent for a process involving rewetting with steam to not greater than 9.0% and preferably 5.5% moisture;
4. Scott (1959) holds a patent for a process involving wetting with a spray of water or milk to 10-14% moisture.

As can be seen, a wide range of rewetting moisture contents are specified in patents, although perhaps the range employed in practice may be much narrower. Mori and Hedrick (1965) studied the effect of some processing variables on dispersibility, moisture content and bulk density of instant milk powders. This is the only work of this type found in the literature, yet they make no mention of effect of rewetting moisture.

The amount of moisture to be added for granulation in the pharmaceutical industry is known to be critical but is largely subjective and a matter of experience. Such practice in wet granulation is described by Peck (1958) and Little and Mitchell (1949).

Some research has been done on the mechanism of formation of granules from moist powdered material, in particular moist sand, in a tumbling type drum mixer; Newitt and Conway-Jones (1958); and Capes and Danckwerts (1965).

Newitt and Conway-Jones (1958) describe three states of water in an assembly of spherical particles. At low moisture contents water is held in the granule as discrete rings at the points of

contact of the particles, i.e. the Pendular state. At somewhat higher moisture content the rings coalesce to form a continuous network of liquid interspersed with air, i.e. the Funicular state. At still higher moisture content the pore spaces of the granule become saturated to form the Capillary state. These workers postulated that initially the feed to a granulator consists of moist particles which have partly coalesced to loose aggregates held together by pendular bonds. Upon kneading action in the granulator the internal pore space in the aggregates is reduced; hence if sufficient water is present the pores may become saturated to form stable granules. They found granule formation in fine sand to be very dependent upon moisture content, an optimum value being approximately 68% v/v.

Capes and Danckwerts (1965) extended the work of Newitt and Conway-Jones, also employing the tumbling action in a rotating drum. Uniformly sized sands were granulated and comparison was made of granulating moistures and void volumes of the samples. Again it was possible to show the dependence of rate of growth of granules upon moisture content, but these workers showed that significant growth occurs only when liquid contents used are equal to between 90% and 110% of the amount required to fill the voids in a highly compacted sample. In other words in the granulation of sand it is necessary to achieve saturation of the voids in the aggregated particles with liquid before a stable system is reached.

(ii) Effect of Granule and Particle Size

The particle size of milk powders has long been appreciated

as an important factor in reconstitution characteristics but little conclusive evidence is presented in the literature.

Bockian et al (1957) investigated factors responsible for increased dispersibility of instant dry milks. They noted that in comparison with spray dried NFDM which consisted of particles less than 200 mesh (74/u), that instant powders are very large aggregates in the range of 80 to 20 mesh (180/u-840/u). They suggested that this may be one of the prime factors affecting the dispersibility of instant NFDM.

Similarly, Peebles (1958) considers particle size to be an important factor in obtaining an instant powder of desired characteristics. He believes it important that approximately 80% of the powder remains on a 200 mesh screen, that is, possessing a particle size greater than 74/u.

Swanson (1955) studied the effect of particle size on dispersibility of NFDM. Using an air elutriation technique he was able to fractionate powders into the different size ranges and test small samples obtained for dispersibility characteristics. He concluded that for NFDM "particles of 30-35/u in diameter seem to wet and dissolve most readily", particle sizes on either side showing reduced dispersibility. There appeared to be no correlation between particle size and dispersibility in the case of FCDM.

Gibson and Raithby (1954) examined powders of different average particle size and concluded that particle size influences the wettability of NFDM. Similarly, Baker and Bertok (1959) graded NFDMs

for particle size by the use of sieves and examined the size fraction. They concluded that with a decrease in particle size there occurred a corresponding decrease in wettability and dispersibility.

Hall and Hedrick (1961) claim that manufacturers of instant NFDM are fully aware of the importance of particle size. They describe a desirable particle size distribution as being in the range 100-500/u; no more than 10-15% of weight of particles should be less than 150/u in size.

Mori and Hedrick (1965) studied the effect of certain processing conditions on the properties of instant milk powders. They found that dispersibilities were not consistently affected by particle size (tested on fractions of sieving).

Claus and Brooks (1965) describe some properties of instantised wheat flours. Normal wheat flour is required to pass a 100 mesh U.S. sieve (150/u), whereas these modified flours are granulated or instantised, to produce a much larger "particle" size. Figures are given for size distributions of instantised flours together with evidence of the much improved wettability, or sinking time, of these flours over the normal product.

It can be seen from a review of the literature that many researchers have illustrated the importance of particle size as a factor in dispersion of a food powder. Results, however, are far from conclusive and there appears to have been no satisfactory elucidation of optimum particle size, even for the case of NFDM. Pyne and Coulter (1960) emphasise that there must exist an optimum

particle size corresponding to optimum dispersibility. They found that dispersion of milk powders is inversely proportional to the surface to mass ratio while the rate of solution is directly proportional to the surface to mass ratio. It is reasonable to deduce, therefore, that an optimum surface to mass ratio, or particle size, exists corresponding to optimum reconstitution characteristics.

(iii) Uniformity of Moisture Distribution and Effect of Mixing during Granulation

Little information is available in the literature on the uniformity of moisture distribution on rewetting of a base powder. In commercial instantising processes this factor will be largely a function of agglomerator design and method of rewetting. As is revealed in the review by Bullock (1962), many different methods of rewetting are employed, including finely atomised water, steam and humidified air.

The uniformity achieved will also be influenced by the degree of mixing occurring during agglomeration, or granulation. Again, in commercial processes this will be largely a function of instantiser design. In wet granulation as practised in the pharmaceutical industry some control is possible as determined by the time of batch mixing employed. For example, Little and Mitchell (1949) state that for a simple formula approximately 15 minutes mixing time is required.

Apart from an effect on uniformity of moisture distribution, mixing of the powder may well have an effect on actual granule formation. This is suggested from the papers of Newitt and Conway-Jones (1958), and Capes and Danckwerts (1965). These workers suggest that a stable

granule, in the case of sand, is not formed until a capillary state of water is reached where saturation of the voids of the agglomerates is satisfied. In this regard mixing of a powder may achieve some degree of compaction, thus reducing voidage and making possible the formation of stable granules at lower moisture contents.

In the present study the main interest in these factors of moisture distribution concerns the technique of wet granulation employed to simulate the instantising process. It is desired to ensure that the methods of rewetting and mixing employed are satisfactory and adequate.

(iv) Additives in Wet Granulation

The use of various additives in wet granulation is most common in the pharmaceutical industry. Their application is described by Peck (1958); Little and Mitchell (1949); and Donaghy (1958). Such additives may be classed into three categories :

1. Binders. These are virtually adhesives which permit a heterogeneous powder to be formed into a granule. They are usually added in solution, some examples being gums, dextrin, gelatin, starch, lactose, and sugar syrups;
2. Disintegrants. These serve to promote capillary penetration of water into a tablet upon reconstitution. The most common disintegrant is starch;
3. Lubricants. Additives such as talc and stearate are employed to improve flow properties and to impart lubricating action during compression of granules.

Very little extension of the application of additives in wet granulation has been made to the granulation of food powders such as in instantising of NFDM. One of the main reasons for this is probably the difficulty in experimentation with commercial scale equipment.

However, the potential benefits to be gained by the use of additives in agglomeration has also stimulated Moore et al (1964). They suggest that where necessary additives may be used to achieve agglomeration of food powders in commercial instantising equipment. Such additives they suggest may be put into two categories :

1. Where acting as a binding agent. An example is given of the addition of sugar to cocoa powder, to the extent of 80% sugar, so as to act as a binder in agglomeration to produce an instant cocoa mix, or drinking chocolate;
2. Where an additive acts as an emulsifying agent or surface active agent to allow wetting of the particle surface.

The addition of surface active agents to milk powders in an attempt to improve dispersibility has been studied by many workers : King (1966); Nelson and Winder (1963); Gibson and Raithby (1958); Mather and Hollender (1955); and Hollender (1952). In all these cases the surface active agent was added to the milk or concentrate before drying. No report appears in the literature of surfactant addition on rewetting in agglomeration. However, it may be mentioned that surfactants form an important constituent of coffee whiteners as manufactured in U.S.A., being employed at levels of 0.3-0.5% dry basis.

Coffee whiteners are described by Hedrick and Armitage (1964) and by Atlas Chemical Industries Inc. (1965).

C. PROCEDURE FOR GRANULATION

Peck (1958) describes wet granulation as employed in the pharmaceutical industry as consisting of the following operations :

1. Mixing the fine powders with a liquid or solution which has or produces the required adhesion;
2. Forcing the moistened materials through a screen of suitable size mesh to form granules;
3. Drying the moist granules;
4. Screening the dried granules to produce the final and required size.

These four basic operations are exactly the same as those employed in this study for the manufacture of NFDM granules. Use was made of a Kenwood Chef mixer for the first two steps. This model Kenwood mixer employs "planetary" mixing ensuring efficient action. The "K" beater was employed for the rewetting operation, while the colander and sieve attachment was employed for forcing moistened particles through a screen. This latter attachment consists of a rotating paddle fitted with scraper blades which travel over the surface of a screen fitted inside the colander bowl. For most of this study the finer of the two standard screens was employed having holes of 1600 μ diameter. It was also found necessary to control the speed of the mixer by means of a "Variac", variable voltage control

as the variable control provided with the Kenwood could not be regulated to the low speeds desired.

The four steps, then, as employed in this procedure are as follows :

1. Two hundred gm of powder is placed in the mixer bowl and the "K" beater is set in motion. The quantity of water to be added is allowed to drip in slowly and in stages. Regular manual stirring using a rubber plate scraper is also employed so as to overcome any possible "dead spots" in the mixer. This mixing stage should take approximately 10-15 minutes;
2. After allowing the moistened mix to stand for 5-10 minutes granulation is carried out in the colander and sieve attachement, using the 1600 μ screen;
3. The moist granules are spread onto a tray and air dried at 140°F in a fan assisted drier. Drying time is adjusted to give a final product of 3.0-4.0% moisture. The granules on the drying tray are stirred periodically during the drying cycle;
4. The dried granules are forced through a 2,000 μ (B.S. 8 mesh) sieve. This is for the sake of uniformity, only, so as to eliminate any large clumps which may have formed during drying.

The stages in this granulating procedure are depicted in Figure 19.

In drying of moist granules it is desired to effect a minimum of heat damage. Some experimentation was, therefore, conducted to

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(1) Mixing and Rewetting of Base Powder

(2) Granulation in Colander and Sieve Attachment

(3) Tray Drying at 140°F

(4) Dry Screening Through 2000/u Sieve

FIGURE 19 The Four Steps Employed in the Granulation Procedure

determine a satisfactory drying temperature/time combination which would give minimum damage. The solubility index of the dried granules was employed as an index of heat damage. Results are presented in Table 5.

TABLE 5

Effect of Various Drying Conditions on Solubility Index of Granules

Drying Conditions on Moist Granules	Initial Moisture	Final Moisture	Solubility Index
Control Niro NFDM	3.5%	-	0.10ml
110°F/165 minutes	11.5	4.0%	0.10
120°F/100 minutes	11.5	3.7	0.10
130°F/100 minutes	11.5	3.3	0.15
140°F/ 55 minutes	11.5	3.2	0.10
160°F/ 35 minutes	11.5	3.2	0.40

As can be seen, for granules initially at 11.5% moisture no heat damage is reflected in the solubility index until drying temperature is raised above 140°F. It was therefore, decided to tray dry all granules at 140°F for approximately 50-60 minutes, i.e. to reduce moistures to 3.0-4.0%.

D. RESULTS AND DISCUSSION

(i) Effect of Rewetting Moisture

As was discussed in the literature review there is considerable evidence to suggest the importance of rewetting moisture in determining stable granule or agglomerate formation. But, there is no report of the effect of rewetting moisture upon the properties of instant powders, as for example instant NFDM. Employing the technique of wet granulation described it is possible to study such relationships.

Two samples of NFDM, viz. Niro NFDM and Rogers NFDM, were granulated over a range of rewetting moistures. All these samples were granulated through the 1600/u screen and then dried and sieved as described in PROCEDURE. Rewetting moistures were determined from sampling of the moist granulated product not from the moistened mix. Some drying does occur during granulation, i.e. as moist powder is forced through the screen but this is not appreciable and it was found more satisfactory to sample after granulation.

Therefore samples for both NFDMs were granulated corresponding to a range of rewetting moistures. These were analysed for dispersibility, sinkability index, solubility index, bulk density and porosity. These results are presented in Figures 20 and 21.

Photographs of samples obtained in the granulation of Niro NFDM are presented in Figure 22.

Points arising from these results are best enumerated :

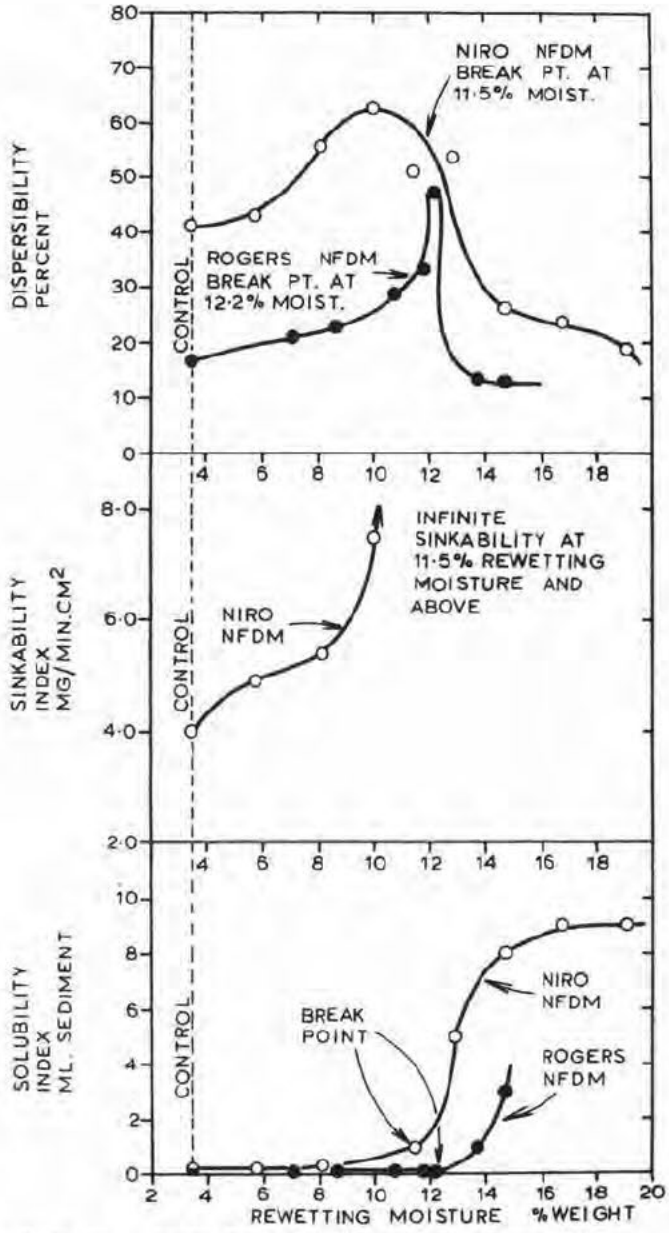

FIG. 20 PROPERTIES OF GRANULATED NFDMs (REDRIED)

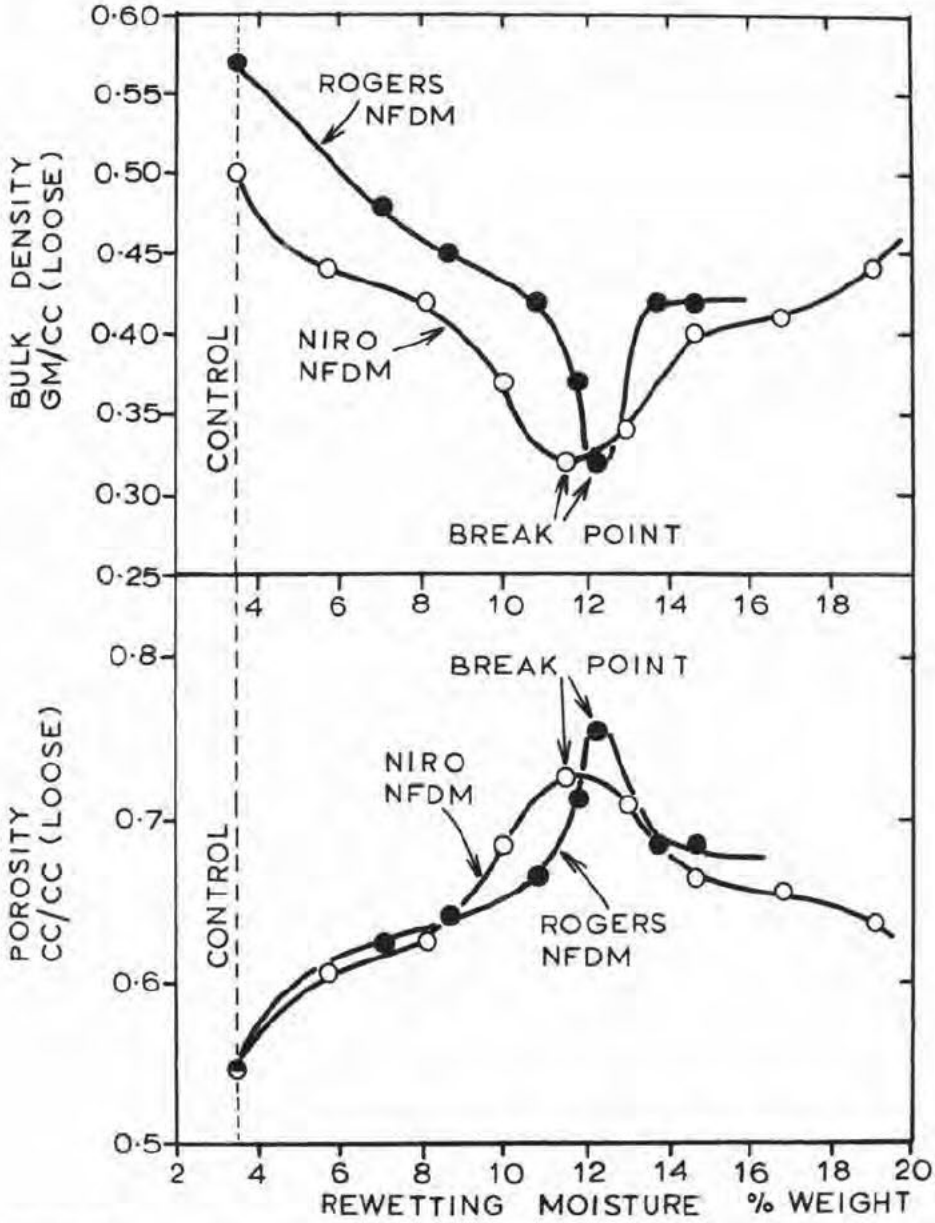

FIG. 21 PROPERTIES OF GRANULATED NFDMs (REDRIED)

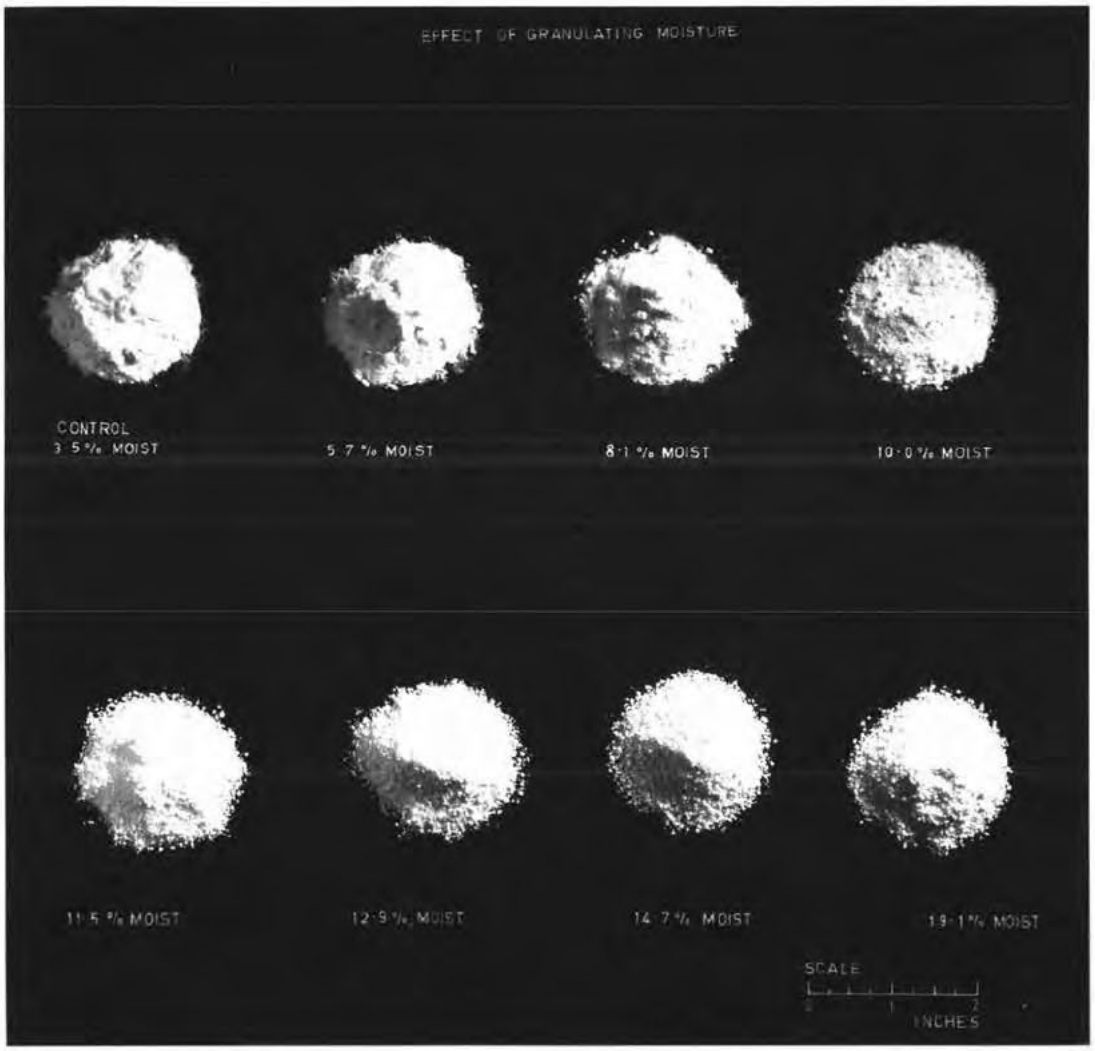

FIGURE 22 Samples of Redried Granulated NFDM Showing Effect of Rewetting Moisture Upon Granule Formation

1. The critical nature of rewetting moisture upon the properties of the final product is almost self-evident in every respect. Firstly, it was found that the rewetting moisture content controls the actual granulating process. As the moisture content is increased a point is reached where the "granulated" product changes from a fluffy type powder with poor flow characteristics to well formed granules of excellent flow properties. This change is quite marked as may be evidenced from Figure 22; the point at which this change occurs has been designated the BREAK POINT;
2. The effect of rewetting moisture upon dispersibility can be seen from Figure 20. The dispersibility of both NFDMs could be increased markedly and at optimum rewetting could be classed an instant NFDM (cf Table 2). The optimum dispersibility coincides with the Break Point rewetting moisture; a sharp decrease in dispersibility occurring as rewetting is increased further;
3. The sinkability index of the Niro NFDM is seen to increase with rewetting moisture, reaching an infinite value at 11.5% moisture; i.e. coinciding again with the Break Point. "Infinite Sinkability Index" is a relative term only since obviously some time is required for disappearance from the water surface, but in this case sinking is so rapid in comparison to sub-Break Point powders that it is termed infinite.

Although sinkability index values were not determined for Rogers NFDM samples they showed an identical trend when examined qualitatively;

4. Beyond Break Point moistures the solubility index of the samples is seen to show a sharp increase (i.e. a decrease in solubility). Below Break Point moistures the solubility index values are quite satisfactory and would pass A.D.M.I. tentative standards of 1.0ml;

5. The bulk density and porosity measurements shown in Figure 21 are quite interesting particularly when compared with the corresponding dispersibility curves in Figure 20. Again it is seen that minimum bulk density values, or maximum porosities, coincide with Break Point rewetting moistures. In fact, it is seen that there exists a strong correlation between dispersibilities and porosities of the samples;

6. Samples of the granulated Niro NFDM were also examined for state of lactose. It was found that as rewetting moisture was increased there occurred a gradual increase in the incidence of crystalline lactose present, with a sharp change to predominantly crystalline lactose coinciding again with the Break Point moisture. Actually, it was at this stage that it was discovered that crystalline lactose was present in the original Niro NFDM. This led to the follow up work previously reported; Morris, Neff and Latimer (1967).

It is interesting to compare the Break Point moistures obtained in the granulation of NFDM with those obtained for the

granulation of sand by Newitt and Conway-Jones (1958) and Capes and Danckwerts (1965). This comparison is made in Table 6.

TABLE 6

Comparison of Break Point Moistures in the Granulation of Sand and NFDM

	Sand	NFDM
Density : gm/cc	2.61	1.20
Void Volume : $\frac{\text{cc void}}{\text{gm solid}}$	0.270	0.83 (= 0.50cc/cc)
Granulation Break Point at :		
v/v moisture	68%	16.4%
cc/gm moisture	0.260	0.136
Void saturation	96%	16%

Using a Break Point value of 12% moisture for NFDM, this works out to 16.4% on a v/v basis, and to 16% void saturation as compared with 96% saturation in the granulation of sand. This illustrates clearly that void saturation is not necessary in the granulation of a non-inert powder such as NFDM; adhesion of particles in this case is no doubt assisted by dissolving solids which form a binder solution.

The increase in dispersibility and sinkability index up to the Break Point suggests that this is due largely to the process of size enlargement. This aspect is to be examined more closely with regard to studies on effect of particle size so will not be discussed

further at this stage. However, the decrease in dispersibility beyond the Break Point deserves some mention. It is seen that this corresponds with a sharp increase in the solubility index (i.e. a decrease in solubility proper). Further, it was observed that beyond Break Point rewetting samples of NFDM granules appeared definitely more yellow in colour than "powder" samples below Break Point. Much of this difference in colour could be attributed to an optical effect due to the increased particle size of granules, (this can be demonstrated by granding up granules to a finer particle size) but it was concluded that some of this yellow colouration, at least, could be attributed to a chemical change in the NFDM. Yet another observation was that at approximately 14% rewetting moisture the NFDM passed through a "doughy" stage during mixing. This was almost as if a gel state had been formed.

These observations suggest that at above Break Point moistures additional water is available for reaction above the minimum required to act as a binding liquid for granulation. The possibility exists that some of this water may now combine with protein to form a gel; removal of such water would be more difficult upon subsequent drying and could account for the increased solubility index and decreased dispersibility. Further support for the critical nature of this rewetting moisture comes from a study of the browning reaction, with associated insolubilisation, in a NFDM system. Such changes are comprehensively discussed by Coulter et al (1951). It is noted that moisture is an important factor in determining rate of browning, the

optimum moisture in a NFDM system being approximately 12-14%.

An interesting point emerges with regard to the curves for Rogers NFDM as seen in Figures 20 and 21, viz. the very critical nature of rewetting moistures over a narrow range. The dispersibility characteristics of Rogers NFDM are modified over a much narrower moisture range than Niro NFDM, and similarly the bulk density and porosity curves are much steeper about the Break Point moisture. This observation serves to illustrate quite satisfactorily the notion held in the dried milk industry in U.S.A. that Rogers NFDM is most difficult to instantise. The reason for this is not clear but it may be noted from Table 2 that this NFDM possesses by far the lowest mean particle size, being less than 10 μ.

The strong correlation observed between dispersibilities of samples and their porosities (or inversely, bulk densities) is interesting in view of the findings of Harper et al (1963). They consider that the concentration of milk solids in the vicinity of powder particles is an important factor in their instant solubility; hence the lower the bulk density the higher the instant solubility of a powder. Although the effect of increasing porosity as the Break Point is approached would certainly assist the dispersibility of the powder it will be shown that the effect of particle size is most important in this regard also.

Peebles (1958) in his patent on instantising of NFDM notes that optimum rewetting, in his case claimed to be 15% moisture,

corresponds with a minimum bulk density of the product. He states : "If too much water is being introduced into the process it becomes readily apparent by a decrease in the apparent bulk of the material". Peebles stated this in the nature of a qualitative observation whereas the present study has shown conclusively the critical nature of rewetting moisture upon both dispersibility characteristics and bulk density of the product.

(ii) Effect of Granule and Particle Size

Up to this stage all granulation has been carried out using the 1600 μ screen as described in PROCEDURE. This does not mean that all samples produced possess a particle size of 1600 μ. Below Break Point rewetting true granulation does not occur and although some agglomeration takes place the powder will have a mean particle size considerably below 1600 μ. At Break Point rewetting true granulation is just occurring and the powder will exhibit a wide size distribution. Above Break Point rewetting the size distribution again narrows and the mean particle size approaches that of the true granules; even the size of these granules, however, will be below 1600 μ since syneresis of particles occurs during drying.

Now from a literature review it is to be expected that particle size would show considerable influence upon reconstitution characteristics. This is further supported from the results showing effect of rewetting moisture upon reconstitution, where it was found that optimum dispersibility was promoted at Break Point rewetting. But the interesting point to note here is that at Break Point rewetting

a wide size distribution is to be expected. This emphasises the desirability of determining optimum particle size of NFDM with respect to dispersibility characteristics.

Determination of optimum particle size was approached in three ways :

(a) Granulation through different size screens at above Break Point moisture;

(b) Sieving of large sample produced at Break Point rewetting to give different size fractions;

(c) Grinding of large sample of granules produced at above Break Point rewetting followed by sieving to obtain different size fractions.

(a) Granulation Through Different Size Screens

The smallest screen supplied with the Kenwood Chef has holes of 1600/u diameter. In order to produce granules of different sizes special screens were made to fit the Kenwood attachment by soldering standard wire mesh onto supporting perforated base plates. Batches of Niro NFDM were then moistened as described in PROCEDURE using the same quantity of rewetting water in each case so as to yield granules of approximately 14% moisture; in this case, however, granulation was achieved through the specially manufactured screens.

Although screens down to 80 mesh were made it was found that the finest mesh through which moistened NFDM could be granulated was 40 mesh. Increasing difficulty was encountered in forcing the

moistened mix through the screens as the mesh aperture size is decreased. This is evidenced in the drying which occurs during actual granulation - increasing difficulty in granulation leading to greater moisture loss. This can be seen from Table 7 showing the moisture content of the granulated samples. All batches were rewet with equal quantities of water.

TABLE 7

Moisture Content of NFDM Granulated Through Different Size Screens

Screen Size	Aperture Microns	Moisture %
10 mesh	2000	14.0
Kenwood screen	1600	13.6
16 mesh	1000	13.7
30 mesh	500	13.3
40 mesh	390	12.7

Since the same amount of moisture was added to all five batches initially, these samples may be assumed to represent equivalent rewetting moistures (viz. 14.0%), the only variable being the granulation size. Rewetting was well above the Break Point and good granules were formed in all cases.

Samples were analysed for dispersibility, porosity and solubility index. These results are presented in Figure 23.

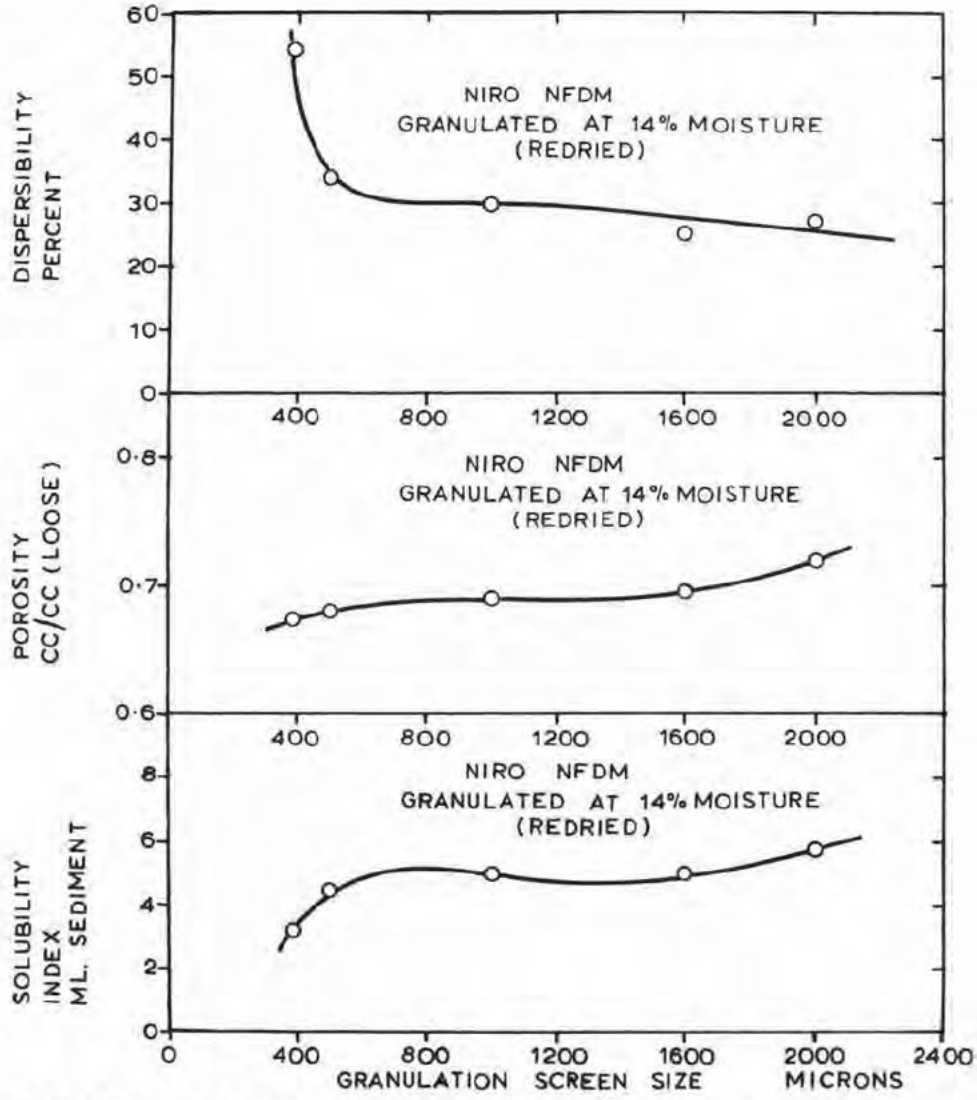

FIG. 23 EFFECT OF GRANULATION SCREEN SIZE UPON PROPERTIES OF NFDM

(b) Sieving of Samples Produced at Break Point

Four batches of Niro NFDM were granulated as described in PROCEDURE using the 1600/u screen. The same quantity of moisture was added to each batch so as to correspond to approximately Break Point rewetting. The moisture content of the moist granules was determined to be 11.6%.

As mentioned previously at approximately Break Point rewetting, 11.6% in this case, a wide size distribution of particles is to be expected. Production of 4 batches therefore, allowed sieving of the dried product to yield sufficient fractions in each size range for analysis. Sieving was carried out using B.S. test sieves together with a mechanical sieve vibrator. All powder handling and sieving was carried out in a R.H. controlled room held at 40% R.H. so as to minimise moisture pickup by the powder and facilitate handling, etc.

Eight sieve fractions were obtained by this technique. These were analysed for dispersibility, and sinkability index, the results being presented in Figure 24. In addition a particle size distribution curve was constructed from the results of sieving, this being presented in Figure 25.

(c) Sieving of Ground Granules

Four batches of Niro NFDM were granulated as described in PROCEDURE, using the 1600/u screen. Again the same quantity of moisture was added to each batch but this time this corresponded to 14% moisture in the granules. The dried granules were then ground to give a wide size distribution for subsequent sieving. It was found that an attrition mill, or coffee type grinder, gave a wide size distribution

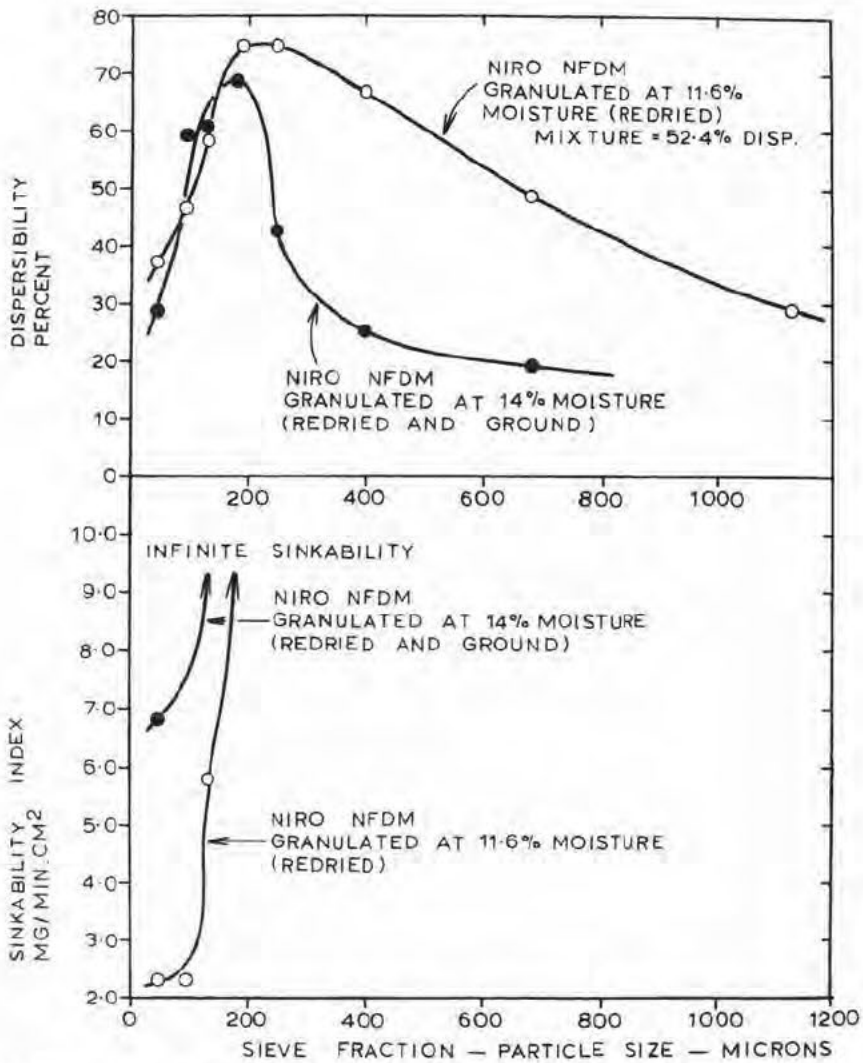

FIG. 24 EFFECT OF PARTICLE SIZE UPON RECONSTITUTION OF NFDM

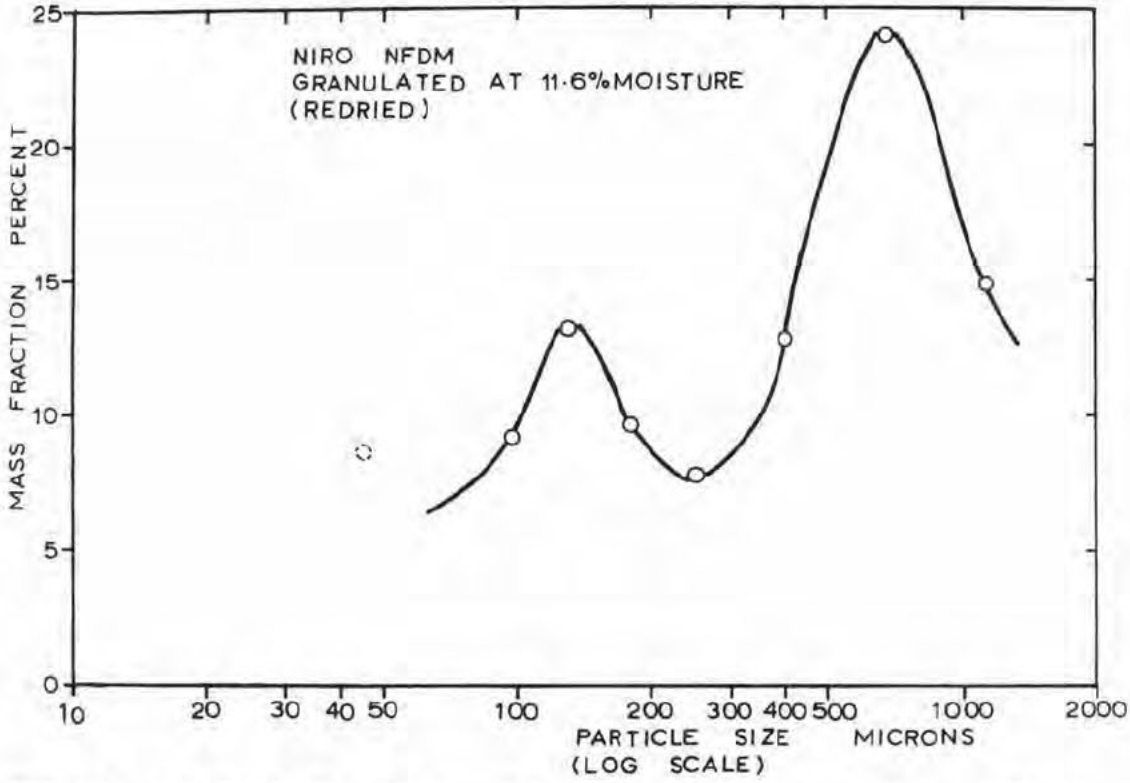

FIG. 25 PARTICLE SIZE DISTRIBUTION OF BREAK POINT GRANULATION OF NFDM

suitable for this purpose.

As before the ground granules were sieve separated to give 8 fractions, sieving and handling being done in a 40% R.H. controlled room. The separated fractions were analysed for dispersibility and sinkability index, these results being presented in Figure 24.

Points arising from the results in Figures 23,24 and 25, may now be discussed :

1. From Figure 23 it may be seen that dispersibility increases as the granulation size is decreased from 2000-390 μ. It must be remembered that this curve represents granules produced at 14% rewetting which, as may be seen from Figure 20, is well beyond the optimum rewetting moisture. Yet even so the dispersibility is increased from 25.0% to 54.3% merely by decreasing granule size. As wet granulation could not be achieved through finer screens an optimum size for granulation was not determined, i.e. all that can be deduced is that an optimum granulation size will be less than 390 μ;
2. Porosity and solubility index determinations in Figure 23 show only very slight change with granulation size. Theoretically, porosity will be independent of particle size providing a population consists of spherical particles all of the same size. This correlates well with the porosity determinations, the decrease in porosity with decrease in particle size being explained by a relative increase in particle size distribution. The slight increase in solubility with decrease

in particle size also appears reasonable, in view of the greater surface/mass ratio of small particles;

3. Figure 24 shows the effect of particle size upon reconstitution characteristics for a more complete size range. In this case an optimum particle size has been determined. In both granulated NFDMs, i.e. rewetting to 11.6% and to 14%, the optimum particle size as determined by sieving is approximately 200 μ. A particle size of 200 μ represents optimum dispersibility together with infinite sinkability. It may be emphasised that the maximum dispersibility of 75% obtained for the optimum size, optimum rewetting, fraction is the highest obtained for any instant powder in this study including several commercial instant NFDMs;

4. It is noted that beyond 130 μ and 180 μ particle size for the 14% and 11.6% rewet granules respectively there is established an infinite sinkability index, i.e. powder no longer "floats" on the surface of reconstituting liquid. The lower size at which this occurs for the 14% rewet granules may be attributed to their higher particle density, although no particle density measurements were made in this instance;

5. An attempt was made to establish a theoretical model to account for the sudden change from low to infinite sinkability of a particle as its size is increased. This proved to be a rather complex problem which, if it was to be treated quantitatively, required a knowledge of solid/liquid surface tensions and contact angles at the water surface. From a qualitative point

of view, however, this phenomena is to be expected. This may be explained as follows :

The force tending to submerge a particle on the surface is its weight less the buoyancy effect. As the radius (R) of a particle increases this force will increase as a function of R^3. On the other hand the force supporting the particle on the surface is due to a surface tension effect, being a function of perimeter in contact with the water. This supporting force will vary as R only. Therefore, on increase in particle size the surface perimeter to mass ratio of the particle will decrease. It is reasonable to predict, therefore, that a critical size exists where the force tending to submerge the particle becomes greater than the force tending to support the particle at the surface. This critical size appears to be approximately 130-180 μ for the NFDM granules studied.

6. From the particle size distribution curve in Figure 25 it is seen that at Break Point rewetting the final product consists of a population with two definite peaks at 130 μ and 680 μ. This is interesting in view of the fact that optimum size is approximately 200 μ; indicating that dispersibility of this product could be increased further by reducing the oversize fraction;

7. Since the weight fraction and dispersibility of each size fraction is known (Figures 24 and 25) in the case of the 11.6% rewet granulation it is possible to calculate a weighted

average dispersibility for the mixed granulation; the weighted average dispersibility works out at 52.7%. In comparison, the measured dispersibility of a sample of this granulation is 52.4%. This close agreement emphasises the importance of particle size in influencing dispersibility;

8. Figure 24 serves well to illustrate the importance of both particle size and rewetting moisture upon the dispersibility of the final granulated product. This is shown by the fact that the 14% rewet granulation exhibits a lower dispersibility than the 11.6% rewet product at any particular particle size. For example, at 400 μ size the former product has a dispersibility of 25.3% while the 11.6% rewet granulation has a dispersibility of 67%.

(iii) Uniformity of Moisture Distribution and Effect of Mixing During Granulation

It has already been shown how the technique of wet granulation may be applied to NFDM in order to simulate an instantising or agglomeration process. Using this technique optimum conditions for reconstitution have been determined with regard to rewetting moisture and particle size.

A question which arises, however, when comparing the dispersibilities of different size fractions is the possibility that the lower dispersibility of large size fractions (e.g. Figure 24) may be due to that fraction having possessed a higher moisture content at rewetting. This could arise due to non-uniform moisture distribution

during mixing and granulation. To some extent it appears unlikely that gross non-uniformity in moisture distribution is occurring since such a sharp and reproducible Break Point is obtained with this wet granulation technique. However, as was seen from the literature review considerable attention is paid to the method of moisture addition in commercial processes. It is reasonable, therefore, to study the efficiency of moisture addition in this simulated technique. Since the time of mixing may also have an effect upon this question of moisture distribution it was decided to examine this point as well.

Three batches of Niro NFDM were wet granulated and treated as follows :

(a) One batch was rewetted to 11.8% moisture corresponding to Break Point rewetting. It was granulated employing the normal procedure as far as the formation of moist "granules". These were not dried but were sieved in the moist state to yield three fractions, which were tested for moisture content;

(b) A second batch was rewetted to 11.8% moisture as in (a) above but in this instance an additional 30 minutes mixing was given after all the water had been added to the NFDM. The mix was then granulated and sieved in the moist state as for (a);

(c) The third batch was rewetted to 13.7% moisture which is well above Break Point rewetting. The normal procedure was employed and three fractions were obtained from sieving of the moist granules.

The results for these three batches are presented in Table 8.

TABLE 8

Sieving of Wet Granulated NFDM in Moist State

Description of Sample	Weight Fraction	Moisture	Nature of Fraction
(a) 11.8% Rewetting Normal Procedure			
+ 850/u Fraction	21%	11.5%	Granules
640/u Fraction	74 *	11.6 *	Fluffy powder*
- 420/u Fraction	5 *	11.6 *	Fluffy powder*
(b) 11.8% Rewetting Additional 30 mins. mixing			
+ 850/u Fraction	19%	11.9%	Granules
640/u Fraction	21	12.0	Granules
- 420/u Fraction	60 *	12.1 *	Fluffy powder*
(c) 13.7% Rewetting Normal Procedure			
+ 850/u Fraction	52%	13.5%	Granules
640/u Fraction	32	13.7	Granules
- 420/u Fraction	16	13.4	Granules

* Fluffy powder in these fractions cannot be sieved satisfactorily since blinding of screens occurs.

The following points may be enumerated from the results :

1. It is seen that no size fraction has been separated having any marked difference in moisture content. The largest difference between fractions noted is 0.3% between the 640/u fraction and the less than 420/u fraction in (c).

This certainly suggests that mixing is sufficient to promote uniform moisture distribution on rewetting;

2. As would be expected sieve separation is most difficult in a moistened powder, while it is still in the "fluffy" state. This leads to blinding of the screens as for example in the 640/u fraction of (a) where only 5% was able to pass the 420/u screen. Where the fraction separated consisted of fluffy powder this has been indicated by an asterisk. As soon as a granular product is formed, however, excellent sieve separation is possible with a minimum of blinding, e.g. as in (c);

3. Since 11.8% rewetting corresponds to Break Point conditions it is to be expected that some granules are formed although as seen in (a) and (b) the majority separated consists of fluffy powder. Nevertheless, the granules separated did not possess a higher moisture content;

4. Upon additional mixing for 30 minutes as in (b) it is seen that a granular fraction was separated above the 420/u screen whereas this did not occur with (a). This suggests that there is present a higher portion of granular product in (b). However, it may also be noted that all fractions in (b) possess a slightly higher moisture content, presumably due to equilibration with the atmosphere during the additional mixing period. This means that the additional granule formation noted in (b) may be due either to the slight

moisture uptake or to the additional mixing performed. Certainly the possibility exists that the degree of mixing may influence granule formation particularly in the Break Point region of rewetting.

(iv) Additives in Wet Granulation

It was mentioned in the literature review that one team of workers, Moore et al (1964) have recognised the potential applications of the use of additives in commercial instantising. One of the main problems of research into this field is the difficulty of establishing controlled trials with commercial scale equipment. However, use of a simulated process such as this technique of wet granulation makes possible a study of the effect of additives on product characteristics such as dispersibility. Obviously, the area of additives is an immense field and only an introduction is intended here so as to demonstrate how the technique may be used in such research.

Batches of Niro NFDM were wet granulated as described in PROCEDURE, using the 1600 μ screen. Four additive treatments were examined, each being compared with a control curve for granulation with water only. Results are presented in Figures 26,27,28 and 29.

(a) Rewetting with 10% Lactose Solution

Lactose is commonly employed as a binder in the pharmaceutical industry. However, in the case of NFDM approximately 50% of the powder composition is lactose so it would be expected that sufficient binder of this type is already present. But it is not clear what relationship exists between the lactose and the water of rewetting during

granulation since at least two distinct possibilities exist :

1. The Break Point in rewetting may occur at a point where sufficient binder solution has been formed, by the solution of lactose, to allow adhesion of particles. If the formation of this binder solution were a limiting factor in granulation then it would be expected that a Break Point would be obtained at lower moistures, where rewetting with lactose solution;
2. The Break Point in rewetting may depend largely upon the volume of liquid added rather than on its binding properties, particularly if formation of a binder solution is not a limiting factor. If this is the case then little shift of the Break Point would be expected on rewetting with lactose solution.

From Figure 26 it is seen that, in fact, rewetting with 10% lactose solution has resulted in little significant change in the Break Point, or in the nature of the dispersibility curve. This would suggest that the availability of lactose to form a binding solution during granulation is not a limiting factor.

(b) Addition of 5% Lactose Powder to NFDM

In this case 5% commercial lactose powder was added to the NFDM prior to granulation using water for rewetting in the normal manner.

It is seen from Figure 27 that this treatment has resulted in a slight shift in the Break Point and a modification of the dispersibility

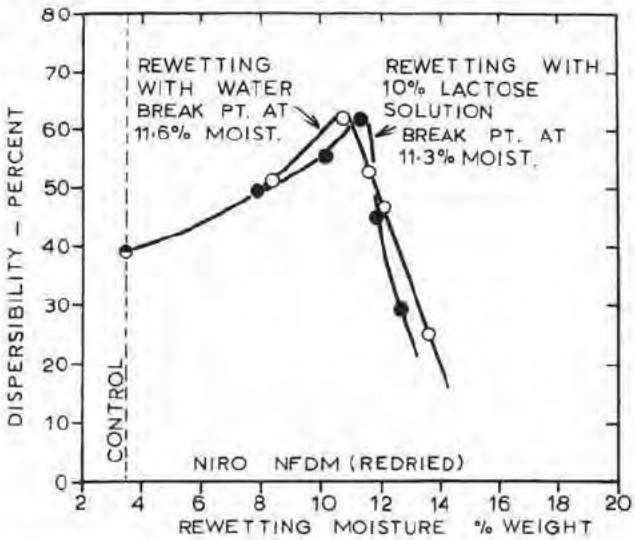

FIG. 26 EFFECT OF ADDITIVES — 10% LACTOSE SOLUTION

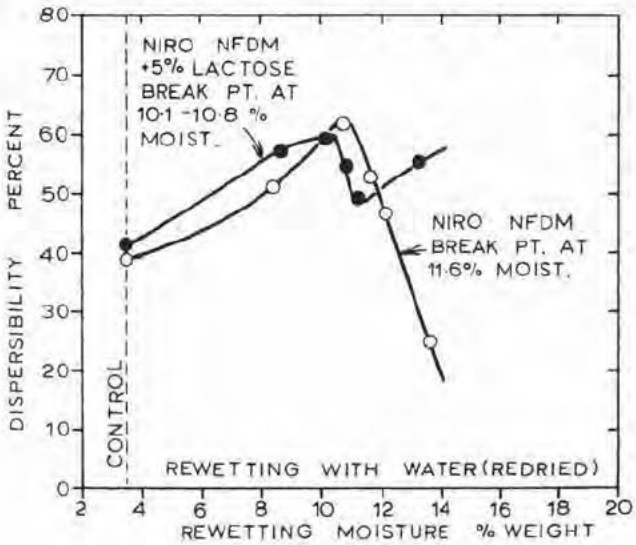

FIG. 27 EFFECT OF ADDITIVES — 5% LACTOSE TO NFDM

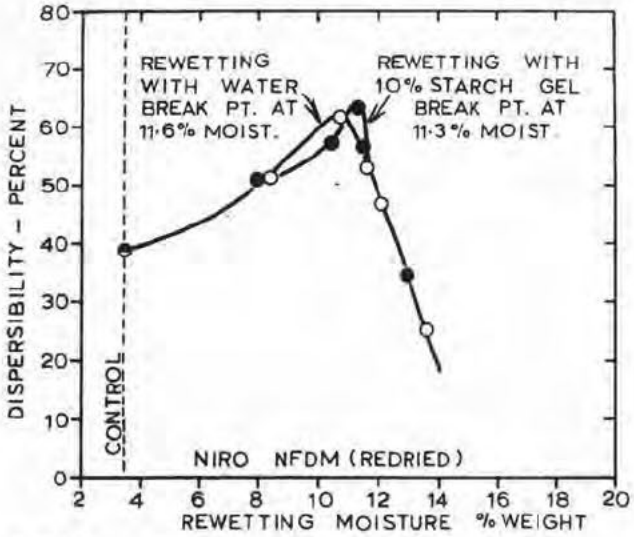

FIG.28 EFFECT OF ADDITIVES — 10% STARCH GEL

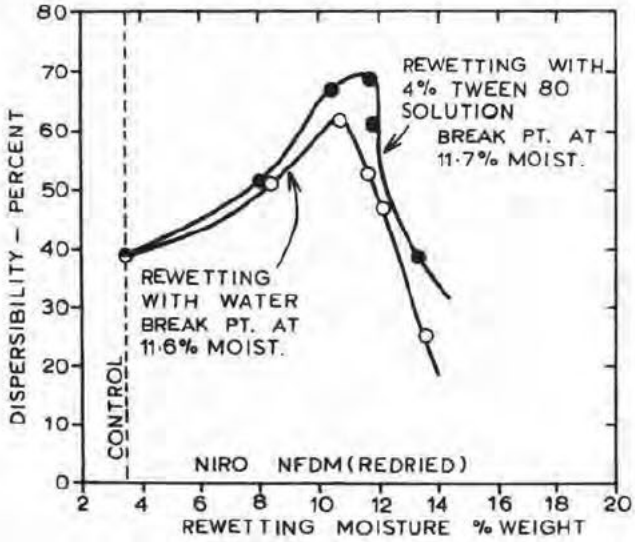

FIG.29 EFFECT OF ADDITIVES — 4% TWEEN 80 SOLUTION

nature of the curves in both cases are very similar. This again would suggest that sufficient binding substances are present in NFDM in order to achieve granulation.

A point of interest here is the fact that wet granulation was achieved in this case by the addition of a GEL, i.e. the water was held within a gel network. Yet even so, the same quantity of water was required, there being no shift in the Break Point for granulation. This emphasises the critical nature of the water in the mechanism of granulation.

(d) Rewetting with 4% Tween 80 Solution

As discussed in the literature review other workers have investigated the effect of surfactant addition to milk before drying upon the dispersibility of the milk powder. In this study, surfactant was added per media of the rewetting liquid during granulation. The surfactant chosen was Tween 80 which represents a rating of 15.0 on the Atlas H.L.B. System. (Atlas Chemical Industries Inc. (1963)). The H.L.B. system rates surfactants from a value of 0.0 for the most lipophilic to a value of 20.0 for the most hydrophilic. Use of 4% Tween 80 represents approximately 0.4% Tween 80 by weight of NFDM solids at Break Point rewetting. This compares with levels employed in coffee whiteners (Atlas Chemical Industries Inc. (1965)).

From Figure 29 it is seen that addition of Tween 80 results in a significant improvement in the dispersibility of the granules formed. The Break Point for granulation is not shifted. It may be predicted that this improvement in dispersibility is brought about by

a reduction in surface and interfacial tensions tending to inhibit rapid dispersion in the control. The fact that an improvement in dispersibility extends also to the above Break Point rewetting granules suggests that surfactant may actually assist penetration of water into the granules, i.e. in the nature of a dispersant.

It must be emphasised that Tween 80 is only one of an immense range of surfactants. Although it has been shown that dispersibility can be improved with this additive it may well be that other surfactants, or blends of surfactants, may be even more suitable for this application.

E. PRINCIPAL RESEARCH FINDINGS

1. A granulation procedure is described which has been successfully applied to NFDM. As this technique, is in effect, a simulated instantising process it may be employed to study the effect of certain variables upon the properties of granulated NFDM;
2. It is shown that the two major factors influencing the reconstitution properties of granulated NFDM are the rewetting moisture content of the powder before redrying and the particle size of the granules;
3. The rewetting moisture content is shown to be a most critical variable, the optimum being approximately 11-12% moisture for the NFDMs studied. This optimum corresponds with maximum reconstitution properties as well as the Break Point in granulation;
4. The effect of particle or granule size upon reconstitution characteristics of NFDM has been clearly demonstrated. Optimum size has been found to be approximately 200 μ; coinciding with optimum dispersibility and infinite sinkability;
5. The rewetting technique employed appears to be satisfactory since a uniform moisture distribution has been demonstrated in different size fractions of a rewet granulated NFDM;
6. Examples have been given of the manner in which this granulation procedure may be employed to study the effect of additives in attempts to improve the dispersibility of

powders. A significant improvement in dispersibility can be achieved by rewetting with Tween 80 solution on instantising as compared with rewetting with water alone.

IV. FIELDS FOR FURTHER RESEARCH

1. Azeotropic distillation of certain food powders has been shown to consist of two phases, viz.: (1) a rapid initial moisture desorption and (2) a slower desorption corresponding to a first order reaction. In the case of NFDMs this first order reaction has been attributed to the dehydration of crystalline lactose hydrate as suggested by Choi et al (1948) while in the case of tomato powder this may be due to a caramelisation or browning reaction to produce water. Further research on the nature of this first order reaction appears warranted since the change in desorption from phase (1) to phase (2) may provide a division mark between desorption of "free water" and "bound water" respectively, thus providing a relatively easy determination of free water in a powder;
2. It has been shown that lactose may exist in a crystalline state in commercial NFDM under present day manufacturing conditions. Research is suggested to assess technological implications of lactose in a crystalline state as compared to the glassy state;
3. A working theory has been proposed to explain the mechanism of dispersion of a soluble food powder. Further applied research may enable modification or enlargement of this theory, while rather more fundamental research would enable quantitative theory to be developed for certain aspects of dispersion. For example, the influence of particle size

upon sinkability of a powder has been clearly demonstrated in this research. It has been shown that a critical particle size exists for a powder above which the sinkability index tends to infinity. This observation suggests that it should be possible to construct a quantitative model to determine critical particle size in terms of particle density, surface tension, interfacial tension, etc. However, a lack of fundamental data of interfacial tensions in these powder/water systems has made this impossible;

4. No significant increase in dispersibility of NFDM has been attained following a compression/regrinding process. However, it is felt that if a suitable non- aqueous adhesive could be found then such a compression technique may well be employed to promote aggregation of particles and thus increase dispersibility. For example, propylene glycol is employed in the tabletting of dry ingredients to form a popular dog "biscuit" in U.S.A. Research with this type of liquid adhesive may be fruitful;

5. It has been shown that the bulk density of a spray dried product such as instant coffee can be markedly increased by a compression treatment without any adverse effect on reconstitution characteristics. Research is warranted with other spray dried products which show similar "balloon" particle structure to ascertain if the technique can be extended. In particular the effect of compression upon spray dried sodium caseinate deserves attention;

6. Results obtained on compression of instant coffee indicate that an improvement in the dispersibility of the powder has been achieved through modification of particle structure. This suggests the desirability of research to define optimum spray drying conditions corresponding with optimum reconstitution characteristics; particularly in view of the fact that some saving in packaging volume appears possible;
7. The optimum temperature of water for reconstitution of NFDM has been determined to be approximately 50°C. A similar procedure may well be employed to study optimum reconstitution temperatures for other food powders;
8. It has been noted that the addition of free flow agents to NFDM appears to involve a compromise between improved flow properties and a slight decrease in dispersibility. However, research appears warranted with a wider range of such flow conditioning agents. Further, an objective measure of flow properties of a powder would be desirable in such a study, as for example, angle of repose;
9. A technique of wet granulation has been developed which simulates the instantising or agglomeration process as applied to NFDM. Although this technique has only been applied to NFDM in the present study a wide field of research remains open in the application of granulation to other foods powders as a means of improving dispersibility and flow characteristics;

10. The critical nature of rewetting moisture as a variable in the granulation, or agglomeration process has been clearly demonstrated. More fundamental research may elucidate the role of water in granulation of NFDM. In particular, it would be interesting to clarify the reasons for increased insolubilisation of NFDM when granulated at above Break Point moistures;

11. It would be expected that in commercial instantising of food powders a major portion of the manufacturing cost would be represented by the redrying operation. This suggests the desirability of reducing the optimum rewetting moisture content of the process. Research may be profitably directed towards a means of reducing the amount of water to be added in granulation; such as by use of binders/adhesives or use of non-aqueous solvents;

12. Only a very introductory examination of the field of additives in granulation has been made in the present study. Even so, the benefits to be gained by the use of a surfactant such as Tween 80 has been demonstrated. Further research with other additives and surfactants and determination of optimum concentrations of such additives may well yield even greater improvement in the reconstitution characteristics of powders and granules.

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105
Adopted:
27.07.95

OECD GUIDELINE FOR THE TESTING OF CHEMICALS

Adopted by the Council on 27th July 1995

Water Solubility

INTRODUCTION

1. This guideline is a revised version of the original Guideline 105 which was adopted in 1981. There are no differences of substance between the current version and that from 1981. Mainly the format has been changed. The revision was based on the EC method "Water Solubility" (1).

INITIAL CONSIDERATIONS

2. The water solubility of a substance can be considerably affected by the presence of impurities. This guideline addresses the determination of the solubility in water of essentially pure substances which are stable in water and not volatile. Before determining water solubility, it is useful to have some preliminary information on the substance, like structural formula, vapour pressure, dissociation constant and hydrolysis as a function of pH.

3. Two methods, the column elution method and the flask method which cover respectively solubilities below and above 10^{-2} g/l are described in this guideline. A simple preliminary test is also described. It allows to determine approximately the appropriate amount of sample to be used in the final test, as well as the time necessary to achieve saturation.

DEFINITIONS AND UNITS

4. The water solubility of a substance is the saturation mass concentration of the substance in water at a given temperature.

5. Water solubility is expressed in mass of solute per volume of solution. The SI unit is kg/m^3 but g/l is commonly used.

REFERENCE SUBSTANCES

6. Reference substances do not need to be employed when investigating a substance.

DESCRIPTION OF THE METHODS

Test conditions

7. The test is preferably run at 20 ± 0,5 °C. The chosen temperature should be kept constant in all relevant parts of the equipment.

Preliminary test

8. In a stepwise procedure, increasing volumes of water are added at room temperature to approximately 0.1 g of the sample (solid substances must be pulverized) in a 10 ml glass-stoppered measuring cylinder. After each addition of an amount of water, the mixture is shaken for 10 minutes and is visually checked for any undissolved parts of the sample. If, after addition of 10 ml of water, the sample or parts of it remain undissolved, the experiment is continued in a 100 ml measuring cylinder. The approximate solubility is given in Table 1 below under that volume of water in which complete dissolution of the sample occurs. When the solubility is low, a long time may be required to dissolve a substance and at least 24 hours should be allowed. If, after 24 hours, the substance is still not dissolved, more time (up to 96 hours) should be allowed or further dilution should be attempted to ascertain whether the column elution method or flask method should be used.

Table 1

ml of water for 0.1 g soluble	0.1	0.5	1	2	10	100	> 100
approximate solubility in g/l	> 1000	1000 to 200	200 to 100	100 to 50	50 to 10	10 to 1	< 1

Column elution method

Principle

9. This method is based on the elution of a test substance with water from a micro-column which is charged with an inert support material, previously coated with an excess of the test substance (2). The water solubility is given by the mass concentration of the eluate when this has reached a plateau as a function of time.

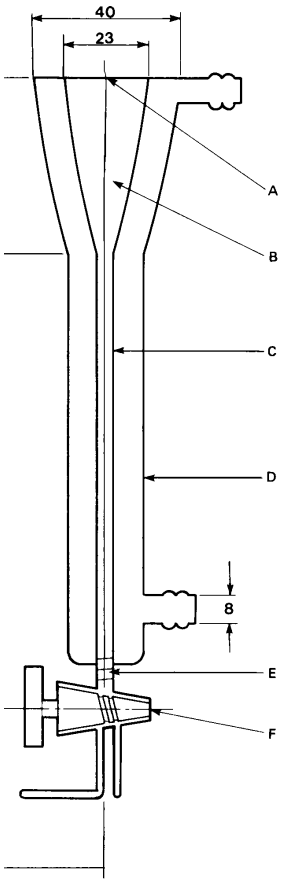
Apparatus

10. The apparatus consists of a microcolumn (Figure 1), maintained at constant temperature. It is connected either to a recirculating pump (Figure 2) or to a levelling vessel (Figure 3). The microcolumn contains an inert support held in place by a small plug of glasswool which also serves to filter out particles. Possible materials which can be employed for the support are glass beads, diatomaceous earth, or other inert materials.

11. The microcolumn shown in figure 1 is suitable for the set-up with recirculating pump. It has a head space providing for five bed volumes (discarded at the start of the experiment) and the volume of five samples (withdrawn for analysis during the experiment). Alternatively, the size can be reduced if water can be added to the system during the experiment to replace the initial five bed volumes removed with impurities. The column is connected with tubing made of an inert material to the recirculating pump, capable of delivering approximately 25 ml/h. The recirculating pump can be, for example, a peristaltic or membrane pump. Care must be taken that no contamination and/or adsorption occurs with the tube material.

12. A schematic arrangement using a levelling vessel is shown in figure 3. In this arrangement the microcolumn is fitted with a one way stopcock. The connection to the levelling vessel consists of a ground glass joint and tubing made of an inert material. The flow rate from the levelling vessel should be approximately 25 ml/h.

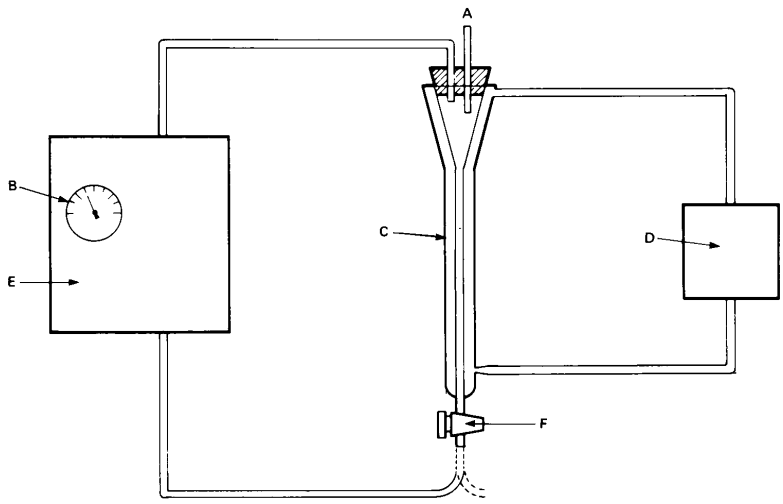
Figure 1



Dimensions in mm

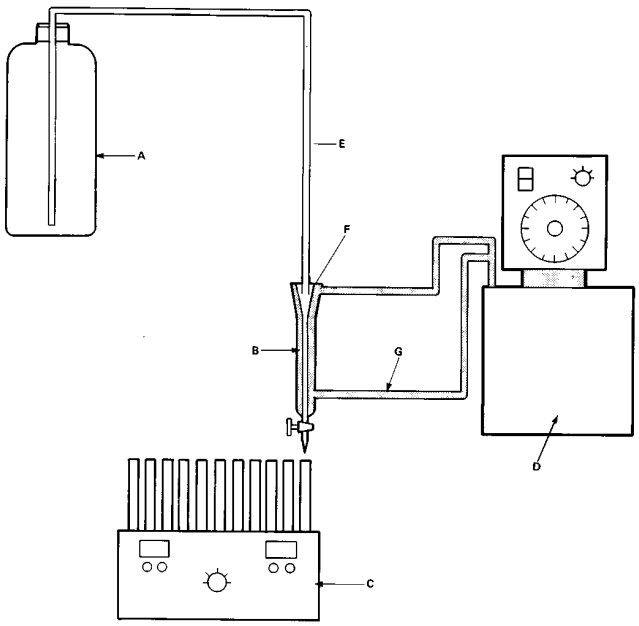
A. Connection for ground glass joint
B. Headspace
C. Interior 5
D. Exterior 19
E. Plug of glass wool
F. Stopcock

Figure 2



A. Atmospheric equilibration
B. Flowmeter
C. Microcolumn
D. Thermostatically controlled circulating pump
E. Recirculating pump
F. Two-way valve for sampling

Figure 3



A. Levelling vessel (e.g. 2.5 litres chemical flask)
B. Column
C. Fraction accumulator
D. Thermostat
E. Teflon tubing
F. Ground glass joint
G. Water line (between thermostat and column, inner diameter approximately 8 mm)

Loading of the support

13. Approximately 600 mg of support material is transferred to a 50 ml round-bottom flask. A suitable amount of test substance is dissolved in a volatile solvent of analytical reagent quality and an appropriate amount of this solution is added to the support material. The solvent is completely evaporated, e.g. using a rotary evaporator, as otherwise water saturation of the support will not be achieved during the elution step because of partitioning on the surface. The loaded support material is soaked for two hours in approximately 5 ml of water and the suspension is poured into the microcolumn. Alternatively, dry loaded support material may be poured into the water-filled microcolumn and two hours are allowed for equilibrating.

14. The loading of the support material may cause problems, leading to erroneous results, e.g. when the test substance is deposited as an oil. These problems should be examined and the details reported.

Procedure using a recirculating pump

15. The flow through the column is started. It is recommended that a flow rate of approximately 25 ml/h, corresponding to 10 bed volumes per hour for the column described, be used. At least the first five bed volumes are discarded to remove water soluble impurities. Following this, the pump is allowed to run until equilibrium is established, as defined by five successive samples whose concentrations do not differ by more than ± 30% in a random fashion. These samples should be separated from each other by time intervals corresponding to the passage of at least ten bed volumes. Depending on the analytical method used, it may be preferable to establish a concentration/time curve to show that equilibrium is reached.

Procedure using a levelling vessel

16. Successive eluate fractions should be collected and analyzed by the chosen method. Fractions from the middle eluate range, where the concentrations are constant within ± 30% in at least five consecutive fractions, are used to determine the solubility.

Notes applicable to both procedures

17. Double distilled water is the preferred eluent. Deionized water with a resistivity above 10 megohms/cm and a total organic carbon content below 0.01% can also be used.

18. Under both procedures, a second run is performed at half the flow rate of the first. If the results of the two runs are in agreement, the test is satisfactory. If the measured solubility is higher with the lower flow rate, then the halving of the flow rate must continue until two successive runs give the same solubility.

19. Under both procedures, the fractions should be checked for the presence of colloidal matter by examination of the Tyndall effect. The presence of particles invalidates the test and the test should be repeated after improvement of the filtering action of the column.

20. The pH of each sample should be measured, preferably by using special indicator strips.

Flask method

Principle

21. The substance (solids must be pulverized) is dissolved in water at a temperature somewhat above the test temperature. When saturation is achieved, the mixture is cooled and kept at the test temperature. Alternatively, and if it is assured by appropriate sampling that the saturation equilibrium is reached, the measurement can be performed directly at the test temperature. Subsequently, the mass concentration of the substance in the aqueous solution, which must not contain any undissolved particles, is determined by a suitable analytical method (3).

Apparatus

22. Following material is needed:

- normal laboratory glassware and instrumentation;
- a device for the agitation of solutions under controlled constant temperature;
- if required for emulsions, a centrifuge (preferably thermostatted); and
- analytical equipment.

Procedure

23. The quantity of test substance necessary to saturate the desired volume of water is estimated from the preliminary test. About five times that quantity is weighed into each of three glass vessels fitted with glass stoppers (e.g. centrifuge tubes, flasks). A volume of water, chosen in function of the analytical method and solubility range, is added to each vessel. The vessels are tightly stoppered and then agitated at 30 °C. A shaking or stirring device capable of operating at constant temperature should be used, e.g. magnetic stirring in a thermostatted water bath. After one day, one of the vessels is equilibrated for 24 hours at the test temperature with occasional shaking. The contents of the vessel are then centrifuged at the test temperature and the concentration of the test substance in the clear aqueous phase is determined by a suitable analytical method. The other two flasks are treated similarly after initial equilibration at 30 °C for two and three days respectively. If the concentrations measured in at least the two last vessels do not differ by more than 15%, the test is satisfactory. If the results from vessels 1, 2 and 3 show a tendency of increasing values, the whole test should be repeated using longer equilibration times.

24. The test can also be performed without preincubation at 30 °C. In order to estimate the rate of establishment of the saturation equilibrium, samples are taken until the stirring time no longer influences the concentrations measured.

25. The pH of each sample should be measured, preferably by using special indicator strips.

Analytical determinations

26. A substance-specific method is preferred since small amounts of soluble impurities can cause large errors in the measured solubility. Examples of such methods are: gas or liquid chromatography, titration, photometry, voltametry.

DATA AND REPORTING

Data

Column elution method

27. For each run, the mean value and standard deviation from at least five consecutive samples taken from the saturation plateau should be calculated. The mean values obtained from two tests with different flows should not differ by more than 30%.

Flask method

28. The individual results from each of the three flasks, which should not differ by more than 15%, are averaged.

Test Report

Column elution method

29. The test report must include the following information:

- the results of the preliminary test;
- chemical identity and impurities (preliminary purification step, if any);
- the concentrations, flow rates and pH for each sample;
- the means and standard deviations from at least five samples from the saturation plateau of each run;
- the average of at least two successive runs;
- the temperature of the water during the saturation process;
- the method of analysis;
- the nature of the support material;
- loading of the support material;
- solvent used;
- evidence of any chemical instability of the substance during the test;
- all information relevant for the interpretation of the results, in particular with regard to impurities and physical state of the substance.

Flask method

30. The test report must include the following information:

- the results of the preliminary test;

- chemical identity and impurities (preliminary purification step, if any);
- the individual analytical determinations and the average where more than one value was determined for each flask;
- the pH of each sample;
- the average of the values for different flasks which were in agreement;
- the test temperature;
- the analytical method;
- evidence of any chemical instability of the substance during the test;
- all information relevant for the interpretation of the results, in particular with regard to impurities and physical state of the substance.

LITERATURE

(1) Official Journal of the European Communities L 383 A, 54-62 (1992)

(2) NF T 20-045 (AFNOR) (September 1985). Chemical products for industrial use - Determination of water solubility of solids and liquids with low solubility - Column elution method

(3) NF T 20-046 (AFNOR) (September 1985). Chemical products for industrial use - Determination of water solubility of solids and liquids with high solubility - Flask method

SWEDISH MATCH

Quality & Environmental Management System

PRD 201 SOP Z Measurement of dimensions of ZYN Pouches

Process Owner: (b) (6)
(Director Product Development)

Document Type: Standard Operating Procedure

Revision No.: 3
Revision Date: 9/21/20

Approved by: (b) (6)

Document Author:
(b) (6)

(b) (4)

[redacted]

(b) (4)

[redacted]

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000593	ZYN Cool Mint 3 mg	900510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000594	ZYN Cool Mint 6 mg	900520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000595	ZYN Peppermint 3 mg	901510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000596	ZYN Peppermint 6 mg	901520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000597	ZYN Spearmint 3 mg	902510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000598	ZYN Spearmint 6 mg	902520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000599	ZYN Wintergreen 3 mg	903510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000600	ZYN Wintergreen 6 mg	903520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000601	ZYN Citrus 3 mg	907510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000602	ZYN Citrus 6 mg	907520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000603	ZYN Coffee 3 mg	904510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000604	ZYN Coffee 6 mg	904520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000605	ZYN Cinnamon 3 mg	906510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000606	ZYN Cinnamon 6 mg	906520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000607	ZYN Smooth 3 mg	914510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000608	ZYN Smooth 6 mg	914520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000609	ZYN Chill 3 mg	920510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000610	ZYN Chill 6 mg	920520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000611	ZYN Fresh 3 mg	921510	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

	STN#	Product Name	SKU #	Production Batch#	Batch Count	MFG Date	Replicate Count	Unit of measure	Length	Width	Avg Height
Data Sets	PM0000612	ZYN Fresh 6 mg	921520	(b) (4)	(b) (4) [redacted]						
				(b) (4)							
				(b) (4)							
Summary of results	Average										
	Standard Deviation										
	Minimum										
	Maximum										
	Count										
Acceptance criteria	Target										
	Lower Limit										
	Upper Limit										

(b) (4) [redacted]

Attachment 4A 20200924

Method

(b) (4) [redacted]

Execution

(b) (4) [redacted]

Swedish Match

Attachment 4B 20200924

Particle size distribution parameters for the PMTA products dispersed in water, as well as for the corresponding ungranulated materials.

	Ungranulated			Granulated			Difference Ungranulated - Granulated		
Product	d_{10} / µm	d_{50} / µm	d_{90} / µm	d_{10} / µm	d_{50} / µm	d_{90} / µm	d_{10} / µm	d_{50} / µm	d_{90} / µm
ZYN Fresh 6mg	(b) (4) [redacted]								
ZYN Fresh 3mg									
ZYN Chill 6mg									
ZYN Chill 3mg									
ZYN Smooth 6mg									
ZYN Smooth 3mg									
ZYN Cinnamon 6mg									
ZYN Cinnamon 3mg									
ZYN Coffee 6mg									
ZYN Coffee 3mg									
ZYN Citrus 6mg									
ZYN Citrus 3mg									
ZYN Wintergreen 6mg									
ZYN Wintergreen 3mg									
ZYN Spearmint 6mg									
ZYN Spearmint 3mg									
ZYN Peppermint 6mg									
ZYN Peppermint 3mg									
ZYN Cool Mint 6mg									
ZYN Cool Mint 3mg									
Average									
STD									

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Original Investigation

Determination of Nicotine Absorption from Multiple Tobacco Products and Nicotine Gum

Helena Digard, B.Sc.,[1] *Christopher Proctor, Ph.D.,*[1] *Anuradha Kulasekaran, M.B.B.S., M.D.,*[1] *Ulf Malmqvist, M.D., Ph.D.,*[2] *& Audrey Richter, Ph.D.*[1]

[1] *Group R&D, British American Tobacco (Investments) Ltd., Southampton, United Kingdom*
[2] *Clinical Research and Trial Centre, Lund University Hospital, Lund, Sweden*

Corresponding Author: Audrey Richter, Ph.D., *Group R&D, British American Tobacco (Investments) Ltd, Regents Park Road, Southampton SO15 8TL, United Kingdom. Telephone: +44-2380-793181; Fax: +44-2380-793480; E-mail: audrey_richter@bat.com*

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Abstract

Introduction: Snus is a smokeless tobacco product traditionally used in Scandinavia and available in pouched or loose forms. The objective of this study was to determine nicotine absorption for current pouched and loose snus products in comparison with a cigarette and an over-the-counter nicotine gum.

Methods: We conducted an open-label, randomized, 6-way, crossover study involving 20 healthy snus and cigarette users. One of 6 products (2 pouched snus, 2 weights of loose snus, a cigarette, and a nicotine gum) was administered at each of 6 visits. Blood samples were taken at intervals over 120 min and sensory perception assessed by questionnaire.

Results: For the 4 smokeless tobacco products and the nicotine gum, blood plasma levels of nicotine were ranked according to total nicotine content as follows: loose snus (27.1 mg nicotine) > pouched snus (14.7 mg nicotine) > loose snus (10.8 mg nicotine) = pouched snus (10.7 mg nicotine) > nicotine gum (4.2 mg nicotine). The area under the plasma concentration–time curve (AUC) and maximum plasma concentration (C_{max}) of nicotine ranged from 26.9 to 13.1 ng.h/ml and 17.9 to 9.1 ng.h/ml, respectively across all the products. Nicotine was absorbed more rapidly from the cigarette but systemic exposure was within the range of the smokeless tobacco products (AUC = 14.8 ng.h/ml; C_{max} = 12.8 ng.h/ml).

Conclusions: This study has generated new information on comparative nicotine absorption from a cigarette, loose snus, and pouched snus typical of products sold in Scandinavia. The similar nicotine absorption for 1 g portions of loose and pouched snus with approximately 11 mg of nicotine indicate that absorption kinetics were dependent on quantity of tobacco by weight and total nicotine content rather than product form.

Introduction

Snus is an oral moist snuff used in Scandinavia and commercially available in several countries. This noncombustible, smokeless form of tobacco has a history of use in Sweden that dates back several hundred years, although its composition and manufacturing processes have evolved over time. The main ingredients are finely ground tobacco, water, salt, humectants, and flavors. It is currently available in two distinct forms: a loose compacted tobacco or portions of tobacco sealed in small sachets termed "pouches." The pouch weight of tobacco ranges from approximately 0.3 to 1.5 g depending on the product.

Based on the epidemiology of tobacco-related disease in Sweden, snus has been reported to be significantly less risky than cigarettes (Foulds, Ramstrom, Burke, & Fagerström, 2003). Some health professionals consider snus to be a safer alternative to smoking for individuals who are unwilling or unable to give up tobacco entirely (Britton, 2008). While the determinants of tobacco use are complex and include environmental and social factors (Tobacco Advisory Group of the Royal College of Physicians, 2007), the rapid absorption of a sufficient dose of nicotine has been proposed to be an important factor for consumer acceptability of tobacco and nicotine products (Foulds et al., 2003). Nicotine replacement therapy (NRT) products, on average, provide the user much slower absorption and lower maximum plasma concentration (C_{max}) of nicotine compared with cigarettes (Benowitz, Porchet, Sheiner, & Jacob, 1988; Russell, Jarvis, Feyerabend, & Ferno, 1983; Sobue, Sekiguchi, Kikkawa, Akasaki, & Irie, 2006). Some authorities suggest this differing pharmacokinetic profile is a contributing factor to NRT products' limited success as aids for quitting smoking (Britton, 2008). There is little published information on nicotine absorption from snus compared with cigarettes, or for different forms of snus. In a review of smokeless tobacco and related health effects in Sweden, the rate of uptake and C_{max} of nicotine obtained from snus was reported to be intermediate between an NRT (such as nicotine gum or dermal patches) and cigarettes (Foulds et al., 2003). However, the composition of nicotine and tobacco products on the market today has changed somewhat since such earlier studies were carried out.

In 2007/2008, we conducted a consumption survey involving 2,914 Swedish snus users and found that the majority (96%) of snus consumers used either pouched or loose snus exclusively

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(Digard, Errington, Richter, & McAdam, 2009). The studied snus users typically kept pouches or portions in the mouth for 60–70 min, considerably longer than the 30 min indicated by prior anecdotal evidence. The average daily consumption of loose snus was higher than for pouched snus (10–12 g for pouched vs. 29–32 g for loose snus); the median number of portions per day was similar for pouched and loose snus users, but consumers of loose snus tended to use more tobacco per portion.

However, a small study of loose and pouched snus users had previously indicated that the average systemic uptake of nicotine for these groups (based on nicotine equivalents in 24 hr urine), were comparable (Andersson, Bjornberg, & Curvall, 1994) despite a higher average level of daily consumption of tobacco by loose snus users compared with pouched. The loose and pouched product types in the study had comparable nicotine content, suggesting that differences in levels of nicotine extraction and/or bioavailability between the two forms of snus might account for the relatively higher proportion of nicotine uptake measured for pouched snus users.

Lunell and Lunell (2005) evaluated the extraction of nicotine from snus and measured steady-state plasma nicotine concentrations following repeated use of four Swedish pouched snus products with nicotine content ranging from 4.53 to 8.84 mg or a 2 mg nicotine gum over the course of 1 day. The amount of nicotine extracted as a percentage of the total nicotine content varied across snus products from 22% to 44%, compared with 44% extraction from the nicotine gum. Overall, the three moist snus samples gave rise to higher steady-state plasma nicotine levels than the dry snus and nicotine gum.

In a more recent study, Lunell and Curvall (2011) investigated single-dose pharmacokinetics and subjective effects for two pouched snus products, each containing approximately 8–10 mg of nicotine per pouch, and a high-dose (4 mg) nicotine chewing gum. They reported faster absorption of nicotine from the snus products, although the C_{max} was significantly higher for one snus product compared with the gum. All products were used for 30 min and there were no significant differences in t_{max} across products. The study concluded that the relatively rapid rise in plasma nicotine, faster onset of "head rush", and reduced urge to smoke in those using snus compared with the nicotine gum could partly explain the common use of snus in Sweden as an aid to quitting smoking.

However, significant gaps in knowledge remain. No published nicotine pharmacokinetics study to date has directly compared cigarettes with snus, tested types of snus with varying nicotine content, or compared loose with pouched snus. Therefore, in this study we investigated the effects of snus product form (pouched vs. loose) and nicotine content on nicotine absorption. We also compared these results with a cigarette and a high-dose (4 mg) nicotine chewing gum (an NRT product available over-the-counter [OTC] in Sweden).

The study was designed to evaluate nicotine absorption from use of a single product. The protocol of use for the pouched snus and the portion weights of loose snus was based on data from our snus consumption survey (Digard et al., 2009). Subjects used snus samples for 60 min, which was the median reported time period for an individual session of use observed in the survey. The weights of loose snus were selected to match the weight of the most frequently used pouched snus (1 g, also included in this study) and the median portion weight reported in the survey (2.5 g). A sensory assessment was performed by questionnaire for the snus products to investigate whether differences in nicotine absorption resulted in variation in reported subjective effects. CYP2A6 genotyping was included because the rate of nicotine metabolism is a potential variable affecting the measured pharmacokinetic endpoints.

Methods

Study Design

This was an open-label, randomized, 6-way, crossover study conducted at the Clinical Research and Trial Centre, Lund University Hospital, Sweden (trial registration number: ISRCTN11703777). The study was conducted in accordance with the "Declaration of Helsinki," ICH GCP and EU Directive 2005/28/EC. The study was approved by the Central Ethics Review Board, Stockholm, Sweden. Written informed consent was obtained from all subjects before entering the study and undergoing any study-related procedures. The Investigator site ensured that subjects were offered health advice and information on tobacco cessation helplines.

The study enrolled 20 healthy subjects. Each subject visited the clinic seven times: once for screening and physical examination and six times for product administration. All 20 subjects tested all the six products; one product per visit was assigned in random order using a validated system. Each product administration visit lasted for 4 hr and there was a gap of at least one whole day between product administration visits. Subjects were asked not to consume tobacco or nicotine products or foods and drinks that could act as cytochrome P450 enzyme inhibitors (specifically caffeine or herbal teas, cruciferous vegetables) for 12 hr prior to product administration. In addition, no food intake was allowed 1 hr prior to product administration. Subjects were excluded if they had used medications with a known mechanism of action on the cyclooxygenase pathway 14 days prior to first product administration.

Screening of urine for drugs of abuse was performed using a standard test kit SYVA® Rapidtest d.a.u® 10. Safety monitoring and reporting, including concomitant medications, was performed throughout the study period and 1 week after completion of last product use. The subjects were also monitored for cardiovascular changes prior to and at intervals after test product administration (pulse rate, blood pressure at 15, 30, and 60 min; heart rate via ECG records at 30, 60, and 90 min).

CYP2A6 has been reported to play a major role in the metabolism of nicotine and a number of genetic polymorphisms have been described which affect the rate of nicotine metabolism and inactivation (Haberl et al., 2005; Schoedel, Hoffmann, Rao, Sellers, & Tyndale, 2004). Therefore, CYP2A6 genotyping was performed to identify subjects' metabolic status and any resulting impact on plasma nicotine concentrations. Subjects were characterized as either extensive (wild-type) or intermediate metabolizers by genotyping for CYP2A6 alleles *1 (wild-type), *2, *4, *9B, and *12B.

Study Population

Adult male and female healthy volunteers were recruited provided that they reported that they consumed snus daily (pouch weight

Table 1. Product Information

Product (brand)	Target weight (g)	Measured nicotine content per product (mg)	Product parameters		
			pH	Moisture (%)	Weight (g)
Cigarette (Lucky Strike Red)	NA	14.6[a]	NA	NA	NA
Loose snus (Granit)	1	10.8	8.0–8.3	50.5–53.5	0.90–1.10
Loose snus (Granit)	2.5	27.1	8.0–8.3	50.5–53.5	2.40–2.60
Pouched snus (Lucky Strike Original, Brown)	1[b]	10.7	8.0–8.2	48.0–52.0	0.90–1.10[b]
Pouched snus (Lucky Strike Bold)	1[b]	14.7	7.9–8.1	47.0–51.0	0.90–1.10[b]
Nicotine gum (Nicorette®)	NA	4.2	NA	NA	NA

Note. NA = not applicable.
[a]Total nicotine present in the tobacco blend.
[b]Total weight including that of the pouch.

≥ 0.8 g) in the preceding 6 months and smoked 9–10 mg ISO Tar factory-made cigarettes occasionally (≤40 cigarettes/week).

Subjects were between the ages of 19–55 years, had a body mass index (BMI) of 18–30 kg/m^2 and agreed to comply with the study restrictions and procedures. Subjects were screened for good health by the Investigator, based on medical history, physical examinations, vital signs, 12-lead ECG, urine drug screen, and reports of routine clinical laboratory tests (analyzed at Lund University Hospital Laboratory, Sweden). Premenopausal females were required to have a negative pregnancy test at screening and be willing to use contraception during the study period.

Study Test Products

The study evaluated five different tobacco products (two pouched snus products with different nicotine contents, one loose snus product that was used at two different portion sizes, and a cigarette) and an OTC nicotine chewing gum (Table 1). All the products were commercially available in Sweden at the time of the study but were unbranded at the point of administration. The subjects were given instructions on how to use each product. Snus was placed under the upper lip for 60 min and the subjects were asked not to move it within the mouth during this time period. The subjects were instructed to smoke the cigarette naturally according to their usual smoking behavior for 5 min or until the cigarette had been smoked to 30 mm from the mouth end (if this occurred in less than 5 min), at which point the cigarette was extinguished. The nicotine gum was used for 30 min according to the manufacturer's guidelines specified on the pack. For the purpose of a standardized instruction, subjects were asked to chew the gum every 2 s (in time with a metronome) and swallow the formed saliva, once every minute for 30 min.

To minimize the effects of product variability, a new container of each snus product was used at each visit and a sample of each snus product (from the container being used for that visit) was checked for pH, moisture content and, in the case of pouched snus, target portion weight prior to administration. Samples from a container were only used if the sample parameters fell within set ranges for each of the snus products (Table 1). For the loose snus products, portions were formed by the clinic staff, using an adapted syringe device and weighed to ensure they were within the target weight range (Table 1).

The snus and nicotine gum portions were collected after use. A corresponding unused portion was also collected from the same container as each test portion. All were placed in individual sealed labeled vials and stored frozen prior to analysis. Used and unused snus and gum samples were analyzed for nicotine, which was expressed on a whole portion, wet-weight basis. The analysis of the snus samples was performed at British American Tobacco (Investments) Ltd., Group R&D, Southampton, United Kingdom by GC-MS. The nicotine gum samples were analyzed at Eurofins Food & Agro Sweden AB, Lidkoping, Sweden by LC-MS.

Sensory Evaluation

While using the administered snus products, subjects were requested to complete a short sensory questionnaire, consisting of four questions, to assess their sensory experiences relating to irritation of lips and throat, level of salivation, or other perceived sensations such as any "buzz" feeling during use of the snus. Subjects scored their experiences on a scale of 1–5 (low to high, respectively). The purpose of this was to evaluate any association between the reported strength of snus' sensory effects and measured nicotine uptake. The questionnaire responses were obtained after 5, 10, 20, and 30 min of placing snus in the mouth.

Blood Sampling

Venous blood was collected by cannulation of the antecubital vein for both nicotine analysis (5 ml at each sampling time) and CYP2A6 genotyping (4 ml at visit 1, prior to any other blood sampling). Each sample was split into two aliquots. The sampling time points for nicotine analysis were preadministration (0) and at 5, 7, 10, 20, 30, 45, 60, 90, and 120 min after the start of each test product use. An additional sampling time point at 2 min was included while the cigarette was smoked.

Bioanalytical Methods

Nicotine

The bioanalysis of nicotine from plasma samples was conducted by Advanced Bioanalytical Service Laboratories Ltd., United Kingdom. Samples were analyzed by HPLC interfaced with an AB/MDS Sciex 4000 mass spectrometer. Quantification of nicotine was by peak area ratio. The determined lower limit of quantification for nicotine in plasma using this method was 0.5 ng/ml.

Genotyping

Genotyping of CYP2A6 alleles *1, *2, *4, *9B, and *12B was performed using whole blood samples collected into K2 EDTA VacutainerTM tubes, stored at −20 °C and analyzed by QIAGEN Manchester Ltd., Manchester, United Kingdom (formerly DxS Ltd.). DNA preparation was performed using a QIAGEN spin column kit. Prepared DNA samples were tested with a standard real time fluorescence assay to ensure quality of the test material. Specific DNA sequences were amplified by quantitative polymerase chain reaction (qPCR). All samples met the qPCR-QC acceptance criterion of Cycle Threshold <30.

Pharmacokinetic and Statistical Analysis

The pharmacokinetic analysis was conducted by Covance Clinical Research Unit (Leeds, United Kingdom) using WinNonlin Enterprise Version 5.2 (Pharsight Corporation, Mountain View, CA). The pharmacokinetic population consisted of all subjects who received at least one test product and had evaluable pharmacokinetic data area under the plasma concentration–time curve from time 0 to t_{last} ($AUCt_{0–tlast}$) (nominal t_{last} for this study was 120 minutes post start of product administration), C_{max} and t_{max} were determined from the plasma concentrations of nicotine using noncompartmental procedures (Committee for Medicinal Products for Human Use, 2010).

Summary statistics for pharmacokinetics were calculated with and without the criterion for exclusion of a preadministration plasma concentration of greater than 4 ng/ml. This criterion was chosen based upon a previously reported cutoff level for noncompliance with the preadministration nicotine and tobacco product abstinence period (Lunell & Lunell, 2005). Comparison of products was performed using a mixed model, including sequence, period, and product as fixed effects and subject (sequence) as a random effect. Statistical comparisons of the plasma nicotine parameters $AUC_{0–tlast}$ and C_{max} following use of the snus products were conducted by ANOVA and adjusted using the Tukey multiple comparison test, at $p < .05$, to show statistically significant differences between products. All statistical analyses were performed using SAS v. 8.2 (SAS Institute Inc., Cary, NC). All figures were produced using SAS v. 9.2.

Results

Subjects

The 20 eligible healthy subjects enrolled onto the study consisted of 19 males (18 caucasians and 1 mixed race) and 1 female (caucasian). The average age of subjects at the time of enrollment was 29 ± 8.8 years (mean ± *SD*). Height, weight, and BMI (mean ± *SD*) were 180 ± 6.8 cm, 77.5 ± 11.1 kg, and 23.9 ± 3.52 kg/m^2, respectively. Based on the genotyping analysis for CYP2A6 alleles, 12 subjects were identified as homozygous wild-type (CYP2A6*1) and hence extensive metabolizers. Eight subjects were heterozygous, possessing one wild-type, and one of the variant alleles or, in the case of one subject, two different variant alleles. All these eight subjects would be expected to metabolize nicotine but at a slower rate compared with wild-type (Benowitz, Swan, Jacob, Lessov-Schlaggar, & Tyndale, 2006). In the absence of more detailed or quantitative metabolic profiling they were classified as intermediate metabolizers for the purpose of this study.

While four subjects were found to have preadministration nicotine plasma concentrations greater than 4 ng/ml and, therefore, were candidates for exclusion due to evident noncompliance with the abstinence guidelines, there was no apparent difference in the summary statistics and statistical analyses when calculated for all subjects or excluding these subjects. Therefore, the reported pharmacokinetic data and safety data include all 20 subjects.

Extraction of Nicotine from Snus and Gum

The nicotine content of snus and gum portions was measured in separate samples taken both before and after use. The amount of extracted nicotine, as mg/portion and as a percentage of total nicotine, was calculated as follows:

Amount extracted = Quantity in an unused portion – Quantity in the used portion

Transfer (%) = 100 * (Amount extracted / Quantity in unused portion)

As shown in Table 2, the percentage of nicotine extracted from the products was highest for the nicotine gum, with 63% extracted. For snus products the mean extraction during use was between 24% and 32%.

Nicotine Pharmacokinetics

In this study, the primary pharmacokinetic parameters for measuring uptake of nicotine from the test products were C_{max}, t_{max}, $AUC_{0–120}$, and the results are given in Table 3. The plasma nicotine concentration/time profiles are shown in Figure 1. Nicotine uptake as measured by nicotine concentration in plasma from the venous circulation is characterized herein as systemic exposure to nicotine.

Table 2. Nicotine Content and Extraction for Snus and Nicotine Gum

Product	Nominal portion weight (g)	Measured nicotine content (g), mean ± *SD*, *N* = 20		Extracted nicotine, mean ± *SD*, *N* = 20	
		Unused	Used	mg/portion	% of total
Pouched snus	1.0	10.72 ± 0.91	7.34 ± 1.96	3.38 ± 1.92	31.41 ± 18.30
Pouched snus	1.0	14.67 ± 0.76	10.14 ± 2.32	4.53 ± 2.09	31.06 ± 15.08
Loose snus	1.0	10.79 ± 0.31	7.34 ± 1.48	3.45 ± 1.42	32.05 ± 13.34
Loose snus	2.5	27.09 ± 0.71	20.67 ± 2.58	6.42 ± 2.35	23.75 ± 8.86
Nicotine gum	1.0	4.15 ± 0.10	1.55 ± 0.36	2.62 ± 0.36	63.13 ± 8.75

Table 3. Pharmacokinetic Parameters of Plasma Nicotine Following Single Use of Different Tobacco Products and a Nicotine Gum

	Product (nicotine content) $N = 20$					
	Cigarette (14.6 mg)	Loose snus (10.8 mg)	Loose snus (27.1 mg)	Pouched snus (10.7 mg)	Pouched snus (14.7 mg)	Nicotine gum (4.2 mg)
AUC_{0-120} ng.h/ml						
Geometric mean*	14.8	16.0[a]	26.9[b]	16.8[a]	20.4[c]	13.1
Geometric coefficient of variation %	30.4	31.2	23.8	39.6	37.6	28.3
C_{max} ng/ml						
Geometric mean*	12.8	10.8[a]	17.9[b]	10.8[a]	13.4[a]	9.1
Geometric coefficient of variation %	41.3	34.4	22.8	41.4	39	28.6
t_{max} h						
Median	0.117	1.00	1.00	1.00	1.00	0.75
Range: minimum–maximum	0.083–0.517	0.75–1.50	0.75–1.50	0.33–1.50	0.75–1.50	0.33–1.50

Note. *Means with different letters are significantly different according to Tukey's multiple comparison test ($p < .05$).

The study showed that systemic exposure (C_{max}, AUC_{0-120}) to nicotine from snus was dependent on the total nicotine content of the portion (Figure 1, Table 3). The AUC_{0-120} for all six test products were ranked as: loose snus (27.1 mg) > pouched snus (14.7 mg) > loose/pouched snus (10.8 mg and 10.7 mg, respectively) > cigarette (14.6 mg) > 4.2 mg nicotine gum. C_{max} followed a similar ranking: loose snus (27.1 mg) > pouched snus (14.7 mg) > cigarette (14.6 mg) > loose/pouched snus (10.8 mg and 10.7mg, respectively) > 4.2 mg nicotine gum. Unlike the oral products, the total amount of nicotine available from the cigarette would have been limited to that inhaled by the smoker. The transfer of nicotine into smoke can be determined by machine smoking. However, no single smoking regime can fully account for the individual and temporal variation in smoking behavior and predict exposure in all smokers. To give an indication of transfer, we measured nicotine yield with the two most commonly used smoking regimes: the ISO standard test method 10315:2000 and Health Canada Method T-115, which yielded 0.9 and 2.1 mg nicotine per cigarette, respectively.

The t_{max} for all snus products in this study was 1 hr, which was also the time of use specified in the study. In comparison, the time of use for the nicotine gum was 30 min and the t_{max} was 0.75 hr (45 min). The t_{max} for the cigarette was considerably less at 0.117 hr

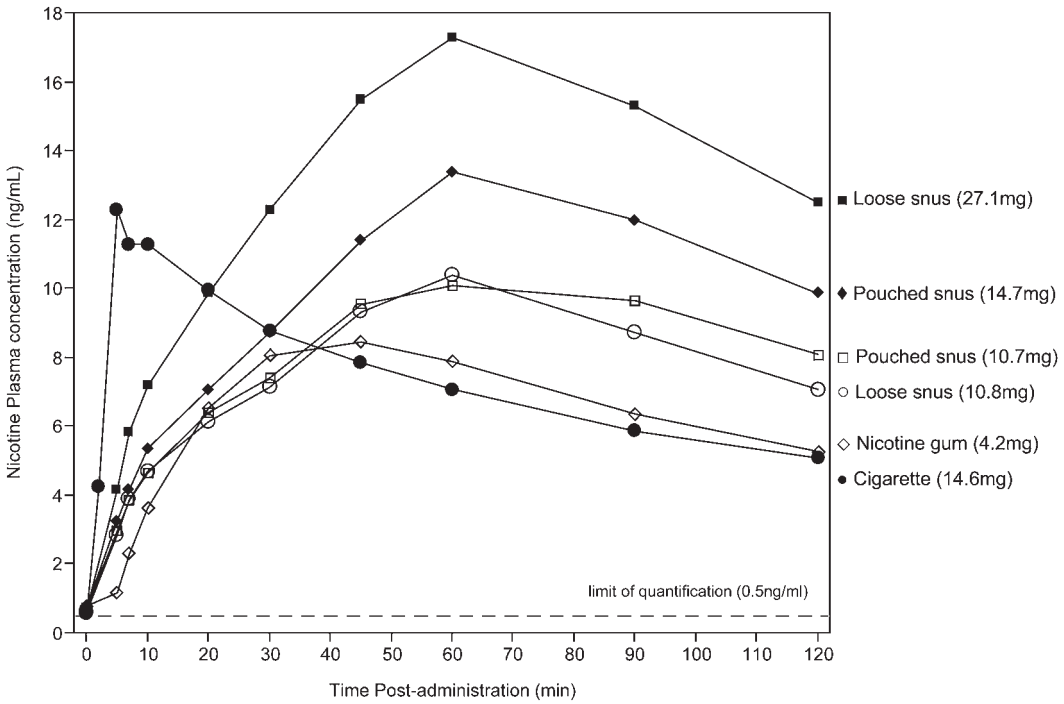

Figure 1. Mean plasma nicotine concentrations at each time point following single use of the different tobacco products and nicotine gum. Products (nicotine content): • Cigarette (14.6 mg); □ Pouched snus (10.7 mg); ○ Loose snus (10.8 mg); ♦ Pouched snus (14.7 mg); ■ Loose snus (27.1 mg); ◊ Nicotine gum (4.2 mg). The dashed line represents the limit of quantification (0.5 ng/ml).

(7 min) consistent with the short time of use (5 min). The range of t_{max} for the cigarette reported in Table 3 (0.083–0.517 hr) was influenced by the accidental loss of one blood sample at 5 min. When this subject was removed from the analysis the range was reduced to 0.083–0.333 hr but the t_{max} remained the same. While nicotine was absorbed more rapidly from the cigarette, systemic exposure was within the range of the smokeless tobacco products (AUC_{0-120} = 14.8 ng.h/ml; C_{max} = 12.8 ng.h/ml).

Comparison of the ratios of geometric means for AUC_{0-120} and C_{max} for increasing nicotine content in snus showed that the increase in plasma nicotine was subproportional to the nicotine content of snus; for loose snus a 2.5 times increase in nicotine content from 10.8 to 27.1 mg was associated with a 1.7 times increase in AUC_{0-120} and C_{max}. Similarly, for pouched snus a 1.4 times increase in nicotine content from 10.7 to 14.7 mg was associated with a 1.2 times increase in AUC_{0-120} and C_{max}.

Statistical comparisons of $AUC_{0-tlast}$ and C_{max} were made for the snus products where the protocol of use and the time of exposure were the same in all cases. Notably, there was no statistically significant difference ($p < .05$) in systemic exposures between pouched and loose snus when the nicotine contents of the products were equivalent (10.7 mg and 10.8 mg, respectively; Table 3). All other pairwise comparisons of $AUC_{0-tlast}$ for snus products did show a significant difference ($p < .05$). Whereas for C_{max}, only loose snus 27.1 mg compared with all other snus products showed a statistically significant difference ($p < .05$; Table 3).

Sensory Evaluation

For all snus products, the degree of irritation of lips and throat, level of salivation, or other perceived sensations such as any "buzz" feeling that subjects reported when using snus were generally low on the scale provided by the questionnaire. Overall there were no trends associated with product form or nicotine content noted in snus sensory questionnaire responses, suggesting that these product parameters had little effect on the level of sensations that subjects reported when using the snus products.

Effect of Genotype

CYP2A6 genotyping classified 12 subjects as extensive metabolizers and eight subjects as intermediate metabolizers. The mean AUC_{0-120} was approximately 10%–30% lower for extensive metabolizers across all products, apart from the 27.1 mg loose snus for which the AUC_{0-120} values were similar for intermediate and extensive metabolizers. However, due to the variability of individual exposure levels across test products for all subjects, regardless of metabolic status, the results of the genotyping analysis were not considered to have any significant impact on the interpretation of the pharmacokinetic data.

Safety

Some changes were observed in blood pressure, pulse rate, and heart rate during the study which were consistent with the recognized effects of nicotine on the sympathetic nervous system (Omvik, 1996; Robertson, Tseng, & Appalsamy, 1988). Increases from baseline systolic and diastolic blood pressure and pulse rate (mean increases of 3–10 mmHg, 4–10 mmHg, and 8–13 bpm, respectively) and heart rate as determined by ECG (mean increases of 6–12 bpm) were noted 15–30 min after product administration. There were no apparent associations between changes in blood pressure, pulse, or heart rate and the nicotine content of the products. No serious or severe adverse events were reported during the study.

Discussion

In this study, we have generated new information on comparative nicotine absorption from a cigarette, loose snus, and pouched snus. The tobacco products were typical of those commercially available in Europe (cigarette) and Scandinavia (snus) at the time of the study. In addition, nicotine absorption from use of a high-dose OTC pharmaceutical nicotine gum was measured for all subjects.

Nicotine plasma levels from smoking the cigarette rose more rapidly than for the oral products, as expected from the literature (Foulds et al., 2003). The total plasma nicotine concentration over the sampling period of 120 min (AUC_{0-120}) was higher for all the snus products than for the nicotine gum and cigarette, likely due to the higher total nicotine content of the snus and longer duration of use. The latter is an important variable; most nicotine pharmacokinetic studies on snus are based on a usage time of 30 min. However, in this study we applied the median time of 60 min reported in a survey of Swedish snus users as this was potentially more consistent with actual product use (Digard et al., 2009). These data showed that nicotine was continually absorbed from the snus portions over the entire 60-min period, which may partly explain the usage time observed in Swedish consumers. Nevertheless, the percentage of nicotine extracted from snus measured in this study (24%–32%) was similar to that observed by Lunell and Lunell (2005; 22%–44%).

The mean quantity of nicotine extracted from the used portions of snus and the nicotine gum followed the same trend as the pharmacokinetic AUC results and was positively correlated with the total nicotine content. However, the AUC_{0-120} for the 11 mg snus was only about 1.3 times higher than for the 4.2 mg gum, suggesting that the nicotine in the oral tobacco may be less bioavailable compared with that in the gum. Overall, the measured CYP2A6 metabolic status of the subjects did not have an impact on the pharmacokinetic end-points measured.

The similar nicotine pharmacokinetics for 1 g portions of loose and pouched snus, both containing similar levels of nicotine (10.8 mg and 10.7 mg, respectively), suggested that product form was not a major influencing factor in this study. Rather, it was dependent on the total amount of nicotine in the snus portion (quantity by weight of tobacco × the nicotine content of the blend). However, the data for the three different levels of total nicotine in snus indicated that the relationship was subproportional.

It is important to note that various behavioral factors not investigated in this study could also affect nicotine absorption such as moving the snus portion around the mouth, spitting saliva during use, or swallowing some amount of loose snus. Hence, while the protocol of use applied in this study was based on observed median usage patterns, in particular the portion sizes and 60-min duration of use (Digard et al., 2009), the data presented here are not representative of all snus users.

There was no significant difference in self-reported sensory perceptions between any of the snus samples. However, these data were derived from a questionnaire that had been adapted for this study and not fully validated. Therefore, while this was an interesting observation further and larger studies would be required to confirm the generality of the finding.

In summary, this study has provided new information on nicotine absorption for typical snus products, including loose snus, which demonstrates relationships between weight of tobacco and total nicotine content and systemic nicotine exposure. This study also provides data on nicotine absorption for a cigarette and an OTC nicotine gum.

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Declaration of Interests

Dr Malmqvist does not act as a consultant for British American Tobacco and has no financial interests in the Company.

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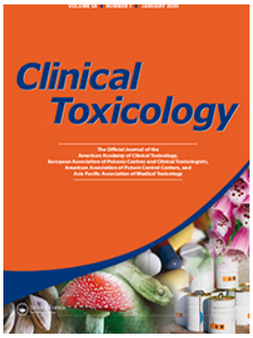

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REVIEW

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Nicotine intoxication by e-cigarette liquids: a study of case reports and pathophysiology

Gerdinique C. Maessen[a]*, Anjali M. Wijnhoven[a]*, Rosalie L. Neijzen[a]*, Michelle C. Paulus[a]*, Dayna A. M. van Heel[a]*, Bart H. A. Bomers[a]*, Lucie E. Boersma[a]*, Burak Konya[a]* and Marcel A. G. van der Heyden[b]

[a]Honours Program CRU + Bachelor, University Medical Center Utrecht, Utrecht, The Netherlands; [b]Department of Medical Physiology, Division of Heart & Lungs, University Medical Center Utrecht, Utrecht, The Netherlands

ABSTRACT

Background: Electronic cigarettes (e-cigarettes), the smokeless alternative to conventional tobacco cigarettes, have become increasingly popular. E-cigarettes vaporise e-liquid, a solution of highly concentrated nicotine, propylene glycol (PG) and vegetable glycerine (VG). With the popularity of e-cigarettes, e-liquid refills have become easily accessible and several cases of intoxication due to the ingestion of e-liquid have been reported. We provide an overview of these cases, their pathophysiology and patients' characteristics.

Methods: We carried out a retrospective evaluation of the scientific literature reporting on cases of liquid nicotine intoxication, using the following inclusion criteria: (1) the article is or contains a case report, (2) describes an intoxication with e-liquid, (3) the substance contains nicotine, and (4) intake is oral, intravenous or subcutaneous.

Results: We found 26 case reports describing a total of 31 patients who suffered from e-liquid intoxication. All intoxications up to the age of six were reported as unintentional, whereas nearly all cases from ages 13 to 53 were due to suicide attempts. The three most prevalent symptoms of e-liquid intoxication were tachycardia, altered mental status and vomiting. Eleven cases resulted in the death of the patient. In the survivors, the highest plasma concentration of nicotine was 800 $\mu g\,L^{-1}$, while the lowest concentration in the non-survivors was 1600 $\mu g\,L^{-1}$.

Conclusions: There is a mismatch between the generally accepted lethal oral nicotine dose of 60 mg, resulting in approximately 180 $\mu g\,L^{-1}$ plasma concentration, and the 4.4- to 8.9-fold higher lethal plasma concentrations we found in cases of e-liquid intoxication. In these severe intoxications, plasma cotinine concentration does not act as a more reliable indicator of nicotine intoxication than nicotine itself. The ages of the patients display a bimodal distribution. In patients above the age of 10, intoxication results mainly from suicide attempts rather than accidental ingestion. The role of PG and VG in e-liquid intoxications is remarkably unclear. However, the similarity across nicotine and PG toxicity symptoms leads us to believe a cumulative effect cannot be excluded.

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Introduction

Electronic cigarettes or "e-cigarettes", also known as smokeless cigarettes, are an alternative to regular cigarettes. They are battery-powered devices similar to normal tobacco cigarettes in use. However, e-cigarettes do not burn tobacco. Instead they vaporise e-liquid, a solution that is typically composed of nicotine, propylene glycol (PG) and vegetable glycerine (VG) often supplemented with various flavouring compounds and/or ethanol [1–3]. The main benefit of e-cigarettes is that they enable nicotine intake without exposure to many other, often hazardous, chemicals which are normally present in tobacco cigarettes [4]. Moreover, e-cigarettes have become a popular supporting tool for those who wish to quit smoking.

In 2003, Hon, a Chinese pharmacist, invented and patented the currently used e-cigarette in China (patent no. US8511318B2) [5]. E-cigarettes were introduced to the Western market in 2004 [6]. The nicotine containing solution can be refilled and a wide variety of such e-liquid refill cartridges, each containing different amounts of nicotine and flavouring agents, are currently available on the market. Moreover, thanks to the internet, e-liquid refills are easily accessible. During the last decade, regulatory parameters for e-liquids with respect to, for example, labelling, packaging, health warning, sale and advertising are set forward worldwide [7–9], which likely will decrease discrepancies between actual content and labelling as found previously [3,10]. However, regulation has not been installed everywhere and

CONTACT Marcel A. G. van der Heyden m.a.g.vanderheyden@umcutrecht.nl Department of Medical Physiology, Division of Heart & Lungs, University Medical Center Utrecht, Yalelaan 50, 3584 CM Utrecht, The Netherlands
*These authors contributed equally to this work.

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often differs between countries [9]. For example, maximum nicotine concentration in e-liquids is set at 20 mg/ml in 32 EU countries [11], whereas many other countries have not put forward an upper limit, and e-liquid preparations with nicotine concentrations up to 60 mg/ml can be found online. Also, minimum age for e-liquid purchase varies (e.g., Belgium: age 16; United States: 18; Honduras: 21) and is often not restricted at all.

Exposure to highly concentrated substances in e-liquids through unwarranted use such as oral consumption, goes hand in hand with a substantial risk of severe toxicity [12]. Life-threatening nicotine intoxication in young children due to accidental ingestion of e-liquid has been reported [13]. Another concern is nicotine intoxication resulting from suicide attempts using e-liquids [14]. With the introduction of e-cigarettes, e-liquids containing highly concentrated nicotine have become widely available. However, the clinical consequences of nicotine intoxication through e-liquid ingestion remain unclear. Moreover, at present, there is no consensus on the lethal dose of nicotine since different values have been reported. For oral intake, 60 mg of nicotine is often suggested as the lethal dose in the literature; although, research has shown that adults survive dosages much higher than this (up to 500 mg) [15]. Furthermore, the implications of combined nicotine and PG/VG intake, the main constituents of e-liquids, are uncertain. The symptoms most frequently seen in nicotine intoxication are vomiting, agitation, pallor, hypertension, tachycardia and headache [16]. Symptoms of PG intoxication vary between hyperosmolality and lactic acidosis to haemolysis, renal failure and CNS depression [17]. VG related symptoms are usually headache, nausea, diuresis and hyperglycaemia, mostly due to dehydration [18,19].

Two epidemiological studies from 2014 and 2019, respectively [13,20], examined exposures involving e-cigarettes reported to the National Poison Data System by all [13] or a single [20] U.S. Poison Center(s) and described trends in these exposures and clinical descriptions. They found that most reports of e-liquid nicotine intoxication involved accidental ingestion by children below the age of five leading to minimal toxicity and only rarely resulted in mortality [13,20].

We took a different approach and studied case reports describing e-liquid intoxication, while being aware of the potential bias towards overrepresentation of severe cases compared to the epidemiological approach. The main objective of this study is to analyse case reports describing oral liquid-nicotine intoxication and to attempt to correlate symptoms to the various components of e-liquids, in order to better understand the pathophysiology and consequences of e-liquid ingestion. We analysed patient characteristics, including age and cause of intoxication, compared derived dose-outcome relationships from concentrations of nicotine and of its main metabolite cotinine, evaluated clinical signs and discussed underlying pathophysiology. We found that severe cases of e-liquid poisoning mainly resulted from suicide attempts in the ages of 13–53 years.

Materials and methods

Data collection

For this literature review, we have carried out a retrospective evaluation of the existing scientific literature reporting on cases of e-liquid intoxication as defined and/or indicated by the authors. We have searched PubMed, Embase, WebMD and Google Scholar using the following search terms: nicotine, liquid nicotine, electronic cigarette liquid, e-cigarette liquid and e-liquid combined with intoxication, ingestion, injection and tachycardia. We have included and evaluated English and non-English articles. We included articles that met the following requirements: (1) the article is or contains a case report, (2) describes an intoxication with e-liquid, (3) the substance contains nicotine, and (4) intake is oral, intravenous, or subcutaneous. One case was presented twice [21,22], for this case we combined the data from both articles.

Data analysis

All case reports in this study have been read and interpreted by at least two authors of the current paper. For translating articles not written in English or Dutch, we have used Google Translate and consulted native speakers. For the statistical analysis of the data on nicotine and cotinine plasma, blood, and urine concentrations, GraphPad Prism 7.04 software was used (GraphPad Software, La Jolla, CA). Data were clustered into two groups based on the patients' outcome (survival; death). Numerical data are presented as mean ± SD. Welch's *T*-test was used to determine statistical significance ($p < .05$).

Results

We found 26 case reports describing a total of 31 patients who suffered from e-liquid nicotine intoxication either due to ingestion or injection. Twenty case reports have been published in English, whereas translation was required for six articles. The published case reports originate from 11 different countries (Tables 1 and 2). Most case reports are from the US ($n = 6$), followed by South Korea ($n = 4$), Poland ($n = 3$) and the Netherlands ($n = 3$). When looking at the number of case reports per continent, most reports originate from Europe. The articles describe a total of 31 intoxications, of which 17 (55%) are male and 14 (45%) are female (Table 1). The mean ages of the male and female population at intoxication are 27 and 20 years, respectively. The ages of the patients described in the case reports display a bimodal distribution (Figure 1).

All nicotine e-liquid intoxications up to the age of 10 were reported as unintentional. From ages 13 to 53, nearly all cases were the result of intentional e-liquid intake, most likely suicide attempts. The symptoms of e-liquid intoxication can be divided into groups: "cardiovascular", "neurological", "gastrointestinal", and "other" symptoms (Figure 2). Tachycardia ($n = 18$), vomiting ($n = 13$), and altered mental status ($n = 11$) are the three most prevalent

Table 1. Overview of case reports reviewed.

Case	Patients	Origin of paper	Remarks	Administration	Age (sex)	Reference
1	1	Germany		Ingestion	34 (M)	[23]
2	1	USA		Ingestion	10 months (M)	[24]
3	1	Italy		Ingestion and intravenous injection	22 (F)	[25]
4	1	USA		Ingestion	24 (F)	[26]
5	3	Denmark	Only abstracts available	Ingestion; ingestion; ingestion	36 (F); 36 (F); 13 (M)	[27]
6	2	Netherlands	Paper in Dutch	Ingestion; ingestion	40 (M)[a]; 20 (F)	[21]
7	1	Germany		Ingestion	24 (M)	[28]
8	1	USA		Ingestion	18 months (M)	[29]
9	1	France		Ingestion	44 (M)	[30]
10	1	Canada		Ingestion	2 (F)	[31]
11	1	Poland	Paper in Polish	Ingestion	42 (F)	[32]
12	1	USA		Ingestion	18 months (F)	[33]
13	2	Finland	Paper in Finnish	Ingestion; subcutaneous injection	26 (M); 29 (F)	[34]
14	1	France	Paper in French	Ingestion	19 (M)	[35]
15	1	UK		Ingestion	32 (M)	[36]
16	1	USA		Ingestion	6 (F)	[37]
17	1	South Korea		Ingestion	53 (M)	[38]
18	2	South Korea		Ingestion; ingestion	27 (M); 17 (F)	[14]
19	1	Finland		Subcutaneous injection	29 (F)	[39]
20	1	Netherlands		Ingestion	27 (M)	[40]
21	1	South Korea		Ingestion	15 months (F)	[41]
22	2	Poland		Ingestion; intravenous injection	21 (F); 32 (M)	[12]
23	1	USA		Intravenous injection	29 (M)	[42]
24	1	Netherlands	Paper in Dutch	Ingestion	42 (M)[a]	[22]
25	1	Poland	Paper in Polish	Ingestion	34 (M)	[43]
26	1	South Korea		Ingestion	39 (M)	[44]

[a]Same case.

Table 2. Overview of the origin of case reports describing acute e-liquid poisoning including the number of patients.

Region	Country	Number of case reports	Number of patients
Europe	Poland	3	4
	Netherlands	3	3
	Finland	2	3
	France	2	2
	Germany	2	2
	Denmark	1	3
	Italy	1	1
	United Kingdom	1	1
North-America	United States	6	6
	Canada	1	1
Asia	South Korea	4	5

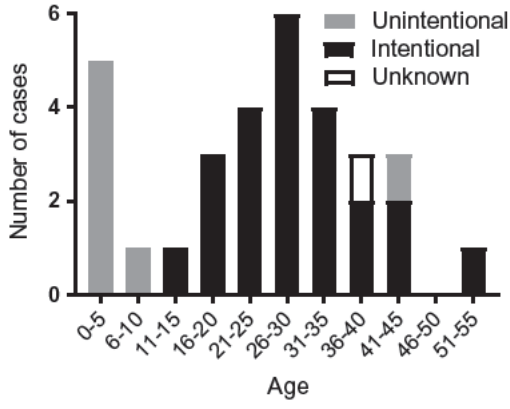

Figure 1. Distribution of cases of e-liquid poisoning by age. Motive for intake is indicated by different shading.

symptoms. Other symptoms, which were reported less frequently, are: pulseless electrical activity ($n = 2$), dizziness ($n = 2$), headache ($n = 2$), paresis ($n = 2$), purple colour ($n = 1$), trunk ataxia ($n = 1$), and grunting ($n = 1$). Eleven of the 31 presented cases of e-liquid intoxication resulted in the death of the patient.

The plasma nicotine concentration had been specifically determined in 11 cases (Figure 3(A)). In cases reporting multiple measurements of nicotine concentration the first, which was also the highest, measurement was used. The mean plasma nicotine concentration among the survivors ($n = 6$) was $307 \pm 312\,\mu g\,L^{-1}$ (median: $222\,\mu g\,L^{-1}$). Among the five patients that died, the mean plasma nicotine concentration was $3360 \pm 1692\,\mu g\,L^{-1}$ ($p < .05$ vs. survivors) (median: $3000\,\mu g\,L^{-1}$). As illustrated by Figure 3(A), the highest plasma concentration of nicotine in the surviving group was $800\,\mu g\,L^{-1}$, while the lowest plasma concentration in the group of patients that had not survived the intoxication was $1600\,\mu g\,L^{-1}$. We omitted one patient, a non-survivor, from Figure 3(A) since the patient's exceptionally high plasma nicotine concentration of $85{,}200\,\mu g\,L^{-1}$ exceeded the mean nicotine concentration in this group by 48.4 times SD [44].

Plasma concentrations of cotinine, the major metabolite of nicotine, had been specifically determined in 12 cases (Figure 3(B)). In cases reporting multiple measurements of cotinine concentration we used the values from the first, which were also the highest, measurements. The mean plasma cotinine concentration in the surviving group was $1224 \pm 971\,\mu g\,L^{-1}$. The patients that did not survive the intoxication had a mean plasma cotinine concentration of $1044 \pm 731\,\mu g\,L^{-1}$ (n.s. vs. survivors).

Discussion

We reviewed 26 case reports on nicotine e-liquid intoxications from 11 different countries. The age of patients ranged between 10 months and 53 years, showing a bimodal distribution. Nicotine and cotinine concentrations were

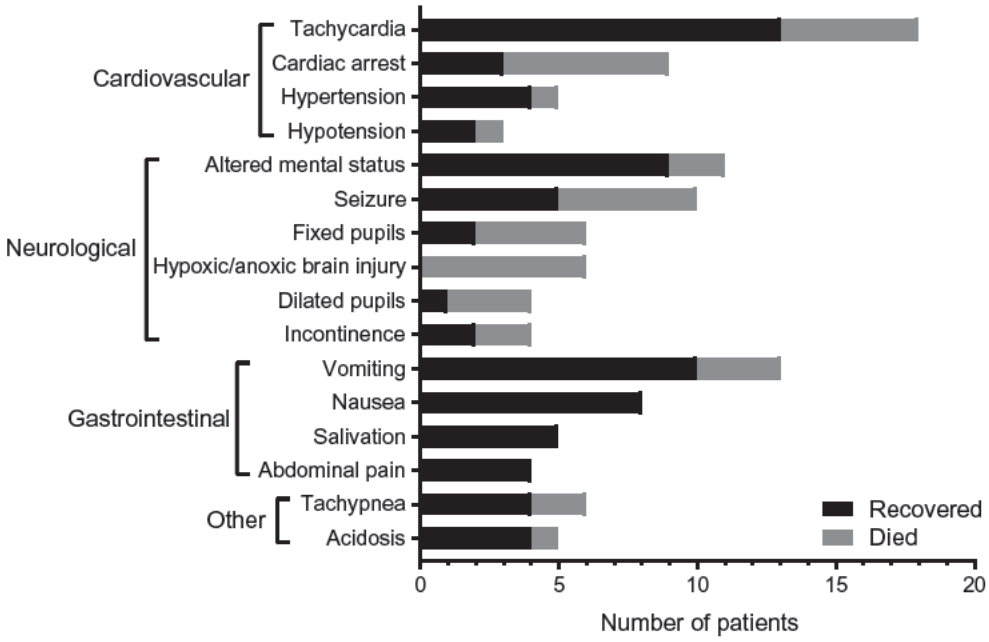

Figure 2. Reported symptoms in patients with acute e-liquid poisoning classified by cardiovascular, neurological, gastrointestinal and other symptoms. Outcome is indicated by different shading. Only symptoms that occurred in three or more cases were included in the figure.

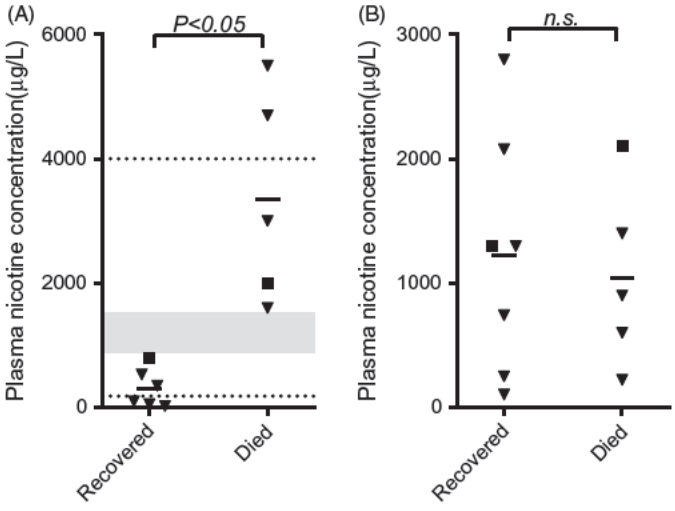

Figure 3. (A) Individual and mean nicotine concentration in the plasma in µg L^{-1} in cases with acute e-liquid poisoning subdivided in the outcome recovered or death. Symbols: triangle, oral intake; squares, intravenous intake. Black horizontal dotted lines (at 180 and 4000 µg L^{-1}) indicate levels of lethal value as found in literature [15]. Grey horizontal bar indicates our own lethal value range. The mean is displayed by the short black lines (at 307 and 3360 µg L^{-1}). (B) Individual and mean cotinine concentration in the plasma in µg L^{-1} in cases with acute e-liquid poisoning subdivided in the outcome. Symbols: triangle, oral intake; squares, intravenous intake. *n.s.*: not significant. The mean is displayed by the short black lines (at 1224 and 1044 µg L^{-1}).

determined in 11 and 12 cases, respectively. Plasma nicotine concentration was significantly higher in patients that had died compared to patients that survived ($p < .05$), whereas cotinine concentrations showed no significant difference. The most frequently reported symptoms (tachycardia, altered mental status, and vomiting) can be explained by a variety of physiological processes relating to the primary active agents in e-liquids which are nicotine, PG and VG. Unfortunately, we were unable to provide comprehensive insights into potential interactions regarding comorbidities and/or intake of other toxic components, such as alcohol, since the case reports rarely provided a full patient history.

Nicotine binds to a variety of nicotinic cholinergic receptors throughout the body, which may explain the many different manifestations of e-liquid intoxication observed. Acute nicotine intoxication can induce both stimulation and inhibition of cholinergic receptors, which usually results in a biphasic clinical manifestation [16]. First, sympathetic symptoms such as tachycardia, hypertension, and involuntary muscle contractions occur. Subsequently, parasympathetic symptoms can appear due to sympathetic receptor desensitisation.

Tachycardia is the most prevalent symptom in the studied case reports. By activation of cholinergic receptors of the paravertebral stellate ganglia leading to the heart, nicotine induces sympathetic activity in the myocardium and vascular smooth muscle cells [45]. Smoking one cigarette usually increases the heart rate by 15–20 beats per minute and causes an increase in systolic as well as diastolic blood pressure by roughly 12 mmHg. Higher doses of nicotine can result in the development of severe tachycardia and acute hypertension [45].

Altered mental status is observed while smoking cigarettes and relates to release of serotonin, dopamine, and other neuroactive agents. Being aware of the notion that high concentrations of nicotine may associate with severe cognitive and behavioural alterations [46], it is tempting to speculate that these symptoms as described in several case reports result from high nicotine levels. Although, one should be aware that the act of cigarette smoking and its resulting tobacco smoke exposure, cannot be directly compared to, often intentional, liquid nicotine intoxication.

The described seizures and myoclonus have two possible explanations, depending on a physician's definition of these

terms. First, nicotinic cholinergic receptors are, besides paravertebrally, situated at the neuromuscular junction. Nicotine acts as a substitute for acetylcholine and as such stimulates more rapid depolarisation of the muscle fibres. In high concentrations, it can induce involuntary contraction of the muscles, even resulting in seizure-like movements [47]. Second, at very high dosage, nicotine can cause epileptic activity in the brain. This mechanism is not yet fully understood, but may be related to desensitisation of the cholinergic receptors after prolonged exposure. The cholinergic receptors in the central nervous system normally stimulate GABAergic interneurons, which in turn have an inhibitory effect on the pyramidal cells. A decrease in cholinergic receptors reduces the GABAergic activity and has an excitatory effect on the pyramidal cells, resulting in seizure [48,49]. The desensitisation of the nicotinic cholinergic receptors eventually induces a similar effect at the neuromuscular junction. Lengthened exposure to nicotine leads to a reduction in available receptors at the muscle cell membrane, followed by decreased cell depolarisation. In this way, partial or complete muscle paralysis may occur [16].

Finally, as is frequently the case in oral intoxications, gastrointestinal symptoms appeared in nearly all of the described patients. These included vomiting, nausea, salivation and abdominal pain. The gastrointestinal symptoms are partially caused by excessive sympathetic stimulation mentioned earlier [16], nicotine stimulation of the area postrema (specifically the chemoreceptor trigger zone), and irritation of the mucosal tissue which activates a natural detoxification reaction [50]. The eventual cause of death due to nicotine intoxication is most likely related to cardiac or cerebral pathology, but can be difficult to determine precisely.

Clinical symptoms described from our reviewed case reports are in line with those reported in an earlier epidemiological study [20], albeit that the amounts of ingested e-liquid in our cases, which involve many events of intentional intake, are likely higher. This may explain absence or low incidence of mortality in the epidemiological studies [13,20] compared to the current study.

There is no consensus on the lethal dose of nicotine. In this study, we provide a clear overview of nicotine plasma concentrations in survivors versus patients that died. In our dataset, the lethal nicotine concentration is between 800 and 1600 $\mu g\,L^{-1}$, which is 4.4- to 8.9-fold higher than the generally accepted lethal oral dose of 60 mg or less that would lead to a plasma concentration of approximately 180 $\mu g\,L^{-1}$ [15]. This latter plasma concentration is an estimate, since there are individual differences in nicotine metabolism, due to genetic polymorphism and other interindividual differences [38]. For example, women generally metabolise nicotine more rapidly than men [51]. Nevertheless, this results in minor differences and does not explain the gap between ±180 $\mu g\,L^{-1}$ and 800–1600 $\mu g\,L^{-1}$. Thus, there is a mismatch between the lethal dose consistently stated in textbooks, databases and safety sheets (30–60 mg), and the lethal doses we found in cases of nicotine intoxication. Such discrepancy has been noticed before, but the 60 mg-value is still widely accepted [15]. Our data thus supports the suggestion of Mayer [15] that revision of the 60 mg lethal dose is necessary.

Nicotine is a water- and lipid-soluble liquid alkaloid, partly present in blood as free base [52]. According to the literature, plasma nicotine half-life is short (40–120 minutes) [53,54]. After oral ingestion, nicotine is absorbed by the mucosa in mouth and bowel and metabolised predominantly in the liver [55]. The first-pass effect decreases the bioavailability of nicotine by 30–40% [38]. Peak plasma concentrations are reached around 60 minutes after oral ingestion, however, in high dosages Tmax is potentially prolonged. Nicotine undergoes rapid biotransformation, mainly in the liver, to one of the six identified primary metabolites, of which cotinine is most abundant. Up to 80% of nicotine is converted to this lactam derivate via cytochrome oxidase routes, primarily by CYP P450 2A6 [56]. In the case reports that we studied, the time-interval between the intake of e-liquid and the collection of biological samples for analysis, ranged from 1 hour to 25 hours. Since the half-life of nicotine is short in biological samples ($T^1/_2$ of two hours) [57], the analytical results of nicotine could be inaccurate depending upon the timing of the sampling. Due to the short half-life of nicotine, cotinine ($T^1/_2$ of 13–19 hours) is widely used as a marker for exposure to nicotine [58], whereas in terms of clinical practice, cotinine has no cardiovascular activity on cigarette smokers by itself [59]. In terms of quantity, cotinine is the most stable metabolite and its concentration is considered directly proportional to the amount of nicotine absorbed [58]. However, according to reports on nicotine poisoning, clinical patterns and survival rates do not always associate with cotinine concentration [38]. Despite the consensus in literature on cotinine being a more reliable indicator of nicotine intoxication than nicotine itself, our results from e-liquid intoxications show the opposite. This could possibly be due to different kinetics of nicotine in the case of e-liquid intoxications compared to nicotine poisoning through (ab)use of other nicotine-containing products. Another possible explanation is that in severe intoxication cases, rapidly occurring liver damage precludes nicotine metabolisation into cotinine. In addition, circulating nicotine and cotinine levels are determined by the rate of nicotine metabolism, which may differ between individuals [38,51].

E-liquids are often based on PG and VG, compounding in various ratios, as primary solvents. The PG/VG ratio can vary between a sole PG or VG base, and may influence nicotine delivery as well as toxicity of the e-liquid [2]. However, the extent to which the PG/VG ratio in e-liquids influences acute effects is unknown.

PG is an alcohol derivative also referred to as propane-1,2-diol. It is widely used as a drug solvent, an additive in foods, and as a moisturiser and emulsifier in cosmetic products [60]. PG is absorbed in the small intestine, metabolised in the liver by alcohol dehydrogenase into lactic acid and finally turned into pyruvic acid through glycolysis. Both lactic acid and pyruvic acid, being normal constituents of the citric acid cycle, are finally converted into the non-toxic end products water and carbon dioxide [61]. 12–45% of PG is

eliminated by the kidneys unchanged or as glucuronide conjugate [62].

In 1982, PG received the "Generally regarded as safe" (GRAS) status by the US Food and Drug Administration (FDA) [63]. Nevertheless, PG toxicity has been reported in some cases [17]. High doses of PG pose a risk especially in infants, children, and elderly [64,65], due to a relatively impaired alcohol dehydrogenase system and kidney disease, respectively. When PG is ingested in very high doses, the excess lactic and pyruvic acid will not be metabolised and will accumulate, potentially causing metabolic acidosis. Additionally, high dosage of PG can cause accumulation of PG itself, in turn leading to hyperosmolarity [62]. The combination of metabolic acidosis and hyperosmolarity may result in serious illness, such as haemolysis, renal failure, CNS depression with seizures and various presentations of cardiovascular decompensation [17].

The role of PG in e-liquid intoxications is remarkably unclear. Although PG is usually a main component of e-cigarette liquid [60], no study has been conducted on the long-term toxic effects of PG in e-cigarettes/e-liquids [66]. As reviewed by Barnes et al. [67], 75% of the cases on symptomatic PG intoxication report plasma concentrations higher than 250 $\mu g\,L^{-1}$. Only one of our case reports measured a PG concentration: 300 $\mu g\,L^{-1}$ after 14 hours, by which the authors estimated the initial plasma concentration to be more than 1000 $\mu g\,L^{-1}$ [30]. This could indicate a dual intoxication of PG and nicotine. As only one of the case reports provided the plasma concentration of PG, we were unable to relate any of the symptoms to PG with full certainty. However, the similarity across nicotine and PG toxicity symptoms leads us to believe a cumulative effect cannot be excluded. No evidence for a possible interaction has been published so far, but in view of e-liquid intoxication, it may be a subject for further studies.

VG, also propane-1,2,3-triol or glycerol, is a simple trihydric alcohol which is naturally present in human tissue as it forms the skeleton of triglycerides [68]. After absorption in the small intestine, VG is metabolised in the liver by glycerol kinase into glycerol-3-phosphate, which then becomes esterified with fatty acids in the citric acid cycle [69]. VG is eliminated by the kidneys, either unchanged or metabolised [70]. Due to its sweet taste, VG is often used in the food industry. It is also widely used in medical applications because of its potent osmotic properties. For example, it is provided as a treatment for cerebral oedema as VG has a dehydrating effect on the brain [18]. VG is considered to be safe for oral ingestion [71]; however, its effects in an overdose are not well researched. Known adverse effects of VG taken orally are mostly due to dehydration: headache, nausea, diuresis, and hyperglycaemia. In very severe cases, symptoms such as apathy, cyanosis, renal failure, and cardiac arrhythmia are reported. Haemolysis seems to be a reaction strictly related to intravenous injection [19]. None of the case reports provided a concentration of VG, and since severe symptoms are only reported for high doses of up to 1.4 g/kg bodyweight [19], we believe that VG has no obvious effect in these cases.

In this study, PG and/or VG in e-liquids could have affected the acidosis seen in several case reports. The reason being that acidic PG metabolites potentially cause metabolic acidosis [62] and that the osmotic dehydration produced by VG may lead to ketoacidosis [70]. Interestingly, the bioavailability of nicotine is dependent upon pH, which varies substantially across different e-liquids. More alkaline e-liquids contain a larger fraction of unionised nicotine, a form that is absorbed more easily and rapidly through biological membranes [2].

Ethanol can be added to the PG/VG base as a solvent for flavourings or other additives. Despite extensive regulations on reporting all components, ethanol has frequently been found as an unlabelled ingredient in e-liquids available in the US [3]. It might be possible that ethanol contributed to the observed acidosis in our case reports as well, although the concentration in the used e-liquids was presumably too low for this effect.

Our study comes with several limitations. There are some concerns about the comparability of the nicotine levels found in the case reports. As described, the moment of biological sample collection varies from one to 25 hours after intake of e-liquid. Besides, several different analytical methods have been reported, using GC, HPLC, GC/MS or LC/MS/MS for the analysis of nicotine and metabolites [44]. Furthermore, we used the highest reported values in the case reports, but cannot determine whether these are equal to the peak concentrations that have occurred in the patients.

Studying only case reports could have led to bias in our results since case reports generally describe more severe cases. Also, the quantity of occurred symptoms may not be fully correct, since some of these symptoms can only be described by patients themselves (such as nausea or abdominal pain), while several patients in our case reports were found post-mortem. This could also have affected the number of other symptoms (such as tachypnoea, hypertension, and altered mental status), which can only be detected during life. Adding to this, we had a concern about the interpretation of some of the symptoms, in particular seizure and myoclonus. As described before, nicotine intoxication can cause both symptoms to occur by two different pathways. We are concerned that, in acute situations, these two symptoms might present themselves similarly and are difficult to distinguish from one another. Therefore, the occurrence ratio of seizure and myoclonus might be different than presented by the case reports.

Conclusions and recommendations

E-liquid cartridges, often containing high doses of liquid nicotine, are easily accessible and unwarranted use can result in severe intoxication. The ages of the patients display a bimodal distribution. In patients above the age of 10, intoxication results mainly from suicide attempt rather than accidental ingestion. In these severe intoxications, we found that cotinine does not act as a more reliable indicator of nicotine intoxication than nicotine itself. Furthermore, there is a

mismatch between the generally accepted lethal nicotine dose of 60 mg (resulting in a plasma concentration of approximately 180 $\mu g\,L^{-1}$) and the 4.4- to 8.9-fold higher lethal plasma concentrations that we found in cases of e-liquid intoxication. The role of PG in e-liquid intoxications is remarkably unclear. However, the similarity across nicotine and PG toxicity symptoms leads us to believe a cumulative effect cannot be excluded. VG and ethanol may also play a part in the manifestation of e-liquid intoxication.

As e-liquids are very easily accessible and purchased by many people, we urge to raise more awareness about the dangers of these substances when ingested or injected. We expect this will especially prevent more cases of accidental ingestion in young children. On a global scale, stricter regulation is necessary to ensure accurate descriptions of contents on e-liquid cartridges. This is also important for healthcare professionals, who need to know the amount of substances ingested by patients. As for further research, we suggest examining possible PG/VG-nicotine interactions.

Disclosure statement

No potential conflict of interest was reported by the authors.

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Manufacturing equipment type and settings

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Quality & Environmental Management System

7.5.1.1.302 SOP B ZYN Fluid Bed Operation – Final Granulate

Process Owner: (b) (6)
(Manufacturing Department Manager I)

Document Type: Standard Operating Procedure

Revision No.: 3
Revision Date: 9/17/20

Approved by: (b) (6)

Document Author:
(b) (6)

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Quality & Environmental Management System

QAD 302 SOP A COA Review of Incoming Ingredients and Materials

Process Owner: (b) (6) [redacted]
Vendor Specialist Supervisor

Document Type: Standard Operating Procedure

Revision No.: 2
Revision Date: 9/15/2020

Approved by:
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Document Author:
(b) (6) [redacted]

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USA

Certificate of Analysis

Sunett® (Acesulfame K) Particle Size C Pharma Grade; 25 kg box

Customer No.:	2091772	**Cert Issue Date**:	13 Jan 2015
Material No.:	20008590	**Qty Shipped**:	125.000 KG
Customer Material:	0121763	**Order Item /date**:	1527774 10 / 19 Nov 2014
Produced at:	Frankfurt am Main	**Delivery item/date**:	83362265 900002 / 01 Dec 2014
Produced on:	14 Oct 2014	**Customer PO No.**:	PO00053076 rel 2
Best before date:	13 Oct 2019		
Country of origin:	Germany		

Batch 0000726481
On the batch, of which the consignment is a part, the following values were determined.

Characteristic	(Method)	UoM	Value	Limits
Abs. max. (in Water)	(UV)	nm	226.8	225.0 - 229.0
Alkalinity	(EP)		Pass	
Acidity	(EP)		Pass	
Appearance	VISUAL		white, crystalline powder	
Appearance of Solution	(EP)		clear and colourless	
Assay	(HPLC)	%	99.9	99.5 - 100.5
Colour	VISUAL		Pass	
Fluoride	(IC)	ppm	< limit of detection	0.1 - 1.0
Heavy metals (calc. as lead)	(Limit-Test)	ppm	< 5	max. 5
Identity Acesulfame	(UV)		Pass	
Identity Potassium	(FAO / WHO)		Pass	
Identity Potassium	(USP)		Pass	
IR spectrum	(EP, IR)		Pass	
Loss on drying (2h/105℃)	(FAO / WHO)	%	0.06	max. 0.20
Loss on drying (3h/105℃)	(EP)	%	0.06	max. 0.20
Odour	(sensoric)		odourless	
Organic volatile impurities	(ICH, GC)	ppm	< limit of detection	2 - 5
Dichloromethane	(ICH, GC)	ppm	< limit of detection	2 - 5
pH-value (1% solution)	(potentiometric)		7.0	5.5 - 7.5
Potassium	(IC)	%	19.2	17.0 - 21.0
Potassium acetate	(IC)	%	< 0.5	max. 0.5
Residue of filtration	(Filtration)		no residue of filtration	

Celanese

Nutrinova
Nutrition Special. & Food Ingred. GmbH
Am Unisys Park 1
D-65843 SULZBACH (TAUNUS)

COLUMBIAN LOGISTICS
900 HALL ST SW
GRAND RAPIDS MI 49503
USA

Certificate of Analysis

Sunett® (Acesulfame K) Particle Size C Pharma Grade; 25 kg box

Customer No.: 2091772
Material No.: 20008590
Customer Material: 0121763
Produced at: Frankfurt am Main
Produced on: 14 Oct 2014
Best before date: 13 Oct 2019
Country of origin: Germany

Cert Issue Date: 13 Jan 2015
Qty Shipped: 125.000 KG
Order Item /date: 1527774 10 / 19 Nov 2014
Delivery item/date: 83362265 900002 / 01 Dec 2014
Customer PO No.: PO00053076 rel 2

Characteristic	(Method)	UoM	Value	Limits
Chromatographic purity (USP)	(HPLC)	ppm	< 2	max. 2
Impurity B/ 5-Cl-Acesulfame K (EP)	(HPLC)	ppm	< 2	max. 2
Unspecified impurities (EP)	(HPLC)	ppm	< 20	max. 20
Total impurities (EP)	(HPLC)	ppm	< 20	max. 20
Acetylacetamide (Imp. A)	(HPLC)	ppm	< limit of detection	0.5 - 1.0
Sulfate	(IC)	ppm	< limit of detection	max. 20.0
Arsenic	(ICP MS)	ppm	< limit of detection	0.02 - 0.10
Lead	(ICP MS)	ppm	< limit of detection	0.02 - 0.10
Mercury	(AAS)	ppm	< limit of detection	max. 0.01
Selenium	(ICP MS)	ppm	< limit of detection	max. 0.20
Cadmium	(ICP MS)	ppm	< limit of detection	0.02 - 0.10

The following values are based upon statistical evaluation and are adhered to with each batch.

Escherichia coli	(PH.EUR)	neg. / 1g
Pseudomonas aeruginosa	(PH.EUR)	neg. / 1g
Salmonella bacilli	(PH.EUR)	neg. /10g
Staphylococcus aureus	(PH.EUR)	neg. / 1g
Enterobacteriaceae	(PH.EUR)	< 10 CFU / 1g
Total mesophilic counts	(PH.EUR)	< 10 CFU / 1g
Yeasts	(PH.EUR)	< 10 CFU / 1g
Moulds	(PH.EUR)	< 10 CFU / 1g

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Produced on:	14 Oct 2014	**Customer PO No.**:	PO00053076 rel 2
Best before date:	13 Oct 2019		
Country of origin:	Germany		

Manufacturing Site: Nutrinova, Nutrition Specialties & Food Ingredients GmbH, Sunett® plant, building D483, Industriepark Höchst, 65926 Frankfurt / Main, Germany

Methods are validated against official PH.EUR. and USP methods. Sunett® Pharma Grade meets the requirements of the European Pharmacopoeia 8.0, the US Pharmacopoeia USP 37-NF 32 and the Japanese Pharmaceutical Excipients list in the updated version.

Sunett® Pharma Grade conforms also to the specifications published by FAO/WHO, those of the Food Chemicals Codex, those of the JSFA and the EC as well as to national specifications published in food regulations for Acesulfame K. The existing legal restrictions for the use in foods and drugs must be observed. Sunett® and its raw materials are manufactured synthetically. Sunett® is as a component of food fit for human consumption.

Based on knowledge of our manufacturing and handling processes, no potential exists for Class 1, 3 or Other Residual Solvents listed in Table 4 to exist as Residual Solvents in our sweetener Sunett® (Acesulfame K) per USP 37-NF 32 requirements. Dichloromethane, as a Class 2 solvent is used during the manufacturing process. Each batch Sunett® Pharma Grade is tested for Residual Solvents and Dichloromethane.

The test results refer exclusively to the examined sample taken from the above-mentioned lot. Any copying of the test report, whether in part or in full is not allowed without Nutrinova's permission.

Retain sample policy:
Please be informed, that since January 1st, 2012 we store retain samples of Sunett® for 6 years from date of manufacture.

If you have any concerns with this shipment, please contact our Customer Service at phone 800-914-6006 .

Nutrinova GmbH

Celanese

Nutrinova
Nutrition Special. & Food Ingred. GmbH
Am Unisys Park 1
D-65843 SULZBACH (TAUNUS)

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Best before date:	13 Oct 2019		
Country of origin:	Germany		

Frank Görgen.
Quality Inspector

Swedish Match

Document type	Date document created	Project name
Validation report	January 23, 2020	Industrialization Fluid Bed
Version	**Date last changed**	**Information class**
1	January 23, 2020	Confidential SM
Created by	**Title**	**Department**
(b) (6)	Research Engineer	Development Purified Product

Validation report – Granules process

Start-up of ZYN Granules production in Owensboro 2019

1 Background

A new production line has been built in Owensboro, Kentucky for manufacturing of ZYN Dry granules. In the initial start-up three new Fluid-Bed towers has been installed together with peripherals equipment for handling raw material and granules produced.

2 Summary of Validation.

Individual reports of each SKU can be found in project folder:

https://swedishmatch.sharepoint.com/sites/wsnb/RnD/Res/Documents/1.%20Activities/Purified/112629_ZYN_Ind_Fluid_bed/US%20FB%20System/Validation

In this report all the calculated values are presented and collected for an overview of the validation. A total of 150 batches has been used to evaluated if the granulate production is fit for purpose.

2.1 Scope of process validation plan

The validation plan shall be applied for each tower in the of fluid bed production. Furthermore, each SKU produced should be validated using at least 3 batches.

All testing will be performed at Swedish Match ISO certified laboratory in Owensboro with validated pH, moisture and nicotine test procedures. For determine particle size distribution a Retch Sieve AS200 with following mesh-size is used 90µm, 100µm, 125µm, 150µm, 200µm, 250µm, 300µm,400µm, 500µm & 900µm. Bulk density is determined using a measuring cylinder and a weighing scale.

Statistical software (Minitab 18) and statistical methods will be used to evaluate each validation setup.

Responsible for the evaluation and reporting: Fredrik Hulting, Research Engineer.

2.1.1 Acceptance criteria

Acceptance testing shall use the average values per batch in the evaluation. The following release criteria is used for 3 and 6 mg versions of the product.

- **Nicotine, per target value**:
  - Acceptance criteria:
  - Nicotine 3mg versions: Target 8.04 mg/g.
    - Average limit within 7.34 - 8.74 mg/g
  - Nicotine 6mg versions Target 16.08 mg/g.
    - Average limit within 14.68 - 17.48 mg/g
  - Homogeneity for Nicotine %RSD <6 %

- **pH:**
  - Acceptance criteria:

Swedish Match

(b) (4)

[redacted]

Swedish Match

(b) (4)

[redacted]

Swedish Match

(b) (4)

[redacted]

Swedish Match

(b) (4)

[redacted]

Swedish Match

(b) (4)

[redacted]

Swedish Match

(b) (4)

[redacted]

Swedish Match

(b) (4)

[redacted]

(b) (4)

[redacted]

Swedish Match

(b) (4)

[redacted]

SWEDISH MATCH

Standard Operating Procedure

Swedish Match **US Division** **Owensboro Factory**	**Title:** Performing Quality Checks in ZYN Pouch Formation	
	Doc. No. 7.5.1.1.321 SOP C	**Page** 1 of 10
	Date: 11/11/19	**Rev. No.** 4
Approved By:		

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

SWEDISH MATCH

Standard Operating Procedure

Swedish Match **US Division** **Owensboro, KY**	**Title:** ZYN Packing Defects - Detection and Corrections	
	Doc. No. 7.5.1.1.323 SOP C	**Page** 1 of 14
	Date: 10/3/19	**Rev. No.** (b) [redacted]
Approved By:		

(b) (4)

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(b) (4)

[redacted]

(b) (4)

[redacted]

ZYN Omnibus Flavor Variety Evaluation

(b) (4) [redacted]

Product Name:	ZYN®
First Subject Enrolled:	January 30, 2020
Last Subject Completed:	February 3, 2020
Principal Investigators:	(b) (4), (b) (6) [redacted]
Sponsor:	(b) (6) [redacted] Vice President, Scientific Affairs Swedish Match North America
Sponsor Signatory:	
Version:	*1.0*
Report Date:	September 8, 2020

Confidentiality Statement

This document and the information it contains is confidential and the proprietary property of Swedish Match North America. The information is not to be disclosed or transmitted to any party without the express approval of Swedish Match North America, or its parent and affiliate companies, and any such unauthorized use or disclosure is expressly prohibited.

Background

Swedish Match North America (SMNA) officially began selling ZYN® in 2014. ZYN delivers nicotine derived from tobacco, but the ZYN product itself does not contain tobacco leaves. It comes in a small pouch that contains nicotine flavoring elements, and other ingredients required to ensure shelf stability, etc. SMNA has no current intention of marketing ZYN as a smoking cessation product, but rather as a nicotine-delivery product that requires no spitting, produces no off-putting odors, is smoke-free, and comes in a variety of flavors and nicotine strengths.

Swedish Match is in the process of expanding distribution of some ZYN varieties. Currently eight varieties have national distribution and are broadly available. SMNA is expanding geographic distribution of other ZYN varieties.

National Distribution	Expanded Distribution
Cool Mint	Chill
Peppermint	Fresh
Spearmint	
Wintergreen	
Cinnamon	
Coffee	
Citrus	
Smooth	

Objectives

The objective of this research was to evaluate if the expanded distribution and availability of additional ZYN varieties will increase the likelihood to buy ZYN among non-tobacco users.

Methodology

This question was studied with a concept assessment of ZYN among a representative sample of individuals age 21+ in the US. A quantitative study was conducted among adult consumers in the United States who participate in a weekly omnibus study. This survey covered 1,000 adults aged 18-64 over a one-week period, representative to U.S. Census, with approximately 50% female and 50% male respondents. As an omnibus study, there was a limit of 6 closed ended questions.

Study Population

Among a total of (b) (4) individuals age 18-64, (b) (4) were of legal age (age 21) to use tobacco/nicotine products and continued with the survey.

Table 1. Demographic Profile of Respondents

(b) (4)

[redacted]

(b) (4)

[redacted]

Most respondents ([redacted]) do not currently consume tobacco/nicotine products.

Table 2. Tobacco/Nicotine Consumption

	Total [redacted]	
	Count	Column N %
I have never smoked a cigarette or used other tobacco/nicotine products	[redacted]	41%
I have only tried cigarettes or other tobacco/nicotine products on 1-2 occasions and am not a user now	[redacted]	15%
I was a fairly regular smoker of cigarettes or user of other tobacco/nicotine products and have now quit	[redacted]	16%
I am now a fairly regular smoker of cigarettes or user of other tobacco/nicotine products	[redacted]	19%
I am now an occasional smoker of cigarettes or user of other tobacco/nicotine products	[redacted]	10%

Note: Base sizes are unweighted.

Results

There is little variation in likelihood to buy ZYN across the variety of offerings. Patterns of flavor preference are similar within each cohort and within each age group (Appendix Tables 4-5). Never smokers having the lowest interest in buying ZYN and current smokers have moderate interest, but there is little difference among flavors. Regarding age, older adults 55-64 have the lowest levels of interest in buying ZYN, followed by those age 21-24, again with little difference by flavor.

Table 3. Likelihood to Buy Each Flavor Variety – Summary Among Total Sample

(Based on 0-10 scale; Appendix Figure 1)	**Total** [redacted]	
	Mean	**Std. Deviation**
Cool Mint	2.1	0.319
Peppermint	2.1	0.320
Spearmint	2.1	0.320
Wintergreen	2.1	0.319
Cinnamon	2.0	0.307
Coffee	2.0	0.316
Citrus	2.0	0.316
Smooth	2.0	0.318
Chill	1.9	0.305
Fresh	2.2	0.327

Conclusions

Expansion of available flavor varieties will not increase the consumer likelihood to buy ZYN nicotine pouches.

APPENDIX

Appendix Table 4. Likelihood to Buy Each Flavor Variety, Mean Summary – by tobacco/nicotine usage

	Total	Never used tobacco/nicotine	Tried tobacco/ nicotine, but not now	Was regular, but quit tobacco/ nicotine	Current tobacco/ nicotine user
	(b) (4) [redacted]				
Cool Mint					
Peppermint					
Spearmint					
Wintergreen					
Cinnamon					
Coffee					
Citrus					
Smooth					
Chill					
Fresh					

Appendix Table 5. Likelihood to Buy Each Flavor Variety, Mean Summary – by age

	(b) (4) [redacted]
Cool Mint	
Peppermint	
Spearmint	
Wintergreen	
Cinnamon	
Coffee	
Citrus	
Smooth	
Chill	
Fresh	

Appendix Figure 1. Likelihood to Buy Question

How likely are you to buy each **variety** of ZYN for yourself, if sold in a store where you usually shop? (select only one)

No chance, almost none (1 in 100)	Very slight possibility (1 in 10)	Slight possibility (2 in 10)	Some possibility (3 in 10)	Fair possibility (4 in 10)	Fairly good possibility (5 in 10)	Good possibility (6 in 10)	Probably (7 in 10)	Very probable (8 in 10)	Almost sure (9 in 10)	Certain, practically certain (99+ in 100)
0	1	2	3	4	5	6	7	8	9	10

CALIFORNIA TOBACCO FACTS AND FIGURES 2019

California Department of Public Health
California Tobacco Control Program

Inquiries may be directed to:

Xueying Zhang, MD, MPH, MS
Chief, Surveillance Unit
California Department of Public Health
CDIC/Tobacco Control Program
P.O. Box 997377, MS 7206
Sacramento, CA 95899-7377
CTCPEvaluation@cdph.ca.gov

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Suggested citation: Vuong TD, Zhang X, Roeseler A. California Tobacco Facts and Figures 2019. Sacramento, CA: California Department of Public Health; May 2019.

Any analyses, interpretations, or conclusions reached from the data are credited to the authors and not the data provider. Several data sources are used in this document. Each data source is based on a different survey or surveillance tool, and therefore readers may see slightly different rates throughout this report. However, the rate differences are not statistically significant and represent the most accurate and complete picture of California to the best of our knowledge.

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INTRODUCTION

The California Department of Public Health (CDPH), California Tobacco Control Program (CTCP) was established in 1989 after California voters passed the *Tobacco Tax and Health Protection Act of 1988* (Proposition 99). Since then, California voters renewed their support in the fight against tobacco use by passing the *California Healthcare, Research and Prevention Tobacco Tax Act of 2016* (Proposition 56).

With a projected $2.1 billion in California tobacco tax revenue to be collected in fiscal year (FY) 2018-19,[1] CDPH/CTCP was appropriated $37.7 million from Proposition 99 and $129.5 million from Proposition 56 by the Legislature and the Governor for health education for fiscal year 2018-19 (Figure 1).

Figure 1. Allocation of health education funding to the California Department of Public Health, FY 2018-19

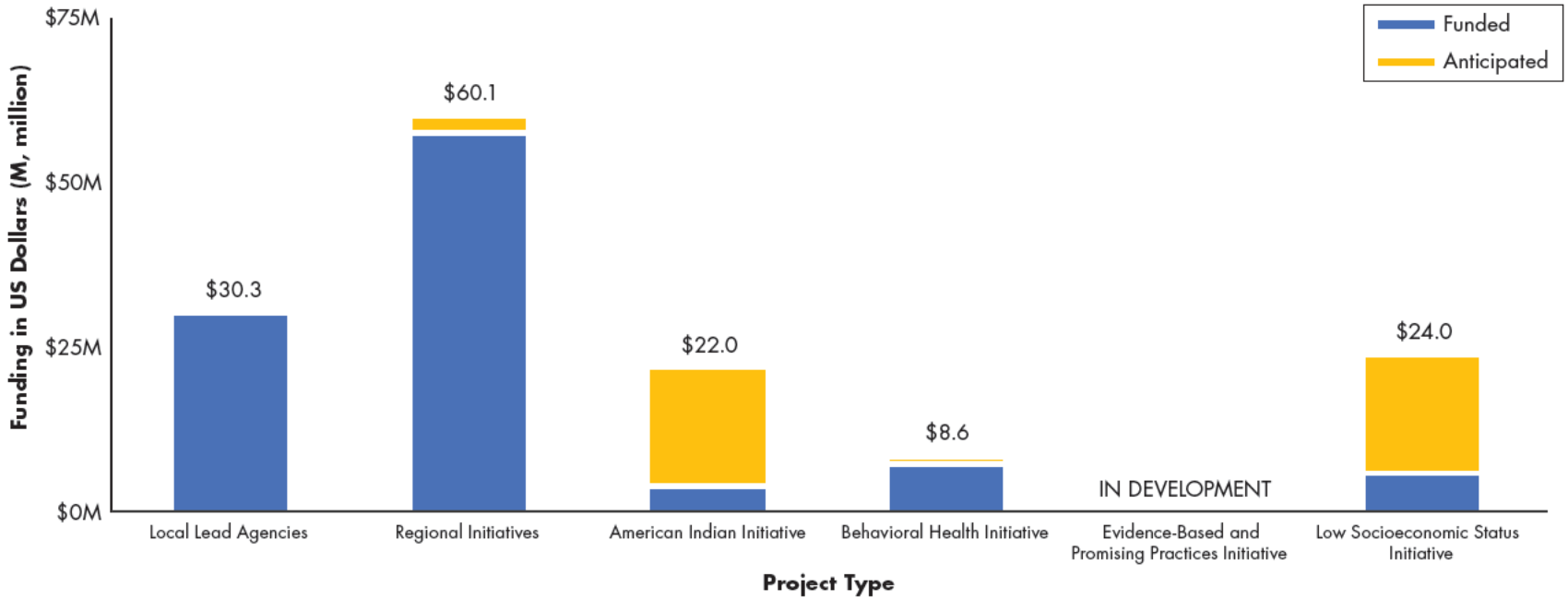
Source: California Department of Public Health, California Tobacco Control Branch; Sacramento, CA: California Department of Public Health; August 2018.

CDPH/CTCP receives guidance from the Tobacco Education and Research Oversight Committee (TEROC), a legislatively-mandated advisory committee charged with overseeing Proposition 99 and Proposition 56 revenues for tobacco control, tobacco use prevention, and tobacco-related research. TEROC established three goals for California's tobacco control efforts:

(1) Reduce all tobacco use to no more than 10 percent in adults and 8 percent in high-school age youth by December 2020;
(2) Accelerate the reduction in tobacco use rates and eliminate tobacco-related disparities among priority population; and
(3) Eliminate the structural, political, and social determinants that sustain the tobacco epidemic in California.[2]

To achieve these goals, CDPH/CTCP seeks to create a climate in which tobacco becomes less desirable, less acceptable, and less accessible. In 2017, CDPH/CTCP launched an initiative to accelerate declines in tobacco-related disparities through extensive engagement of priority population groups in tobacco control efforts. To date, CDPH/CTCP has funded over $100 million in grants and contracts towards this initiative, which includes a minimum 15 percent of the funds allocated to local health departments for comprehensive tobacco control efforts (Figure 2).[3]

Figure 2. Total project funding for the Initiative to Reduce Tobacco-Related Disparities, FY 2017-18 to FY 2020-21



Note: Project funding is as of April 12, 2019 and may change if the Budget Act of the current year and/or any subsequent years covered by each individual grants or contracts agreement does not appropriate sufficient funding for the program. Source: California Department of Public Health, California Tobacco Control Program; Sacramento, CA: California Department of Public Health; March 2019.

This publication serves as a quick reference and snapshot of the current state of tobacco control in California. With the changing landscape of tobacco use in California, a tremendous amount of work remains to be done in order to achieve TEROC's goals of reducing adult tobacco use to no more than 10 percent and teen use to 8 percent by 2020.

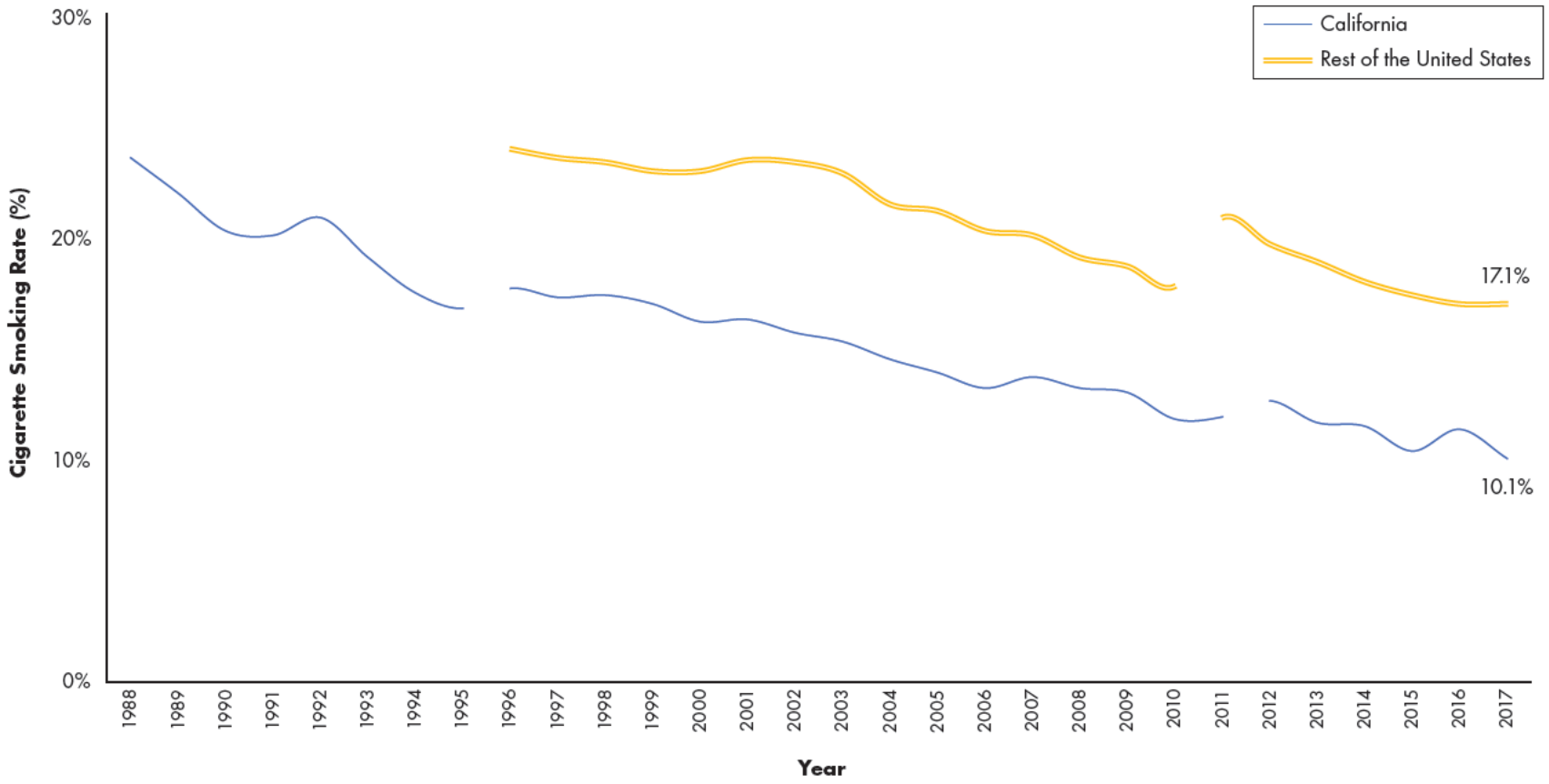
April Roeseler, Tobacco Control Branch Chief
California Department of Public Health

ADULT TOBACCO USE

ADULT CIGARETTE USE

Fewer adults are smoking cigarettes than ever before.[4,5] The adult cigarette smoking rate in California declined by 57.4 percent between 1988 and 2017 (Figure 3),[4] with a current rate of 10.1 percent or about 2.8 million adults.

Figure 3. Cigarette smoking rate among California adults, 1988 to 2017

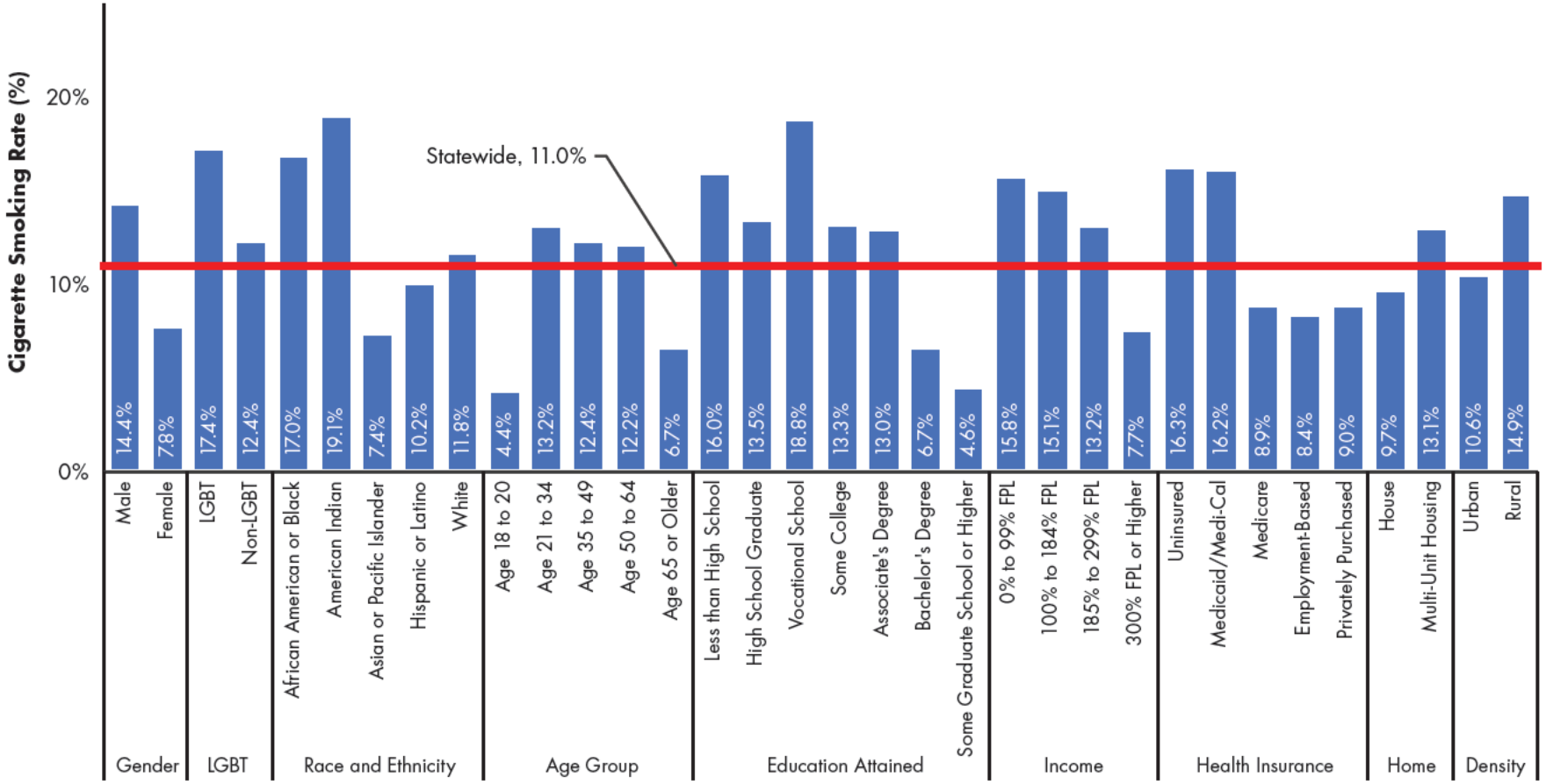


Note: Restricted to respondents aged 18 or older. Cigarette use is based on self-reported current use. A break in the trend line is shown for California data between 1995 and 1996 and between 2011 and 2012 due to methodological change. A break in the trend line is shown for the Rest of the United States data between 2010 and 2011 due to methodological change. Source: (1) Behavioral Risk Factor Surveillance System, 1988 to 2017. Sacramento, CA: California Department of Public Health; October 2018. (2) Behavioral Risk Factor Surveillance System, 1996 to 2017. Atlanta, GA: Centers for Disease Control and Prevention; October 2018.

ADULT CIGARETTE USE BY DEMOGRAPHICS

Disparities remain for cigarette use among groups defined by gender and sexual orientation, race and ethnicity, age, educational attainment, income, health insurance type, housing type, and community density as depicted in Figure 4.[6]

Figure 4. Cigarette smoking among California adults by demographics, 2016-17

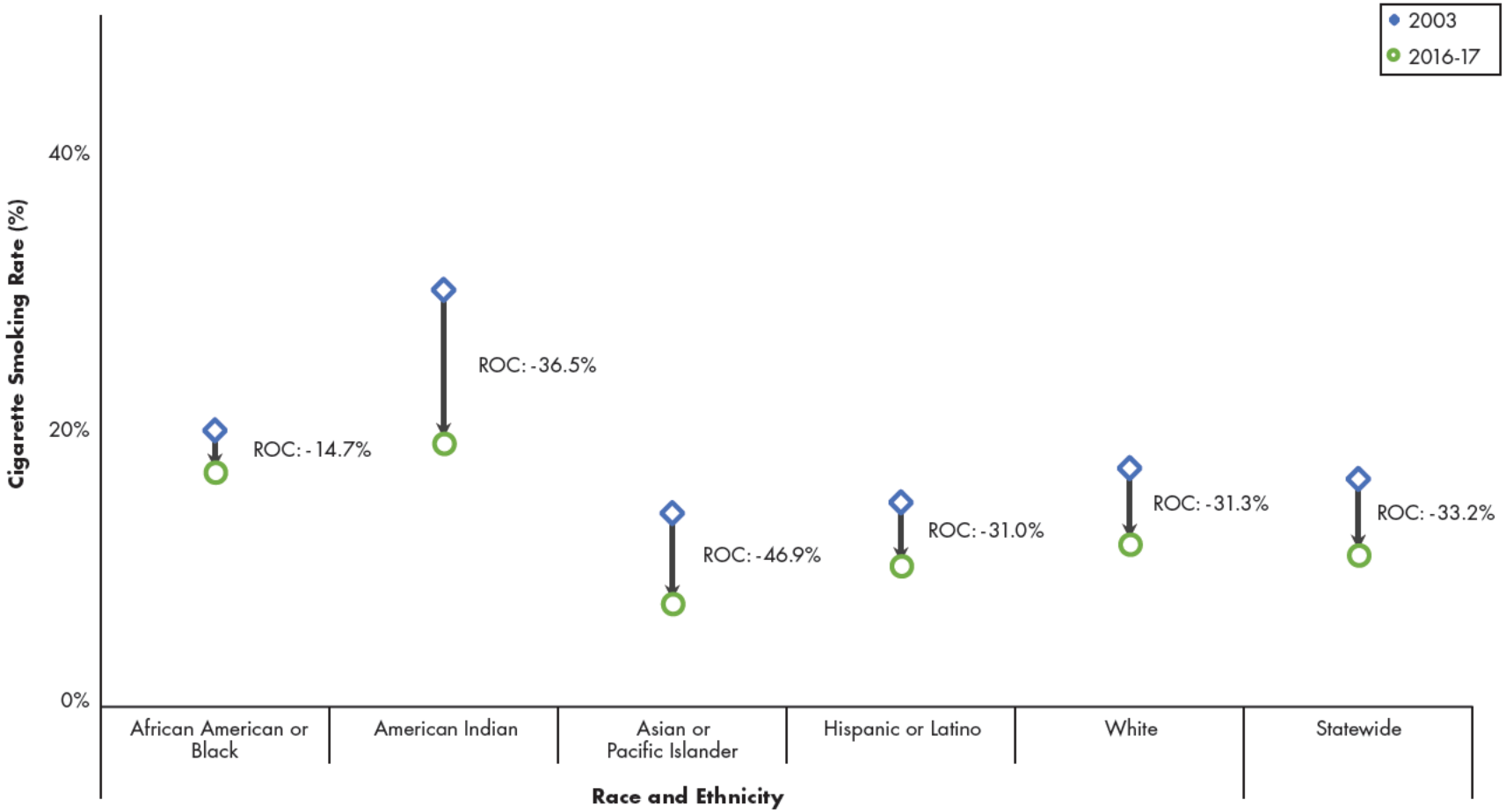


Note: Restricted to respondents aged 18 or older, except for LGBT status which is restricted to respondents aged 18 to 70 (the statewide rate for aged 18 to 70 is 11.8 percent). Cigarette use is based on self-reported current use. The race and ethnicity categories are non-Hispanic or Latino unless otherwise noted. American Indian includes Alaska Native. Asian or Pacific Islander includes Native Hawaiian. LGBT refers to lesbian, gay, bisexual, or transgender. FPL refers to the Federal Poverty Level. Rural is based on definition from the Nielsen Consumer Activation, where the population density is fewer than 1,000 persons per square mile. Source: California Health Interview Survey, 2016-17. Los Angeles, CA: UCLA Center for Health Policy Research; October 2018.

ADULT CIGARETTE USE RATE OF CHANGE BY RACE AND ETHNICITY

African American or Black adults saw a smaller decrease in the reduction of cigarette use over the past fifteen years compared to other groups, reducing their rate by only 14.6 percent from 2003 (Figure 5).[6,7] American Indian adults saw a greater rate of decrease at 20.6 percent, but overall use rate still remains high.

Figure 5. Rate of change (ROC) in cigarette smoking among California adults by race and ethnicity, 2003 to 2016-17

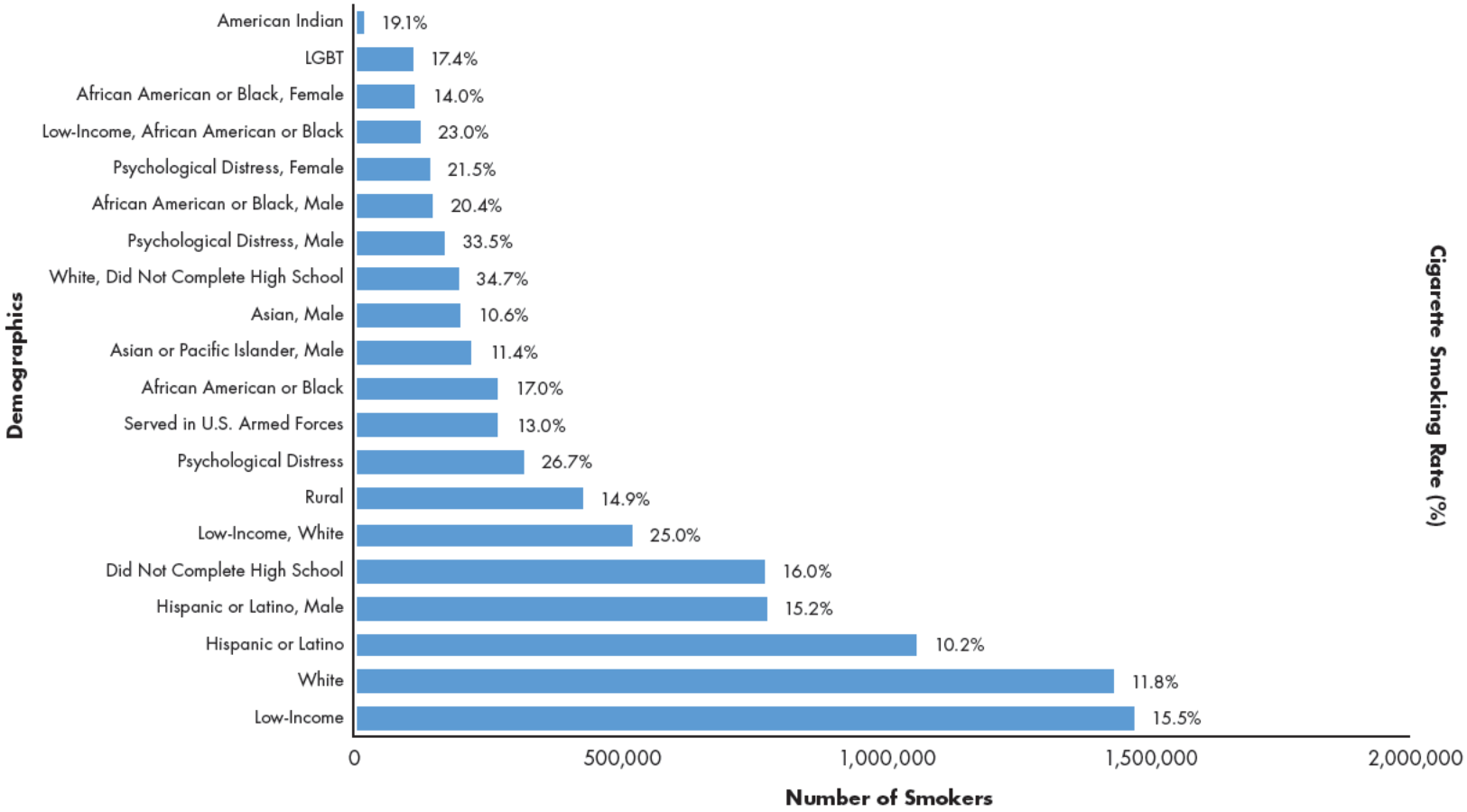


Note: Restricted to respondents aged 18 or older. Cigarette use is based on self-reported current use. The race and ethnicity categories are non-Hispanic or Latino unless otherwise noted. ROC refers to the rate of change between CHIS 2003 and CHIS 2016-17. Source: California Health Interview Survey, 2003 and 2016-17. Los Angeles, CA: UCLA Center for Health Policy Research; October 2018.

NUMBER OF ADULT CIGARETTE SMOKERS BY DEMOGRAPHICS

Cigarette smoking rates vary considerably; however, in considering the burden of smoking by demographic group, it is important to recognize that while the smoking rate may be lower in a group such as Hispanic or Latinos, this group makes up over 1 million of California's adult smoking population (Figure 6).[6]

Figure 6. Number of cigarette smokers among California adults by demographics, 2016-17



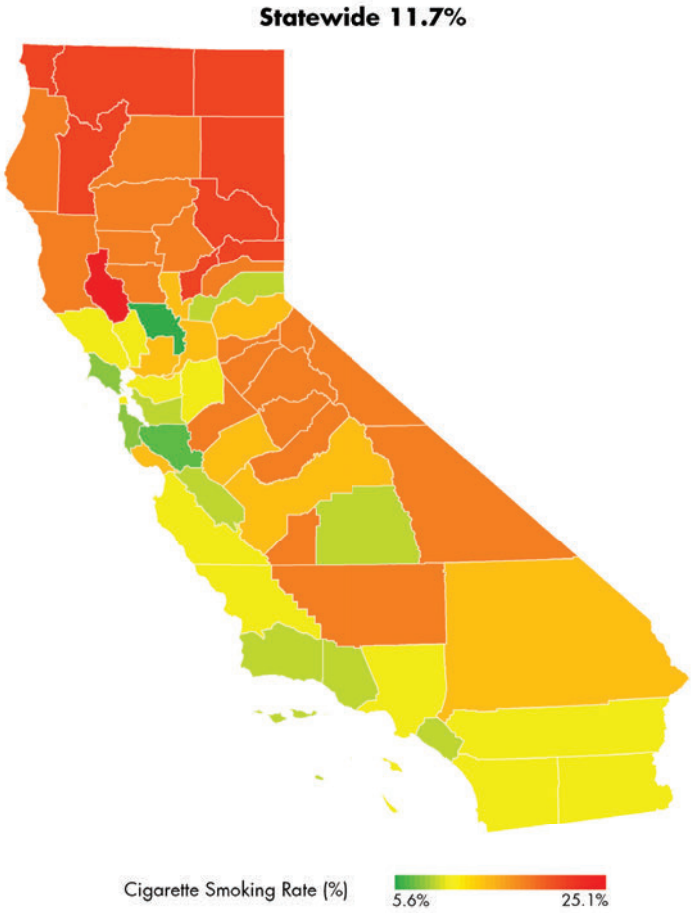
Note: Restricted to respondents aged 18 or older, except for LGBT status which is restricted to respondents aged 18 to 70. Cigarette use is based on self-reported current use. The race and ethnicity categories are non-Hispanic or Latino unless otherwise noted. American Indian includes Alaska Native. Asian or Pacific Islander includes Native Hawaiian. LGBT refers to lesbian, gay, bisexual, or transgender. Low-income is defined as below 185 percent of the Federal Poverty Level. Rural is based on definition from the Nielsen Consumer Activation, where the population density is fewer than 1,000 persons per square mile. Psychological distress is defined as experiencing psychological distress in the past month based on the Kessler 6 scale. Source: California Health Interview Survey, 2016-17. Los Angeles, CA: UCLA Center for Health Policy Research; October 2018.

ADULT CIGARETTE USE BY REGION

There are geographical differences in the cigarette smoking rate in California. Higher rates of smoking are mainly found in rural counties as illustrated in Figure 7.[8]

Figure 7. Cigarette smoking rate among California adults by geographic regions, 2015-17

County	Rate	County	Rate
Alameda	10.0%	Orange	10.5%
Alpine	15.3% (a)	Placer	10.2%
Amador	15.3% (a)	Plumas	20.3% (b)
Butte	17.3%	Riverside	11.8%
Calaveras	15.3% (a)	Sacramento	13.6%
Colusa	19.8% (c)	San Benito	10.6%
Contra Costa	11.8%	San Bernardino	14.4%
Del Norte	20.3% (b)	San Diego	11.1%
El Dorado	14.6%	San Francisco	11.0%
Fresno	14.9%	San Joaquin	11.6%
Glenn	19.8% (c)	San Luis Obispo	11.8%
Humboldt	16.9%	San Mateo	9.3%
Imperial	11.4%	Santa Barbara	9.6% (e)
Inyo	15.3% (a)	Santa Clara	7.8%
Kern	16.1%	Santa Cruz	13.4%
Kings	15.5%	Shasta	19.4%
Lake	25.1%	Sierra	20.3% (b)
Lassen	20.3% (b)	Siskiyou	20.3% (b)
Los Angeles	11.0%	Solano	14.5%
Madera	16.1%	Sonoma	12.3% (d)
Marin	8.7%	Stanislaus	17.1%
Mariposa	15.3% (a)	Sutter	13.9%
Mendocino	15.9%	Tehama	19.8% (c)
Merced	14.7%	Trinity	20.3% (b)
Modoc	20.3% (b)	Tulare	10.4%
Mono	15.3% (a)	Tuolumne	15.3% (a)
Monterey	11.7%	Ventura	9.6% (e)
Napa	12.3% (d)	Yolo	5.6%
Nevada	15.6%	Yuba	22.4%

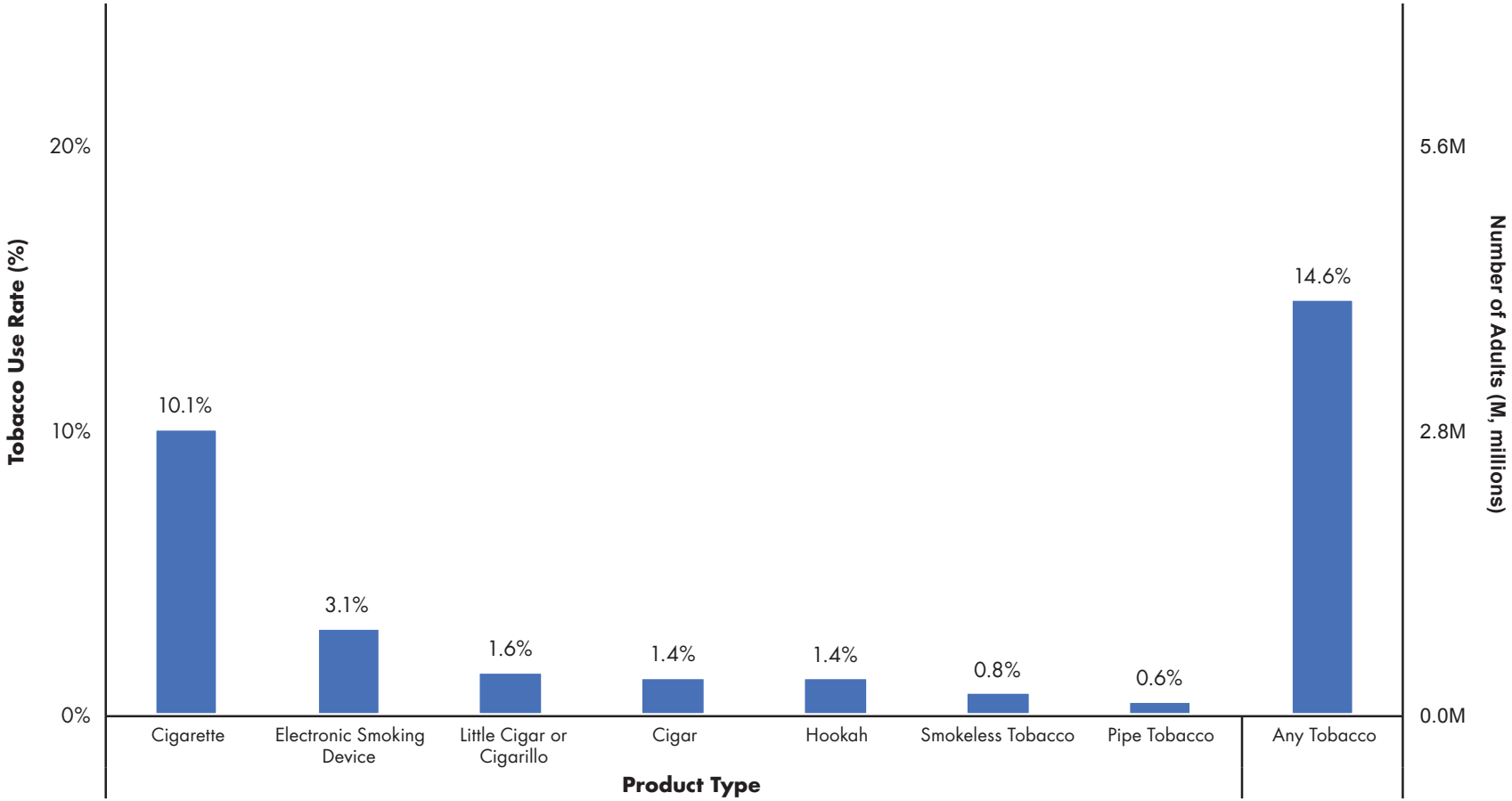


Note: Restricted to respondents aged 18 or older. Cigarette use is based on self-reported current use. Several counties were categorized together to produce stable estimates: (a) Alpine, Amador, Calaveras, Inyo, Mariposa, Mono, Tuolumne; (b) Del Norte, Lassen, Modoc, Plumas, Sierra, Siskiyou, Trinity; (c) Colusa, Glenn, Tehama; (d) Napa, Sonoma; and (e) Santa Barbara, Ventura. Source: California Health Interview Survey, 2015-17. Los Angeles, CA: UCLA Center for Health Policy Research; February 2019.

ADULT TOBACCO USE

Despite the decline in cigarette smoking rate, approximately four million adults in California currently use or had used a tobacco product in the past 30 days (Figure 8).[9] The number of adult tobacco users in California exceeds the population in 23 states.[10]

Figure 8. Tobacco use rate among California adults by product type, 2017

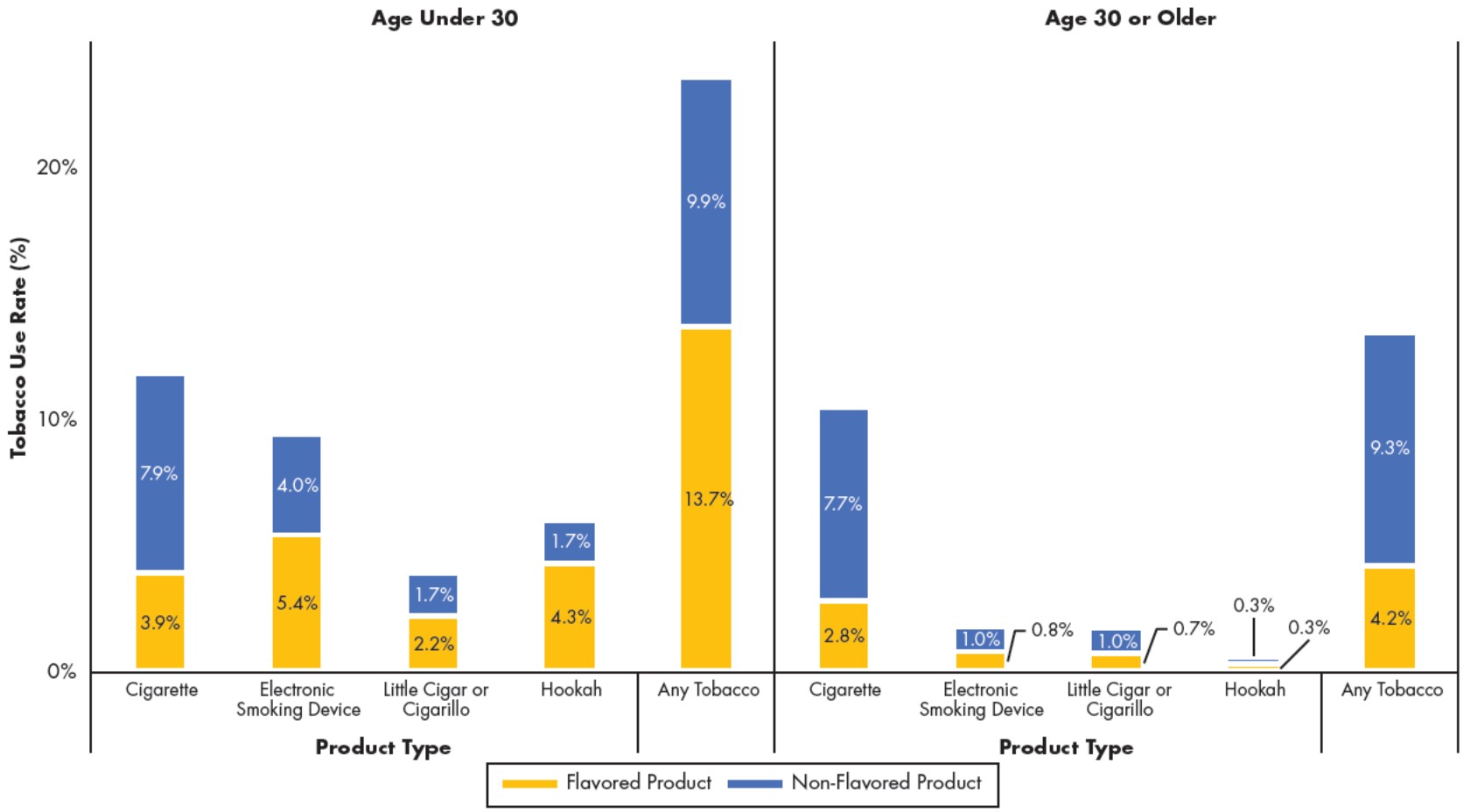


Note: Restricted to respondents aged 18 or older. Cigarette and electronic smoking device use are based on self-reported current use. Cigar, hookah, little cigar or cigarillo, pipe tobacco, or smokeless tobacco use are based on self-reported past 30-day use. Any tobacco use is based on current use of cigarette or electronic smoking device or past 30-day use of cigar, hookah, little cigar or cigarillo, hookah, pipe tobacco, or smokeless tobacco. Source: Behavioral Risk Factor Surveillance System, 2017. Sacramento, CA: California Department of Public Health; October 2018.

YOUNG ADULT TOBACCO USE

Young adults (under age 30) in California use electronic smoking devices (9.4 percent) and hookah (6.0 percent) at a higher rate compared to older adults (Figure 9).[11] Furthermore, of young adult tobacco users, 57.7 percent use a flavored tobacco product.

Figure 9. Tobacco use rate among California by age group and product type, 2016-17



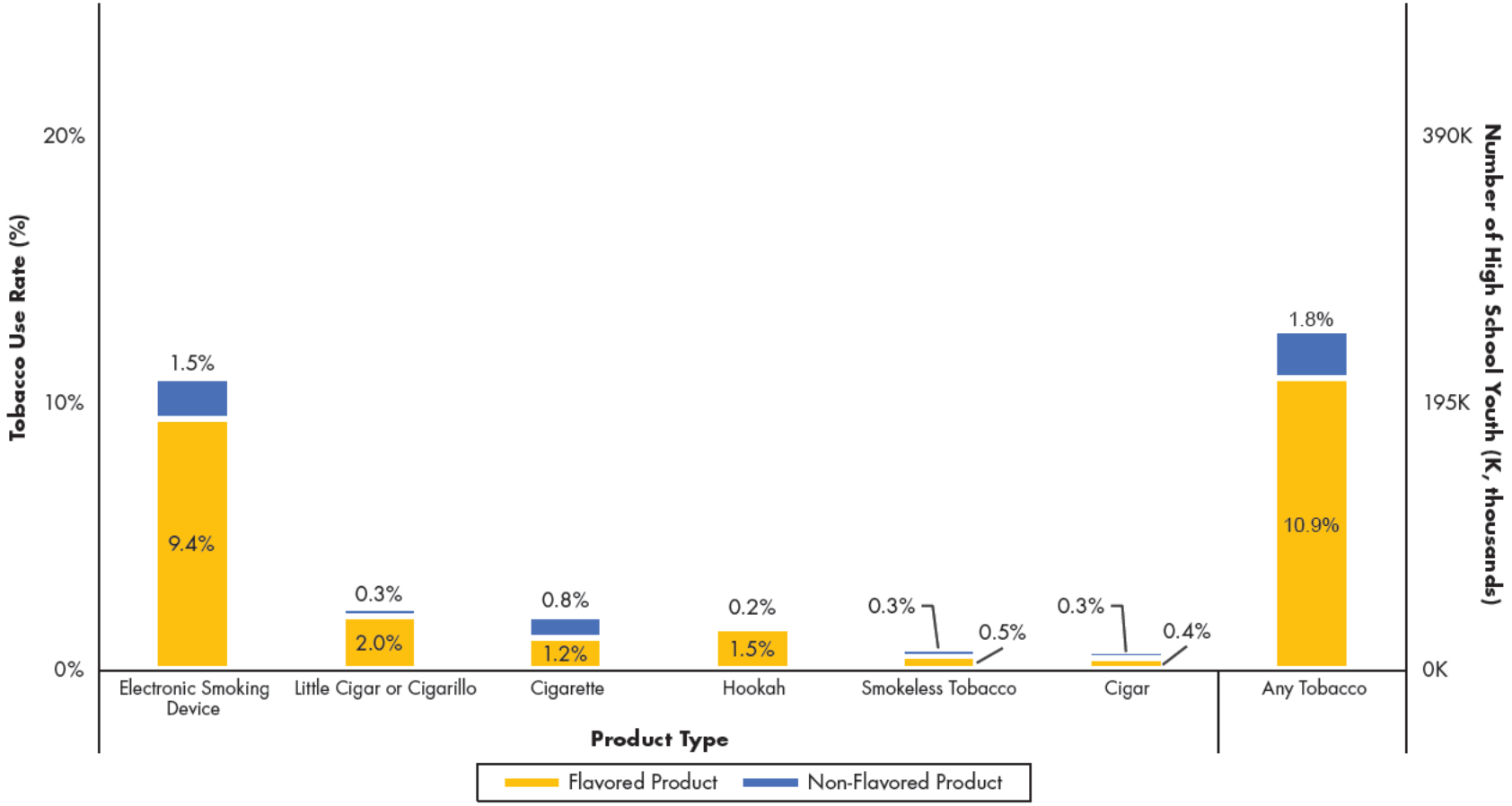
Note: Cigarette and electronic smoking device use are based on self-reported current use. Cigar (not shown), hookah, little cigar or cigarillo, and smokeless tobacco (not shown) use are based on self-reported past 30-day use. Any tobacco use is based on current use of cigarette or electronic smoking device or past 30-day use of cigar, hookah, little cigar or cigarillo, hookah, or smokeless tobacco. Source: Behavioral Risk Factor Surveillance System, 2016-17. Sacramento, CA: California Department of Public Health; October 2018.

YOUTH TOBACCO USE

YOUTH FLAVORED TOBACCO USE

One in eight California high school students currently use any tobacco product,[12] with the most used product among all students being electronic smoking devices (10.9 percent). Of those that currently use tobacco, an overwhelming majority use electronic smoking devices (84.3 percent). In addition, 86.4 percent of youth tobacco users reported using flavored tobacco products (Figure 10).

Figure 10. Tobacco use rate among California youth by product type, 2018



Note: Restricted to respondents in high school. Cigar, cigarette, electronic smoking device, hookah, little cigar or cigarillo, and smokeless tobacco use are based on self-reported past 30-day use. Any tobacco use is based on past 30-day use of cigar, cigarette, electronic smoking device, hookah, little cigar or cigarillo, or smokeless tobacco. Source: California Student Tobacco Survey, 2017-18. San Diego, CA: Center for Research and Intervention in Tobacco Control, University of California, San Diego; April 2019.

YOUTH TOBACCO USE BY DEMOGRAPHICS

Disparities in tobacco use exists among California high school students, with higher rates found in LGBTQ, American Indian, and Pacific Islander youth (Figure 11).[12]

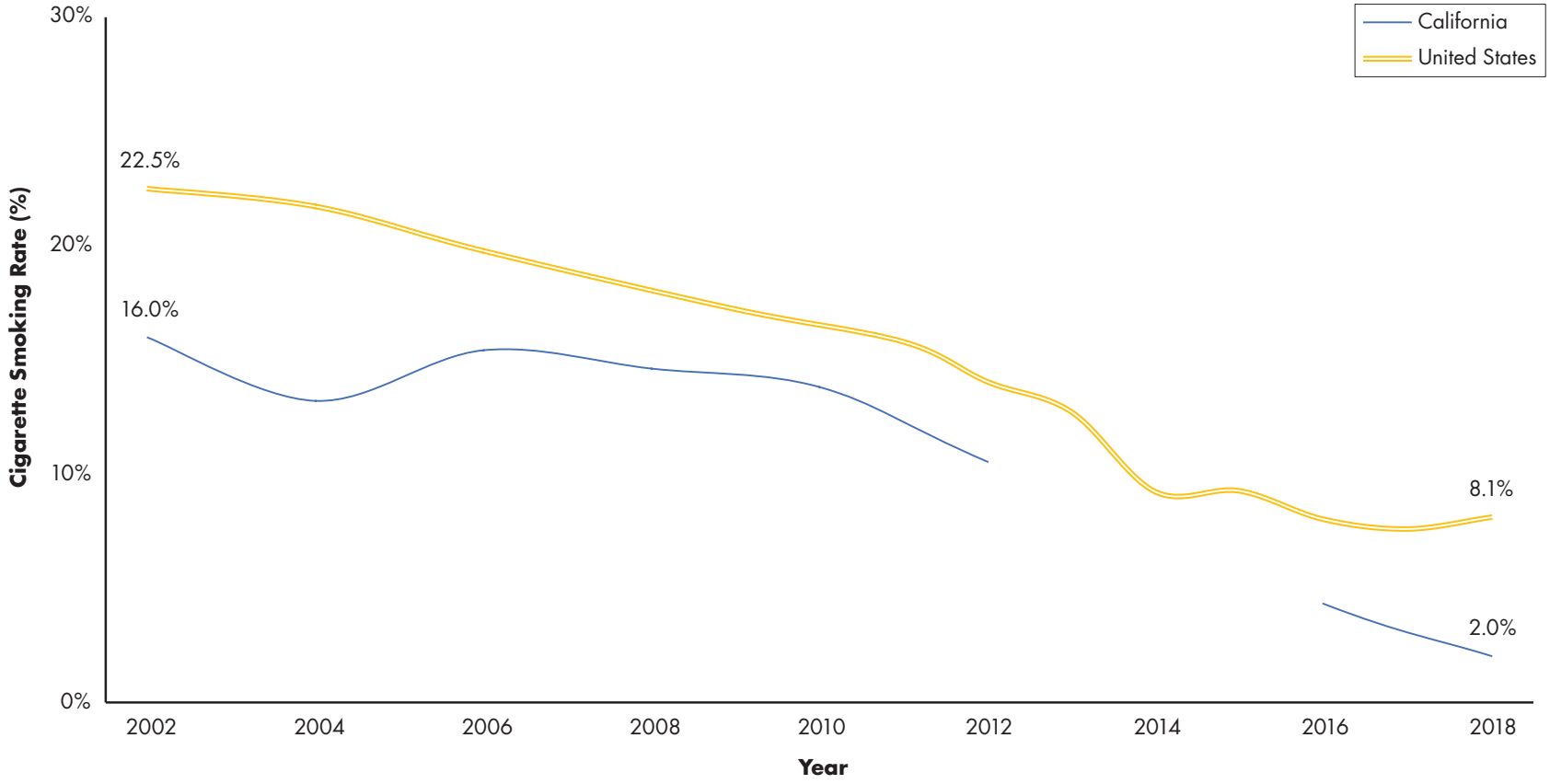
Figure 11. Tobacco use rate among California youth by demographics, 2018

Note: Restricted to respondents in high school. Cigar, cigarette, electronic smoking device, hookah, little cigar or cigarillo, and smokeless tobacco use are based on self-reported past 30-day use. Any tobacco use is based on past 30-day use of cigar, cigarette, electronic smoking device, hookah, little cigar or cigarillo, or smokeless tobacco. The race and ethnicity categories are non-Hispanic or Latino unless otherwise noted. American Indian includes Alaska Native. Pacific Islander includes Native Hawaiian. LGBTQ refers to lesbian, gay, bisexual, transgender, or queer. Caution should be utilized when comparing previous years of the California Student Tobacco Survey due to changes to the race/ethnicity response option. Source: California Student Tobacco Survey, 2017-18. San Diego, CA: Center for Research and Intervention in Tobacco Control, University of California, San Diego; April 2019.

YOUTH CIGARETTE USE

Since 2000, youth cigarette smoking rate in both California and the United States decreased considerably (Figure 12).[13,14] California reported its lowest high school cigarette smoking rate in 2018 at 2.0 percent.[12]

Figure 12. Cigarette smoking rate among California youths, 2002 to 2018



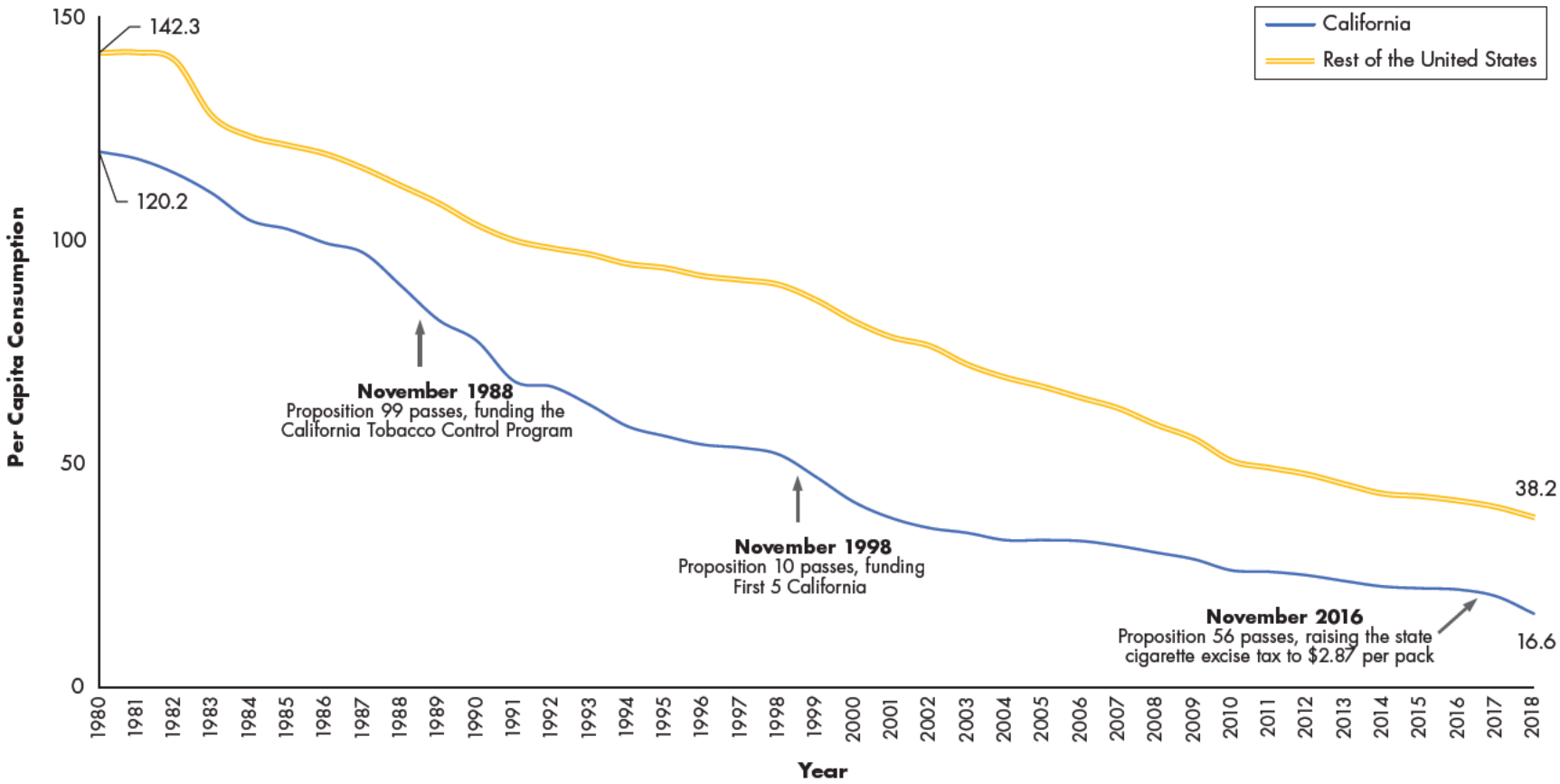
Note: Restricted to respondents in high school. Cigarette use is based on self-reported past 30-day use. A break in the trend line is shown for California data between 2012 and 2016 due to methodological change. Source: (1) California Student Tobacco Survey, 2001-02 to 2011-12. Sacramento, CA: California Department of Public Health; 2013. (2) California Student Tobacco Survey, 2015-16 to 2017-18. San Diego, CA: Center for Research and Intervention in Tobacco Control, University of California, San Diego; April 2019. (3) National Youth Tobacco Survey, 2002 to 2018. Atlanta, GA: U.S. Department of Health and Human Services; February 2019.

TOBACCO CONSUMPTION AND DISTRIBUTION

CIGARETTE CONSUMPTION PER CAPITA

Per capita consumption of cigarettes has declined steadily since the 1980s (Figure 13),[15] with the greatest rate of decline in California occurring in those years subsequent to increases in the cigarette excise tax. The current per capita consumption in California is 56.5 percent lower than the rest of the United States at 16.6 packs in 2018.[15]

Figure 13. Per capita cigarette consumption for California and Rest of the United States, 1980 to 2018

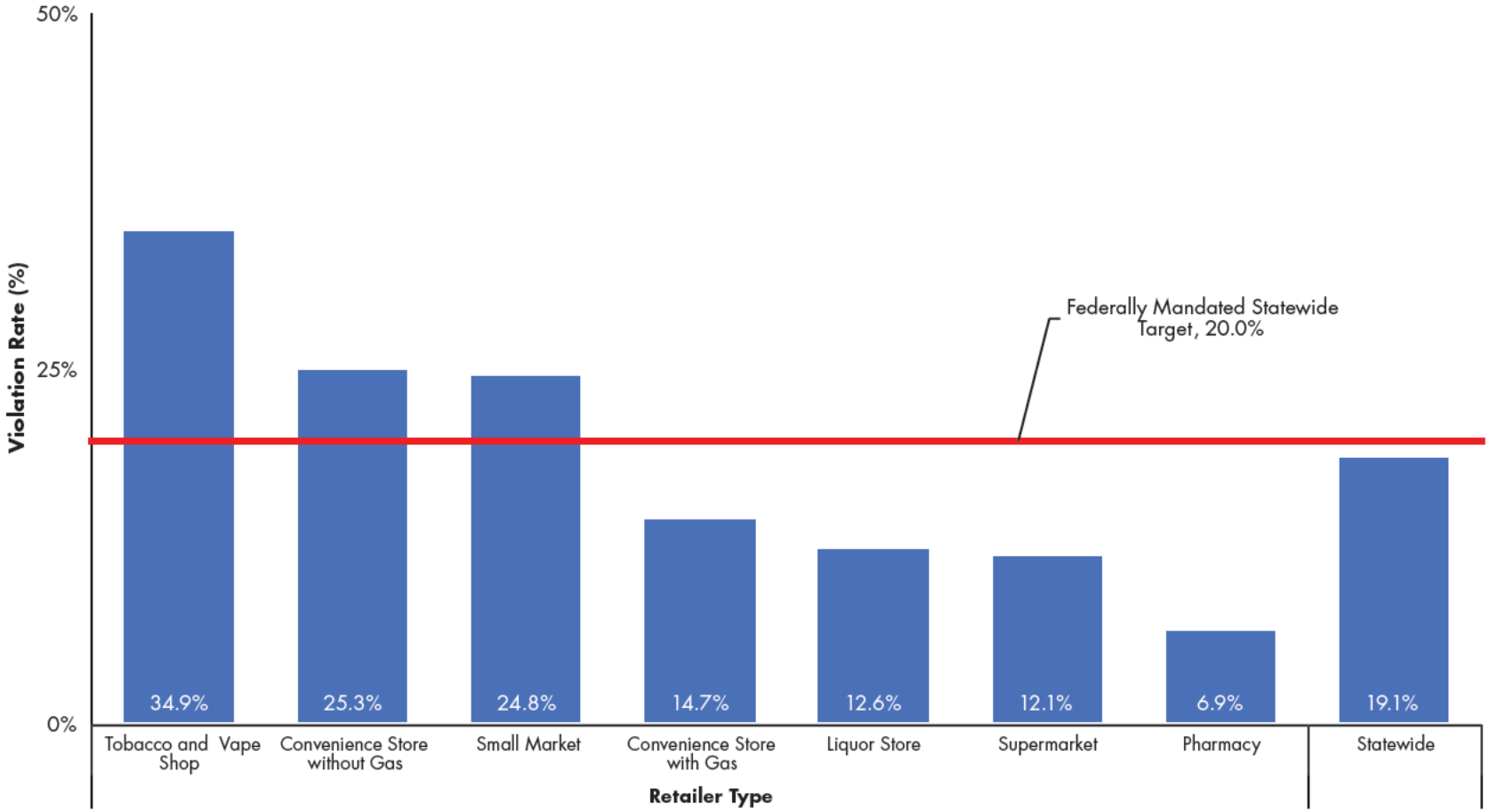


Note: Cigarette consumption is based on tax-paid cigarette sales. Source: Orzechowski and Walker. The Tax Burden on Tobacco: Historical Compilation, Volume 53, 2018. Arlington, VA: Orzechowski and Walker; 2019.

UNDERAGE TOBACCO SALES

In 2016, California raised the minimum legal sales age for tobacco products to 21. Tobacco and vape shops have the lowest compliance with this law,[16] with one out of three tobacco and vape shops selling to underage minors (Figure 14).

Figure 14. Underage sales rate to young adults among licensed tobacco retailers in California by retailer type, 2018



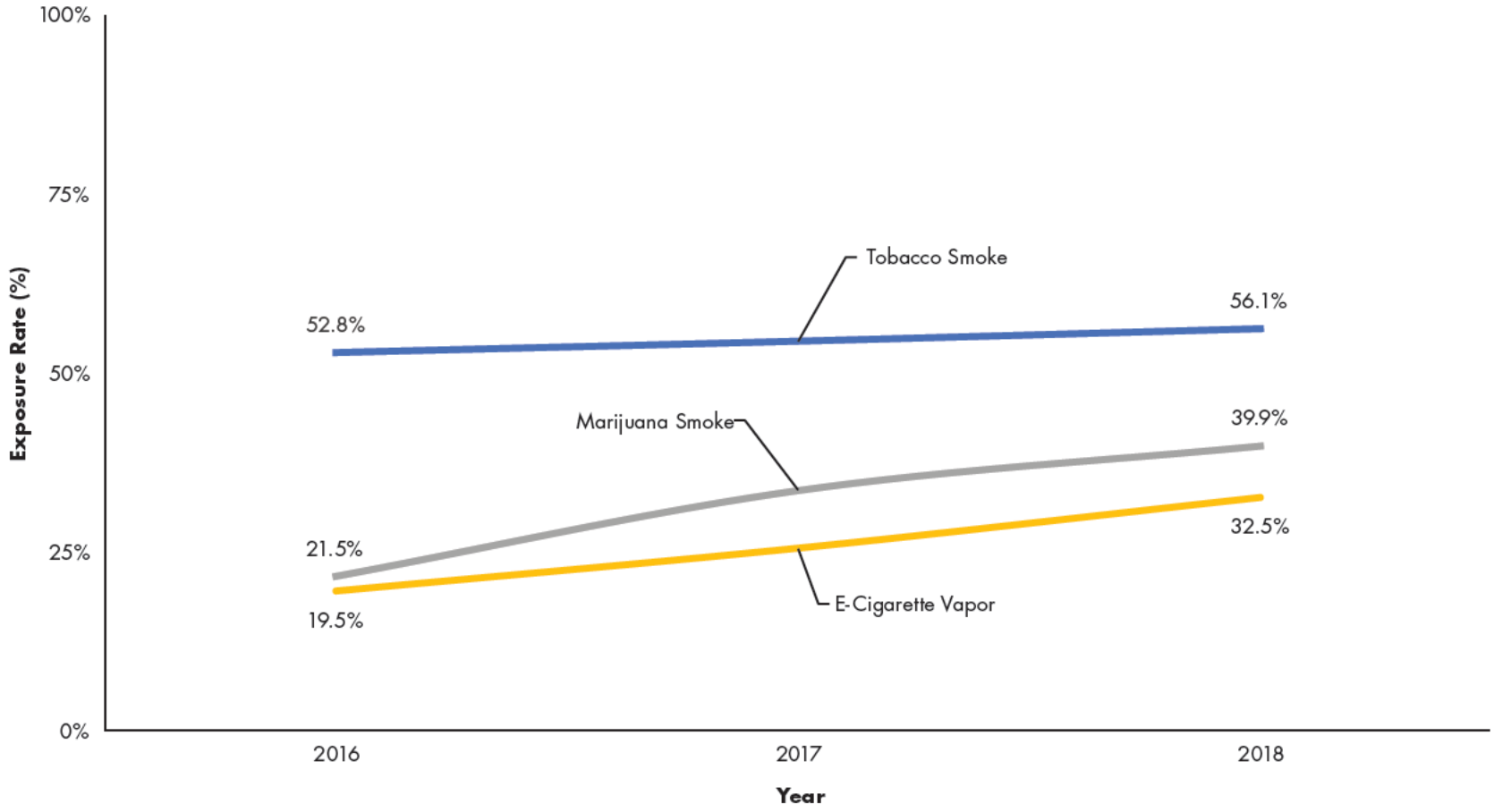
Note: Decoys age 18 and 19 attempted to purchase conventional tobacco (e.g. cigarette, little cigar or cigarillo) and electronic smoking devices or vaping products (e.g. e-liquid, e-cigarette). Source: Young Adult Tobacco Purchase Survey, 2018. Sacramento, CA: California Department of Public Health; October 2018.

SECONDHAND EXPOSURE

ADULT SECONDHAND EXPOSURE

California has a comprehensive smoke-free law;[17] nevertheless, over the past three years, the rate of Californians reporting exposure to tobacco smoke, e-cigarette vapor, and marijuana smoke increased (Figure 15).[18]

Figure 15. Secondhand exposure among California adults age 18 to 64, 2016 to 2018

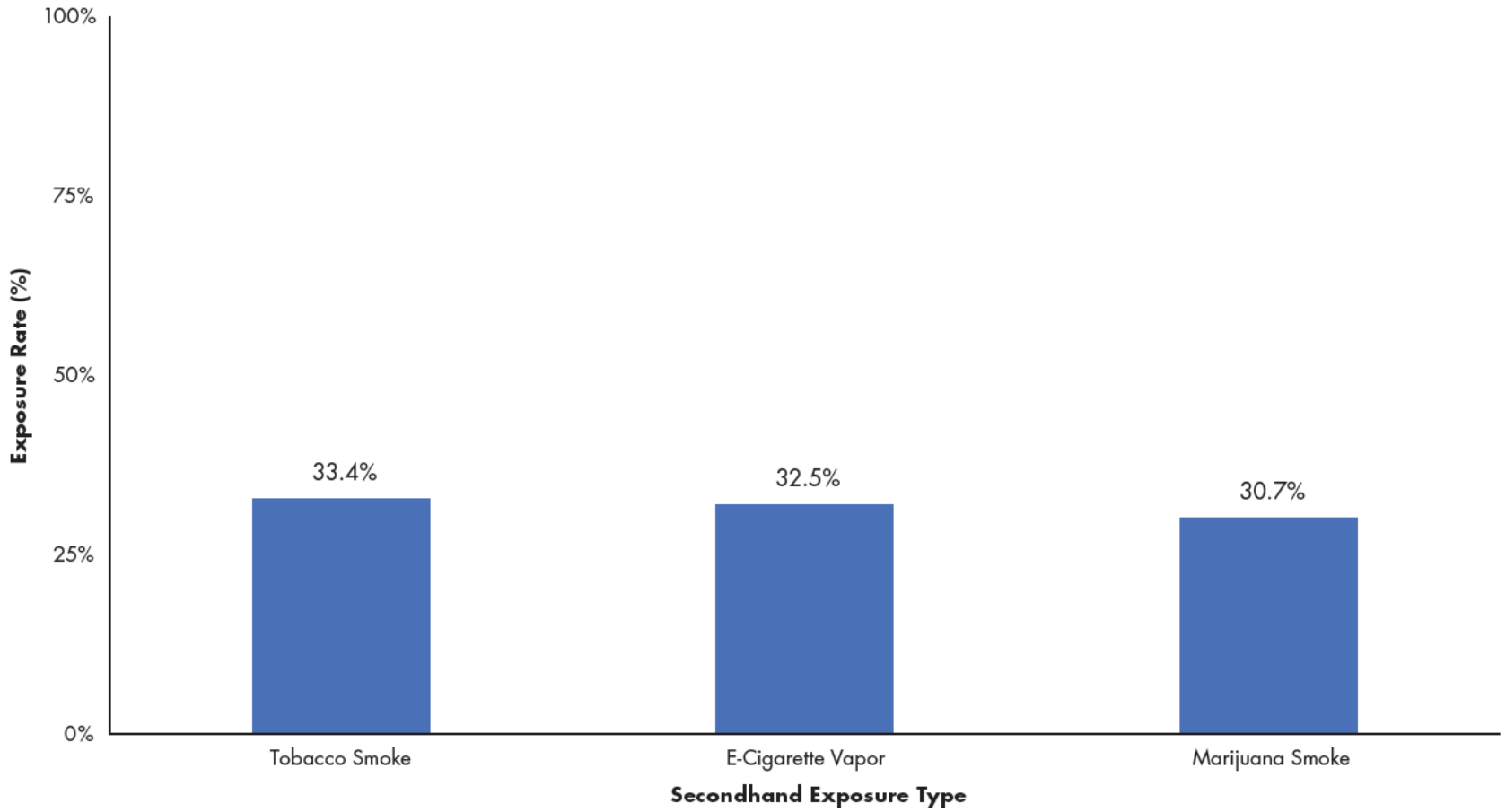


Note: Secondhand tobacco smoke, secondhand e-cigarette vapor, and secondhand marijuana smoke is based on self-reported past 2-weeks exposure in California. Source: Online California Adult Tobacco Survey, 2016 to 2018. Sacramento, CA: California Department of Public Health; November 2018.

YOUTH SECONDHAND EXPOSURE

Secondhand exposure remains a concern in youth, with roughly 30 percent of high school students reporting exposure to tobacco smoke, e-cigarette vapor, or marijuana smoke while in a room or in a car (Figure 16).[12]

Figure 16. Secondhand exposure among California youth, 2018



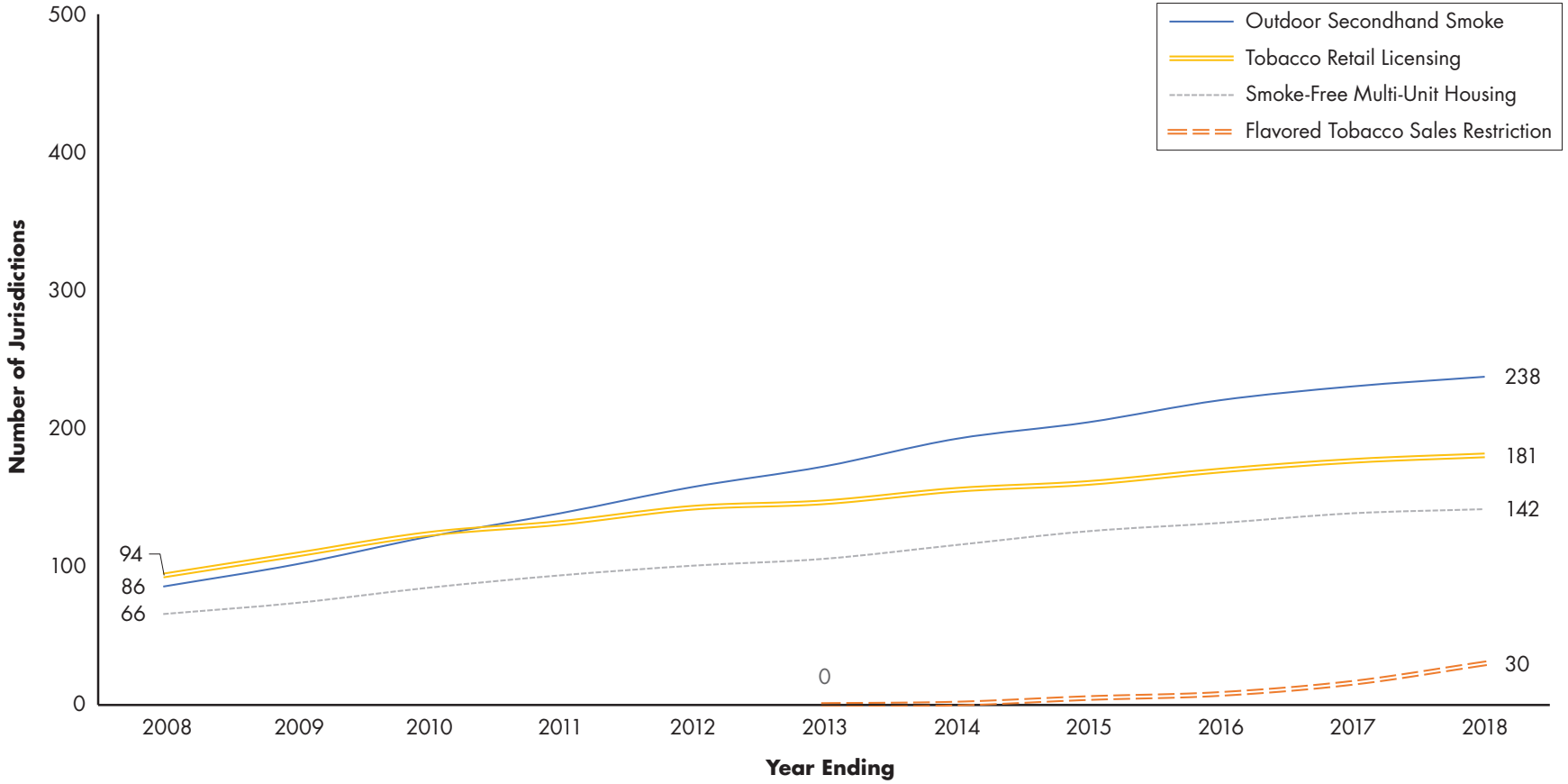
Note: Restricted to respondents in high school. Secondhand tobacco smoke, secondhand e-cigarette vapor, and secondhand marijuana smoke is based on self-reported past 30-day exposure in a room or in a car. Source: California Student Tobacco Survey, 2017-18. San Diego, CA: Center for Research and Intervention in Tobacco Control, University of California, San Diego; April 2019.

TOBACCO CONTROL POLICIES

LOCAL TOBACCO CONTROL POLICIES

Over the past decade, local jurisdictions made great strides in passing tobacco control ordinances, specifically policies related to outdoor secondhand smoke, tobacco retail licensing, smoke-free multi-unit housing, and restricting flavored tobacco sales (Figure 17).[19]

Figure 17. Number of California jurisdictions with local tobacco control policies by policy type, 2008 to 2018

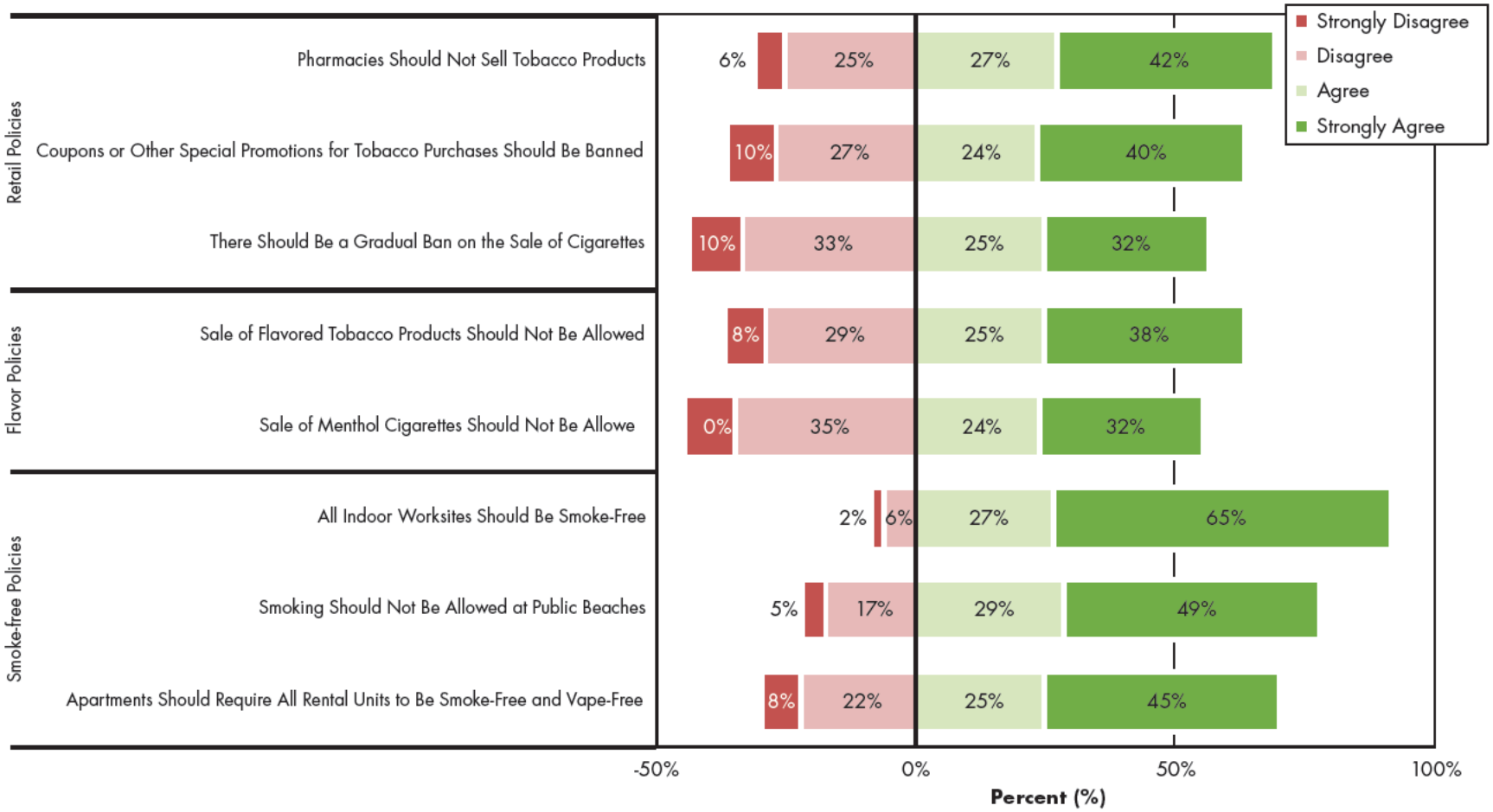


Note: The number of jurisdictions with local policy enacted as of December 31, 2018. Source: Policy Evaluation Tracking Database. Sacramento, CA: California Department of Public Health; January 2019.

PUBLIC SUPPORT FOR TOBACCO CONTROL POLICIES

A majority of California adults agreed with a variety of CDPH/CTCP-policy priorities as detailed in Figure 18,[20] with 57 percent agreeing that there should be a gradual ban on the sale of cigarettes.

Figure 18. Public agreement with tobacco control policies among California adults age 18 to 64, 2018



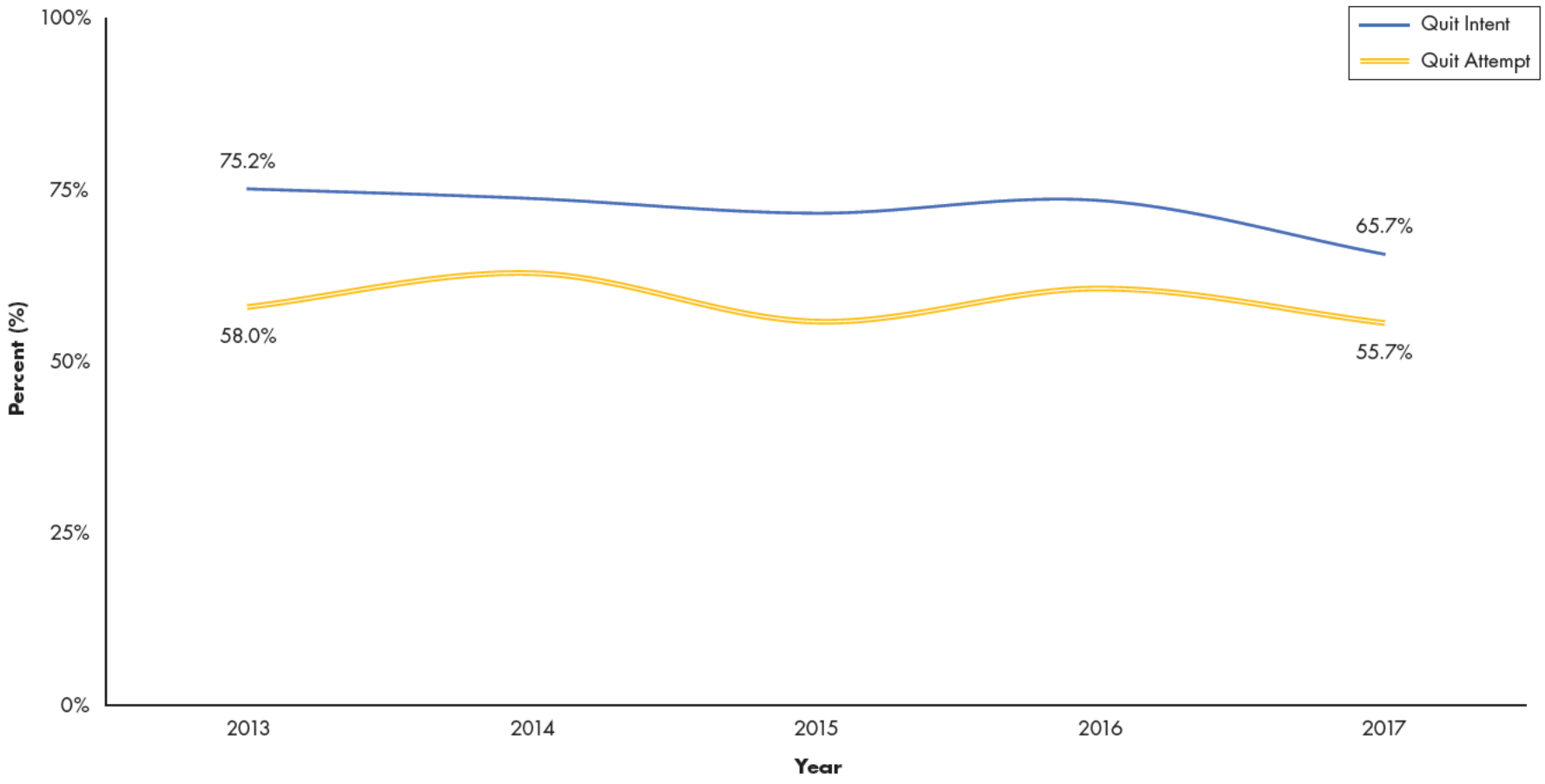
Note: Exact full wording for each survey question can be found on the CDPH/CTCP website. Source: Online California Adult Tobacco Survey, 2018. Sacramento, CA: California Department of Public Health; November 2018.

CESSATION

CESSATION INTENT AND ATTEMPT

The rate of adult cigarette smokers who thought about quitting or made a quit attempt decreased or remained stagnant over the past five years (Figure 19).[21]

Figure 19. Quit intention and attempt among current adult cigarette smokers in California, 2013 to 2017

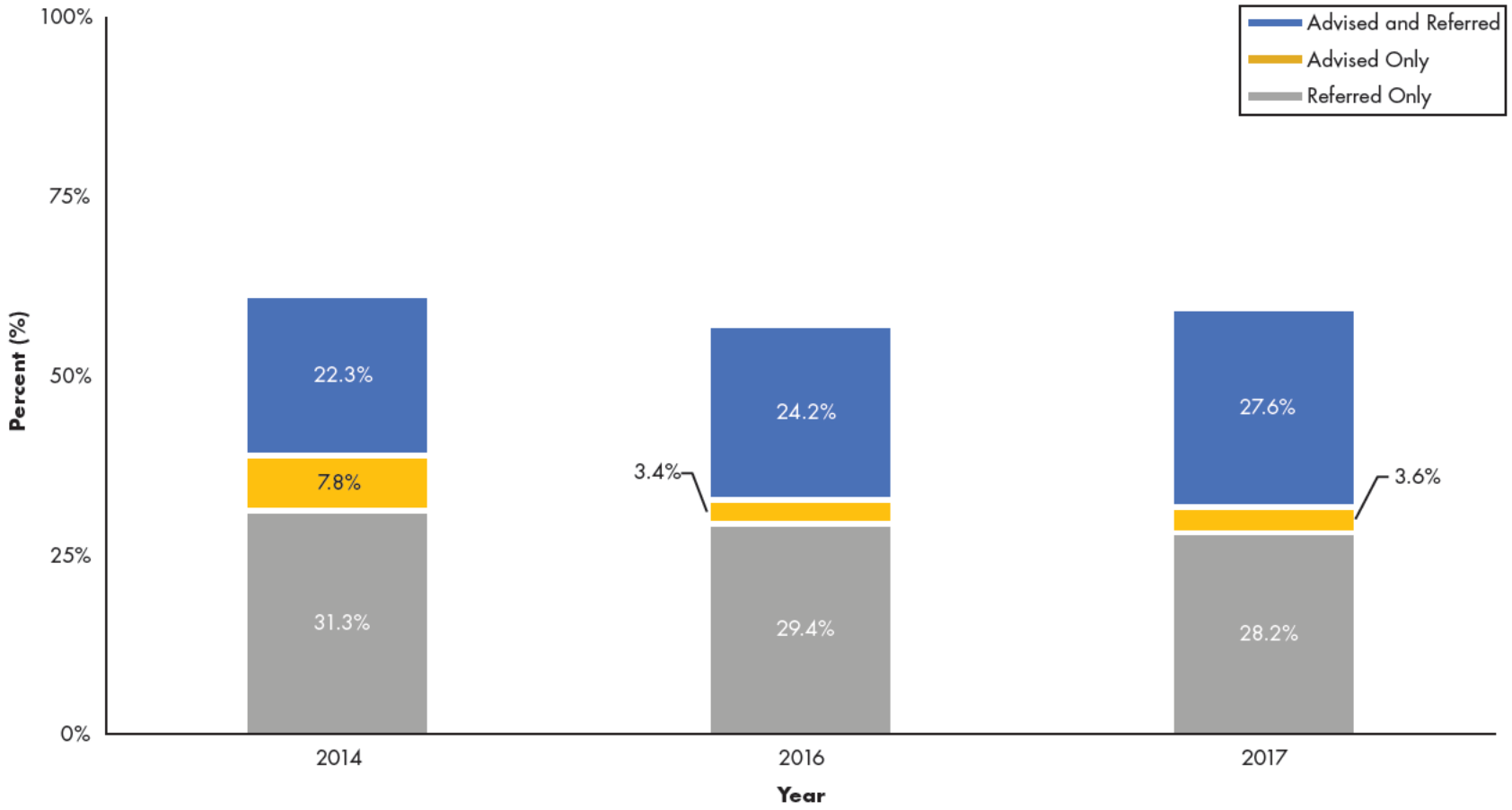


Note: Restricted to respondents aged 18 or older who are current smokers. Thinking about quitting in the next 6 months (quit intent) and quit attempt in the past 12 months are based on self-reported responses. Source: California Health Interview Survey Public Use File, 2013 to 2017. Los Angeles, CA: UCLA Center for Health Policy Research; October 2018.

DOCTOR REFERRALS TO CESSATION PROGRAMS

Doctors should follow evidence-based models to promote cessation among all patients, such as the 5A's (Ask, Advise, Assess, Assist, Arrange), Ask-Advise-Refer (AAR), or Ask-Advise-Connect (AAC).[22-24] About one in four adult smokers report that their doctor advised them to quit smoking and also referred them to a cessation program (Figure 20).[25]

Figure 20. Advised to quit and referred to cessation programs among adult cigarette smokers in California, 2014 to 2017

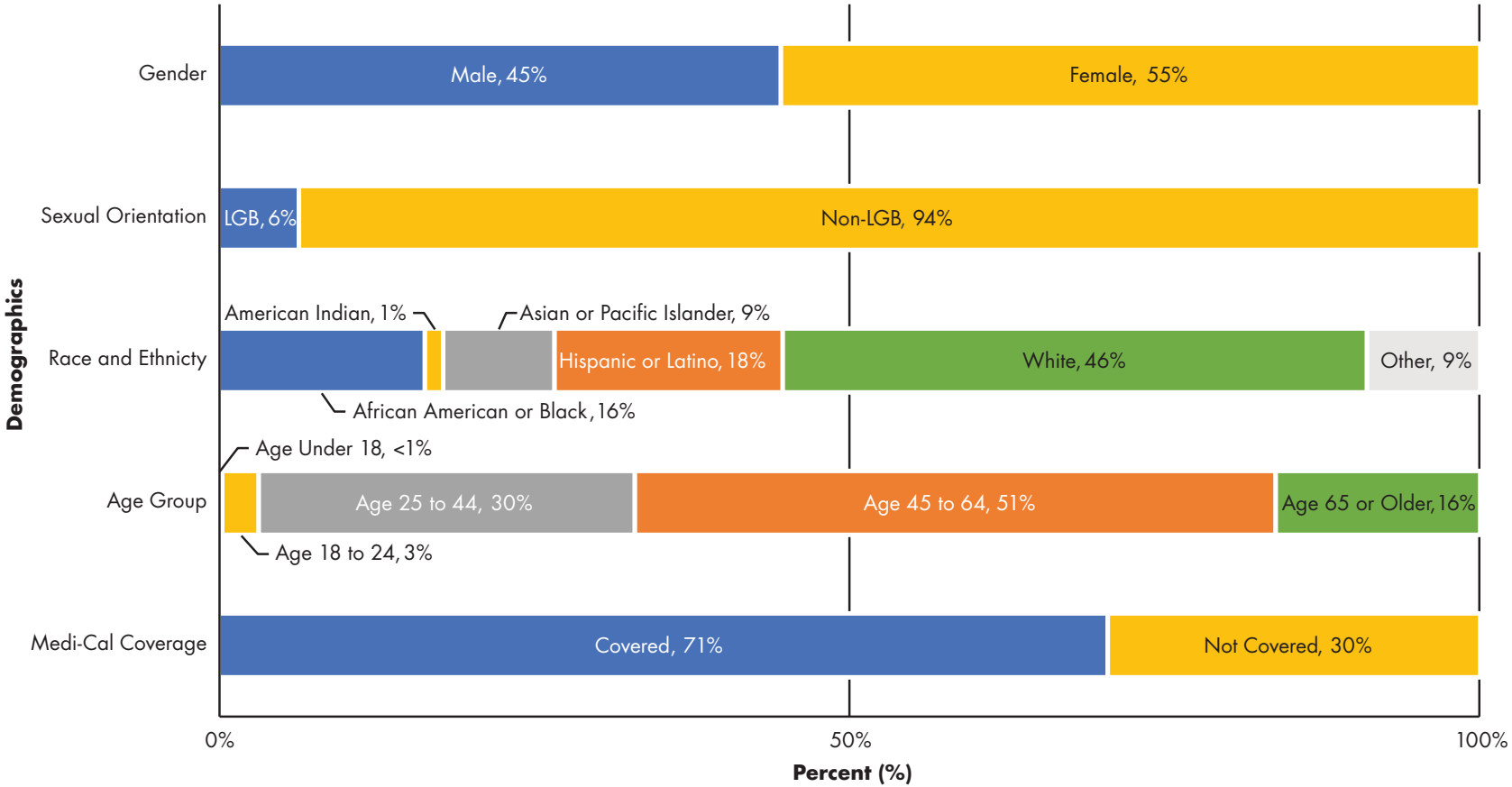


Note: Restricted to respondents aged 18 or older who are current smokers and self-reported seeing a medical doctor in the past 12 months. Survey question was not asked in 2015. Source: California Health Interview Survey Public Use File, 2014 to 2017. Los Angeles, CA: UCLA Center for Health Policy Research; October 2018.

CALIFORNIA SMOKERS' HELPLINE

The California Smokers' Helpline (Helpline) has provided free and confidential cessation services to over 800,000 Californians since its beginning in 1992.[26] Services are provided via telephone, chat, text messaging and mobile apps. A profile of the 20,000 individuals that utilized the Helpline in 2018 is illustrated in Figure 21.[27]

Figure 21. Profile of California Smokers' Helpline callers, 2018

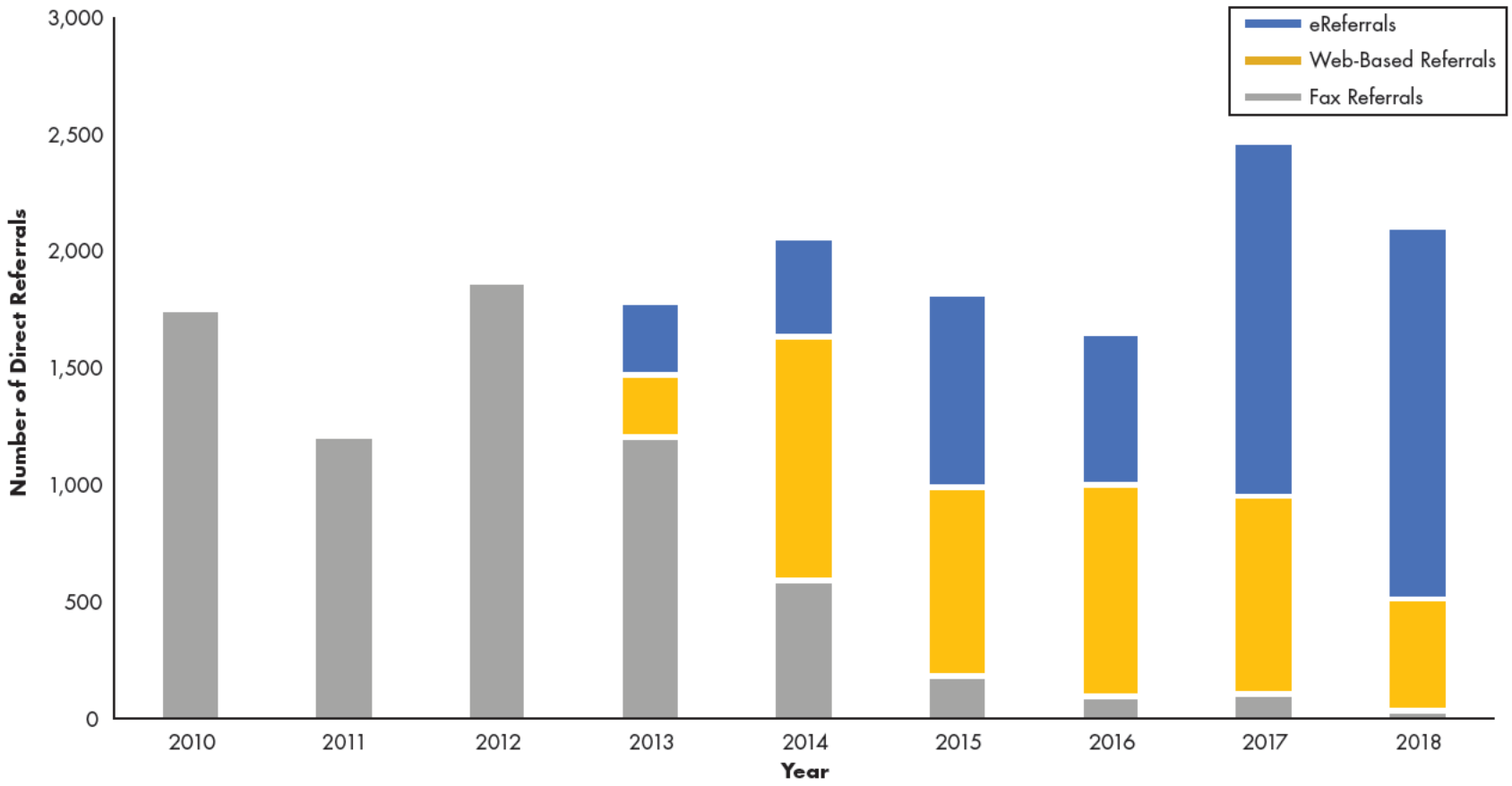


Note: Percentages may not total to 100 percent due to rounding. The race and ethnicity categories are non-Hispanic or Latino unless otherwise noted. American Indian includes Alaska Native. LGB refers to lesbian, gay, or bisexual. Source: Helpline Caller Intake Reports, 2018. San Diego, CA: California Smokers' Helpline, University of California, San Diego; March 2019.

DIRECT REFERRALS TO THE CALIFORNIA SMOKERS' HELPLINE

The Helpline began accepting two-way electronic health record (EHR) referrals (eReferral) in 2013,[28] allowing providers to order referrals and receive patient's progress towards quitting tobacco within the EHR system. As of December 2018, over 5,000 Californians utilized the Helpline after being directly referred through eReferrals (Figure 22).[28,29]

Figure 22. Health care provider direct referrals to the California Smokers' Helpline by referral type, 2010 to 2018



Source: California Smokers' Helpline began accepting electronic health record referrals, or eReferrals, and web-based referral services in 2013. Source: (1) Harms KR, Anderson CM, Cummins SE, Zhu S-H. California Smokers' Helpline: Final Evaluation Report, Objective 2: Promoting Helpline Services. San Diego, CA: California Smokers' Helpline, University of California, San Diego; 2015. (2) California Smokers' Helpline. CG 14-10611 Progress Report to CDPH/CTCP. Sacramento, CA: California Department of Public Health; 2019.

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Flavored e-cigarette use: Characterizing youth, young adult, and adult users

M.B. Harrell [a,*], S.R. Weaver [b], A. Loukas [c], M. Creamer [a], C.N. Marti [c], C.D. Jackson [a], J.W. Heath [d], P. Nayak [d], C.L. Perry [a], T.F. Pechacek [e], M.P. Eriksen [e]

[a] UTHealth School of Public Health in Austin, Michael & Susan Dell Center for Healthy Living, , 1616 Guadalupe, Suite 6.300, Austin, TX 78701, USA
[b] Georgia State University Tobacco Center of Regulatory Science & Division of Epidemiology & Biostatistics, School of Public Health, Georgia State University, 33 Gilmer Street SE, Atlanta, GA 30303, USA
[c] Department of Kinesiology & Health Education, University of Texas at Austin, 2109 San Jacinto Blvd., Stop D3700, Austin, TX 78712-1415, USA
[d] Georgia State University Tobacco Center of Regulatory Science, Urban Life Building, 140 Decatur Street, NE, Atlanta, GA 30303, USA
[e] Georgia State University Tobacco Center of Regulatory Science & Division of Health Management & Policy, Urban Life Building, 140 Decatur Street, NE, Atlanta, GA 30303, USA

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ABSTRACT

The purpose of this study is to investigate how the use of flavored e-cigarettes varies between youth (12–17 years old), young adults (18–29 years old), and older adults (30 + years old). Cross-sectional surveys of school-going youth ($n = 3907$) and young adult college students ($n = 5482$) in Texas, and young adults and older adults ($n = 6051$) nationwide were administered in 2014–2015. Proportions and 95% confidence intervals were used to describe the percentage of e-cigarette use at initiation and in the past 30 days that was flavored, among current e-cigarette users. Chi-square tests were applied to examine differences by combustible tobacco product use and demographic factors. Most e-cigarette users said their first and "usual" e-cigarettes were flavored. At initiation, the majority of Texas school-going youth (98%), Texas young adult college students (95%), and young adults (71.2%) nationwide said their first e-cigarettes were flavored to taste like something other than tobacco, compared to 44.1% of older adults nationwide. Fruit and candy flavors predominated for all groups; and, for youth, flavors were an especially salient reason to use e-cigarettes. Among adults, the use of tobacco flavor at initiation was common among dual users (e-cigarettes + combustible tobacco), while other flavors were more common among former cigarette smokers ($P = 0.03$). Restricting the range of e-cigarette flavors (e.g., eliminating sweet flavors, like fruit and candy) may benefit youth and young adult prevention efforts. However, it is unclear what impact this change would have on adult smoking cessation.

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1. Introduction

An astonishing number of "characterizing flavors" are now widely available for those who use e-cigarettes – by one estimate, over 7500 (Zhu et al., 2014). In addition to tobacco and menthol, e-cigarettes come in sweet flavors, like fruit, candy, and dessert. Enticing flavors like these were banned from conventional cigarettes in 2009 to reduce youth smoking, as they were often used as a starter product (FDA. Family Smoking Prevention and Tobacco Control Act, 2015; US Department of Health Human Services, 2012). Flavors alone are harmful to health (Barrington-Trimis et al., 2014; Hutzler et al., 2014; Grana et al., 2014; Kosmider et al., 2016; Tierney et al., 2015; Behar et al., 2014). Toxic compounds like diacetyl, which has been linked to severe respiratory disease, have been found in 75% of flavored e-cigarettes (Allen et al., 2015; Farsalinos et al., 2014).

Data on the occurrence of flavored e-cigarette use across different age groups are sparse. The prevalence of flavored e-cigarette use among youth current (i.e., past 30 day) e-cigarette users is estimated between 63.3% (Corey et al., 2015) and 85.3%, (Ambrose et al., 2015) according to the 2014 National Youth Tobacco Survey (NYTS) and the 2013–2014 Population Assessment of Tobacco and Health Study (PATH), respectively. Preliminary, unpublished results from 2013 to 2014 PATH suggest the proportion of flavored e-cigarette use among 18–24 year old young adult current users is similar to youth, at 83.0%, while that among adults 25 + years old is lower, at 63.0% (Hyland et al., 2016). Only one published study of young adults' flavored tobacco products use is available, which showed only 17% of 18–34 year old young adult current e-cigarette users used a flavored e-cigarette in 2012, before the sharp increase in e-cigarette use nationwide (Villanti et al., 2013). There are no published studies on adults' flavored e-cigarette use. Until more data on this topic are available, it remains unclear whether preferences for flavored e-cigarettes vary by age group. This evidence will be important to determine whether regulation, like the ban on cigarette flavors, is also needed for e-cigarettes.

* Corresponding author.
E-mail address: Melissa.B.Harrell@uth.tmc.edu (M.B. Harrell).

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Though some adults begin using e-cigarettes as a device to stop smoking conventional cigarettes (Grana & Ling, 2014; McRobbie et al., 2014), other reasons, like curiosity (Schmidt et al., 2014; Biener et al., 2015; Kong et al., 2014; McDonald & Ling, 2015; Surís et al., 2015; Sutfin et al., 2015; Biener & Hargraves, 2014), are more relevant to youth and young adult e-cigarette users. Among these reasons, flavors play a particularly prominent role. In the 2013–2014 PATH survey, 81.5% of youth e-cigarette users said that they used e-cigarettes "because they come in flavors I like" (Ambrose et al., 2015). Data from smaller, qualitative studies of young adults suggest flavors are an attractive aspect of using e-cigarettes, contributing to the novelty of these devices, which are "fun toys" (McDonald & Ling, 2015; Choi et al., 2012). Among adults use e-cigarettes to quit conventional cigarette smoking, tobacco flavor is often preferred at the start, though sweet flavors become more relevant as e-cigarette use continues (Farsalinos et al., 2014; Dawkins et al., 2013).

The impact of flavors on the uptake of e-cigarettes among youth compared to adults is not without controversy. The most influential study to date that drives this debate is that by Shiffman and colleagues (Shiffman et al., 2015). Nonsmoking youth ($n = 216$, 13–17 years old) and adult cigarette smokers with varied histories of e-cigarette use ($n = 432$, 19–80 years old) were asked to rate their preferences for flavors being offered in 2014 by NJOY e-cigarettes. Across all flavors, adult smokers' interest surpassed that of nonsmoking youth. The authors concluded their data do *not* support the hypothesis that flavors in e-cigarettes will entice nonsmoking youth to use them. Concerns about the reliability and validity of this study, funded by NJOY, have been raised (Glantz, 2015). Additional research is needed to elucidate if flavors are disproportionately preferred by young people or adults.

The purpose of this paper is to investigate whether the use of flavored e-cigarettes varies between youth (12–17 years old), young adults (18–29 years old), and adults (30+ years old). We examine the use of flavored e-cigarettes at initiation and whether "usual" e-cigarettes, for current users, are flavored. Differences in flavored e-cigarette use by combustible tobacco product use are considered, as are differences by sex and race/ethnicity. We investigate a variety of flavors: tobacco; menthol or mint; fruit (e.g., cherry, strawberry); candy (e.g., gummy bear) or dessert (e.g., chocolate, vanilla); coffee or alcohol; and spice (e.g., cinnamon); as well as unflavored e-cigarettes, among adults. Finally, we consider the relevance of flavors as a reason to use e-cigarettes.

2. Methods

2.1. Data sources

Data are derived from three separate studies to represent e-cigarette use profiles across three age groups and include studies of youth (12–17 years old), young adults (18–29 years old), and adults (30+ years old). The studies are the (a) Texas Adolescent Tobacco and Marketing Surveillance System (TATAMS); (b) Marketing and Promotions Across Colleges in Texas Project (M-PACT); and (c) the Tobacco Products and Risk Perceptions Survey (TPRPS). The first two studies are characteristic of the 4 largest metropolitan areas in Texas (i.e., Houston, Dallas/Fort Worth, San Antonio, and Austin), while the last study is representative of non-institutionalized adults in the United States. This study was a collaboration across two different Tobacco Centers of Regulatory Science (TCORS) recently established by the Food and Drug Administration and, as such, represents value in cross-institutional collaboration.

2.1.1. TATAMS

The Texas Adolescent Tobacco and Marketing Surveillance System (TATAMS) is a multiple component, rapid response surveillance system administered by the Texas Tobacco Center of Regulatory Science on Youth & Young Adults (Texas TCORS). Data from the Texas Education Agency, Texas Private School Accreditation Commission, and the National Center for Education Statistics were used to generate a sampling frame of all public, private and charter schools with 6th, 8th and 10th graders in 2014–15 in the 5 counties surrounding the 4 largest cities in Texas (Houston, Dallas/Ft. Worth, Austin, San Antonio). A complex multistage probability sample of public schools was drawn using probability proportional to the grades' enrollment, and all private and charter schools were invited to participate. Details about this procedure are provided in Pérez et al. (Pérez et al., 2015). Data for this manuscript are taken from the baseline survey, which was administered October 2014–June 2015, on an electronic form on computerized tablets (Delk et al., n.d.). Seventy nine schools and 3907 middle and high school students participated, representing a population of 461,069 6th, 8th, and 10th graders in these major metropolitan areas (Pérez et al., 2015). The Institutional Review Board at University of Texas' Health Science Center, Houston approved all protocols (HSC-SPH-13-0377).

2.1.2. M-PACT

The Marketing and Promotions Across Colleges in Texas Project (M-PACT) is also affiliated with the Texas TCORS and is a rapid-response surveillance system that runs parallel to TATAMS in 2- and 4-year colleges across the same cities. Three colleges of each type were selected from each city, for a total of 24. Participants were full- or part-time degree- or certificate-seeking 18–29 year old undergraduate students attending the 4-year college or a vocational/technical program at the 2-year college. Recruitment at 2-year colleges was limited to students enrolled in vocational/technical programs as they have an elevated prevalence of cigarette use (Loukas et al., 2008). Over 13,000 college students ($n = 13{,}714$) were eligible to participate and recruited via an e-mail invitation. Of these, 5482 (40%) completed the baseline survey in November 2014–February 2015, from which the data here are drawn. More details regarding the sampling for this study can be found elsewhere (Loukas, 2015). The University of Texas at Austin's Institutional Review Board approved all protocols (2013-06-0034).

2.1.3. TPRPS

The Tobacco Products and Risk Perceptions Survey (TPRPS) is administered by the Georgia State University Tobacco Center of Regulatory Science (GSU TCORS). The survey presented here was conducted August to September 2015 and was administered to a cross-sectional, probability sample drawn from GfK's KnowledgePanel, a probability-based web panel representative of non-institutionalized US adults. Of these KnowledgePanel members, 8135 were invited to participate in the online survey and 6091 qualified as completers. Forty cases were excluded due to refusing to answer more than one-half of the survey questions, for a final sample of 6051 adults, representing 238,226,996 nationwide. The average panel recruitment rate (RECR) for this study, reported by GfK, was 13.8% (rate at which those from the target population accept the invitation to join KnowledgePanel), the average profile rate (PROR) was 64.6% (rate at which those of the target population who accept the invitation to join KnowledgePanel complete the required GfK profile surveys to become members of KnowledgePanel), and the study completion rate (COMR) was 76.0% (the percentage invited to participate in the survey that completed the survey) for a cumulative response rate of 6.8% (RECR*PROR*COMR). More details about this design and the computation of these response rates are found here (Callegaro & DiSogra, 2008; Weaver et al., n.d.). The Institutional Review Board at Georgia State approved all study protocols (H14028).

2.2. Experimental

2.2.1. Measures

Survey questions for all three studies were developed from a catalogue of valid and reliable measures used in state and national tobacco

Table 1
Constructs, questions, and operationalization of e-cigarette measures (2014–2015).

	Questions and responses			
Constructs	TATAMS[a]	M-PACT[b]	TPRPS[c]	Operationalization
Behaviors				
Ever use	Have you EVER used an electronic cigarette, vape pen, or e-hookah, even one or two puffs? No/Yes	Have you ever used an ENDS[d] product, (i.e. e-cigarette, vape pen, or e-hookah) as intended (i.e. with nicotine cartridges and/or e-liquid/e-juice), even one or two puffs? No/Yes	Have you ever used electronic vapor products, even one or two times? No/yes	0 = No; 1 = Yes
Current use	During the past 30 days, on how many days did you use an electronic cigarette, vape pen, or e-hookah? Please enter the number of days (from 0 to 30 days) 0–30	During the past 30 days, have you used any ENDS product, (i.e. an e-cigarette, vape pen, or e-hookah), even one or two puffs, as intended (i.e. with nicotine cartridges and/or e-liquid/ejuice)? No/yes	In the past 30 days, have you used electronic vapor products, even one or two times? No/yes	TATAMS: 0 = no; 1 = yes, ≥1 day Others: 0 = no; 1 = yes
Flavors				
Flavor use at initiation	Think back to the FIRST electronic cigarette, vape pen, or e-hookah you tried. What flavor was it? Tobacco; menthol or mint; Candy, such as gummy bear Fruit, such as grape; Coffee or an alcoholic drink, such as wine; Spice, such as cinnamon; other flavor; I don't remember	When you first started using any ENDS products (i.e. e-cigarettes, vape pens, or e-hookah), were they flavored to taste like… Check all that apply Tobacco; Not flavored; Menthol or Mint; Candy (e.g. chocolate, vanilla); Fruit (e.g. strawberry, banana); Coffee or an alcoholic drink (e.g. pina colada); Other I don't remember, but I know it was flavored	When you first started using electronic vapor products, were they flavored? No-unflavored; yes-tobacco flavored; yes-flavored but not tobacco flavor; don't remember	Unflavored; Tobacco flavored; Flavored, not tobacco
Current flavor use	When you use an electronic cigarette, vape pen, or e-hookah, do you usually use any of the following flavors? (yes or no response for each flavor) Tobacco; menthol or mint. Candy, such as gummy bear; Fruit, such as grape; Coffee or an alcoholic drink, such as wine; Spice, such as cinnamon; other flavor	Is your usual brand of disposable e-cigarette or e-cigarette with disposable nicotine cartridges flavored to taste like… AND When you use a vape pen/personal vaporizer, do you usually use e-liquid/e-juice flavored to taste like… (yes or no response for each flavor) Tobacco; Not flavored; Menthol or Mint; Candy (e.g. chocolate, vanilla) Fruit (e.g. strawberry, banana); Coffee or an alcoholic drink (e.g. pina colada); Other	In the past 30 days, have you used electronic vapor products that are flavored (including tobacco flavor)? Yes/no If NO, they are coded as unflavored product users. If YES, they are asked the question stated here. Which flavors have you used in electronic vapor products in the past 30 days? (yes or no response for each flavor) Mint, wintergreen, menthol; fruit (e.g. cherry, blueberry, strawberry, watermelon, coconut, etc.); coffee (coffee or any related flavor–e.g. espresso, latte, cappuccino, etc.); candy or dessert flavors (e.g. caramel, vanilla, chocolate, ice cream, mud pie); Spice (e.g. clove, cinnamon, nutmeg); Alcohol or cocktail (e.g. wine, bourbon, rum, brandy, tequila, whiskey beer, mai-tai, daiquiri); Tobacco flavor; Some other flavor	Unflavored; Tobacco flavored; Flavored, not tobacco Tobacco flavored; mint/menthol; fruit Coffee/alcohol; candy/dessert; spice; other
Reasons to use: flavors	How much do you agree or disagree with the following statements? I tried using electronic cigarette, vape pen, or e-hookah because electronic cigarettes come in flavors I like. Strongly disagree; disagree; agree; strongly agree	I tried ENDS products (i.e. e-cigarettes, vape pens, or e-hookah) as intended because… they came in flavors I liked.	Please indicate how important it is to you in your use of electronic vapor products. They come in flavors I like was measured using 6 point Likert scale where, 0 (not at all important) and 6 (very important)	TATAMS: 0 = strongly disagree/disagree; 1 = agree/ strongly agree M-PACT: 0 = no; 1 = yes TPRPS: 0–3 = no; 4–6 = yes

[a] TATAMS-The Texas Adolescent Tobacco and Marketing Surveillance System.
[b] M-PACT- Marketing and Promotions Across Colleges in Texas Project.
[c] TPRPS- The Tobacco Products and Risk Perceptions Survey.
[d] ENDS- Electronic Nicotine Delivery Systems.

surveillance, including the PATH study (United States Department of Health and Human Services. National Institutes of Health. National Institute on Drug Abuse, a.U.S.D.o.H.a.H.S.F.a.D.A. Population Assessment of Tobacco and Health (PATH) Study, 2013-2016). Measures specific to e-cigarettes in the three studies are summarized in Table 1. The constructs are included ever and current use; use of flavors at initiation and "regularly"; and flavors as a reason to use e-cigarettes. The differences across studies in these measures include the following. For *flavor use at initiation*, TATAMS did not ask about unflavored e-cigarette use, and M-PACT participants were asked to check all flavor

categories that applied. If any flavor was chosen, respondents were categorized as "flavored, not tobacco" in Table 2. This same rule was applied to all studies for *current use of flavors* in Table 2. In Fig. 1, the raw "check all that apply" form of current use item was retained instead to illustrate the maximum variability in flavors across the studies. M-PACT applied the *flavor use at initiation* question to only current users, while the other studies also applied it to ever users. For *flavors as a reason to use*, responses were dichotomized across all studies. The TPRPS survey only asked this question of adult current e-cigarette users (Table 3).

The measure of combustible tobacco product use included cigarettes, hookah, and all types of cigar products (large cigars, cigarillos, and little filtered cigars). *Former combustible* use was defined as participants who reported ever use of any combustible product, but not current use. TPRPS defined ever use of cigarettes as reporting smoking 100 or more cigarettes in their lifetime; ever use of all other products was defined as having used the product even one or two times in their lifetime. TATAMS and M-PACT defined ever use of each product the same: reporting using the product (even one or two times) in their lifetime. *Current combustible* product use was defined as participants who reported use of any combustible product at least 1 day in the past 30 (for TATAMS or M-PACT participants) or "every day" or "some days" (for TPRPS participants). In addition, we also focused in analyses on the subset of current combustible users that were currently smoking cigarettes, regardless of their other combustible product use; these are noted as *current cigarette* (Tables 2 and 3). *Never combustible* use was defined as those who reported "no" to ever use of all of these products. Questions that define ever use and current use of these products are identical to the questions in Table 1 for e-cigarette use, except e-cigarettes are replaced by these other tobacco products, each with a separate question.

2.2.2. Data analysis

Proportions and 95% confidence intervals were used to describe the percentage of e-cigarette use at initiation and in the past 30 days that can be attributed to the use of flavored e-cigarettes (Table 2). Statistics were calculated overall and then stratified by combustible tobacco product use. Sample sizes for never combustible users were only large enough to be examined in TATAMS and M-PACT, as most adult e-cigarette users had already used combustible tobacco products. Chi-square tests were used to study differences between current and former combustible users (Table 2) and to investigate differences by sex and race/ethnicity across e-cigarette flavor categories among current e-cigarette users (results presented in text). Proportions of e-cigarette use in the past 30 days that could be attributed to all types of flavors, including tobacco, mint/menthol, fruit, coffee/alcohol, candy/dessert, spice, or other flavor were calculated (Fig. 1). To determine the salience of flavors as a reason to use e-cigarettes, proportions and 95% confidence intervals were calculated (Table 3). Analyses of TPRPS data were stratified by age group (18–29 years old vs. 30 + years old) to provide estimates for young adults nationwide that could be compared with those from Texas (M-PACT). Sampling weights were applied to the TATAMS and TPRPS data, but not to M-PACT, as M-PACT employed a convenience sample, while TATAMS and TPRPS used random sampling protocols that allow the results to generalize back to the population from which the sample was drawn, when weights are applied. Detailed information about the calculation and application of sampling weights is provided elsewhere (Pérez et al., 2015; Callegaro & DiSogra, 2008; Weaver et al., n.d.). Estimates that relied on denominators ≤50 were suppressed as the results would be statistically unreliable.

3. Results

E-cigarette use was most common among young adult college students in Texas. The prevalence of ever e-cigarette use among Texas youth and young adult college students (18–29 years old) was 19.5% (95% CI: 15.9%, 24.0%) and 44.6% (95% CI: 43.3%, 46.0%), respectively, while it was 29.5% (95% CI: 26.0%, 33.3%) and 13.8% (95% CI: 12.6%, 15.0%) among young adults (18–29 years old) and adults (30 + years old) nationwide. Current e-cigarette use was 7.4% (95% CI: 5.9%, 9.0%), 15.3% (95% CI: 14.3%, 16.3%), 9.3% (95% CI: 7.2%, 12.0%) and 4.5% (95% CI: 3.8%, 5.2%) across these different samples, respectively.

3.1. Use of flavored e-cigarettes at initiation

Most youth, young adult, and adult e-cigarette users said their first e-cigarette was flavored, with the majority reporting their first e-cigarette was flavored to taste like something

other than tobacco (Table 2). The proportion of current users who started with an e-cigarette flavored with something other than tobacco was considerably higher in Texas youth (98.6%) and young adults in Texas (95.2%) and nationwide (71.2%) compared to older adults nationwide (44.1%). Tobacco flavor was significantly more common among older adults nationwide (47.5%), compared to young adults nationwide (21.0%) and young adult college students (4.8%), and youth (1.4%) in Texas.

No significant differences were noted by combustible tobacco product use for youth in Texas, but significant differences emerged for young adult college students in Texas and adults nationwide. At initiation, the use of tobacco-flavored e-cigarettes was more common among current dual users (e-cigarette and combustible tobacco product users) than exclusive e-cigarette users (i.e., former combustible tobacco product users), for both age groups ($p < 0.05$, both). Among adults nationwide, 43.5% of current combustible users said their first e-cigarette was flavored to taste like tobacco, compared to 27.8% of former combustible product users.

3.2. Current use of flavored e-cigarettes

Similar trends in flavored e-cigarette use in the past 30 days were noted (Table 2). Overall, most youth, young adult, and adult e-cigarette users reported the "usual" e-cigarette they used in the past 30 days was flavored, with the majority reporting that it was flavored to taste like something other than tobacco. The proportion of current users whose "usual" e-cigarette was flavored but not with tobacco was appreciably higher for Texas youth (97.9%) and young adults (96.7%) in Texas and nationwide (82.2%) compared to older adults nationwide (69.3%). In older adults, current use of an e-cigarette flavored with something other than tobacco (69.3%) was also significantly higher than the same at initiation (44.1%). No differences by combustible product use were observed for any age group.

3.3. Preference for and salience of flavors

Among current e-cigarette users, there were no significant differences in use of flavored e-cigarettes at initiation or "usually" by sex or racial/ethnic group for any age group (all $p > 0.05$, data not shown in Table). Fig. 1 illustrates preferences for specific flavors among current e-cigarette users, for the "usual" e-cigarette. Across all studies, fruit flavors predominated, endorsed by 76% of Texas youth, 83% of Texas young adult college students, 74% of young adults nationwide, and 47% of older adults nationwide. The next most popular flavor was candy or dessert, reported by 57% of Texas youth, 52% of Texas young adult college students, 50% of young adults nationwide, and 27% of older adults nationwide. Tobacco flavor was the least commonly reported as a usual flavor among all groups, at 13% of Texas youth, 23% of Texas young adult college students, 1% of young adults nationwide, and 13% of older adults nationwide.

Table 2
Use of flavored e-cigarettes among youth, young adult, and adult current e-cigarette users (2014–2015).

		n	N	Unflavored		Tobacco flavored		Flavored, not tobacco		P-value
				%	95% CI	%	95% CI	%	95% CI	
Use of flavored e-cigarettes at initiation										
TATAMS [a]	**Youth (overall)**	218	28,301			1.4%	0.5%, 3.9%	98.6%	96.1%, 99.5%	
	Never combustible[d]	78	9853			0.2%	0.0%, 1.4%	99.8%	98.6%, 100.0%	
	Current combustible[e]	88	12,317			1.8%	0.4%, 7.2%	98.2%	92.8%, 99.6%	
	Current cigarette[f]	42	5477			2.5%	0.4%, 15.0%	97.5%	85.0%, 99.6%	
	Former combustible[g]	52	6132			2.5%	0.4%, 13.4%	97.5%	86.6%, 99.6%	0.33
M-PACT [b]	**Young adults (overall)**	944	NA			4.8%	3.6%, 6.3%	95.2%	93.7%, 96.4%	
	Never combustible[d]	21	NA			***	***	***	***	
	Current combustible[e]	740	NA			5.5%	4.1%, 7.4%	94.5%	92.6%, 95.9%	
	Current cigarette[f]	498	NA			7.4%	5.4%, 10.1%	92.6%	89.9%, 94.6%	
	Former combustible[g]	183	NA			1.6%	0.6%, 4.7%	98.4%	95.3%, 99.4%	0.05
TPRPS [c]	**Adults (overall)**	355	11,020,944	8.2%	5.1%, 12.9%	37.7%	31.3%, 44.6%	54.1%	47.0%, 61.1%	
	Never combustible[d]	6	375,247	***	***	***	***	***	***	
	Current combustible[e]	279	7,650,505	9.2%	5.3%, 15.5%	43.5%	35.4%, 51.9%	47.3%	38.8%, 56.0%	
	Current cigarette[f]	256	6,483,643	9.0%	4.8%, 16.2%	47.4%	38.6%, 56.3%	43.6%	34.9%, 52.8%	
	Former combustible[g]	70	29,95,192	6.5%	2.7%, 14.9%	27.8%	17.9%, 40.3%	65.7%	52.7%, 76.7%	0.03
	Young adults (18–29 y)	86	4,074,947	7.8%	2.9%, 19.6%	21.0%	12.9%, 32.4%	71.2%	58.2%, 81.4%	
	Never combustible[d]	4	288,503	***	***	***	***	***	***	
	Current combustible[e]	58	2,416,473	11.6%	3.9%, 30.0%	25.2%	14.1%, 41.0%	63.2%	45.5%, 77.9%	
	Current cigarette[f]	49	1,747,919	***	***	***	***	***	***	
	Former combustible[g]	24	1,369,971	***	***	***	***	***	***	
	Older adults (30 + y)	269	6,945,996	8.3%	5.1%, 13.4%	47.5%	39.8%, 55.4%	44.1%	36.5%, 52.1%	
	Never combustible[d]	2	86,744	***	***	***	***	***	***	
	Current combustible[e]	221	5,234,031	8.1%	4.5%, 14.0%	51.9%	42.7%, 61.0%	40.0%	31.3%, 49.4%	
	Current cigarette[f]	207	4,735,724	7.3%	3.9%, 13.4%	53.5%	43.8%, 63.0%	39.2%	30.1%, 49.1%	
	Former combustible[g]	46	1,625,221	***	***	***	***	***	***	
Current or "usual" use of flavored e-cigarettes										
TATAMS [a]	**Youth (overall)**	235	30,756			2.1%	0.5%, 8.7%	97.9%	91.3%, 99.5%	
	Never combustible[d]	87	11,340			0.2%	0.0%, 1.2%	99.8%	98.8%, 100.0%	
	Current combustible[e]	93	13,604			3.5%	0.5%, 20.8%	96.5%	79.2%, 99.5%	
	Current cigarette[f]	46	6543			7.2%	1.0%, 36.3%	92.8%	63.7%, 99.0%	
	Former combustible[g]	55	5813			2.6%	0.4%, 13.8%	97.4%	86.2%, 99.6%	0.26
M-PACT [b]	**Young adults (overall)**	798	NA			3.3%	2.2%, 4.7%	96.7%	95.3%, 97.8%	
	Never combustible[d]	21	NA			***	***	***	***	
	Current combustible[e]	626	NA			3.8%	2.6%, 5.6%	96.2%	94.4%, 97.4%	
	Current cigarette[f]	444	NA			4.7%	3.1%, 7.1%	95.3%	92.9%, 96.9%	
	Former combustible[g]	152	NA			0.7%	0.1%, 3.6%	99.3%	96.4%, 99.9%	0.07
TPRPS [c]	**Adults (overall)**	378	11,802,533	17.3%	12.6%, 23.1%	8.7%	6.0%, 12.2%	74.1%	67.9%, 79.5%	
	Never combustible[d]	7	410,639	***	***	***	***	***	***	
	Current combustible[e]	298	8,126,307	16.9%	11.8%, 23.6%	9.1%	6.1%, 13.3%	74.0%	66.9%, 80.1%	
	Current cigarette[f]	271	6,832,639	16.8%	11.4%, 24.1%	10.3%	6.9%, 15.2%	72.9%	65.1%, 79.5%	
	Former combustible[g]	73	3,265,586	18.9%	9.8%, 33.1%	8.7%	4.0%, 17.8%	72.5%	58.5%, 83.1%	0.89
	Young adults (18–29 y)	92	4,352,335	16.7%	9.2%, 28.4%	1.1%	0.3%, 4.8%	82.2%	70.5%, 89.9%	
	Never combustible[d]	4	288,503	***	***	***	***	***	***	
	Current combustible[e]	62	2,452,927	10.2%	5.0%, 19.7%	0.6%	0.1%, 4.3%	89.2%	79.6%, 94.6%	
	Current cigarette[f]	52	1,734,218	9.0%	4.2%, 18.2%	0.9%	0.1%, 6.0%	90.1%	80.7%, 95.2%	
	Former combustible[g]	26	1,610,905	***	***	***	***	***	***	
	Older adults (30 + y)	286	7,450,198	17.6%	12.3%, 24.6%	13.1%	9.1%, 18.4%	69.3%	61.9%, 75.9%	
	Never combustible[d]	3	122,136	***	***	***	***	***	***	
	Current combustible[e]	236	5,673,380	19.8%	13.3%, 28.4%	12.8%	8.6%, 18.6%	67.4%	58.7%, 75.1%	
	Current cigarette[f]	219	5,098,420	19.5%	12.7%, 28.7%	13.5%	9.0%, 19.8%	67.0%	57.7%, 75.2%	
	Former combustible[g]	47	1,654,682	***	***	***	***	***	***	

*** Estimates suppressed as denominators <50 and are therefore statistically unreliable. Note. P-values obtained from a chi-square test of differences in flavored e-cigarette use by combustible product use status.

[a] TATAMS-The Texas Adolescent Tobacco and Marketing Surveillance System.

[b] M-PACT- The Marketing and Promotions Across Colleges in Texas Project.

[c] TPRPS- The Tobacco Products and Risk Perceptions Survey

[d] Never combustible: reported never using cigarettes, hookah, and cigar products.

[e] Current combustible: reported past 30-use (TATAMS and M-PACT) or "every day"/"someday" use (TPRPS) of cigarettes, cigar products, or hookah.

[f] Current cigarette: subset of current combustible; reported current use of cigarettes.

[g] Former combustible: reported ever use of cigarettes, cigar products or hookah, but not current use of these products; n = survey sample size; N = weighted sample size or the population size to which estimates generalize back to cells are grayed out because unflavored e-cigarette use was not assessed in TATAMS and only three participants reported exclusive unflavored e-cigarette use in the M-PACT study, so tobacco and unflavored were combined.

Table 3 presents the proportion of participants who said they used e-cigarettes because they "come in flavors I like". Among current e-cigarette users, more Texas youth (72.9%) than young adult college students in Texas (57.4%) and young adults (64.8%) and adults (54.0%) nationwide endorsed this item. The same trend was noted for ever users, overall, comparing youth (64.9%) to young adult college students (49.5%) in Texas. Among youth and young adult ever e-cigarette users in Texas, this was lowest among those who had never used a combustible tobacco product (53.5% and 34.0% respectively) and higher among those who had some experience with combustible tobacco product use (79.8% and 50.9% respectively).

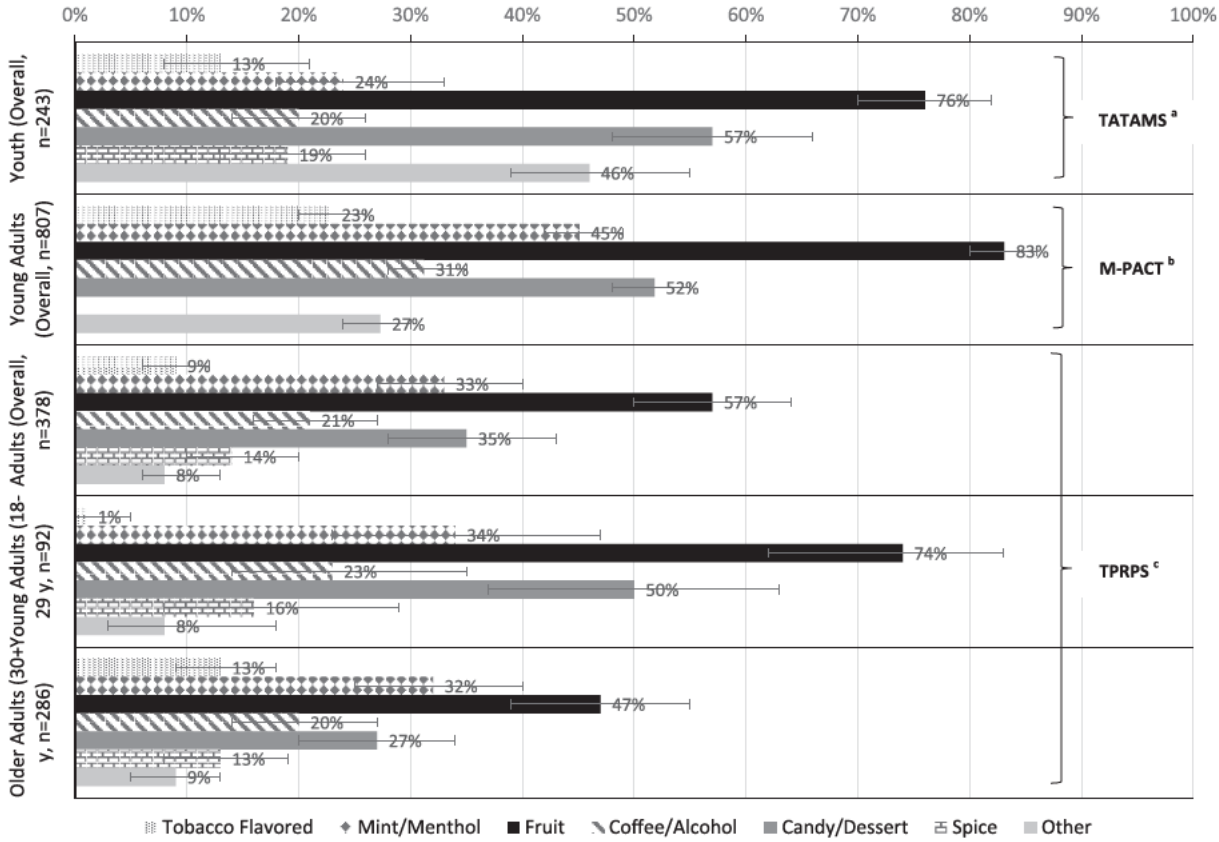

Fig. 1. Variability in flavored e-cigarette use among youth, young adult and adult current e-cigarette users.

4. Discussion

Although the use of flavored e-cigarettes was not uncommon among older adults, our study underscores the relevance and importance of this issue for both youth and young adults. For school-going youth and young adult college students in Texas, almost all first (>95%) and "usual" (>96%) e-cigarette use was with a product flavored to taste like something other than tobacco. The large majority of young adults nationwide also preferred flavored e-cigarettes (71.2% and 82.2%, at first and "usual" use respectively). By comparison, fewer adults nationwide reported the same at initiation (44.1%), and at "usual" use (69.3%). The latter finding suggests flavors other than tobacco become increasingly relevant to older adults as they continue using e-cigarettes.

This study is the first one to date that explicitly compares patterns of flavored e-cigarette use across age groups. Our findings are troubling and suggest that, like conventional cigarettes (US Department of Health Human Services, 2012), characterizing flavors could be especially enticing to young people, at onset and with continued use. Eliminating or restricting e-cigarette flavors in future could be an essential element of comprehensive tobacco control policies designed to reduce the appeal of tobacco products for young people. Already, Chicago and New York City have begun to restrict the sale of flavored tobacco products and e-cigarettes (Emanuel, 2013). As e-cigarettes are now under the authority of FDA to regulate (FDA/USDA, 2014), other regulations like the ban placed on flavored cigarettes (FDA. Family Smoking Prevention and Tobacco Control Act, 2015) could be considered, also. No rules specific to flavorings in e-cigarettes were set forth in the recent deeming action taken by the FDA.

Given our findings and that of others', regulatory actions would not only impact youth and young adults, but also older adults. Preferences for certain flavors differ slightly by age group in studies to date, including this one, and also by cigarette smoking status (Krishnan-Sarin et al., 2015; Berg, 2015). Sweet flavors, like fruit and candy, are most commonly preferred by youth, young adults, and adults alike and exceed >75% of flavored e-cigarette use in most studies (Farsalinos et al., 2014; Dawkins et al., 2013; Krishnan-Sarin et al., 2015; Berg, 2015). In one study from the UK, sweet flavors reduced perceptions of harm from e-cigarettes among youth (Ford et al., 2015). In our study, preference for sweet flavors was appreciably lower among older adults, at <50%. Across studies of youth, young adults, and adults, mint or menthol and tobacco flavors are preferred more often among e-cigarette users who also smoke cigarettes (dual users), compared to exclusive e-cigarette users, and those who have never smoked a cigarette, especially at initiation (Farsalinos et al., 2014; Dawkins et al., 2013; Krishnan-Sarin et al., 2015; Berg, 2015). Still, use of these flavors is at considerably lower rates than sweeter flavors, varying between 25% and 50% of youth and adult cigarette smokers, respectively (Farsalinos et al., 2014; Dawkins et al., 2013; Krishnan-Sarin et al., 2015; Berg, 2015). These data suggest that tobacco and mint/menthol flavored e-cigarettes could be most relevant to and helpful for adult cigarette smokers who may use e-cigarettes to try to quit smoking. Thus, restricting the range of flavors by eliminating sweet ones may offer the most benefit to youth and young adult prevention efforts, without doing harm to adults. Though e-cigarettes are not a proven tool for adult cigarette smoking cessation, it is unclear what impact this action may have on these efforts, instead (Grana et al., 2014; Grana & Ling, 2014; McRobbie et al., 2014). Remarkably, trends in flavored e-cigarette use reported here did not vary by sex or race/ethnicity for any of the age groups, suggesting the impact of any actions specific to this issue might only differ across different life stages and/or by combustible product use.

Limitations include the study's reliance on self-report and cross-sectional analyses that do not allow for the direct estimation of the role that flavors have in initiation or cessation among youth, young adults, or

Table 3
Salience of flavors as a reason to use e-cigarettes among youth, young adults, and adults (2014–2015).

		Ever e-cigarette users					Current e-cigarette users				
		n	N	%	95% CI	P-value	n	N	%	95% CI	P-value
TATAMS [a]	**Youth (overall)**	681	88,953	64.9%	61.0%, 68.8%		259	34,005	72.9%	65.4%, 80.3%	
	Never combustible[d]	315	38,511	53.5%	45.6%, 60.9%		99	12,793	58.2%	42.5%, 73.9%	
	Current combustible[e]	136	22,551	79.8%	70.1%, 89.5%		103	14.727	83.7%	76.0%, 91.3%	
	Current cigarette[f]	68	12,496	76.9%	60.5%, 93.3%		50	7086	88.4%	79.8%, 97.1%	
	Former combustible[g]	230	27,892	68.8%	61.4%, 76.2%	< 0.01	57	6492	77.2%	57.1%, 97.3%	0.03
M-PACT [b]	**Young adults (overall)**	2636	NA	49.5%	47.6%, 51.4%		944	NA	52.2%	49.0%, 55.4%	
	Never combustible[d]	144	NA	34.0%	26.8%, 42.1%		21	NA	***	***	
	Current combustible[e]	1493	NA	50.9%	48.4%, 53.4%		740	NA	53.0%	49.4%, 56.5%	
	Current cigarette[f]	1003	NA	48.0%	44.9%, 51.0%		498	NA	51.2%	46.8%, 55.6%	
	Former combustible[g]	997	NA	49.6%	46.6%, 52.8%	< 0.01	183	NA	50.3%	43.1%, 57.4%	0.55
TPRPS[c]	**Adults (overall)**						355	1,1370,853	57.9%	50.2%, 65.1%	
	Never combustible[d]						7	410,639	***	***	
	Current combustible[e]						279	7,627,740	52.6%	44.0%, 61.0%	
	Current cigarette[f]						259	6,536,123	48.9%	40.0%, 57.8%	
	Former combustible[g]						69	3,332,474	69.8%	52.0%, 83.1%	0.22
	Young adults (18–29 y)						86	4,092,588	64.8%	49.6%, 77.4%	
	Never combustible[d]						4	288,503	***	***	
	Current combustible[e]						63	2,570,723	60.9%	43.6%, 75.9%	
	Current cigarette[f]						54	1,894,898	51.8%	33.4%, 69.8%	
	Former combustible[g]						19	1,233,361	***	***	
	Older adults (30 + y)						269	7,278,265	54.0%	45.4%, 62.3%	
	Never combustible[d]						3	122,136	***	***	
	Current combustible[e]						216	5,057,017	48.4%	39.1%, 57.8%	
	Current cigarette[f]						205	4,641,225	47.7%	37.9%, 57.5%	
	Former combustible[g]						50	2,099,112	***	***	

Notes. P-values obtained from a chi-square test of differences in salience of flavored e-cigarette use by combustible product use status.
***Estimates suppressed as denominators <50 and are therefore statistically unreliable.
[a] TATAMS-The Texas Adolescent Tobacco and Marketing Surveillance System.
[b] M-PACT- The Marketing and Promotions Across Colleges in Texas Project.
[c] TPRPS- The Tobacco Products and Risk Perceptions Survey.
[d] Never combustible: reported never using cigarettes, hookah, and cigar products.
[e] Current combustible: reported past 30-use (TATAMS and M-PACT) or "every day"/"someday" use (TPRPS) of cigarettes, cigar products, or hookah.
[f] Current cigarette: subset of current combustible; reported current use of cigarettes.
[g] Former combustible: reported ever use of cigarettes, cigar products or hookah, but not current use of these products; n = survey sample size; N = weighted sample size or the population size to which estimates generalize back to; salience of flavors as a reason to use e-cigarettes was not assessed among ever e-cigarette users in TPRPS, so these cells are grayed out in the table.

older adults. TATAMS and M-PACT are specific to school-going participants, who may not generalize to out-of-school youth. Also, these studies from Texas may not be representative of similarly-aged students living elsewhere, though e-cigarette use rates are comparable to those from national studies (Ford et al., 2015; Singh, 2016). Studies have not yet evaluated whether e-cigarette use rates are similar between young people who do and do not attend school, though data indicate that youth and young adults who do not attend school are more likely to smoke combustible cigarettes (United States Department of Health and Human Services, 2012). Finally, minor differences in the wording of items and procedures used across all three studies to assess flavored e-cigarette use may be a potential limitation of the study, too. Though these three studies were not designed to be directly comparable, every effort was made post-hoc to align measures and analyses.

5. Conclusion

Characterizing flavors, especially sweet ones (e.g., fruit, candy, dessert), appear to be particularly relevant to e-cigarette use among young people, the rates of which have risen substantially in recent years (Singh, 2016; United States Department of Health and Human Services, 2012; Neff et al., 2015; Arrazola et al., 2015). Nationwide, past 30 day e-cigarette use was highest in 2014 among youth (13.4%) (Neff et al., 2015) and young adults (14.2%, 18–24 year olds) (Arrazola et al., 2015) compared to adults (2.4%, 25–44 year olds). (Agaku et al., 2014) Given new longitudinal research that shows that e-cigarette use also predicts the onset of combustible tobacco product use among both youth and young adults (Leventhal et al., 2015; Primack et al., 2015; Wills et al., 2016), acting like a "gateway" drug, it is imperative to identify feasible and effective intervention strategies that could potentially decrease the onset of and continued e-cigarette use. Eliminating or restricting characterizing flavors for e-cigarettes, especially sweet ones (e.g., fruit, candy, dessert) may offer the most benefit to youth and young adult prevention efforts. However, it is unclear what impact this strategy might have on adult cigarette smoking cessation.

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MH led the development of the manuscript, which included obtaining funding for the study, conceptualizing the study, and drafting the manuscript. SW, AL, MC, CP, TP, and ME also obtained funding for the study and revised the manuscript for important intellectual content. NM, JWH, and CJ analyzed the data and revised the manuscript for important intellectual content.

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CONFIDENTIAL

Supplemental statistical report – Post-hoc analyses

Sponsor:	*Swedish Match*
Study code:	*Supplemental post-hoc analyses*
CTC project no:	*Post-hoc SM*
Study title:	(b) (4) [redacted]
SAP version and date:	*Final version 1.0 02SEP2020*

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2 VERSION HISTORY

This is a supplemental post-hoc report for the post-hoc report dated 04SEP2019.

Table 1 Complimentary post-hoc version history summary

Post-hoc version	Approval Date	Changes	Rationale
0.1	26AUG2020	-	Version ready for internal review
0.2	28AUG2020	Minor adjustments	Version ready for Sponsor review
0.3	01SEP2020	-	Sponsor review
1	02SEP2020	NA	Original version

3 INTRODUCTION

This is a brief statistical report as a supplemental for the post-hoc report from 04SEP2019 and with raw data from the study SM 18-01.

4 CLINICAL STUDY DETAILS

4.1 Post-hoc hypothesis

(b) (4)

[redacted]

5 STATISTICAL AND ANALYTICAL METHODOLOGY

5.1 Definition of analysis sets

5.1.1 Per protocol analysis set (PPS)

The definition of the PPS is stated in the study SM 18-01 and was used in the post-hoc analysis from 04SEP2019.

5.2 Definitions of baseline for pharmacokinetics calculations

Calculations of baseline-adjusted pharmacokinetics parameters are defined in the post-hoc report from 04SEP2019. All pharmacokinetic data was calculated for the post-hoc report.

5.3 Summary statistics and listings

Summary statistics are stated and has been performed in the post-hoc report from 04SEP2019.

$AUC_{0\text{-}120min}$ and C_{max} have been listed and sorted by IP, subject, and timing of assessments.

5.4 Confidence interval

A confidence interval at 90% was be applied for the linear mixed-effects analysis of variance (ANOVA).

6 STATISTICAL ANALYSIS AND RESULTS

6.1 Hypothesis #1

- *That the flavour in ZYN Wintergreen has not significant effect on the plasma exposure to nicotine in respect to plasma C_{max} and $AUC_{0\text{-}120min}$.*

The plasma exposure to nicotine was analysed using the linear mixed-effects analysis of variance (ANOVA) model with fixed effects for product, and a random effect for subject. A 90% confidence interval which lies between 0.80 to 1.25 will be judged as equivalent.

Sequence and period were not included as an independent and fixed variable in the model. The absorption and/or the metabolism of nicotine are assumed not have an impact of the sequence and period in the model, since all subjects are daily users of nicotine and the intake was not controlled before and/or between the visits.

6.1.1 Results hypothesis #1

Table 1 - Comparison between ZYN Wintergreen 4.5mg vs ZYN Smooth 4.5mg, with baseline adjustments

PK variable	n	90% CI lower bound	Ratio of geometric mean	90% CI upper bound
AUC0-120min	30	0.867	0.9174	0.971
Cmax	30	0.840	0.9101	0.986

SM18_01_extraFDA_01.rtf. , SAS program: Run by: Linnea Eriksson, linnea.eriksson@ctc-ab.se 2020-08-28T16:07:50

Table 2 - Comparison between ZYN Wintergreen 4.5mg vs ZYN Smooth 4.5mg, without baseline adjustments

PK variable	n	90% CI lower bound	Ratio of geometric mean	90% CI upper bound
AUC0-120min	30	0.882	0.9317	0.985
Cmax	30	0.852	0.9211	0.996

SM18_01_extraFDA_02.rtf. , SAS program: Run by: Linnea Eriksson, linnea.eriksson@ctc-ab.se 2020-08-28T16:07:50

7 CONCLUSION

The flavour in ZYN Wintergreen has no significant effect on the plasma exposure to nicotine in respect to plasma C_{max} and $AUC_{0\text{-}120min.}$ With a 90% confidence interval the comparison between ZYN Wintergreen 4.5mg and ZYN Smooth 4.5mg lies within the bioequivalence criterium 80-125% (0.80-1.25), for both baselines adjusted data and data without baseline adjustments.

8 STATISTICAL DELIVERABLES

The following documents will be delivered:

- Brief statistical post-hoc report
- Statistical analyses and listings

9 SOFTWARE

All statistical analyses have been performed using (b) (4) [redacted] and all pharmacokinetic parameters have been performed using (b) (4) [redacted]

10 APPROVAL

Issued by:

(b) (6)

[redacted]

07SEP2020

Date (dd-Mmm-yyyy)

07SEP2020

Date (dd-Mmm-yyyy)

11 SUPPORTIVE DOCUMENTATION

11.1Appendix 1 – list of abbreviations

Abbreviation of term	Explanation
CSP	Clinical study protocol
CSR	Clinical study report
PPS	Per protocol set
SAS	Statistical analysis system

11.2 Appendix 2 – other documentations

SM 18-01 Protocol_Final 3.0_16JAN2019

196-71-2017_CSR_Final v 1.0 28JUN2019

Post-hoc_statistical_report_final (from 04SEP2019)

12 LISTINGS

Table 3 - Listings, with baseline adjustments

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

Table 4 - Listings, without baseline adjustments

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4) [redacted]

In vitro release of nicotine from 20 different ZYN products

Author: (b) (6) [redacted]

Signature:

(b) (6) [redacted]

(b) (4) [redacted]	
Date: 11-09-2020	Edition no.: 2
Responsible scientist: (b) (6) [redacted]	Responsible technician(s): (b) (6) [redacted]

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1. Introduction

1.1 Aim

To study the release of nicotine from 20 different ZYN non-tobacco based nicotine products in artificial saliva using a µDISS Profiler™ dissolution method. This *in vitro* method was previously validated against *in vivo* extraction data from two marketed products (General® White 8 mg and ZYN® Cool Mint 6 mg) with significantly different release profiles. In accordance with guidelines, the dissolution testing was performed on 12 dosage units of each formulation.

1.2 Background

Swedish Match is developing different non-tobacco based nicotine products for oromucosal delivery. In order to study if the performance of ZYN products with different flavor can be considered equivalent, the release of nicotine from these 20 different products was investigated in an *in vitro* dissolution experiment. As there is currently no standard dissolution method for oromucosal tobacco products, a recently developed µDISS Profiler™ dissolution method was used.

2. Materials

Table 1: Raw materials used in this study.

Generic name	Supplier	Quality	Batch no.
ZYN Coffee 3 mg	Swedish Match NA	-	(b) (4) [redacted]
ZYN Coffee 6 mg	Swedish Match NA	-	
ZYN Cinnamon 3 mg	Swedish Match NA	-	
ZYN Cinnamon 6 mg	Swedish Match NA	-	
ZYN Chill 3 mg	Swedish Match NA	-	
ZYN Chill 6 mg	Swedish Match NA	-	
ZYN Smooth 3 mg	Swedish Match NA	-	
ZYN Smooth 6 mg	Swedish Match NA	-	
ZYN Citrus 3 mg	Swedish Match NA	-	
ZYN Citrus 6 mg	Swedish Match NA	-	
ZYN Peppermint 3 mg	Swedish Match NA	-	
ZYN Peppermint 6 mg	Swedish Match NA	-	
ZYN Cool Mint 3 mg	Swedish Match NA	-	
ZYN Cool Mint 6 mg	Swedish Match NA	-	
ZYN Spearmint 3 mg	Swedish Match NA	-	
ZYN Spearmint 6 mg	Swedish Match NA	-	
ZYN Wintergreen 3 mg	Swedish Match NA	-	
ZYN Wintergreen 6 mg	Swedish Match NA	-	
ZYN Fresh 3 mg	Swedish Match NA	-	
ZYN Fresh 6 mg	Swedish Match NA	-	
Nicotine	IPO Poland	>99.9	
Saliva Orthana®	Pharmadan A/S	-	

3. Methods

3.1 Sinker preparation

As there is no suitable sinker commercially available, a custom-made sinker was prepared by 3D printing a 12 mm tall, hollow tube with an outside diameter of 21 mm and a wall thickness of 2 mm using polylactic acid (PLA). The tube was then fitted with a 20-mesh stainless steel sieve (0.84 mm sieve opening) by molding it into the PLA material to allow for water flow through the sinker/pouch, while preventing pouch discharge. A picture of the custom-made sinker can be found in Appendix A.

3.2 *In vitro* dissolution experiments

The nicotine release experiments were carried out using a µDISS Profiler™ from Pion Inc. (MA, USA) with six channels without the UV probes connected. The pouches were weighed (target weight 400 ± 20 mg), loaded face-up in the sinkers and placed on the bottom (mesh up) of 20 mL dissolution vessels along with 20 mm cross-shaped magnetic stirrers operating at 100 rpm. The experiment was initiated by addition of 10 mL of artificial saliva (preheated to 37 °C) to each of the six dissolution vessels. Samples of 250 µL were taken at t = 5, 10, 15, 30, 45, 60, 90 and 120 min and replaced with 250 µL of preheated artificial saliva. The samples were diluted immediately with 500 µL ethanol 96% and 500 µL acetonitril in a 1.5 mL Eppendorf tube to precipitate mucin from the saliva and avoid potential precipitation of the nicotine upon cooling. The diluted samples were then centrifuged at 10,000 rpm for 10 min and the supernatant analyzed directly for nicotine content using HPLC-UV. The dissolution testing was performed on 12 dosage units for each formulation.

3.3 Quantitative analysis

A HPLC method was used for quantification of nicotine using an Ultimate 3000 HPLC system from Dionex (Sunnyvale, USA). A reverse phase Kinetex Evo C18 100A column (4.6 × 100 mm, 2.6 µm) from Phenomenex (Værløse, Denmark) was used for the separation and the mobile phases consisted of A) 15 mM ammonium formate adjusted to pH 10.5 using triethylamine and B) acetonitrile, which were pumped isocratically at 75% A and 25% B. A volume of 10 µL was injected and eluted at a flow rate of 0.5 mL/min, and the effluent was detected at a wavelength of 260 nm with a retention time of approximately 4.3 min. The concentration of nicotine in the samples was calculated using the mean value of the peak areas obtained from a calibration standard curve prepared in triplicate.

3.4 **Method validation**

Linearity
Standard solutions were prepared at six concentrations covering minimum 25-150% of the target concentration. Three individually prepared replicates at each concentration were analyzed. The coefficient of determination (r^2) should be >0.998 for six concentration levels and the y-intercept <2% of the target concentration response.

Accuracy (recovery)
Spiked samples were prepared at 100, 200 and 300 µg/mL corresponding to 50, 100 and 150% of the target concentration of nicotine. Three individually prepared replicates at each concentration were analyzed. The mean recovery should be within 100 ± 2% of the theoretical value at each concentration.

Range
The data obtained during the linearity and accuracy studies were used to assess the range of the method. The range is defined as the concentration interval over which linearity and accuracy are obtained per the above criteria, and in addition, the precision should be < 3%.

Precision (repeatability)
The precision of the method was evaluated by assaying ten replicate injections at the target concentration (200 µg/mL), during the same day, under the same experimental conditions. The precision for retention time, peak height and peak area should be <1%.

Limit of detection
The lowest detectable concentration of the standard curve was assayed in six replicate injections. The limit of detection is defined as 3x the standard deviation of these six replicates divided by the slope of the calibration curve.

Limit of quantification
The limit of quantification is defined as 3.3x the limit of detection.

4. Results and discussion

4.1 Method validation

The HPLC method was validated for linearity, accuracy (recovery), range, precision (repeatability) and limit of detection and quantification. Please see Appendix B for validation of the nicotine standard curve. The standard curves for nicotine were linear (y = 0.3513x + 0.6072) with an r^2 > 0.9998 over the range 1.95–500 µg/mL and a y-intercept at 0.86% of the target concentration response (200 µg/mL). At 50%, 100% and 150% of the target concentration response, the recovery of nicotine was 98.95–99.62%. The precision of the retention time, peak area and peak height for nicotine was 0.12–0.50%. The limit of detection and limit of quantification for nicotine was 0.23 µg/mL and 0.75 µg/mL, respectively. Consequently, the proposed HPLC method passed all validation tests and can be considered suitable for quantification of nicotine.

4.2 *In vitro* dissolution experiments

The average nicotine release profiles from the 20 different ZYN products in artificial saliva are shown in Figures 1–2. The raw (average ± SD) data is tabulated in Appendix C and as an illustrative example, the individual release profiles (in mg) from the ZYN Smooth products can be found in Appendix D. The calculation of the difference factor (f1) and similarity factor (f2) was performed by Swedish Match and can be found in Appendix E. In order to account for differences in nicotine dose due to pouch weight variance, the release profiles are plotted as % of dose.

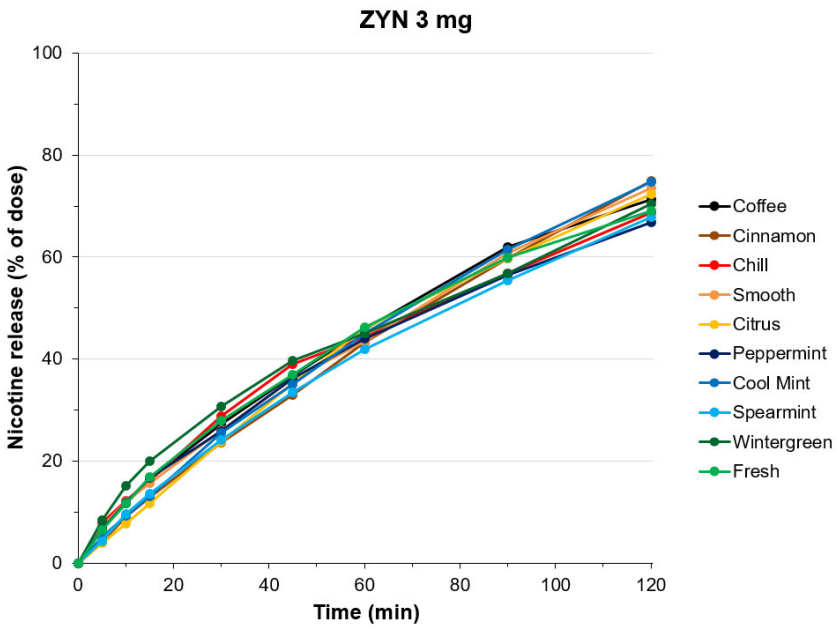

Figure 1: Nicotine *in vitro* release profiles from ZYN 3 mg Coffee (black), Cinnamon (brown), Chill (red), Smooth (orange), Citrus (yellow), Peppermint (dark blue), Cool Mint (blue), Spearmint (light blue), Wintergreen (dark green) and Fresh (light green) in artificial saliva. Data represent average nicotine release in % of dose (n = 12).

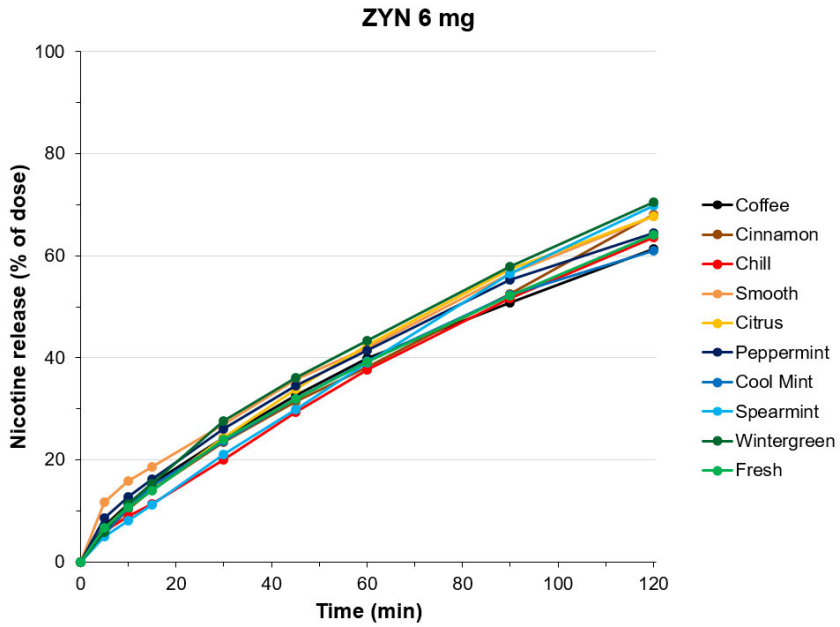

Figure 2: Nicotine *in vitro* release profiles from ZYN 6 mg Coffee (black), Cinnamon (brown), Chill (red), Smooth (orange), Citrus (yellow), Peppermint (dark blue), Cool Mint (blue), Spearmint (light blue), Wintergreen (dark green) and Fresh (light green) in artificial saliva. Data represent average nicotine release in % of dose (n = 12).

As can be seen, the release of nicotine for all products with equivalent dose (ZYN 3 mg and 6 mg, respectively), but different flavor, is almost identical and seem to follow zero-order kinetics i.e. relatively constant dissolution rate over time expect for the first 15 min. For the ZYM 3 mg products, the nicotine release was between 23.6% and 30.6% (0.64 mg and 0.84 mg) after 30 min for Cinnamon and Wintergreen, respectively, and between 42.0% and 46.3% (1.13 mg and 1.31 mg) after 60 min for Spearmint and Fresh, respectively. For the ZYM 6 mg products, the nicotine release was between 20.1% and 27.7% (1.10 mg and 1.61 mg) after 30 min and between 37.7% and 43.3% (2.07 mg and 2.52 mg) after 60 min for Chill and Wintergreen, respectively. The difference in the nicotine release (% of dose) after 30 min and 60 min from all 20 ZYN products are not statistically significant (i.e. $p > 0.05$) in a t-test.

5. Conclusion

In this study, the release of nicotine from 20 different ZYN products was studied using a recently developed µDISS Profiler™ *in vitro* dissolution method. Based on the *in vitro* release experiments, the nicotine release seem to follow zero-order kinetics except for the first 15 min. Furthermore, the nicotine release (in % of dose) after 30 min and 60 min between the products with equivalent dose (ZYN 3 mg and 6 mg, respectively), but different flavor, are not significantly different and therefore, the release profiles may be considered equivalent.

Appendix A

(b) (4)

[redacted]

Appendix B

(b) (4)

[redacted]

Appendix C

(b) (4)

[redacted]

Table C4: Average nicotine release for ZYN Smooth ([redacted]).

Time	ZYN Smooth 3 mg		ZYN Smooth 6 mg	
min	mg ± SD	% ± SD	mg ± SD	% ± SD
(b) (4) [redacted]				

Table C5: Average nicotine release for ZYN Citrus [redacted]

Time	ZYN Citrus 3 mg		ZYN Citrus 6 mg	
min	mg ± SD	% ± SD	mg ± SD	% ± SD
(b) (4) [redacted]				

Table C6: Average nicotine release for ZYN Peppermint [redacted]

Time	ZYN Peppermint 3 mg		ZYN Peppermint 6 mg	
min	mg ± SD	% ± SD	mg ± SD	% ± SD
(b) (4) [redacted]				

Table C7: Average nicotine release for ZYN Cool Mint [redacted]).

Time	ZYN Cool Mint 3 mg		ZYN Cool Mint 6 mg	
min	mg ± SD	% ± SD	mg ± SD	% ± SD
(b) (4) [redacted]				

Table C8: Average nicotine release for ZYN Spearmint (b) (4) [redacted]

Time	ZYN Spearmint 3 mg		ZYN Spearmint 6 mg	
min	mg ± SD	% ± SD	mg ± SD	% ± SD
(b) (4) [redacted]				

Table C9: Average nicotine release for ZYN Wintergreen (b) (4) [redacted]**).**

Time	ZYN Wintergreen 3 mg		ZYN Wintergreen 6 mg	
min	mg ± SD	% ± SD	mg ± SD	% ± SD
(b) (4) [redacted]				

Table C10: Average nicotine release for ZYN Fresh (b) (4) [redacted]

Time	ZYN Fresh 3 mg		ZYN Fresh 6 mg	
min	mg ± SD	% ± SD	mg ± SD	% ± SD
(b) (4) [redacted]				

Appendix D

(b) (4)

[redacted]

Appendix E

Swedish Match

Document type	Date document created	Project name
Report	September 11, 2020	Name
Version	**Date last changed**	**Information class**
Version	September 11, 2020	Class
Created by	**Title**	**Department**
(b) (6)	Senior Research Scientist	Product Science

Statistical Analysis of *In vitro* Release of Nicotine from 20 Different ZYN Products

f_1/f_2 dissolution profile characterization

1. Introduction

To analyze the release behavior of nicotine from twenty ZYN Dry products, with different strength and flavors, that have had dissolution data generated, and to evaluate their similarity and dissimilarity using f_1/f_2 factors.

Bioneer: Farma recently developed a µDISS ProfilerTM dissolution method to study the release profiles of tobacco and nicotine products. The curves generated from this data need to be analyzed in order to quanity the degree of similarity and dissimilarity between the different products.

2. Methods

The FDA has put out a Guidance for Industry for the Dissolution Testing of Immediate Release Solid Oral Dosage Forms. Included in this is a guideline for dissolution profile comparisons. "…a dissolution profile comparison is performed under identical conditions for the product before and after the changes is recommended."

A mathematical approach was developed by J. Moore and H. Flanner in 1996 and has been identified by the FDA for the use in comparing the similarities and differences in dissolution profiles. The difference factor (f_1), calculates the percent difference between the two curves at each time point, measuring the absolute relative error between the two points. (Equation 1)

Equation 1:

$$f_1 = \left(\frac{\sum_{t=1}^{n}|R_t - T_t|}{\sum_{t=1}^{n} R_t}\right) \times 100$$

R_t : cumulative percentage dissolved of Reference Product at time t
T_t : cumulative percentage dissolved of Test Product at time t

The similarity factor (f_2), is a measurement of the similarity in the percent dissolution between two curves. (Equation 2)

Equation 2:

$$f_2 = 50 \times \log\left(100 \times \left(1 + \frac{\sum_{t=1}^{n}(R_t - T_t)^2}{n}\right)^{-\frac{1}{2}}\right)$$

R_t : cumulative percentage dissolved of Reference Product at time t
T_t : cumulative percentage dissolved of Test Product at time t
n: number of time points

For curves to be considered similar, f_1 values should be close to 0, and f_2 values should be close to 100. Generally, dissolution profiles are judged to be equivalent if f_1 values are below 15 and if f_2 values are greater than 50.

3. Results

The average percent (%) nicotine extracted for the 12 units tested of each product were used in Equation 1 and 2 to determine the difference (f_1) and similarity (f_2) factors for the dissolution profiles. ZYN Smooth

of the same strength (3mg or 6mg) was used as the reference product in the calculations. The results can be seen in Table 1.

For all products, the difference factor (f_1), for the dissolution profile comparisons was below 15, with the exception of ZYN Chill 6mg, for which the f_1 factor was slightly higher: 16.9. The similarity factor (f_2) was above 50 for all comparisons. In conclusion, the dissolution profiles of the ZYN products with different flavors are similar to the unflavored reference product (ZYN Smooth).

Table 1: Summary of f_1/f_2 results

Flavor	Strength	f_1	f_2
Wintergreen	3mg	9.3	72.6
	6mg	7.3	74.3
Spearmint	3mg	8.9	72.6
	6mg	14.2	62.5
Cool Mint	3mg	4.5	84.8
	6mg	13.1	65.8
Cinnamon	3mg	6.2	79.5
	6mg	11.7	67.4
Peppermint	3mg	5.0	76.2
	6mg	5.7	80.6
Fresh	3mg	4.8	82.0
	6mg	11.8	68.5
Citrus	3mg	6.9	77.0
	6mg	7.4	73.8
Chill	3mg	6.0	77.4
	6mg	16.9	61.1
Coffee	3mg	3.4	88.6
	6mg	11.8	67.8

4. Conclusion

The dissolution profile comparison of the Reference product (ZYN Smooth) and the Test products (ZYN Wintergreen, Spearmint, Cool Mint, Cinnamon, Peppermint, Fresh, Citrus, Chill and Coffee, 3 mg and 6 mg, respectively) show that the nicotine release profiles of the products are equivalent, thereby demonstrating that the various flavorings do not affect the *in vitro* dissolution profiles.

Swedish Match

ZYN Patterns of Use Study

Post-Hoc Flavor Analysis:

Addendum to Study Report

(b) (4) [redacted]

Product Name:	ZYN®
First Subject Enrolled:	November 27, 2017
Last Subject Completed:	April 12, 2018
Principal Investigators:	(b) (4), (b) (6) [redacted]
Sponsor:	(b) (6) [redacted] Vice President, Scientific Affairs Swedish Match North America
Sponsor Signatory:	
Version:	*1.0*
Report Date:	8 September 2020

Confidentiality Statement

This document and the information it contains is confidential and the proprietary property of Swedish Match North America. The information is not to be disclosed or transmitted to any party without the express approval of Swedish Match North America, or its parent and affiliate companies, and any such unauthorized use or disclosure is expressly prohibited.

Background

From November 27, 2017 through April 12, 2018, (b) (4) conducted a 10-week prospective study for Swedish Match America for their product, ZYN. The objectives of the prospective study were to:

1. Explore daily TNP patterns of use among ZYN users and ZYN non-users, including reasons for ZYN use, over a prospective 10-week observational period.

2. Compare the tendencies of ZYN users to quit TNP or use the product in an incremental fashion, in a supplemental fashion, or in complete substitution of other TNP.

The outputs of that study were submitted to the FDA as part of the ZYN premarket tobacco product application (PMTA). On July 24, 2020, the FDA issued a letter (STNs: PM0000593-PM0000612) to Swedish Match America asking for additional information in regards to the prospective data. Specifically, the letter stated:

> *All of your PMTAs provide data on ZYN flavors and switching from cigarettes to ZYN products overall from a prospective study. This study showed that 24% of ZYN users completely substituted ZYN in place of other tobacco and nicotine products (i.e., switching), including cigarettes. This study also provided the overall percentage of ZYN flavors used each week during the 10-week prospective study. However, although you collected data on the flavored products used in the study, you did not provide any information about ZYN product use or uptake by flavor. Flavors play an important role in tobacco use behavior, and, in the absence of data on patterns of ZYN use by flavor, FDA is unable to provide a complete assessment of these PMTAs from the epidemiology perspective. In order to address this concern, provide analyses of ZYN patterns of use by flavor from your prospective study of product switching.*

Objectives

The objective of this post-hoc analysis was to address the FDA's request to examine ZYN patterns of use and product switching by flavor from the 10-week prospective study.

Methods

Data was analyzed from the ZYN 10-week prospective study, please refer to Study Protocol and Final Report for details on methodology, including study design and sample inclusion and exclusion criteria.

Statistical Analyses

This post-hoc analyses included a replication of Study Final Report Table 17 (TNP Patterns of Use Among ZYN Users During the Prospective Observational Period. Outcomes Include Percent of Days That ZYN is Used, Average Number of ZYN Pouches Used Per Day, and Average Number of Minutes ZYN was Kept in the Mouth) and Table 19 (Among ZYN Users, Quitting All TNP Use at the End of the Prospective Observational Period, and Completely Substituting Other TNP for ZYN) by flavor. As it was possible for participants to use multiple flavors throughout the 10-week period, we grouped participants according to

their most frequently used flavor during the 10-week period. Flavors included cool mint, peppermint, wintergreen, spearmint, cinnamon, and coffee.

Descriptive statistics were reported for these ad hoc analyses and included the number of non-missing observations, means, standard deviations, and 95% confidence intervals (CIs), for numeric variables. For categorical variables, they included the number of non-missing observations, frequencies, percentages, and 95% CIs for the percentage of respondents endorsing each category.

Results

TNP Patterns of Use Among ZYN Users During the Prospective Observational Period by Flavor. Outcomes Include Percent of Days That ZYN is Used, Average Number of ZYN Pouches Used Per Day, and Average Number of Minutes ZYN was Kept in the Mouth.

Table 1 shows the results for TNP patterns of use among ZYN users during the 10-week prospective period by their most frequently used flavor during the period. Cool Mint had the highest number of users ((b) (4) and coffee had the lowest ((b) (4)

Table 1 - Distribution of Flavors
Most Frequently Used Flavor over 10-Week Period

	N	%
Total	(b) (4)	100.0%
Cool Mint	[redacted]	24.9%
Wintergreen	[redacted]	21.7%
Spearmint	[redacted]	18.5%
Peppermint	[redacted]	14.7%
Cinnamon	[redacted]	14.2%
Coffee	[redacted]	6.6%

Across all flavors, the percent of days in which ZYN was used decreased from week 1 to week 10 (Appendix Table 1). Average consumption by flavor was also relatively consistent across the ten-week period (Appendix Table 1). Table 2 below shows the percentage of days used at week 10 with the percentage of days used ranging from 96% to 81%. Coffee and spearmint users had had the overall highest percentage of days used ZYN (96%). However, these results do not necessarily mean that the coffee or spearmint flavor was used every day, only that it was the most frequently used flavor during the observational period. Cinnamon users had the lowest percentage of days used ZYN at week 10 (81%).

Table 2 - Percentage of Days - Week 10
Average Percentage of Days Used

	(b) (4)	% Days
Coffee	[redacted]	96%
Spearmint	[redacted]	96%
Wintergreen	[redacted]	92%
Cool Mint	[redacted]	91%
Peppermint	[redacted]	91%
Cinnamon	[redacted]	81%

Number of pouches used per day was also fairly consistent across the 10-week period. Table 3 shows that at week 10, consumption by flavor fell within a range of 6.69 pouches per day for Cinnamon to 10.48 pouches per day for Coffee.

Table 3 - Daily Consumption by Flavor - Week 10
Average Number of Pouches Used per Day

	(b) (4)	# Pouches
Cinnamon	[redacted]	6.69
Cool Mint	[redacted]	7.54
Peppermint	[redacted]	7.97
Spearmint	[redacted]	8.38
Wintergreen	[redacted]	9.21
Coffee	[redacted]	10.48

Flavors had minimal impact on the average number of minutes ZYN pouches were used. There was little variation from week to week and for simplicity, Table 4 shows the results for Week 10. Spearmint was kept in the mouth the longest (53.6 minutes) and cinnamon the shortest (46.9 minutes).

Table 4 - Minutes Used - Week 10
Average Number of Minutes Pouches Used

	(b) (4)	# Minutes
Spearmint		53.6
Wintergreen		49.3
Peppermint		49.2
Cool Mint		49.0
Coffee		48.9
Cinnamon		46.9

Among ZYN Users, Quitting All TNP Use at the End of the Prospective Observational Period, and Completely Substituting Other TNP for ZYN) by Flavor.

Appendix Table 2 shows the results for quitting all TNP and completely substituting other TNP for ZYN at the end of the prospective period by flavor. A small percentage of ZYN users quit all TNP by weeks 9 and 10 (b) (4)). Due to the small absolute counts by flavor, the percentage of quitting all TNP were similar across flavors ((b) (4)). As previously reported, (b) (4) of all ZYN users had completely substituted ZYN in place of other TNP by end of the prospective period. When examining this by flavor, the highest percentage of complete substitution were coffee (b) (4) and spearmint users ((b) (4)). The percentage of complete substitution for cool mint, peppermint, cinnamon, and wintergreen were fairly similar across these flavors ((b) (4)

Conclusions

Post hoc analyses by flavor on ZYN patterns of use and complete substitution of ZYN for all other TNPs by end of prospective period found minor differences by flavor. For percentage of days in which ZYN was used, users who most frequently used spearmint and coffee had the highest usage in absolute terms but the difference only varied about 5% compared with cool mint, peppermint, and wintergreen. Users who most frequently used cinnamon had the lowest percentage of days using ZYN. Thus, flavors appear to have little impact on usage patterns.

Quitting all TNP by end of prospective period was similar across the flavors. Complete substitution of TNP with ZYN was highest among those who most frequently used spearmint and coffee, mirroring the results for percentage of days using ZYN. Overall, results need to be interpreted with caution due to low sample sizes for some flavors. Additionally, it is

possible that ZYN users used more than one flavor during the course of the prospective period as ZYN users were classified based on their most frequently used flavor during the 10 weeks.

APPENDIX

Appendix Table 1. Secondary Objective 5 – TNP patterns of use among ZYN® users during the prospective observational period by flavor. Outcomes include percent of days that ZYN® is used, average number of ZYN® pouches used per day, and average number of minutes ZYN® was kept in the mouth.

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

Appendix Table 2. Secondary Objective 6 - Among ZYN® Users, quitting all TNP use at the end of the prospective observational period, and completely substituting other TNP for ZYN® by flavor.

(b) (4)

[redacted]

ATTACHMENTS – ENVIRONMENTAL ASSESSMENTS

1 **Environmental Assessment for the ZYN Chill (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Chill (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Chill. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Chill product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Chill (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Chill (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Chill (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

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60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Chill 3 mg	920510	8136

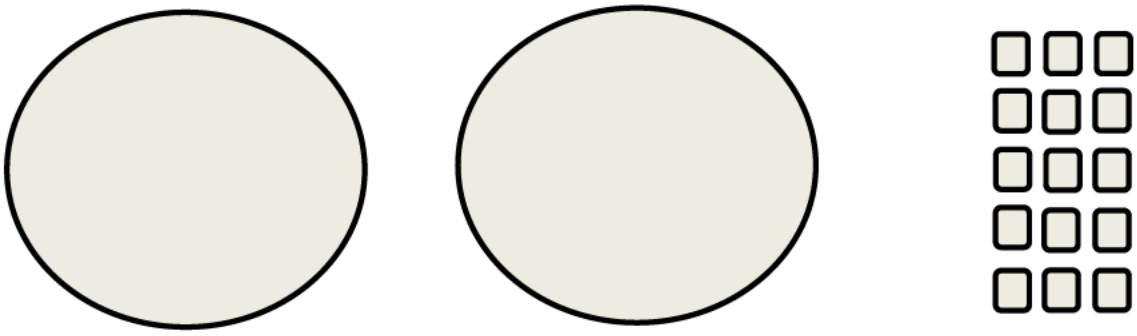
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volume in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

353 mile radius), based on the 2010 US Census and American Community Service data, minorities
354 make up 16% of the population and the facility is not located in proximity to Indian Country.[6]
355 White residents make up approximately 86% of the population near the facility.[7] Accordingly,
356 manufacture of the new product is not expected to affect subsistence patterns of consumption of
357 fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes).
358 Further, no disproportionate disruption of the community structure or patterns of living of low
359 income or minority populations is expected as a result of manufacturing the new product.
360
361 Use. Marketing materials and consumer research included in the application do not indicate
362 health impacts related to the new product would disproportionately affect minority or low-
363 income populations. This application includes marketing materials reflecting that the target
364 audience of the new product is a consumer who currently uses a tobacco or nicotine product and
365 who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher
366 incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also
367 finds a correlation between consumers and quitting behavior, indicating that the more times a
368 tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch
369 products. Consumer research also indicates that nicotine pouches have minimal appeal to
370 consumers who do not currently use tobacco or nicotine products.[9]
371
372 This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of
373 Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income
374 or minority populations[10] would disproportionately adopt use of the new product. In addition to
375 the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020),
376 all of which arrive at the following conclusions:
377
378 • Individuals who do not currently use tobacco or nicotine products were found not
379 likely to initiate or re-initiate the use of tobacco or nicotine products after viewing
380 the ZYN products description and packaging material.[11]
381 • Moreover, users of ZYN products who were smokers were found to have a greater
382 intention to quit than non-users of ZYN products.[12]
383 • ZYN users who smoke also reported intention to quit smoking that tended to
384 increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] Marketing Plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free smokeless tobacco product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of exotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[redacted]

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, as a reminder to FDA, there is a high likelihood that certain tobacco product
551 users will cease using – or reduce the amount they use of – cigarettes, moist snuff, or chewing
552 tobacco based upon Swedish Match's consumer research. This likelihood would result in a
553 corresponding effect on the materials associated with the production, manufacture, transport, and
554 disposal after use of these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 (b) (6) [redacted]

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Chill (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Chill (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Chill. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Chill product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Chill (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Chill (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Chill (6 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

59

60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Chill 6 mg	920520	8137

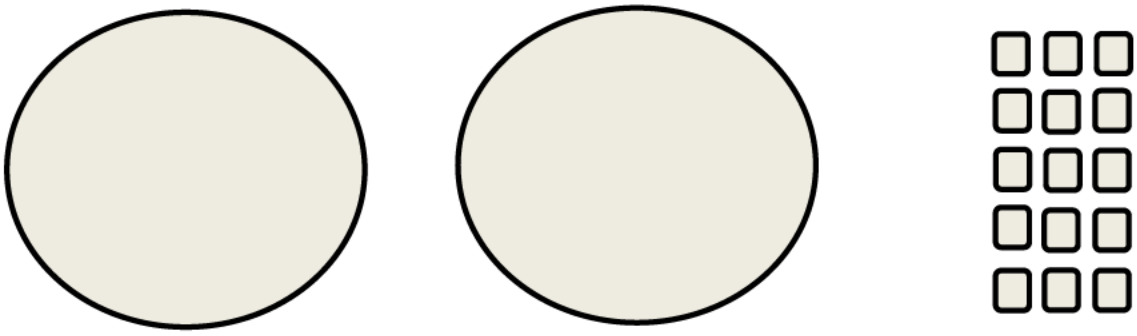
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

353 mile radius), based on the 2010 US Census and American Community Service data, minorities
354 make up 16% of the population and the facility is not located in proximity to Indian Country.[6]
355 White residents make up approximately 86% of the population near the facility.[7] Accordingly,
356 manufacture of the new product is not expected to affect subsistence patterns of consumption of
357 fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes).
358 Further, no disproportionate disruption of the community structure or patterns of living of low
359 income or minority populations is expected as a result of manufacturing the new product.
360
361 Use. Marketing materials and consumer research included in the application do not indicate
362 health impacts related to the new product would disproportionately affect minority or low-
363 income populations. This application includes marketing materials reflecting that the target
364 audience of the new product is a consumer who currently uses a tobacco or nicotine product and
365 who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher
366 incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also
367 finds a correlation between consumers and quitting behavior, indicating that the more times a
368 tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch
369 products. Consumer research also indicates that nicotine pouches have minimal appeal to
370 consumers who do not currently use tobacco or nicotine products.[9]
371
372 This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of
373 Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income
374 or minority populations[10] would disproportionately adopt use of the new product. In addition to
375 the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020),
376 all of which arrive at the following conclusions:
377
378 • Individuals who do not currently use tobacco or nicotine products were found not
379 likely to initiate or re-initiate the use of tobacco or nicotine products after viewing
380 the ZYN products description and packaging material.[11]
381 • Moreover, users of ZYN products who were smokers were found to have a greater
382 intention to quit than non-users of ZYN products.[12]
383 • ZYN users who smoke also reported intention to quit smoking that tended to
384 increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of exotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreoever, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[redacted]

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4)	[redacted]									
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4)	[redacted]			
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
551 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
552 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
553 the materials associated with the production, manufacture, transport, and disposal after use of
554 these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 (b) (6)

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Cinnamon (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cinnamon (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Cinnamon. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Cinnamon product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Cinnamon (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Cinnamon (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cinnamon (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

60

61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Cinnamon 3 mg	906510	8128

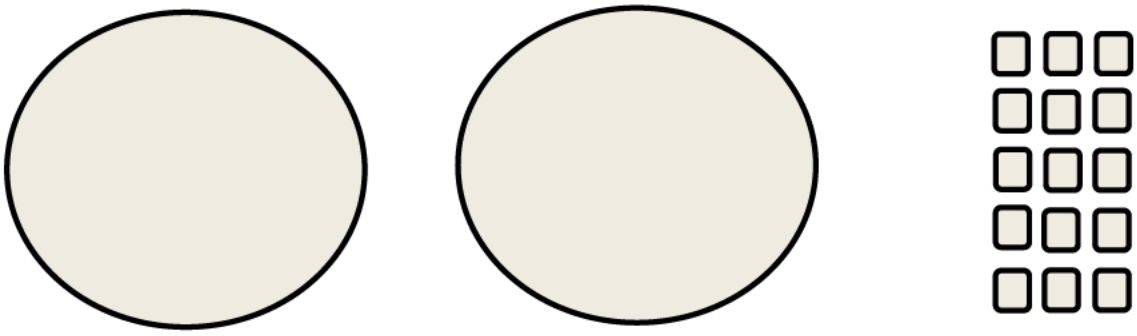
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of exotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 (b) (6)

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743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Cinnamon (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cinnamon (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Cinnamon. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Cinnamon product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Cinnamon (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Cinnamon (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cinnamon (6 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

60

61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Cinnamon 6 mg	906520	8129

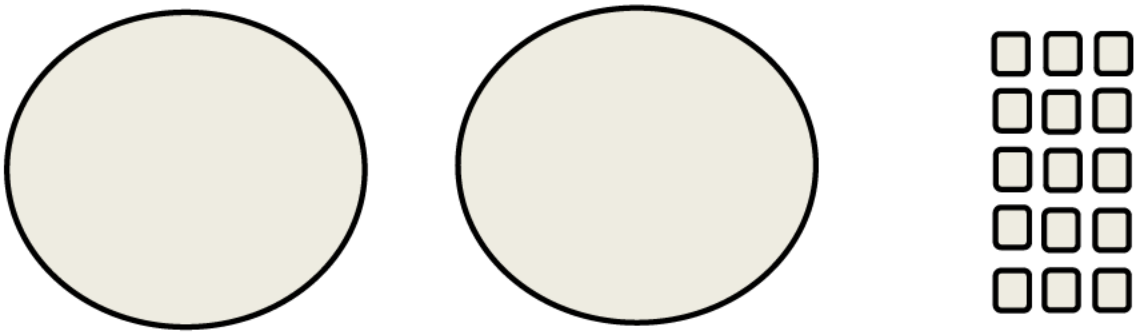
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volume in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of -0.78%.

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 [redacted]

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Citrus (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Citrus (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Citrus. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Citrus product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Citrus (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Citrus (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Citrus (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

59

60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Citrus 3 mg	907510	8122

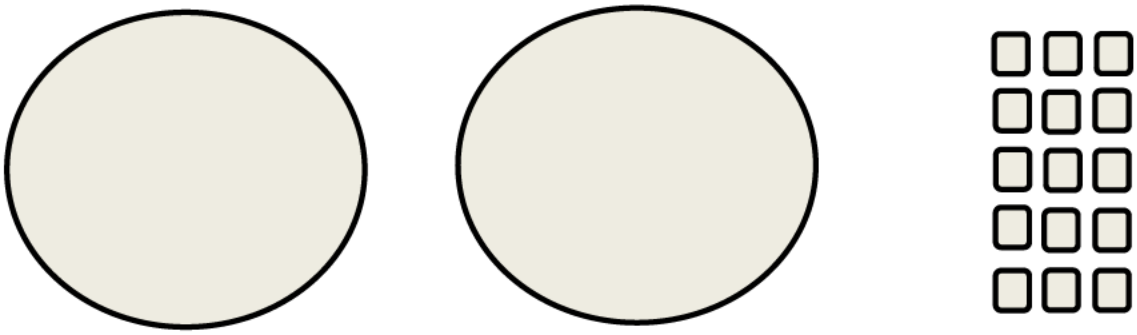
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
551 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
552 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
553 the materials associated with the production, manufacture, transport, and disposal after use of
554 these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted], Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Swedish Match.

9/24/2020

(b) (6)

Gerry Roerty, Jr., VP, General Counsel & Sec.
(Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Citrus (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Citrus (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Citrus. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Citrus product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Citrus (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Citrus (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Citrus (6 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

59

60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Citrus 6 mg	907520	8123

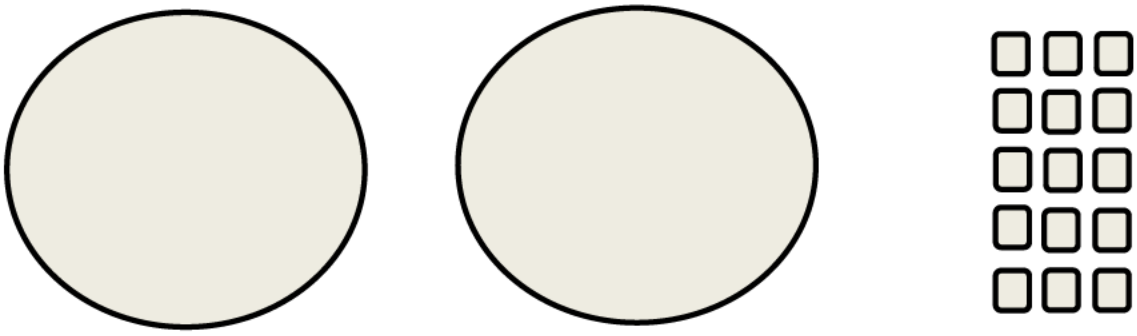
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

105 In order to quantitatively assess the environmental impact of manufacturing, use, and disposal
106 from use of the new product, Swedish Match is providing current year data (2020) plus five
107 years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the
108 Confidential Appendix to the Environmental Assessment).

109 III. DESCRIPTION OF PROPOSED ACTION

110 A. Purpose of and Need for Action

111 The proposed action, requested by the applicant, is for FDA to issue a marketing order finding
112 the "deemed" new tobacco product appropriate for the protection of public health under the
113 provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The
114 applicant wishes to continue commercially distributing the new tobacco product in interstate
115 commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after
116 considering the application submitted by the applicant, the new product is found appropriate for
117 the protection of public health.

118 B. Location of Use

119 The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY,
120 with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold
121 to adult consumers at a variety of retail establishments and consumed primarily in homes and
122 automobiles. The new product will be widely distributed and use of the new product will
123 correspond with national population density, as do tobacco products from other categories,
124 including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco"
125 or "snus").

126 C. Location of Disposal

127 Used tobacco products and empty packaging, including that associated with the new product, are
128 typically disposed of in community solid waste management systems, which may include
129 landfills, incineration, and recycling. This disposal by the end user would be in the same manner
130 as other products contained in similar recyclable packaging, including the recyclable packaging
131 used in smokeless tobacco products manufactured in the same facility. According to the U.S.
132 Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United
133 States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and
134 35.2% was recovered (recycled and composted). The types of environments present at and
135 adjacent to these disposal locations will not differ for the new product.

136 D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

353 mile radius), based on the 2010 US Census and American Community Service data, minorities
354 make up 16% of the population and the facility is not located in proximity to Indian Country.[6]
355 White residents make up approximately 86% of the population near the facility.[7] Accordingly,
356 manufacture of the new product is not expected to affect subsistence patterns of consumption of
357 fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes).
358 Further, no disproportionate disruption of the community structure or patterns of living of low
359 income or minority populations is expected as a result of manufacturing the new product.
360
361 Use. Marketing materials and consumer research included in the application do not indicate
362 health impacts related to the new product would disproportionately affect minority or low-
363 income populations. This application includes marketing materials reflecting that the target
364 audience of the new product is a consumer who currently uses a tobacco or nicotine product and
365 who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher
366 incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also
367 finds a correlation between consumers and quitting behavior, indicating that the more times a
368 tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch
369 products. Consumer research also indicates that nicotine pouches have minimal appeal to
370 consumers who do not currently use tobacco or nicotine products.[9]
371
372 This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of
373 Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income
374 or minority populations[10] would disproportionately adopt use of the new product. In addition to
375 the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020),
376 all of which arrive at the following conclusions:
377
378 • Individuals who do not currently use tobacco or nicotine products were found not
379 likely to initiate or re-initiate the use of tobacco or nicotine products after viewing
380 the ZYN products description and packaging material.[11]
381 • Moreover, users of ZYN products who were smokers were found to have a greater
382 intention to quit than non-users of ZYN products.[12]
383 • ZYN users who smoke also reported intention to quit smoking that tended to
384 increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreever, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4)										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4)				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
551 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
552 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
553 the materials associated with the production, manufacture, transport, and disposal after use of
554 these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

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742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Coffee (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Coffee (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Coffee. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Coffee product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Coffee (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Coffee (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Coffee (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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56
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58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

59

60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Coffee 3 mg	904510	8124

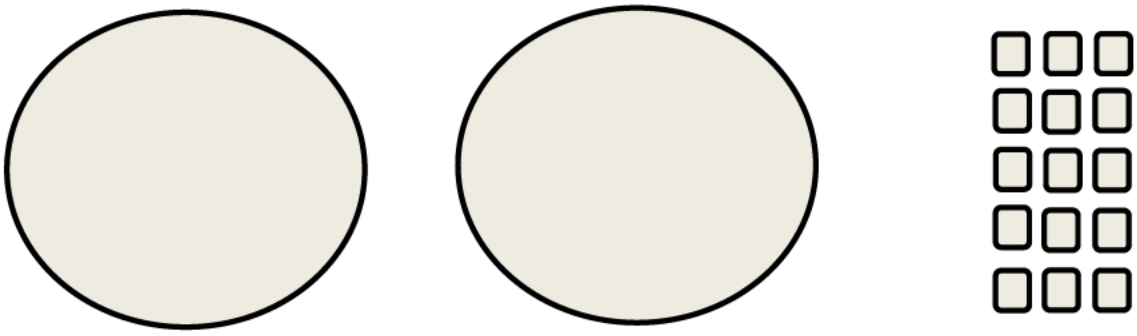
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

353 mile radius), based on the 2010 US Census and American Community Service data, minorities
354 make up 16% of the population and the facility is not located in proximity to Indian Country.[6]
355 White residents make up approximately 86% of the population near the facility.[7] Accordingly,
356 manufacture of the new product is not expected to affect subsistence patterns of consumption of
357 fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes).
358 Further, no disproportionate disruption of the community structure or patterns of living of low
359 income or minority populations is expected as a result of manufacturing the new product.
360
361 Use. Marketing materials and consumer research included in the application do not indicate
362 health impacts related to the new product would disproportionately affect minority or low-
363 income populations. This application includes marketing materials reflecting that the target
364 audience of the new product is a consumer who currently uses a tobacco or nicotine product and
365 who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher
366 incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also
367 finds a correlation between consumers and quitting behavior, indicating that the more times a
368 tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch
369 products. Consumer research also indicates that nicotine pouches have minimal appeal to
370 consumers who do not currently use tobacco or nicotine products.[9]
371
372 This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of
373 Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income
374 or minority populations[10] would disproportionately adopt use of the new product. In addition to
375 the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020),
376 all of which arrive at the following conclusions:
377
378 • Individuals who do not currently use tobacco or nicotine products were found not
379 likely to initiate or re-initiate the use of tobacco or nicotine products after viewing
380 the ZYN products description and packaging material.[11]
381 • Moreover, users of ZYN products who were smokers were found to have a greater
382 intention to quit than non-users of ZYN products.[12]
383 • ZYN users who smoke also reported intention to quit smoking that tended to
384 increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
551 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
552 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
553 the materials associated with the production, manufacture, transport, and disposal after use of
554 these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 [redacted]

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Coffee (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Coffee (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Coffee. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Coffee product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Coffee (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Coffee (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Coffee (6 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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57

58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

59

60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Coffee 6 mg	904520	8125

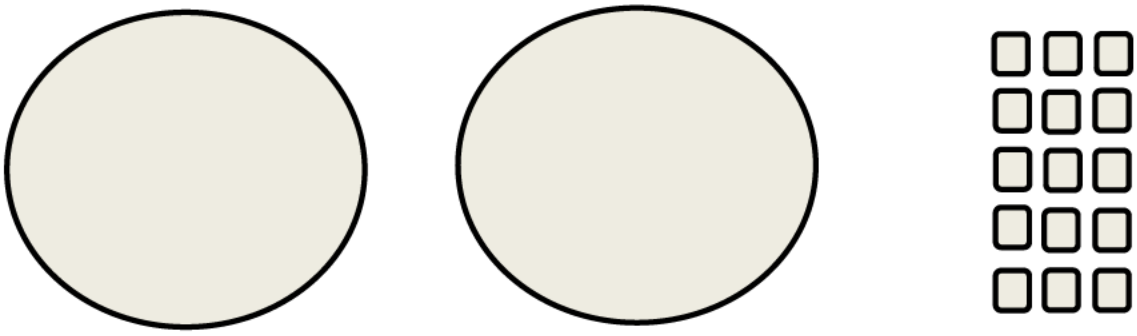
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco products users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

353 mile radius), based on the 2010 US Census and American Community Service data, minorities
354 make up 16% of the population and the facility is not located in proximity to Indian Country.[6]
355 White residents make up approximately 86% of the population near the facility.[7] Accordingly,
356 manufacture of the new product is not expected to affect subsistence patterns of consumption of
357 fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes).
358 Further, no disproportionate disruption of the community structure or patterns of living of low
359 income or minority populations is expected as a result of manufacturing the new product.
360
361 Use. Marketing materials and consumer research included in the application do not indicate
362 health impacts related to the new product would disproportionately affect minority or low-
363 income populations. This application includes marketing materials reflecting that the target
364 audience of the new product is a consumer who currently uses a tobacco or nicotine product and
365 who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher
366 incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also
367 finds a correlation between consumers and quitting behavior, indicating that the more times a
368 tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch
369 products. Consumer research also indicates that nicotine pouches have minimal appeal to
370 consumers who do not currently use tobacco or nicotine products.[9]
371
372 This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of
373 Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income
374 or minority populations[10] would disproportionately adopt use of the new product. In addition to
375 the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020),
376 all of which arrive at the following conclusions:
377
378 • Individuals who do not currently use tobacco or nicotine products were found not
379 likely to initiate or re-initiate the use of tobacco or nicotine products after viewing
380 the ZYN products description and packaging material.[11]
381 • Moreover, users of ZYN products who were smokers were found to have a greater
382 intention to quit than non-users of ZYN products.[12]
383 • ZYN users who smoke also reported intention to quit smoking that tended to
384 increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4)	[redacted]									
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4)	[redacted]			
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
551 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
552 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
553 the materials associated with the production, manufacture, transport, and disposal after use of
554 these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

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World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

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739 9/24/2020

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743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Cool Mint (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cool Mint (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Cool Mint. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Cool Mint product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Cool Mint (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Cool Mint (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cool Mint (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

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61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Cool Mint 3 mg	900510	8105

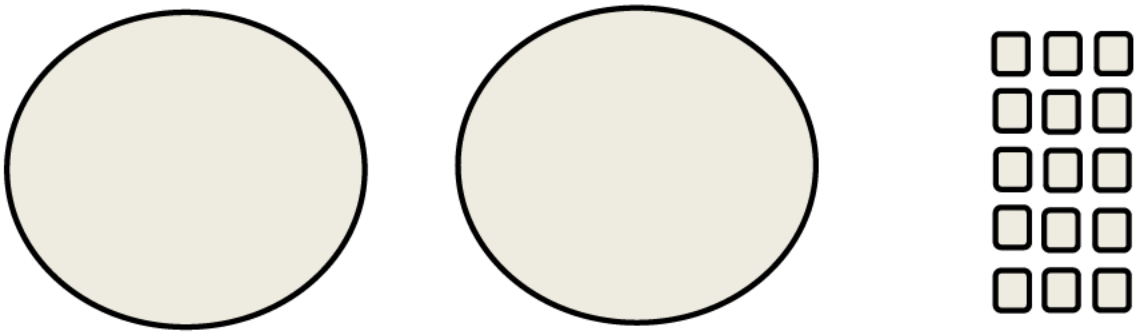
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 (b) (6)

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Cool Mint (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cool Mint (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Cool Mint. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Cool Mint product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Cool Mint (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Cool Mint (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cool Mint (6 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

60

61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Cool Mint 6 mg	900520	8106

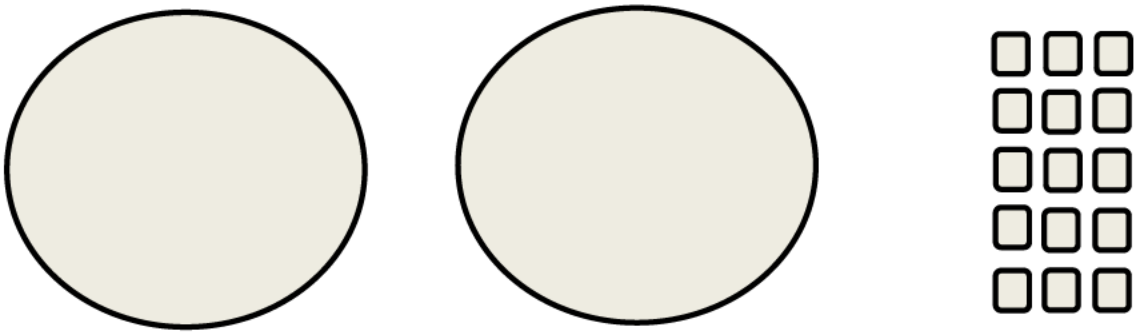
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (6) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 [redacted]

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743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Fresh (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Fresh (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Fresh. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Fresh product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Fresh (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Fresh (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Fresh (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

59

60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Fresh 3 mg	921510	8140

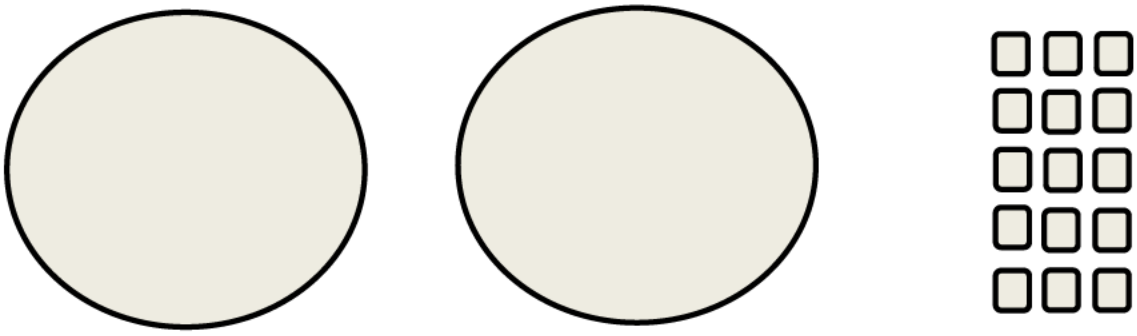
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the ontinued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., (b) (4) [redacted]) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a -(b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
551 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
552 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
553 the materials associated with the production, manufacture, transport, and disposal after use of
554 these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 [redacted]

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Fresh (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Fresh (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Fresh. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Fresh product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Fresh (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Fresh (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Fresh (6 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

59

60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Fresh 6 mg	921520	8141

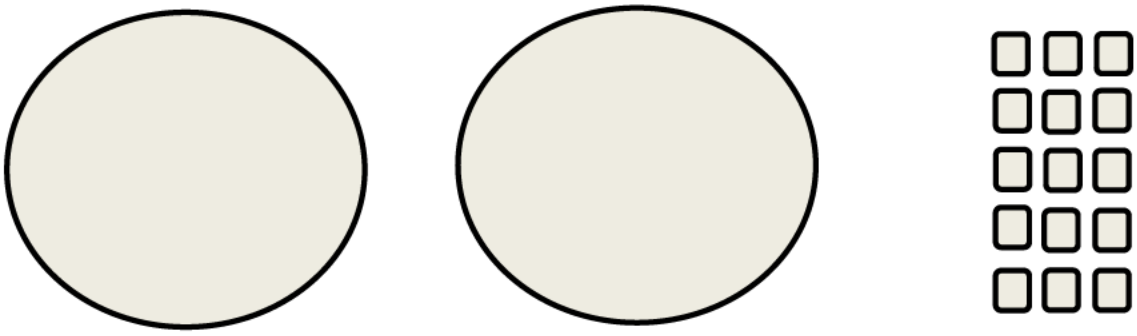
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

105 In order to quantitatively assess the environmental impact of manufacturing, use, and disposal
106 from use of the new product, Swedish Match is providing current year data (2020) plus five
107 years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the
108 Confidential Appendix to the Environmental Assessment).

109 III. DESCRIPTION OF PROPOSED ACTION

110 A. Purpose of and Need for Action

111 The proposed action, requested by the applicant, is for FDA to issue a marketing order finding
112 the "deemed" new tobacco product appropriate for the protection of public health under the
113 provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The
114 applicant wishes to continue commercially distributing the new tobacco product in interstate
115 commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after
116 considering the application submitted by the applicant, the new product is found appropriate for
117 the protection of public health.

118 B. Location of Use

119 The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY,
120 with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold
121 to adult consumers at a variety of retail establishments and consumed primarily in homes and
122 automobiles. The new product will be widely distributed and use of the new product will
123 correspond with national population density, as do tobacco products from other categories,
124 including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco"
125 or "snus").

126 C. Location of Disposal

127 Used tobacco products and empty packaging, including that associated with the new product, are
128 typically disposed of in community solid waste management systems, which may include
129 landfills, incineration, and recycling. This disposal by the end user would be in the same manner
130 as other products contained in similar recyclable packaging, including the recyclable packaging
131 used in smokeless tobacco products manufactured in the same facility. According to the U.S.
132 Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United
133 States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and
134 35.2% was recovered (recycled and composted). The types of environments present at and
135 adjacent to these disposal locations will not differ for the new product.

136 D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and other tobacco product users to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of -0.78%.

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
551 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
552 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
553 the materials associated with the production, manufacture, transport, and disposal after use of
554 these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

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739 9/24/2020

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743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Peppermint (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Peppermint (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Peppermint. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Peppermint product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Peppermint (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Peppermint (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Peppermint (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

60

61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Peppermint 3 mg	901510	8107

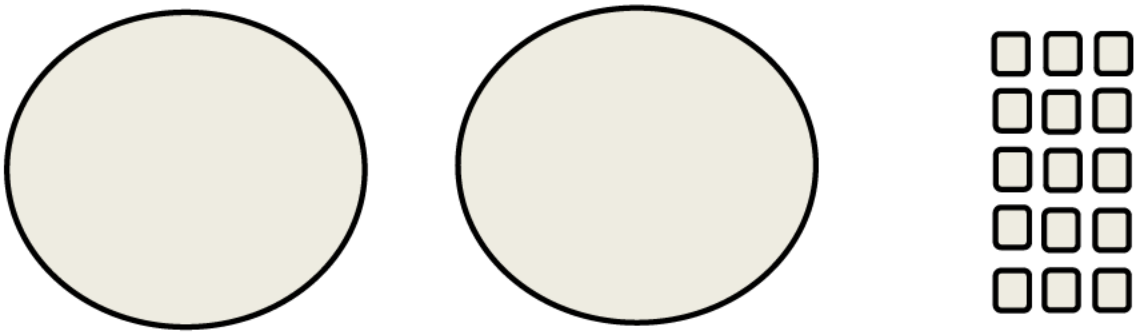
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 [redacted]

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Peppermint (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Peppermint (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Peppermint. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Peppermint product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Peppermint (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Peppermint (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Peppermint (6

mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

60

61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Peppermint 6 mg	901520	8108

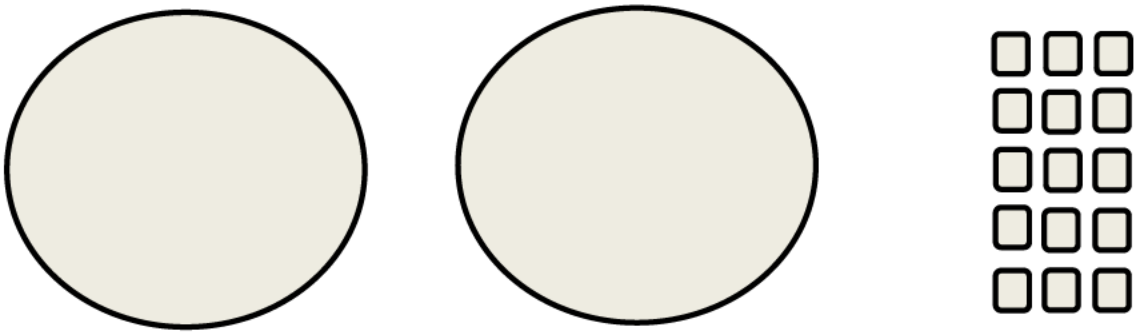
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and other tobacco product users to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of -0.78%.

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) [redacted] annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

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742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Smooth (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Smooth (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Smooth. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Smooth product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Smooth (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Smooth (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Smooth (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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57

58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

59

60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Smooth 3 mg	914510	8134

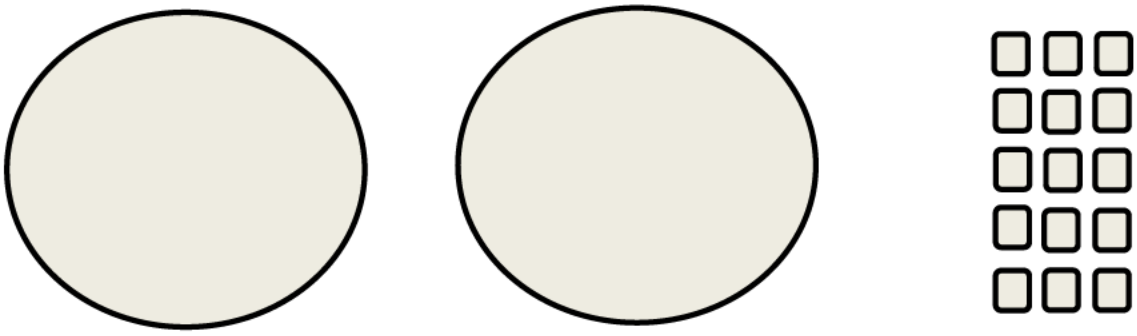
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and other tobacco product users to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

353 mile radius), based on the 2010 US Census and American Community Service data, minorities
354 make up 16% of the population and the facility is not located in proximity to Indian Country.[6]
355 White residents make up approximately 86% of the population near the facility.[7] Accordingly,
356 manufacture of the new product is not expected to affect subsistence patterns of consumption of
357 fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes).
358 Further, no disproportionate disruption of the community structure or patterns of living of low
359 income or minority populations is expected as a result of manufacturing the new product.
360
361 Use. Marketing materials and consumer research included in the application do not indicate
362 health impacts related to the new product would disproportionately affect minority or low-
363 income populations. This application includes marketing materials reflecting that the target
364 audience of the new product is a consumer who currently uses a tobacco or nicotine product and
365 who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher
366 incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also
367 finds a correlation between consumers and quitting behavior, indicating that the more times a
368 tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch
369 products. Consumer research also indicates that nicotine pouches have minimal appeal to
370 consumers who do not currently use tobacco or nicotine products.[9]
371
372 This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of
373 Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income
374 or minority populations[10] would disproportionately adopt use of the new product. In addition to
375 the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020),
376 all of which arrive at the following conclusions:
377
378 • Individuals who do not currently use tobacco or nicotine products were found not
379 likely to initiate or re-initiate the use of tobacco or nicotine products after viewing
380 the ZYN products description and packaging material.[11]
381 • Moreover, users of ZYN products who were smokers were found to have a greater
382 intention to quit than non-users of ZYN products.[12]
383 • ZYN users who smoke also reported intention to quit smoking that tended to
384 increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4) [redacted].

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4)										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4)				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
551 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
552 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
553 the materials associated with the production, manufacture, transport, and disposal after use of
554 these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 (b) (6)

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Smooth (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Smooth (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Smooth. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Smooth product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Smooth (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Smooth (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Smooth (6 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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58 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

59

60 # II. PRODUCT INFORMATION

61 ## A. Identification of the Products

62 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
63 Location
64

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Smooth 6 mg	914520	8135

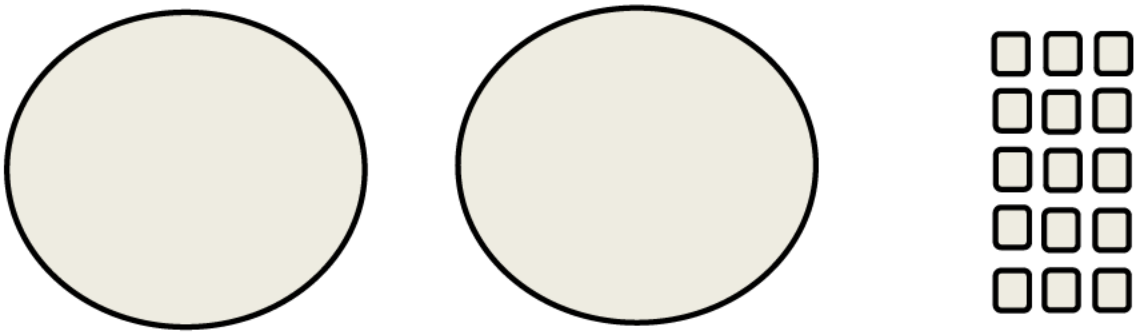
65
66 ## B. Description of the Products

67 The new product is a portioned pouched tobacco product within the deemed "other tobacco
68 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
69 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
70 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

71 The new product's application has been submitted under the premarket tobacco product
72 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
73 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
74 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
75 FDA extended the timeline for manufactures to submit tobacco product review applications for
76 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

353 mile radius), based on the 2010 US Census and American Community Service data, minorities
354 make up 16% of the population and the facility is not located in proximity to Indian Country.[6]
355 White residents make up approximately 86% of the population near the facility.[7] Accordingly,
356 manufacture of the new product is not expected to affect subsistence patterns of consumption of
357 fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes).
358 Further, no disproportionate disruption of the community structure or patterns of living of low
359 income or minority populations is expected as a result of manufacturing the new product.
360
361 Use. Marketing materials and consumer research included in the application do not indicate
362 health impacts related to the new product would disproportionately affect minority or low-
363 income populations. This application includes marketing materials reflecting that the target
364 audience of the new product is a consumer who currently uses a tobacco or nicotine product and
365 who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher
366 incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also
367 finds a correlation between consumers and quitting behavior, indicating that the more times a
368 tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch
369 products. Consumer research also indicates that nicotine pouches have minimal appeal to
370 consumers who do not currently use tobacco or nicotine products.[9]
371
372 This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of
373 Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income
374 or minority populations[10] would disproportionately adopt use of the new product. In addition to
375 the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020),
376 all of which arrive at the following conclusions:
377
378 • Individuals who do not currently use tobacco or nicotine products were found not
379 likely to initiate or re-initiate the use of tobacco or nicotine products after viewing
380 the ZYN products description and packaging material.[11]
381 • Moreover, users of ZYN products who were smokers were found to have a greater
382 intention to quit than non-users of ZYN products.[12]
383 • ZYN users who smoke also reported intention to quit smoking that tended to
384 increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

536

537 **2.** As a Result of Use

538 The new product will be used similarly to other portioned tobacco products, including smokeless
539 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
540 disposal of used product and "spit" generated during product use are anticipated. When the
541 pouch has been consumed by the consumer practically none of the contents of the pouch will
542 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
543 the pouch during consumption and should not result in spitting. The use of the new product
544 would result in the direct introduction of little or no change in the complexity of the ingredients
545 nor any of the other ingredients into the environment because these ingredients are consumed
546 during use.
547
548 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
549 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
550 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
551 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
552 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
553 the materials associated with the production, manufacture, transport, and disposal after use of
554 these tobacco products.

555

556 **3.** As a Result of Disposal

557 The new product and any associated waste will be disposed of by the end user in the same
558 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
559 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
560 ultimate consumer of plastic cans, used product, and any other waste material will be by
561 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
562 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
563 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
564 corresponding effect on the materials associated with the production, manufacture, transport, and
565 disposal after use of this tobacco product. The proposed action may result in an increased
566 product sale. However, this increase is expected to be offset by the reduction in the use of other
567 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
568 completely to the new product or substitute their more harmful tobacco product with the new
569 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
570 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
571 tobacco) in the United States, and waste from the product will make up a very small portion of
572 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
573 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

It will not significantly alter the emissions from properly operating municipal solid waste combustors. As a result, those municipal solid waste incinerators will continue to operate in compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant state and local laws.

B. Fate of Products Released into the Environment

The new product is expected to enter the environment in extremely small, negligible,[17] quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not anticipate that the fate of any materials from this product will be different from other smokeless tobacco products commercially available. Thus, no meaningful impacts are expected on air, water, and land resources or on the organisms that inhabit these media as a result of the proposed action.

Consumers would dispose of the new product's used pouch and packaging materials in appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of excreted materials occurs through the sewage discharge of human solid waste.

Swedish Match assessed any potential impact from disposal following use of the new product through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and Google Scholar search; citations discussed in more detail below). To our knowledge, there is no peer-reviewed research specifically assessing the environmental impact of the disposal after use of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible tobacco products, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned authors extrapolated from these results and applied them to the context of "other tobacco products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish Match does not find any correlation between the post-consumer waste of the new product with the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014: 208). The new product's manufacture, transport, use and disposal should be viewed with a low level of concern, as it is not expected to contribute to any significant new or additional environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted], Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

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743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Spearmint (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Spearmint (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Spearmint. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Spearmint product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Spearmint (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Spearmint (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Spearmint (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

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61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Spearmint 3 mg	902510	8109

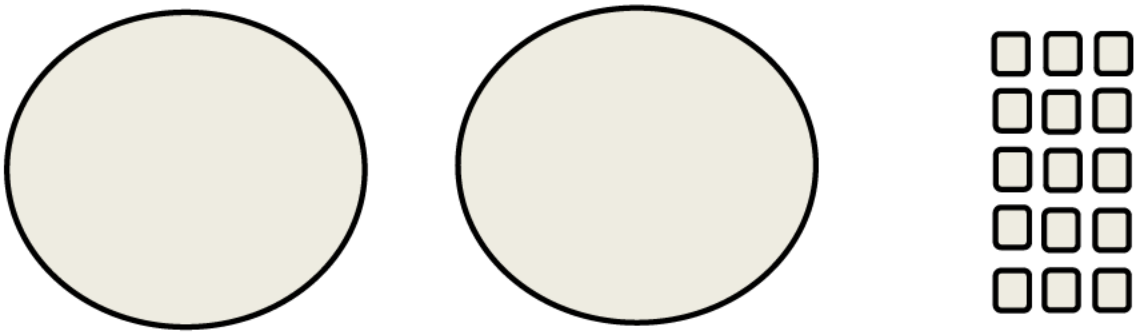
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted]., Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 (b) (6)

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Spearmint (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Spearmint (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Spearmint. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Spearmint product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Spearmint (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Spearmint (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Spearmint (6 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

60

61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Spearmint 6 mg	902520	8110

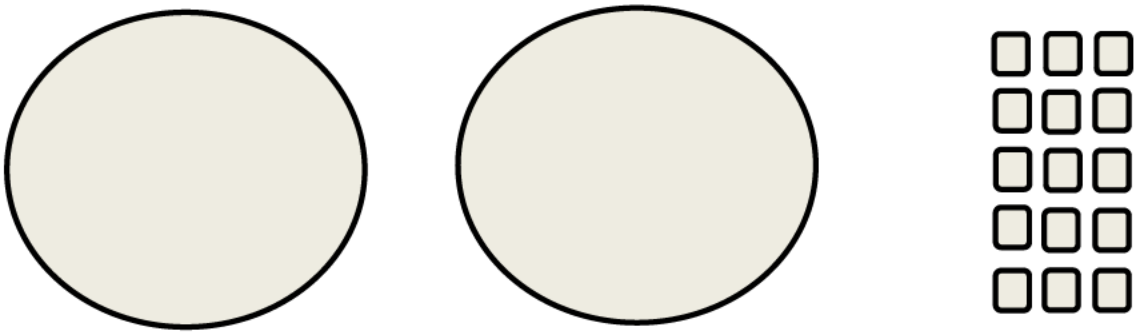
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4) [redacted]										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4) [redacted]				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 [redacted]

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Wintergreen (3 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Wintergreen (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Wintergreen. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Wintergreen product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Wintergreen (3 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Wintergreen (3 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Wintergreen (3 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

60

61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Wintergreen 3 mg	903510	8111

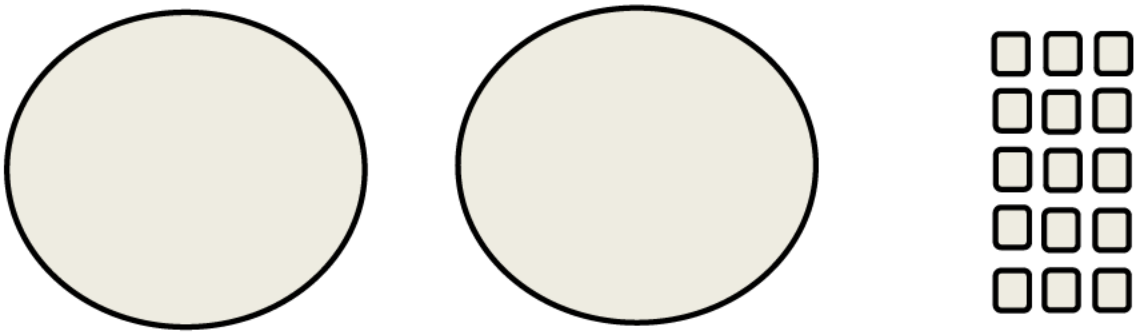
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4)										
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4)				
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 (b) (6)

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

1 **Environmental Assessment for the ZYN Wintergreen (6 mg)[1] New Product**

Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Wintergreen (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

[1] The new product name is ZYN Wintergreen. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Wintergreen product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Wintergreen (6 mg.). The nicotine strength is not part of the name of the new product.

SUMMARY

Swedish Match's ZYN Wintergreen (6 mg.) tobacco leaf-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. The new product contains nicotine that is derived from tobacco leaves as well as certain ingredients. The new product is packaged in a child-resistant round can.

The new product is produced in two Swedish Match factories. The principal manufacturing facility is in the United States ("U.S.") in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce the new product via the same manufacturing steps with the same quality control measures. Except for a few chemically identical single chemical substances, the sources of all components are the same regardless of manufacturing location. Thus, the finished products are the same, regardless of manufacturing location, i.e., have the same per weight composition, design features, heating source, and all other features. Except for a difference in manufacturing location and suppliers of two chemically identical additives, the new product is otherwise identical to the other produced ZYN products.

This environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Wintergreen (6 mg.), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the U.S. As detailed below, there is no significant environmental impact associated with FDA's potential decision to issue a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act in this instance. Additionally, a net positive benefit from the introduction of the new product into the U.S. market may exist in that manufacturing the new product may result in a decrease in the use of tobacco products at the most harmful end of the continuum of risk and is, therefore, appropriate for the protection of the public health. As stated in 21 CFR 25.22(a), "There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."

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59 # I. APPLICANT AND MANUFACTURER INFORMATION

Applicant/Submitter Name:	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA, Inc.
Applicant/Submitter Address:	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
Primary Product Manufacturing Name and Address	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
Secondary Product Manufacturing Name and Address:	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

60

61 # II. PRODUCT INFORMATION

62 ## A. Identification of the Products

63 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing
64 Location
65

New Product Trade Names & Strength	SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#	SM Unique ID no (Kungälv)
ZYN Wintergreen 6 mg	903520	8112

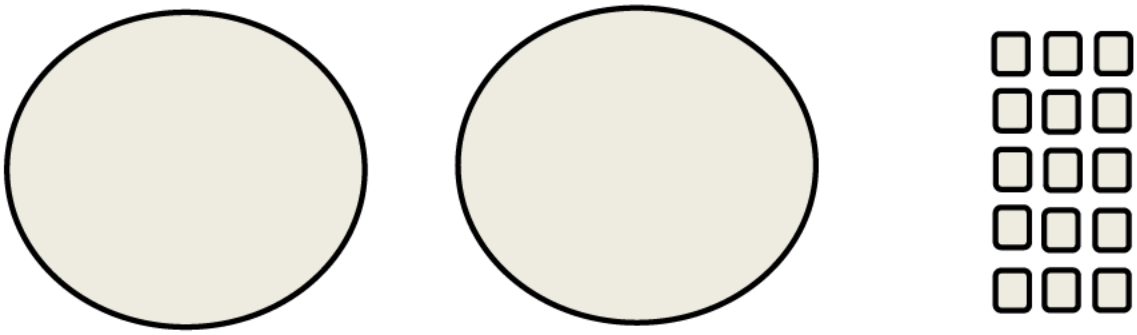
66
67 ## B. Description of the Products

68 The new product is a portioned pouched tobacco product within the deemed "other tobacco
69 product" sub-category. The new product is comprised of nicotine salts, extracted from tobacco
70 leaves, as well as flavoring ingredients, and is tobacco leaf-free. The portion weight for each
71 pouch is 0.4 g, each can contain 15 pouches and the net can weight is 6 g (0.21 oz).

72 The new product's application has been submitted under the premarket tobacco product
73 application (PMTA) pathway. The new product is currently marketed pursuant to FDA's
74 "Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to
75 the Final Deeming Rule." In this document, published August 2017 and revised March 2019,
76 FDA extended the timeline for manufactures to submit tobacco product review applications for
77 certain deemed tobacco products that were on the market as of August 8, 2016. FDA extended

the deadline for non-combusted newly deemed tobacco products, including the new product, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due September 9, 2020.

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid | One (1) base | Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1.1 in the Confidential Appendix to the Environmental Assessment.

The container and the lid of the new "other tobacco product" product are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in the Confidential Appendix to the Environmental Assessment (see Table CA.1.2 in the Confidential Appendix to the Environmental Assessment).

In order to quantitatively assess the environmental impact of manufacturing, use, and disposal from use of the new product, Swedish Match is providing current year data (2020) plus five years of market volume projections data (2020-2024) for the new product (see Table CA.2 in the Confidential Appendix to the Environmental Assessment).

III. DESCRIPTION OF PROPOSED ACTION

A. Purpose of and Need for Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order finding the "deemed" new tobacco product appropriate for the protection of public health under the provisions of sections 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S."). The Agency shall issue a marketing order if, after considering the application submitted by the applicant, the new product is found appropriate for the protection of public health.

B. Location of Use

The new product will be manufactured primarily at Swedish Match's facility in Owensboro, KY, with support from Swedish Match's facility in Kungälv, Sweden. The new product will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new product will be widely distributed and use of the new product will correspond with national population density, as do tobacco products from other categories, including those of "other tobacco products" and smokeless tobacco (e.g., "moist snuff tobacco" or "snus").

C. Location of Disposal

Used tobacco products and empty packaging, including that associated with the new product, are typically disposed of in community solid waste management systems, which may include landfills, incineration, and recycling. This disposal by the end user would be in the same manner as other products contained in similar recyclable packaging, including the recyclable packaging used in smokeless tobacco products manufactured in the same facility. According to the U.S. Environmental Protection Agency's 2017[2] update regarding municipal solid waste in the United States, about 52.13% of municipal solid waste was land disposed, 12.71% was combusted, and 35.2% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new product.

D. Alternative to the Proposed Action

[2] See Table 1 of the U.S. Environmental Protection Agency's Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020.

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition. The no-action alternative would not change trends in nationwide use of combusted, filtered cigarettes. Thus, under the no-action alternative, no changes are expected in trends in the overall level of municipal solid waste generated from cigarette butts and cigarette packaging disposal in the United States. The environmental effects of cigarette butt litter, including the leaching of toxic substances into aquatic environments and soil would remain unchanged in the no-action alternative. These effects were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide . . . The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste . . . Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.[3]

Littered cigarette butts also are a notable worldwide environmental concern. For example, it has been estimated that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreational sites, bars/restaurants, retail stores, medical/hospital facilities, and city center) were littered (Action Research, 2009).[4] Under the no-action alternative, no changes are expected in the overall level of cigarette butt litter in the United States.

IV. ENVIROMENTAL ISSUES

A. Introduction of Products into the Environment

The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Swedish Match expects certain tobacco product users to cease using – or reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This action may result in a corresponding reduction of the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products. Continued declines in other statutory smokeless tobacco products produced by Swedish Match, as well as the historical national tobacco product use declines, should also mitigate any increases, resulting in a net positive for public health.

[3] Novotny et al. (2015): The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. Bulletin of the World Health Organization 93 (12): 877-880.

[4] Action Research (2009): Littering Behavior in America: Results of a National Study. Keep America beautiful. See www.kab.org/

1. As a Result of Manufacture and Transport

The new product is manufactured at the facility addresses listed in Section I of this document, above. The new product is intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk.

The Owensboro facility is in a highly industrialized portion of Owensboro, KY, in the northwestern part of the city. Land use is decidedly industrial and urban around the facility. Beyond the city lie rural areas to the west, south, and east, and the Ohio River to the north. More rural areas exist beyond the river, into Indiana.

Swedish Match's Kungälv facility is located in a highly industrialized portion of Sweden. Land use is decidedly industrial and urban around the facility. Environmental laws are regulated by EU and Swedish national laws. Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a great deal of national laws and regulations for companies to comply with.

Swedish Match's manufacturing locations are in compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Table CA.3 in the Confidential Appendix to the Environmental Assessment).

To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

Swedish Match's Owensboro, KY, facility is the primary producer of the new product. This facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not, and will not be affected by, the manufacturing of the new product at the Owensboro facility. The Owensboro facility will manufacture the new product and continue to manufacture the already existing statutory tobacco products.

Compliance of environmental laws is audited by local government agencies. Swedish Match's production site is classified as a manufacturing establishment. The Owensboro production facility producing the new product is certified according to ISO 9001: 2015 by SAI Global and ISO 14001: 2015 by SAI Global.

Manufacturing the new product results in an expansion of the Owensboro manufacturing facility. No expansion of the Kungälv manufacturing facility regarding the new product for the U.S. market has occurred or is planned.

The portion of the Owensboro manufacturing facility dedicated to producing the new product is a combination of remodeled internal space and new external facilities. The minor expansion includes the following:

- internal packaging area remodeled within the existing facility;
- new process expansion;
- new ethanol storage building.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County. The construction site on the Swedish Match Owensboro campus was not occupied by wildlife. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans and species profiles provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County. The clams listed above are classified as endangered, threatened, and "under review." The clams are primarily found in the Tennessee River and Cumberland region, or the Mississippi River area, in areas outside of Daviess County, and their recovery is focused on those regions. No critical habitat for these clams was identified in Daviess County. The Least tern is primarily found in breeding habitats in the Mississippi and Rio Grande River basins (i.e., Montana to Texas and from eastern New Mexico and Colorado to Indiana and Louisiana) and, accordingly, the recovery plans center around stabilizing adult populations in the Missouri River, Lower Mississippi River, Arkansas River, Red River, and Rio Grande River systems. No critical habitat for the Least tern was identified in Daviess County. The Least tern's growth in population has prompted the U.S. Fish and Wildlife agency's recent proposal to delist the bird from the ESA due to recovery.[5] Based on the foregoing, Swedish

[5] https://www.fws.gov/news/ShowNews.cfm?ref=recovery-of-america%E2%80%99s-smallest-tern-prompts-proposal-to-delist-&_ID=36484

Match would not expect any impact to these mammal, bird, and clam species from manufacturing, use, and disposal of the new product.

Manufacturing the new product requires additional environmental controls at the Owensboro manufacturing facility. Additional controls were not necessary for the Kungälv manufacturing facility.

Regarding the Owensboro facility, a completed waste analysis identified several areas in which additional resources would be needed. New additional environmental controls were required and implemented in the Owensboro manufacturing facility. These controls were the result of the production of the new product, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving no measurable ethanol content in the finished product.

To accommodate this production requirement, two (2) above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two (2) 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed.

Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), which were placed in the facility by the start of production. The expected performance of the RTOs is 95 – 99% destruction efficiency of ethanol.

Nicotine Waste:

Due to the manufacturing of the new product, when the bulk powder containing nicotine is not used for its intended purpose, it is considered a waste and is handled as a hazardous waste (i.e., p075 waste code for nicotine). The production of the new product differs from the Owensboro facility's already manufactured statutory products. The nicotine, added to the new product, required additional considerations for handling and waste disposal.

Any Nicotine bitartrate dehydrate (NiBT) waste will be considered hazardous. This includes any unsaleable returns returning to the plant from the market. A third-party contractor will be responsible for disposal of NiBT, including that found in unsaleable returns. Waste NiBT will be handled in a controlled method. Unsaleable returns must be segregated from other returns and they are not run through the unsaleable shredder.

NiBT is stored and handled in a separate room in the process expansion. Handling occurs through the use of a laboratory style glove box. NiBT is added to the process through a special container with mechanically interlocked valving so no direct contact with personnel can be

made. Once transformed into the final product, the NiBT is no longer considered toxicological or hazardous.

Any NiBT waste will be considered hazardous. Multiple waste streams due to production and resulting in NiBT waste exist, including the following:

- Stream #1: Granulate Waste Stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags);
- Stream #2: Finished Waste Stream (e.g., destruction of returned unsaleables, which are segregated from other returns and not run through unsaleable shredder);
- Stream #3: Lab Waste Stream (e.g., residual materials from samples and the analysis of the new product); and
- Stream #4: Ethanol Waste Stream (e.g., resulting from the rinsing of process equipment parts with ethanol).

All waste streams are accumulated locally then shipped (via EPA-approved shipping boxes for Streams #1 - 2 and EPA-approved steel containers for Streams # 3 - 4) to a certified incinerator for destruction. A third-party contractor will be responsible for disposal of NiBT and unsaleable returns, including arranging shipments, assisting with obtaining necessary supplies (e.g., labels, manifests, pallets, EPA approved containers, and coordinating shipping schedules). Waste NiBT will be handled in a controlled method, including the application of shipping labels, verification of containers for shipping, and completing the manifest and providing copies for later reporting.

Swedish Match intends for the new product to compete for cigarette smokers and other tobacco product users. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of other tobacco products to switch to the new product or substitute their products out for the new product.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new product, the production of the new product would not impede the continued decline in forecasted sales volumes in other products manufactured at the Owensboro facility.

These declines are expected to offset the impact, if any, of the expansion of the facility and the production of the new product, resulting in no significant environmental impact (see Table CA.4 in the Confidential Appendix to the Environmental Assessment).

Revised air emissions and water discharge permits are required as a result of manufacturing of the new product.

Air Quality Permit Revisions:

Manufacturing the new product required modifications to the air permit. Swedish Match received a revised Commonwealth of Kentucky Air Quality Permit for its Owensboro, KY, facility on 2/25/2018. The permit allows the plant to be able to emit up to 90 TPY ethanol. Pollution controls are required above 90 TPY ethanol emission. Pollution controls were implemented at the time of process commissioning.

Swedish Match received a revised Air Quality Permit with accommodations for the new product from the state of Kentucky, on 2/25/2018 (permit # V-14-019 R1).

Wastewater Discharge Permit Revisions:

Swedish Match has been working with the local Regional Water Resource Agency (Daviess Co, KY) and is in compliance with all applicable regulations.

Manufacturing the new product resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new product resulting in an increase in changes to water discharge flow rates. RWRA issued an additional water permit for building expansion. The facility added in additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations.

Storm Water Permit Revisions:

No revisions were necessary as a result of the expansion to the facility.

U.S. Environmental Protection Agency's Toxic Release Inventory (TRI):

The Owensboro facility does not meet TRI reporting criteria and, accordingly, the U.S. Environmental Protection Agency's Toxic Release Inventory (TRI) does not provide reports for the Owensboro facility.

Socioeconomics and Environmental Justice: Potential Impacts from the Proposed Action.

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects on minority populations and low-income populations.

Manufacture. No disproportionate impacts to minority or low-income populations would occur due to the manufacture of the new product. Manufacturing of the new product is not expected to result in new or increased compounds being emitted at the Owensboro facility. Manufacturing is also not expected to result in disproportionate multiple and cumulative exposures to environmental hazards for minority or low-income populations. As illustrated in EPA's Enforcement and Compliance History Online (ECHO) database, which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3

mile radius), based on the 2010 US Census and American Community Service data, minorities make up 16% of the population and the facility is not located in proximity to Indian Country.[6] White residents make up approximately 86% of the population near the facility.[7] Accordingly, manufacture of the new product is not expected to affect subsistence patterns of consumption of fish, wildlife, and vegetation for minority or low-income populations (e.g., Indian tribes). Further, no disproportionate disruption of the community structure or patterns of living of low income or minority populations is expected as a result of manufacturing the new product.

Use. Marketing materials and consumer research included in the application do not indicate health impacts related to the new product would disproportionately affect minority or low-income populations. This application includes marketing materials reflecting that the target audience of the new product is a consumer who currently uses a tobacco or nicotine product and who is over the age of 21. Consumer research indicates that nicotine pouch users have a higher incidence of higher income than consumers of moist snuff tobacco.[8] Consumer research also finds a correlation between consumers and quitting behavior, indicating that the more times a tobacco consumer has tried quitting tobacco products, the more interest there is in nicotine pouch products. Consumer research also indicates that nicotine pouches have minimal appeal to consumers who do not currently use tobacco or nicotine products.[9]

This application includes a Patterns of Use Study (see Section H.3.1.1.1) and a Likelihood of Use Study (see Section H.3.1.1.2.), neither of which indicate that never-smokers in low-income or minority populations[10] would disproportionately adopt use of the new product. In addition to the aforementioned studies, the application also cites findings from Plurphanswat et al. (2020), all of which arrive at the following conclusions:

- Individuals who do not currently use tobacco or nicotine products were found not likely to initiate or re-initiate the use of tobacco or nicotine products after viewing the ZYN products description and packaging material.[11]
- Moreover, users of ZYN products who were smokers were found to have a greater intention to quit than non-users of ZYN products.[12]
- ZYN users who smoke also reported intention to quit smoking that tended to increase over the 10-week study period, unlike non-users of ZYN.[13]

[6] https://echo.epa.gov/detailed-facility-report?fid=110013765559

[7] Per the definition of "minority population" in Executive Order 12898, minority populations do not exceed 50% of the affected area and minority populations are not meaningfully greater than the minority population percentage in the general populace. Reasonably, manufacturing, use, and disposal of the new product would not be expected to disproportionately affect these Environmental Justice populations.

[8] See e-2-marketing-plan, at 4 (PMTA, section e-2).

[9] *Id.* at 4-5 (PMTA, section e-2).

[10] Demographics for these studies included populations identified in the literature as disproportionately high users of tobacco products, such as Native American/Alaska Natives.

[11] See attached Likelihood of Use Study

[12] See attached Patterns of Use Study

[13] *Id.*

As the above studies sampled respondents representing low-income or minority populations, Swedish Match reasonably concludes that these Environmental Justice populations would not be disproportionately affected by exposure to or use of the new product.

Disposal. No significant human health or environmental impacts were identified as a result of disposal of the new product. No disproportionate disruption of the community structure of low income or minority populations is expected as a result of disposal of the new product. Thus, no disproportionate impacts to minority or low-income populations would occur.

Continued Discussion of Manufacturing:

Manufacturing the new product should not result in new or increased compounds being emitted from the manufacturing of the new product at the Owensboro the facility. Release of new chemicals (i.e., acesulfame-potassium) into the environment due to manufacturing the new product is not anticipated due to the proposed action. Additives used in the manufacture of the new product include ones that have been historically used in the facility for the manufacture of prior tobacco products. Many of the ingredient materials of the new product are used in other tobacco product categories (e.g., moist snuff tobacco) and the new product contains nicotine derived from tobacco leaves. No increases in the quantity of certain compounds (e.g., nicotine waste, which would be disposed of in a controlled manner) are anticipated given ongoing declines in manufacture of other smokeless tobacco products produced in Swedish Match facilities. Users of the ZYN new product, which is intended as a spit-free product, would not be expected to expectorate the new product into the environment. Any urine and bowel excretions would be processed through local municipal waste systems. Reasonably, the ability of these municipal waste systems to process these historically common ingredients (e.g., commonly found in smokeless tobacco products and foodstuffs) would present a low level of ecotoxic concern.

Sales and Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal. The new product's current market volume and market volume projections for the first and fifth year of marketing are supplied in Table C.2 to the Confidential Appendix to the Environmental Assessment.

Reasonably, any assessment of potential impacts on waste and energy use are linked to market volume projections as whole and the new product projections cannot be viewed in a vacuum. Although Swedish Match sales of the new product are forecasted to increase through 2024, the period of time covered by this environmental assessment, sales of the other statutory tobacco products from the Owensboro facility are forecasted to decline (e.g., loose leaf chewing tobacco)

or remain flat (e.g., loose moist snuff tobacco) over this same timeframe. Moreover, over the past few decades, the tobacco market as a whole has been contracting (rather than expanding) in the U.S.

Swedish Match expects declines in its own moist snuff tobacco and chewing tobacco products to continue.

Production of the new product would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility.

There may be a net increase in manufacturing due to the new product. However, this would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

Swedish Match forecasts that the waste generated from the production of all existing statutory and deemed new tobacco products manufactured at the Owensboro facility would represent a (-(b) (4)) decrease (metric tons) from Year 1 to Year 5.

Table 1.1: Waste Generation at Owensboro Facility (2020 – 2024)[14]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table 2, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

This forecast takes into account:

- Swedish Match's focus on sustainability and historically declining waste generation at the Owensboro facility (see Section C.5 in the Confidential Appendix to the Environmental Assessment);
- A contracting tobacco market as a whole and specifically the smokeless tobacco category that Swedish Match participates in and our production facilities support;
- The new product's current market volume and market volume projections for the first and fifth year of marketing (see Section C.2 in the Confidential Appendix to the Environmental Assessment);

[14] (t)= Metric tons

- Current market volume and market volume projection of existing statutory tobacco product produced at the same facility as the new product (see Section C.4 in the Confidential Appendix to the Environmental Assessment).

Manufacturing the new product is not expected to result in a net increase of energy use at the facility.

The Owensboro facility does not produce its own energy and does not generate electricity. Swedish Match purchases its electrical energy from a local municipal supplier, Owensboro Municipal Utilities, who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, Atmos Energy.

Total energy usage at the Owensboro facility decreased in the period between 2007 and 2017.

Based on the tables below, we saw a (b) (4) reduction in natural gas and a (b) (4) reduction in electricity used at the Owensboro facility during the 2007 – 2017 time period.

Figure 1.1: Energy Resources Used by the Owensboro Manufacturing Facility[15]

(b) (4)

[15] (MW-h) =Megawatt-Hour

Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

Type (MW-h)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Gas	(b) (4)	[redacted]									
Electricity											
Total											

Energy use for the time frame 2020 – 2024 (the time frame covered by this environmental assessment) for the statutory and deemed products made by the Owensboro facility is projected in the following table:

Table 1.3: Forecasted Energy Resources by the Owensboro Manufacturing Facility (2020 – 2024)

Type (MW-h)	2020	2021	2022	2023	2024
Gas	(b) (4)	[redacted]			
Electricity					
Total					

As noted previously, although sales of the new product are forecasted to increase through 2024, sales of the other tobacco products from the factory are forecasted to decline (e.g., loose leaf chewing tobacco) or remain flat (e.g., loose moist snuff tobacco) over time. Even with production of the new product, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new product is not expected to impact greenhouse gas (GHG) emissions. It is the company's target to reduce greenhouse emissions company-wide by 75% by 2050 (with 2017 as the base year). It is Swedish Match's expectation that, even with possible increased production at the Owensboro facility due to the new product, the facility would maintain these target goals.

Regarding the Kungälv facility: Swedish Match is in full compliance with all environmental laws today and there is no risk in terms of critical habitats, animal species or plants (see Section C.3 of the Confidential Appendix to the Environmental Assessment).

- To Swedish Match's knowledge, no critical habitat is affected by the materials or ingredients used to manufacture the new product, or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

- There are no anticipated adverse effects on any endangered species or the critical habitat of the species identified under CITES ("Convention on International Trade on Endangered Species") and ESA ("Endangered Species Act") due to (i) the materials used to manufacture the new product; (ii) the manufacturing process itself; (iii) the disposal of the new product.

- There will not be an expansion of the manufacturing facility regarding the new product. Swedish Match produces the new product both for U.S. and non-U.S. markets in the production facility, with U.S. production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new product will not result in expansion or give rise to any additional environmental impacts.

Furthermore:

- Manufacturing due to the new product would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

- There would be no new or increase of currently emitted compounds emitted from manufacturing the new product.

- Manufacturing the new product would not lead to changes in air emissions or wastewater discharges from increased manufacturing. A revised or new air emissions or wastewater discharge permit would not be required.

- Manufacturing the new product would not require any additional environmental controls.

- Manufacturing the new product would not result in a net increase of energy use at the manufacturing location.

- Manufacturing the new product would not impact greenhouse gas (GHG) emissions.

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly[16] affect the quality of the human environment. Accordingly, the new product remains appropriate for the protection of the public health.

[16] Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

537

538 **2.** As a Result of Use

539 The new product will be used similarly to other portioned tobacco products, including smokeless
540 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of
541 disposal of used product and "spit" generated during product use are anticipated. When the
542 pouch has been consumed by the consumer practically none of the contents of the pouch will
543 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from
544 the pouch during consumption and should not result in spitting. The use of the new product
545 would result in the direct introduction of little or no change in the complexity of the ingredients
546 nor any of the other ingredients into the environment because these ingredients are consumed
547 during use.
548
549 The new tobacco product's characteristics are similar to other portioned smokeless tobacco
550 products in the market. Thus, consumer perceptions of harm and addictiveness should not be
551 affected. Further, there is a high likelihood that certain tobacco product users will cease using –
552 or reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco based upon
553 Swedish Match's consumer research. This likelihood would result in a corresponding effect on
554 the materials associated with the production, manufacture, transport, and disposal after use of
555 these tobacco products.

556

557 **3.** As a Result of Disposal

558 The new product and any associated waste will be disposed of by the end user in the same
559 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,
560 moist snuff, snus). The new product's container is not intended for repeat use. Disposal by the
561 ultimate consumer of plastic cans, used product, and any other waste material will be by
562 conventional rubbish disposal and, therefore, primarily by sanitary landfill or incineration. There
563 is a high likelihood that certain tobacco product users will cease using – or reduce the amount
564 they use of – cigarettes, moist snuff, or chewing tobacco. This likelihood would result in a
565 corresponding effect on the materials associated with the production, manufacture, transport, and
566 disposal after use of this tobacco product. The proposed action may result in an increased
567 product sale. However, this increase is expected to be offset by the reduction in the use of other
568 tobacco products as adult consumers on the more harmful end of the continuum of risk switch
569 completely to the new product or substitute their more harmful tobacco product with the new
570 product. Moreover, by 2024, all SKUs of ZYN combined are expected to comprise
571 approximately 3% of the total smokeless tobacco sales (measured in pounds of smokeless
572 tobacco) in the United States, and waste from the product will make up a very small portion of
573 total municipal solid waste. Further, each individual SKU represents less than 1% of the 131.43
574 million pounds of smokeless tobacco sold in the U.S. per 2016 FTC Smokeless Tobacco Report.

575 It will not significantly alter the emissions from properly operating municipal solid waste
576 combustors. As a result, those municipal solid waste incinerators will continue to operate in
577 compliance with applicable laws and regulations such as 40 C.F.R. Part 60, as well as relevant
578 state and local laws.

579
580
581 **B.** Fate of Products Released into the Environment

582 The new product is expected to enter the environment in extremely small, negligible,[17]
583 quantities, if at all, as a result of the use and disposal of the product. Swedish Match does not
584 anticipate that the fate of any materials from this product will be different from other smokeless
585 tobacco products commercially available. Thus, no meaningful impacts are expected on air,
586 water, and land resources or on the organisms that inhabit these media as a result of the proposed
587 action.
588
589 Consumers would dispose of the new product's used pouch and packaging materials in
590 appropriate waste receptacles, including recycling centers, waste cans, or landfills. Disposal of
591 excreted materials occurs through the sewage discharge of human solid waste.

592 Swedish Match assessed any potential impact from disposal following use of the new product
593 through a review of the available peer-reviewed research (via a 5/6/2019 PubMed search and
594 Google Scholar search; citations discussed in more detail below). To our knowledge, there is no
595 peer-reviewed research specifically assessing the environmental impact of the disposal after use
596 of "other tobacco products," like the new product, or smokeless tobacco generally. Further, the
597 available research assessing the external environmental impact of tobacco products has focused
598 on combustible tobacco products, while not addressing any potential impact from "other tobacco
599 products," or smokeless tobacco products generally (e.g., see Novotny and Zhao, 1999 and
600 Novotny and Slaughter, 2014). The waste from these prominent tobacco product categories are
601 "butts, packages, cellophane wrappers, and cartons" discarded either in waste disposal or in the
602 natural environment itself (Novotny and Zhao, 1999: 75 – 76). None of the aforementioned
603 authors extrapolated from these results and applied them to the context of "other tobacco
604 products," or non-combusted products, like smokeless tobacco generally. Accordingly, Swedish
605 Match does not find any correlation between the post-consumer waste of the new product with
606 the existing tobacco products assessed by the available literature (Novotny and Slaughter, 2014:
607 208). The new product's manufacture, transport, use and disposal should be viewed with a low
608 level of concern, as it is not expected to contribute to any significant new or additional
609 environmental impacts. Nor is it likely to impact the environment in the manner of other waste

[17] EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: 2017 Fact Sheet found at https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf, accessed July 29, 2020. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.

materials connected to the use and disposal of other, far more prevalent, tobacco product categories. The type of significant environmental impact outlined in the available literature would not be expected to occur as a result of the introduction of the new product.

C. Environmental Effect of Released Products

Only extremely small quantities of the ingredients of the new product, if any, are expected to be released into the environment through leaching and combustion, and this quantity is not expected to be any different than currently marketed tobacco products. Consequently, no adverse effects on organisms in the environment are expected.

Manufacturing the new product is not expected to affect any endangered species or result in the adverse modification of the habitat of any such species. To Swedish Match's knowledge, no critical habitat is adversely affected by the materials or ingredients used to manufacture the new product or from the production of the new product. The plant-based materials or ingredients used in the new product are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new product.

The expansion to the Owensboro facility was conducted on the existing Swedish Match campus which was not occupied by wildlife.

Moreover, production of the new product does not affect critical habitat. The new product is produced at a manufacturing facility in Owensboro, Kentucky in Daviess County. The facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. According to the U.S. Fish and Wildlife Service's Environmental Conservation Online System, the only threatened or endangered species potentially present in Daviess County are the following mammals (i.e., bats), migratory bird, and clams: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for the Gray and Northern Long-Eared bats in Daviess County. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of Daviess County. The recovery plans provided by U.S. Fish and Wildlife Service do not identify critical habitats for the Least tern or the aforementioned clams in Daviess County.

There are no anticipated adverse effects on any endangered species, or the critical habitat of the species identified under ESA and CITES due to:

(i) materials used to manufacture the new product;
(ii) the manufacturing process itself; or
(iii) the disposal of the new product

Support for the above statement is provided in the following paragraphs:

(i) No effects on protected species or critical habitat are anticipated from materials used to manufacture the new product. As noted above, the materials are purchased from agricultural commodities on the existing market or are synthetic, artificial, or inorganic. No rare or protected flora or fauna are used as materials to manufacture the new product.

(ii) No effects on protected species or critical habitat are anticipated from the manufacturing process. The new product is manufactured at a facility located in Owensboro, Kentucky in an area of significant industrial development. There is no critical habitat in the vicinity of the facility and the presence of protected species is highly unlikely in this area that has numerous manufacturing facilities for a variety of industries. As noted above, the U.S. Fish and Wildlife Service's Environmental Conservation Online System, identifies the following mammals (i.e., bats), migratory bird, and clams as endangered, threatened, or "under review," and potentially present in Daviess County: Indiana bat (Myotis sodalis), Gray bat (Myotis grisescens), Northern Long-Eared bat (Myotis septentrionalis), Least tern (Sterna antillarum), Pink mucket pearly mussel (Lampsilis abrupta), Rough pigtoe pearly mussel (Pleurobema plenum), Orangefoot pimpleback pearly mussel (Plethobasus cooperianus), Ring pink (Obovaria retusa), Fat pocketbook (Potamilus capax), Clubshell (Pleurobema clava), Fanshell (Cyprogenia stegaria), Snuffbox mussel (Epioblasma triquetra), Rabbitsfoot (Quadrula cylindrica cylindrica), and Longsolid (Fusconaia subrotundra). Critical habitat has not been designated for these species in Daviess County; the only critical habitat in Kentucky for the Indiana bat consists of caves, outside of Daviess County. Based on the U.S. Fish & Wildlife Service's recent status review of these bat species, the primary threat to these species is White Nose Syndrome, a devastating fungal disease that causes mortality and has resulted in significant reductions in bat populations since its identification in 2006. Other main threats to these species are disturbances to their winter hibernacula (mines and caves) and summer habitat (forests). None of these threats would be anticipated to result from the manufacturing process of the new product. The Least tern has been proposed to be delisted from the ESA. The recovery plans and species profiles on the U.S. Fish and Wildlife website for the Least tern and the aforementioned clams do not identify critical habitat in Daviess County.

(iii) No effects on species or critical habitat are anticipated from disposal of the new product. The new product is consumed primarily in homes and automobiles and disposed of in the municipal solid waste chain.

D. Use of Resources and Energy

As is the case with other smokeless tobacco and moist snuff products and their ingredients, the production, use, and disposal of the new product and their ingredients require the use of natural resources such as petroleum products and coal. However, the new product will not differ from the currently marketed smokeless tobacco products in the market.

V. MITIGATION MEASURES

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, mitigation measures need not be discussed.

VI. ALTERNATIVES TO THE PROPOSED ACTION

An alternative to the proposed action would be if an order authorizing the new product as a PMTA is not issued. The environmental impact of this action would not change the existing condition.

VII. LIST OF PREPARERS

Gerard J. Roerty, Jr., Swedish Match USA, Inc.
Title: Vice President, General Counsel & Secretary
Education: J.D., Vanderbilt University Law School; B.B.A., University of Notre Dame
Experience: 23+ years with the company, charged with regulatory compliance
Expertise: Regulatory Affairs

(b) (6) [redacted] Swedish Match USA, Inc.
Title: Regulatory Scientist
Education: (b) (6) [redacted]
(b) (6) [redacted]
Experience: (b) (6) in various scientific activities
Expertise: Scientific and Regulatory Affairs

Deborah Hayden, Swedish Match USA, Inc.
Title: Director Compliance & Risk Management
Education: B.S., Chemistry, Brescia University
Experience: 36 years in various product development and regulatory activities
Expertise: Scientific and Regulatory Affairs

VIII. REFERENCES

Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce Tobacco Consumption. Current Environment Health Report. 1:208-216.

Novotny and Zhao (1999): Tobacco Control. 8:75-80.

U.S. Environmental Protection Agency, Advancing Sustainable Materials Management: 2017 Fact Sheet. EPA-530-F-19-007, November 2019, Washington, D.C.

World Health Organization (2017): Tobacco and its environment impact: an overview. 1-72.

IX. AGENCIES AND PERSONS CONSULTED

N/A

735 The undersigned official certifies that the information presented is true, accurate, and

736 complete to the best of the knowledge of Swedish Match.

737

738

739 9/24/2020

740 (b) (6)

741

742

743 Gerry Roerty, Jr., VP, General Counsel & Sec.

744 (Name and title of responsible official, printed)

ATTACHMENTS – CONFIDENTIAL APPENDIX TO EA

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Chill (3 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Chill (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

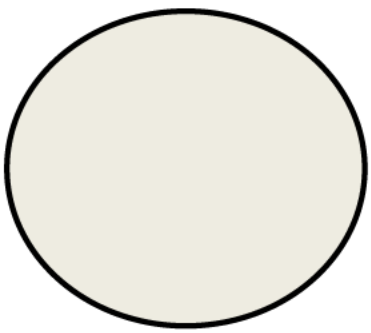
[1] The new product name is ZYN Chill. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Chill product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Chill (3 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

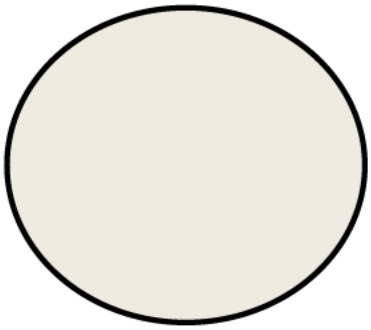
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

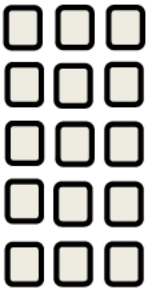
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted]. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000609				CHILL 3MG	CHILL 3MG
Estimated municipal solid waste loads for individual packaging material components				Year 1 (2020)	Year 5 (2024)
				can volume (individual selling unit)	can volume (individual selling unit)
		OWENSBORO	OWENSBORO	(b) (4)	(b) (4)
Item #	Item Name	Material Description	Weight Per Individual Selling Unit (g)	Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29	(b) (4)	(b) (4)
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Chill 3 MG	Units (pounds)	(b) (4)	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

D. CA.4: Forecasted Sales Volumes in other Products

Although sales of the new product are forecasted to increase through 2024 and are produced at the Owensboro facility, in addition to other statutory tobacco products, sales of these other statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf chewing tobacco) over time.

Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

[1]Based on an assumed (b) (4) in product produced per fiscal year.

Swedish Match estimates that the waste generated from statutory tobacco products manufactured at the Owensboro facility would represent a (b) (4) decrease (metric tons).

The projected total tobacco products produced at the Owensboro facility, including the deemed new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) decrease (metric tons) from Year 1 to Year 5.

131 **E.** CA.5: Facility Waste Generation

132 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
133 history of waste generation of all statutory tobacco products at the Owensboro facility has been
134 the following:

135

136 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
137

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

138
139

140 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
141

142
143
144

145 This decline was due, primarily, to the flat or declining sales associated with the statutory
146 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
147 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
148 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
149 most current usage rate data comes from the recently released 2017 National Health Information
150 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
151 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
152 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
153 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

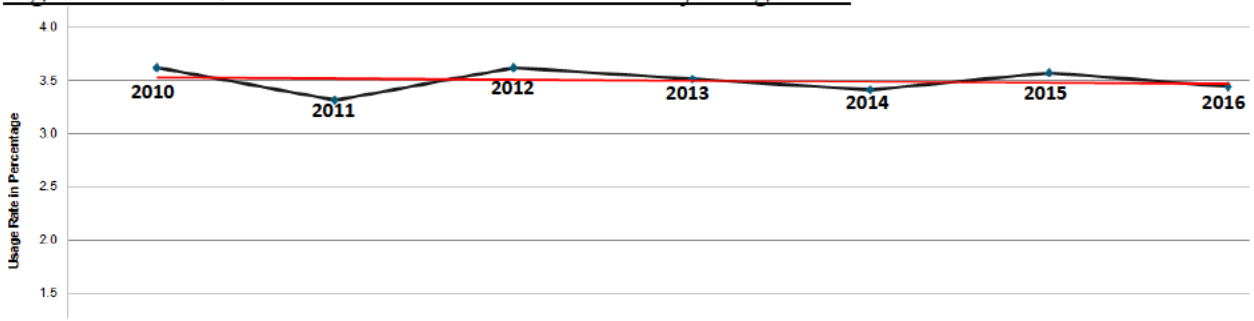
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Chill (6 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Chill (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

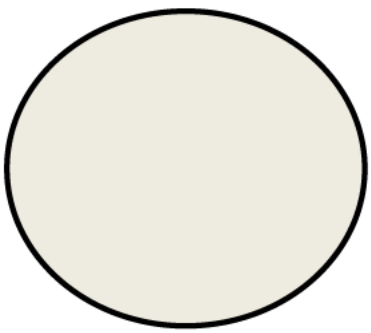
[1] The new product name is ZYN Chill. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Chill product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Chill (6 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

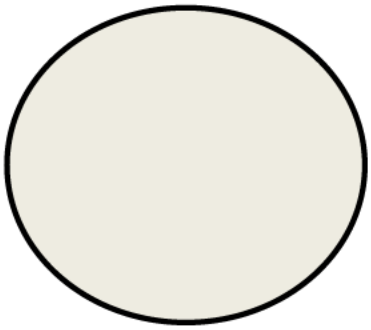
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted]. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



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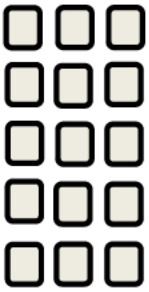

Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

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The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000610

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	CHILL 6MG Year 1 (2 ear 5 (2024) can me (individual selling unit) can volume (individ g) (b) (4) Waste Load Estimates in metric tonnes	CHILL 6MG Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29		
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4)

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Chill 6 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

D. CA.4: Forecasted Sales Volumes in other Products

Although sales of the new product are forecasted to increase through 2024 and are produced at the Owensboro facility, in addition to other statutory tobacco products, sales of these other statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf chewing tobacco) over time.

Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf		(b) (4)				
Plug						
Moist Snuff						
Other (NTC)						
Total						

[1]Based on an assumed (b) (4) in product produced per fiscal year.

Swedish Match estimates that the waste generated from statutory tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons).

The projected total tobacco products produced at the Owensboro facility, including the deemed new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

130 **E.** CA.5: Facility Waste Generation

131 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
132 history of waste generation of all statutory tobacco products at the Owensboro facility has been
133 the following:

134

135 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
136

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
(b) (4)									

137
138

139 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
140

(b) (4)

141
142
143

144 This decline was due, primarily, to the flat or declining sales associated with the statutory
145 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
146 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
147 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
148 most current usage rate data comes from the recently released 2017 National Health Information
149 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
150 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
151 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
152 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

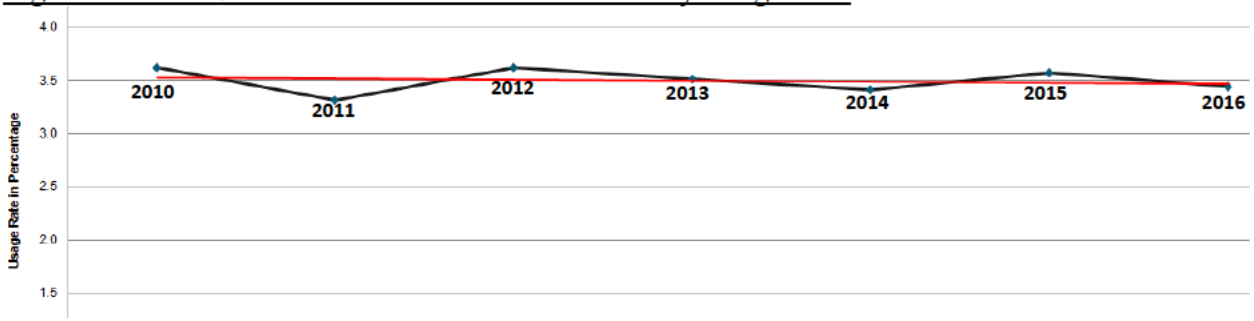
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Cinnamon (3 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

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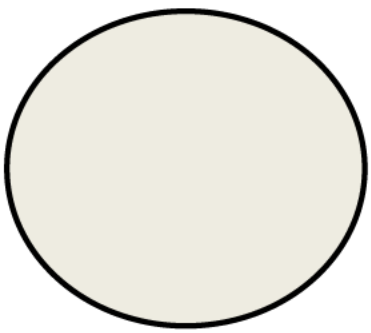
[1] The new product name is ZYN Cinnamon. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Cinnamon product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Cinnamon (3 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

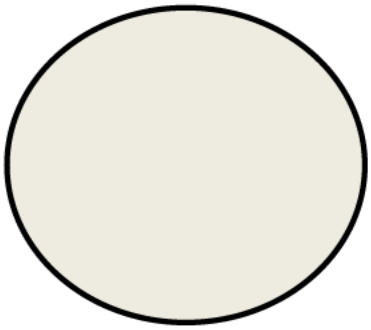
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted]. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



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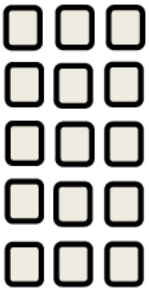

Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

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The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000605				CINNAMON 3MG	CINNAMON 3MG
Estimated municipal solid waste loads for individual packaging material components				Year 1 (2	ear 5 (2024)
				can me (individual selling unit)	can volume (individ
		OWENSBORO	OWENSBORO	(b) (4) [redacted]	
Item #	Item Name	Material Description	Weight Per Individual Selling Unit (g)	Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
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		Currently in Market	Currently in Market		
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8	Case	Shipping Case (90 - cans per case)	2.14		
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	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume
ZYN Cinnamon 3 MG	Units (pounds)	(b) (4)
	Metric Tons	

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

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106 **D.** CA.4: Forecasted Sales Volumes in other Products

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108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

E. CA.5: Facility Waste Generation

As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent history of waste generation of all statutory tobacco products at the Owensboro facility has been the following:

Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

Figure CA.5.1: Waste Generation at Owensboro Facility[5]

(b) (4)

This decline was due, primarily, to the flat or declining sales associated with the statutory products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man), moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all tobacco product categories that, on a national level, are experiencing flat or declining sales. The most current usage rate data comes from the recently released 2017 National Health Information Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip, snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

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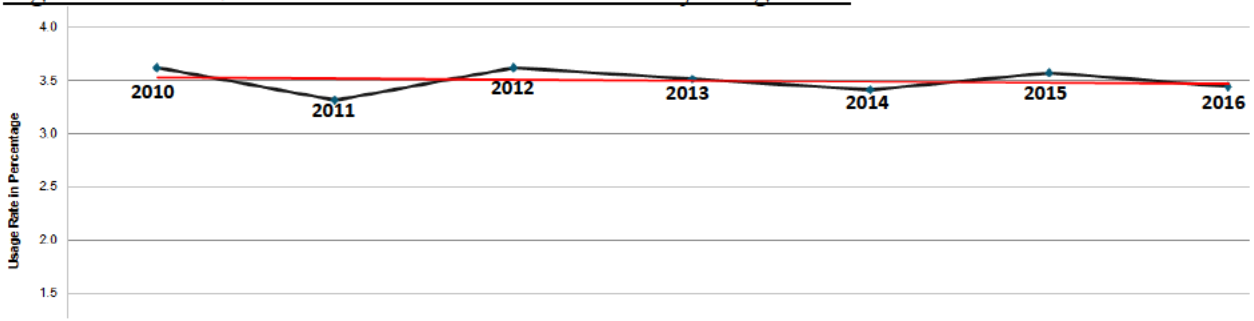
Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
(b) (4) [redacted]					

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

Confidential Appendix to the Environmental Assessment for the ZYN Cinnamon (6 mg)[1] New Product

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cinnamon (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

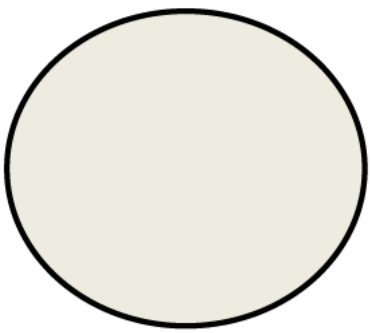
[1] The new product name is ZYN Cinnamon. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Cinnamon product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Cinnamon (6 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

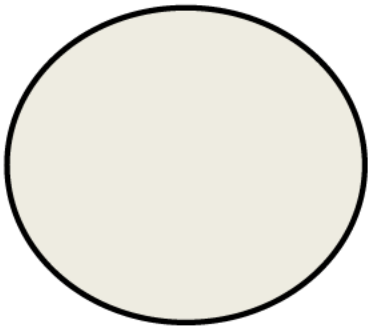
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

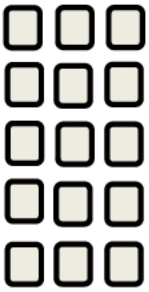
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted]. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000606

Estimated municipal solid waste loads for individual packaging material components

				CINNAMON 6MG	CINNAMON 6MG
				Year 1 (2	ear 5 (2024)
				can me (individual selling unit)	can volume (individ g)
		OWENSBORO	OWENSBORO	(b) (4) [redacted]	
Item #	Item Name	Material Description	Weight Per Individual Selling Unit (g)	Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29	[redacted]	
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Cinnamon 6 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
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[4] (t)= Metric tons

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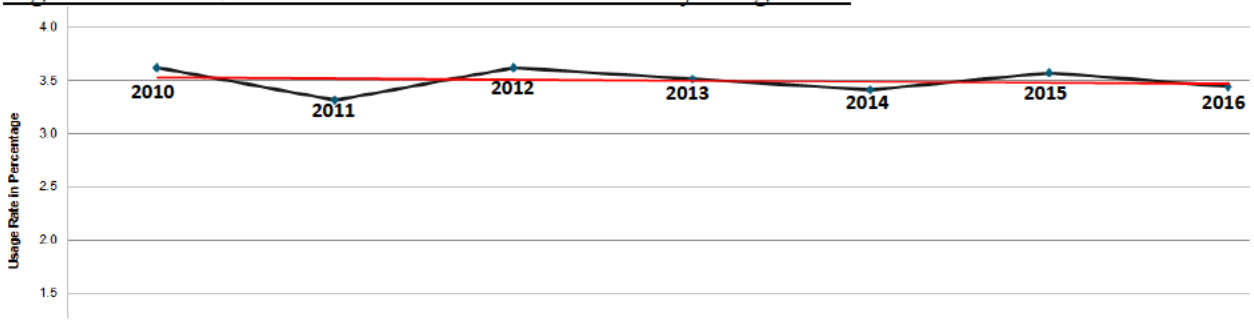
155 Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category,
156 Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless
157 tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and
158 Figure CA.5.2, below).

159

160 Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)
161

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

162
163
164 Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



165
166

167 The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016
168 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the
169 past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's
170 quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example,
171 in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing
172 tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco
173 product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first
174 quarter 2018). We expect these declines to continue during the next five years, the time frame
175 aligned with the first- and fifth-year sales figures discussed in the context of the new product's
176 environmental assessment.

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178 production of these smokeless tobacco products at the Owensboro facility. As these smokeless
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[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
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The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

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We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

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F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Citrus (3 mg)[1] New Product**

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[1] The new product name is ZYN Citrus. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Citrus product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Citrus (3 mg.). The nicotine strength is not part of the name of the new product.

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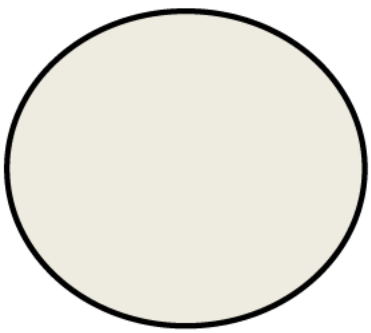
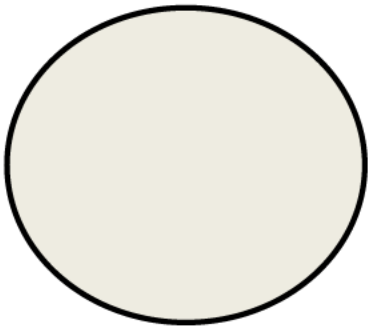


One (1) lid



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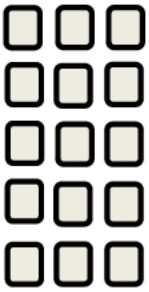

Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

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Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000601				CITRUS 3MG	CITRUS 3MG
Estimated municipal solid waste loads for individual packaging material components				Year 1 (2	ear 5 (2024)
				can me (individual selling unit)	can volume (individ
		OWENSBORO	OWENSBORO	(b) (4) [redacted]	
Item #	Item Name	Material Description	Weight Per Individual Selling Unit (g)	Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29	[redacted]	
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Citrus 3 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

D. CA.4: Forecasted Sales Volumes in other Products

Although sales of the new product are forecasted to increase through 2024 and are produced at the Owensboro facility, in addition to other statutory tobacco products, sales of these other statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf chewing tobacco) over time.

Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

[1]Based on an assumed (b) (4) in product produced per fiscal year.

Swedish Match estimates that the waste generated from statutory tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons).

The projected total tobacco products produced at the Owensboro facility, including the deemed new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

E. CA.5: Facility Waste Generation

As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent history of waste generation of all statutory tobacco products at the Owensboro facility has been the following:

Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

Figure CA.5.1: Waste Generation at Owensboro Facility[5]

(b) (4) [redacted]

This decline was due, primarily, to the flat or declining sales associated with the statutory products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man), moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all tobacco product categories that, on a national level, are experiencing flat or declining sales. The most current usage rate data comes from the recently released 2017 National Health Information Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip, snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

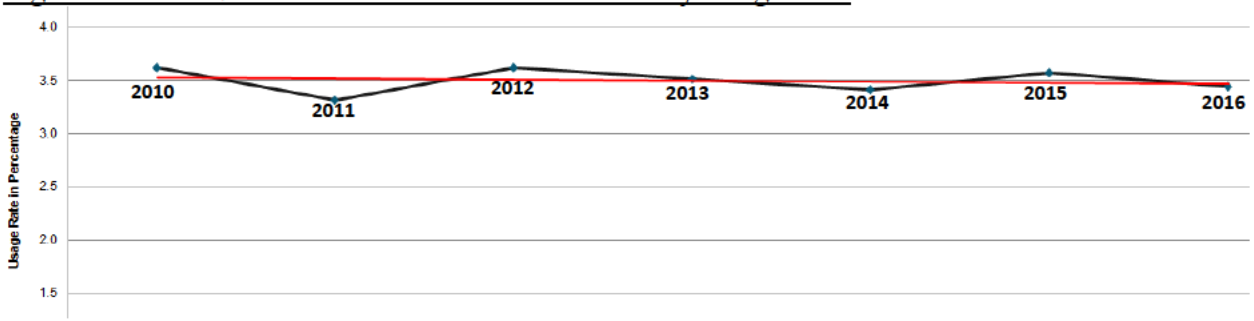
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Citrus (6 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Citrus (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

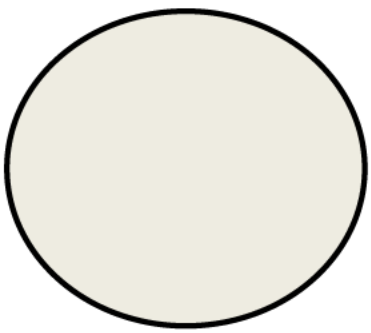
[1] The new product name is ZYN Citrus. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Citrus product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Citrus (6 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

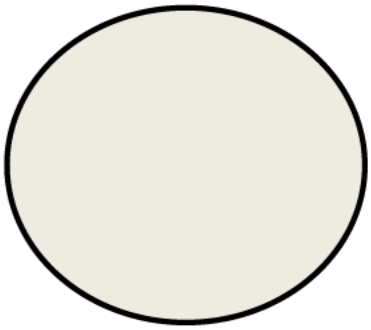
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

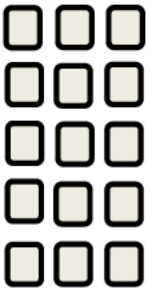
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000602

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	CITRUS 6MG Year 1 (2 ear 5 (2024) can me (individual selling unit) can volume (individ g) (b) (4) Waste Load Estimates in metric tonnes	CITRUS 6MG Year 1 (2 ear 5 (2024) can me (individual selling unit) can volume (individ g) (b) (4) Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29		
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
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6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4)

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Citrus 6 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
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	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
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	Groundwater Protection Plans	401 KAR Chapter 5:037
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	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, I(b) (4) [redacted], to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

D. CA.4: Forecasted Sales Volumes in other Products

Although sales of the new product are forecasted to increase through 2024 and are produced at the Owensboro facility, in addition to other statutory tobacco products, sales of these other statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf chewing tobacco) over time.

Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf		(b) (4)				
Plug						
Moist Snuff						
Other (NTC)						
Total						

[1]Based on an assumed (b) (4) in product produced per fiscal year.

Swedish Match estimates that the waste generated from statutory tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons).

The projected total tobacco products produced at the Owensboro facility, including the deemed new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

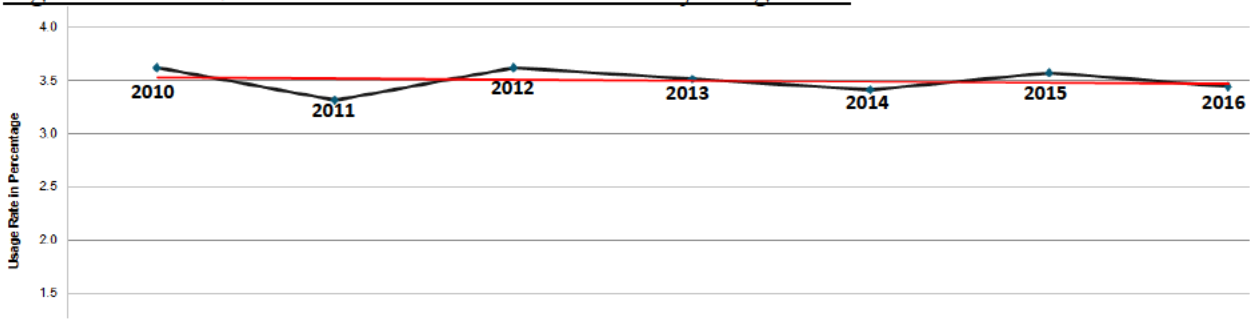
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Coffee (3 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Coffee (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

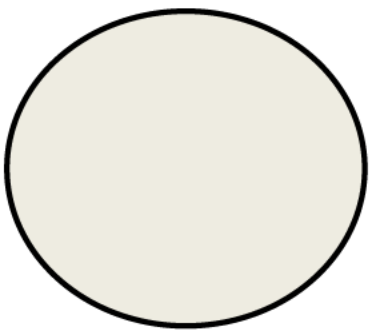
[1] The new product name is ZYN Coffee. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Coffee product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Coffee (3 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

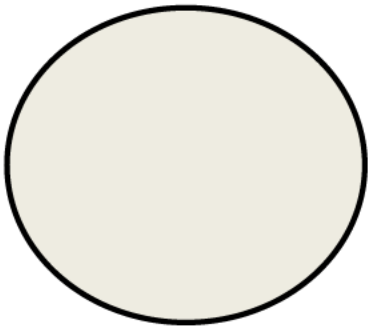
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

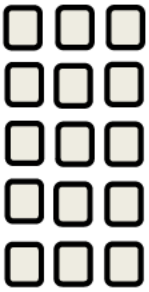
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted]. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000603				COFFEE 3MG	COFFEE 3MG
Estimated municipal solid waste loads for individual packaging material components				Year 1 (2	ear 5 (2024)
				can me (individual selling unit)	can volume (individ
		OWENSBORO	OWENSBORO	(b) (4) [redacted]	
Item #	Item Name	Material Description	Weight Per Individual Selling Unit (g)	Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29	[redacted]	
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Coffee 3 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

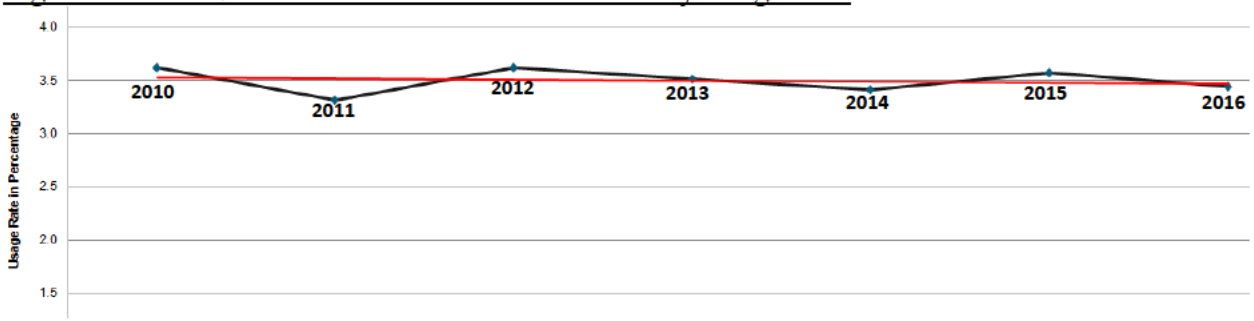
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
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these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Coffee (6 mg)[1] New Product**

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Prepared by Swedish Match USA, Inc.

September 24, 2020

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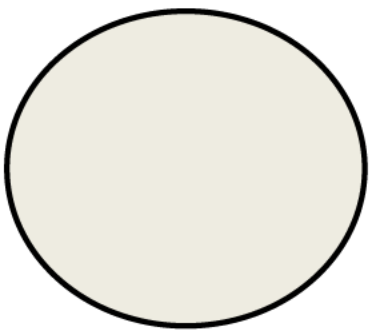
[1] The new product name is ZYN Coffee. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Coffee product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Coffee (6 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

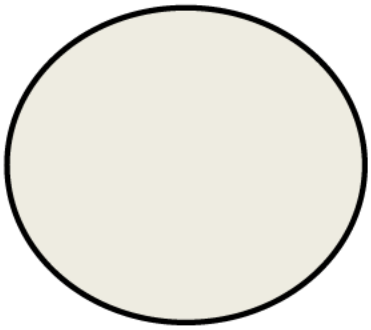
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted]. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



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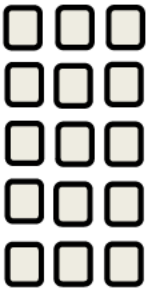

Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

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The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000604				COFFEE 6MG	COFFEE 6MG
Estimated municipal solid waste loads for individual packaging material components				Year 1 (2	ear 5 (2024)
				can me (individual selling unit)	can volume (individ g)
		OWENSBORO	OWENSBORO	(b) (4) [redacted]	
Item #	Item Name	Material Description	Weight Per Individual Selling Unit (g)	Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
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		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29	(b) (4) [redacted]	
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7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Coffee 6 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
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- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

D. CA.4: Forecasted Sales Volumes in other Products

Although sales of the new product are forecasted to increase through 2024 and are produced at the Owensboro facility, in addition to other statutory tobacco products, sales of these other statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf chewing tobacco) over time.

Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

[1]Based on an assumed (b) (4) in product produced per fiscal year.

Swedish Match estimates that the waste generated from statutory tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons).

The projected total tobacco products produced at the Owensboro facility, including the deemed new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
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146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

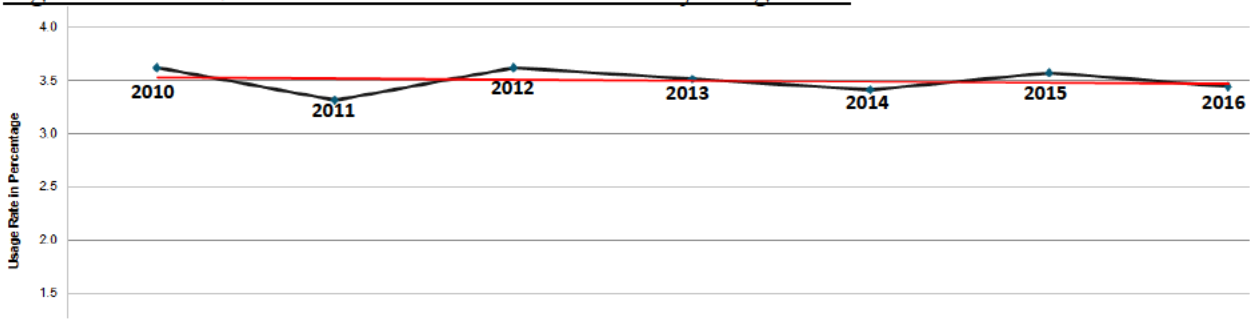
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

Confidential Appendix to the Environmental Assessment for the ZYN Cool Mint (3 mg)[1] New Product

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cool Mint (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

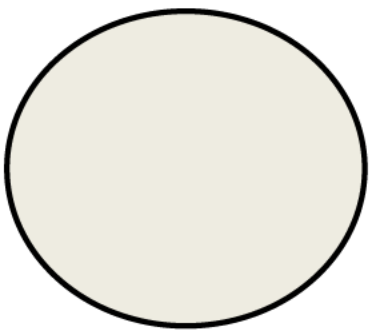
[1] The new product name is ZYN Cool Mint. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Cool Mint product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Cool Mint (3 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

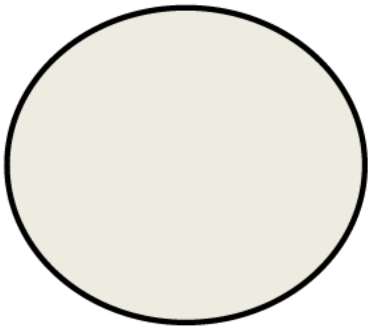
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

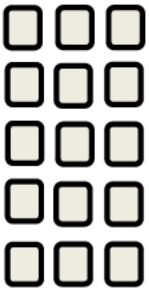
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

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The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000593

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	COOL MINT 3MG Year 1 (2 ... ear 5 (2024) Waste Load Estimates in metric tonnes	COOL MINT 3MG Year 1 (2 ... ear 5 (2024) Waste Load Estimates in metric tonnes
		ZYN Currently in Market 0.21 oz can (6 g)	ZYN Currently in Market 0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29		
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side Label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4)

[redacted]

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume
ZYN Cool Mint 3 MG	Units (pounds)	(b) (4) [redacted]
	Metric Tons	

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

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Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

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Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

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106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) decrease (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

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146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
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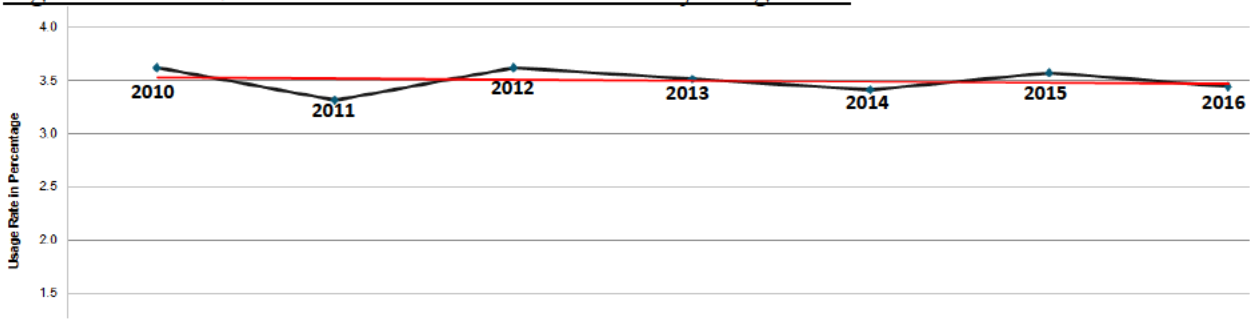
Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
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- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Cool Mint (6 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Cool Mint (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

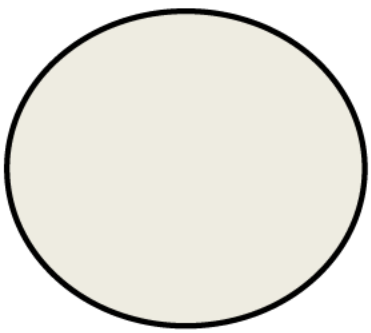
[1] The new product name is ZYN Cool Mint. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Cool Mint product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Cool Mint (6 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

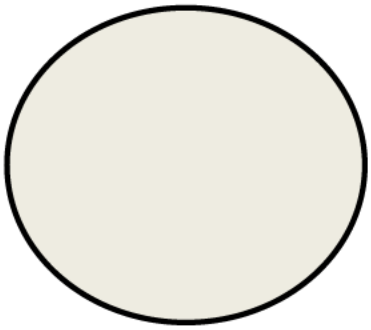
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

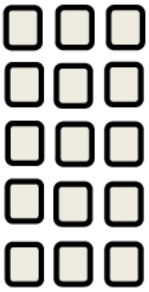
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000594				COOL MINT 6MG	COOL MINT 6MG
Estimated municipal solid waste loads for individual packaging material components				Year 1 (2	ear 5 (2024)
				can me (individual selling unit)	can volume (individ
				(b) (4) [redacted]	
		OWENSBORO	OWENSBORO		
Item #	Item Name	Material Description	Weight Per Individual Selling Unit (g)	Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29	[redacted]	
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side Label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume
ZYN Cool Mint 6 MG	Units (pounds)	(b) (4)
	Metric Tons	

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) decrease (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

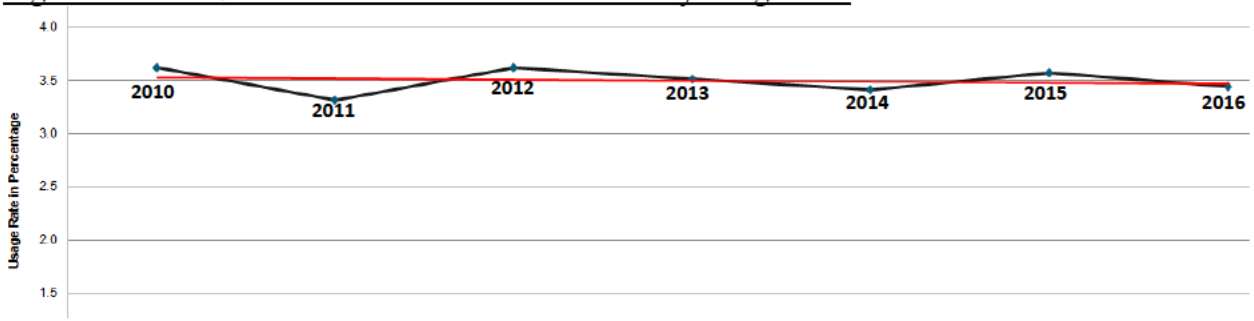
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Fresh (3 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Fresh (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

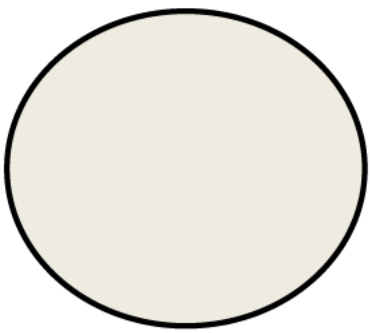
[1] The new product name is ZYN Fresh. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Fresh product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Fresh (3 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

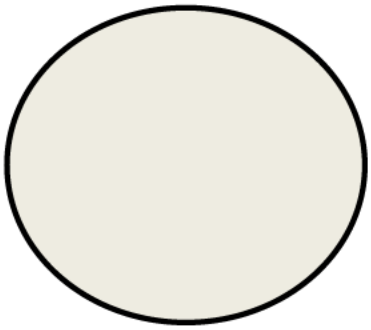
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



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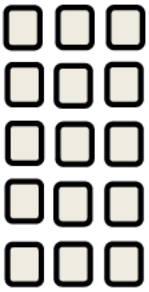

Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

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The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000611

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	FRESH 3MG Year 1 (2 can me (individual selling unit) Waste Load Estimates in metric tonnes	FRESH 3MG ear 5 (2024) can volume (individ g) Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29		
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8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4)

(b) (4)

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Fresh 3 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
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Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

E. CA.5: Facility Waste Generation

As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent history of waste generation of all statutory tobacco products at the Owensboro facility has been the following:

Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

Figure CA.5.1: Waste Generation at Owensboro Facility[5]

(b) (4)

This decline was due, primarily, to the flat or declining sales associated with the statutory products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man), moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all tobacco product categories that, on a national level, are experiencing flat or declining sales. The most current usage rate data comes from the recently released 2017 National Health Information Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip, snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

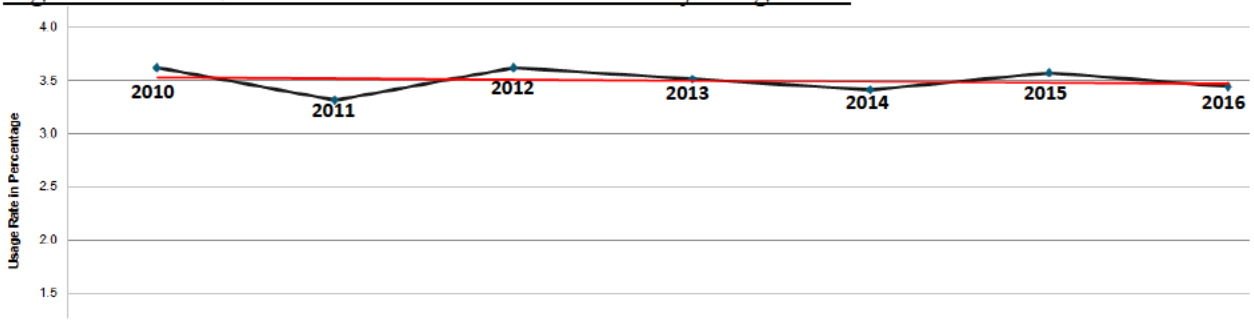
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Fresh (6 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Fresh (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

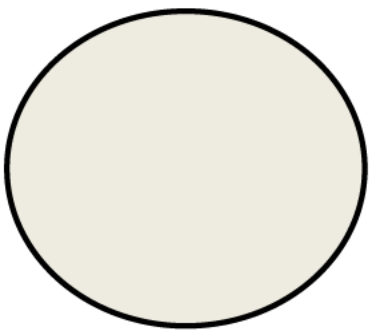
[1] The new product name is ZYN Fresh. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Fresh product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Fresh (6 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

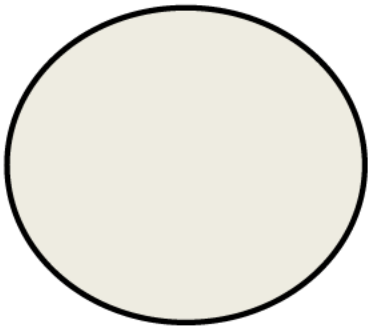
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

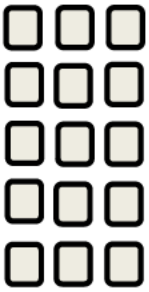
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000612

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	FRESH 6MG Year 1 (2	FRESH 6MG ear 5 (2024)
				can me (individual selling unit)	can volume (individ
				(b) (4) [redacted]	
				tonnes	tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29		
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4) [redacted]

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Fresh 6 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) decrease (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

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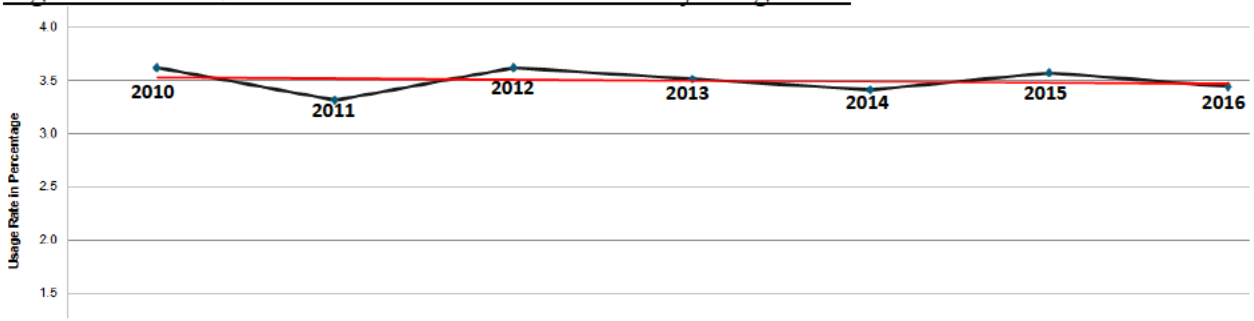
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

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these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

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In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

Confidential Appendix to the Environmental Assessment for the ZYN Peppermint (3 mg)[1] New Product

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Prepared by Swedish Match USA, Inc.

September 24, 2020

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[1] The new product name is ZYN Peppermint. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Peppermint product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Peppermint (3 mg.). The nicotine strength is not part of the name of the new product.

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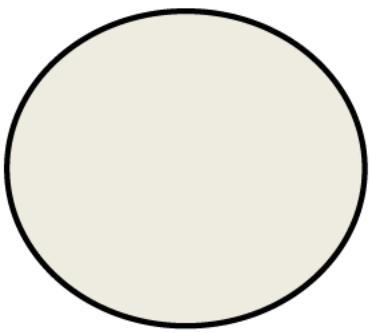
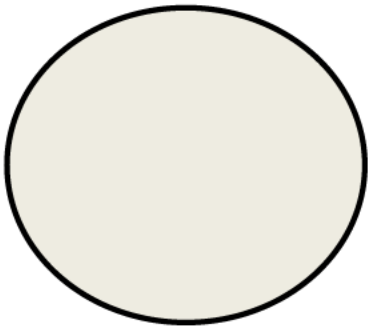
A. CA.1: Packaging Characteristics

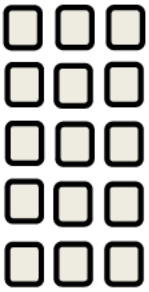
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000595

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	PEPPERMINT 3MG Year 1 (2 ear 5 (2024) Waste Load Estimates in metric tonnes	PEPPERMINT 3MG Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29		
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4)

(b) (4)

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Peppermint 3 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

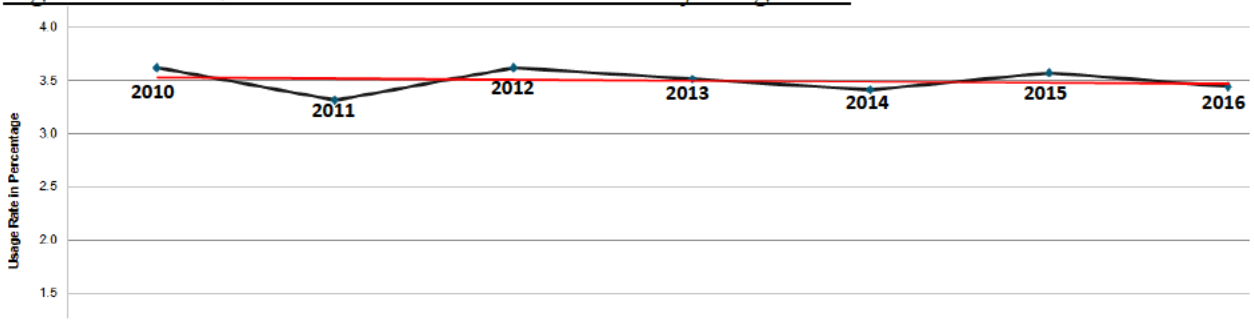
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Peppermint (6 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Peppermint (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

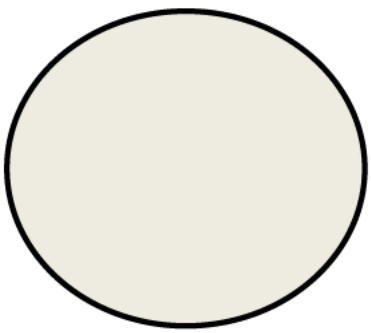
[1] The new product name is ZYN Peppermint. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Peppermint product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Peppermint (6 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

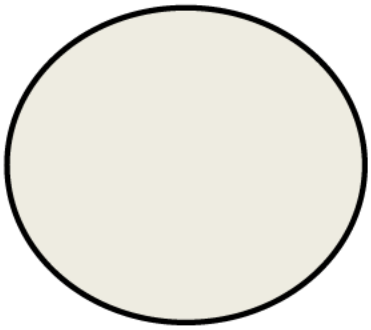
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

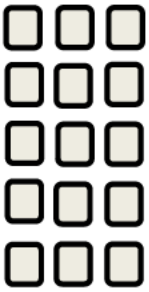
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000596

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	PEPPERMINT 6MG Year 1 (2	PEPPERMINT 6MG ear 5 (2024)
				can me (individual selling unit)	can volume (individ
				(b) (4) [redacted]	
				Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29	[redacted]	
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7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Peppermint 6 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
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Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

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	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

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D. CA.4: Forecasted Sales Volumes in other Products

Although sales of the new product are forecasted to increase through 2024 and are produced at the Owensboro facility, in addition to other statutory tobacco products, sales of these other statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf chewing tobacco) over time.

Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

[1]Based on an assumed (b) (4) in product produced per fiscal year.

Swedish Match estimates that the waste generated from statutory tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons).

The projected total tobacco products produced at the Owensboro facility, including the deemed new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) decrease (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

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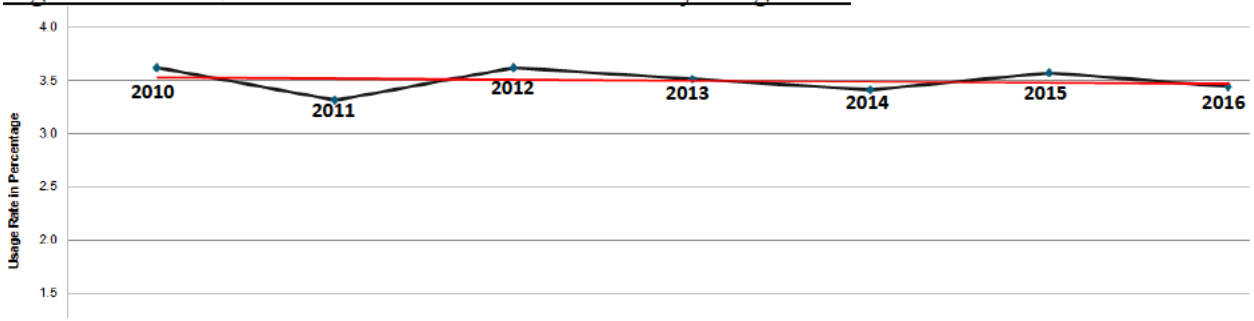
Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Smooth (3 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Smooth (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

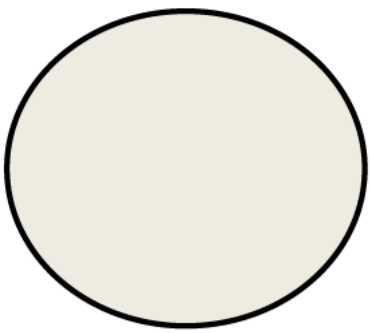
[1] The new product name is ZYN Smooth. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Smooth product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Smooth (3 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

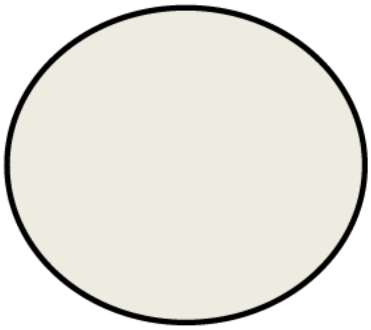
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

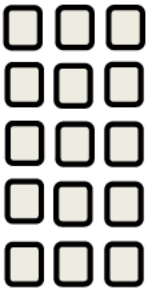
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted]. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000607

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	SMOOTH 3MG Year 1 (2 can me (individual selling unit) Waste Load Estimates in metric tonnes	SMOOTH 3MG ear 5 (2024) can volume (individ Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29		
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4)

(b) (4)

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Smooth 3 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
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136

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146 This decline was due, primarily, to the flat or declining sales associated with the statutory
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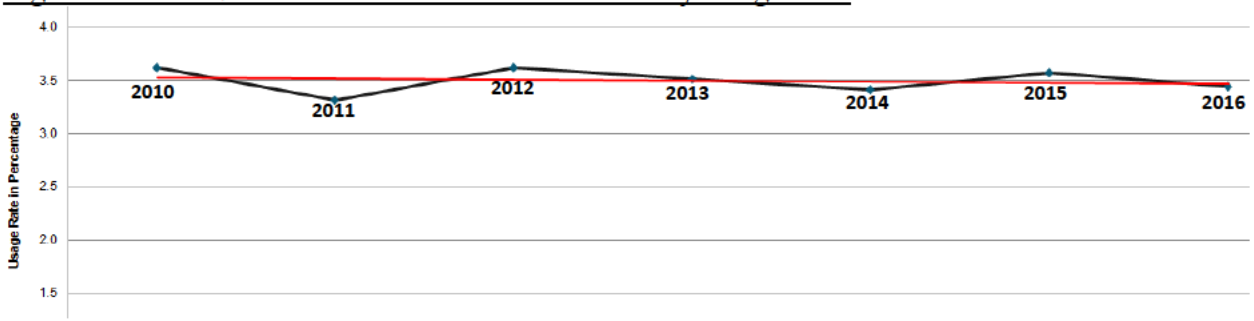
Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



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There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
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The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

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In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

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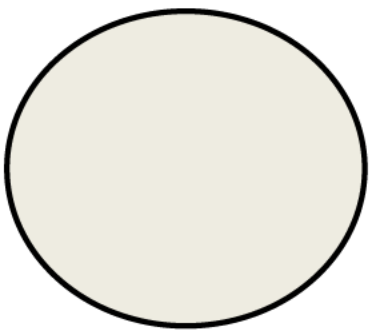
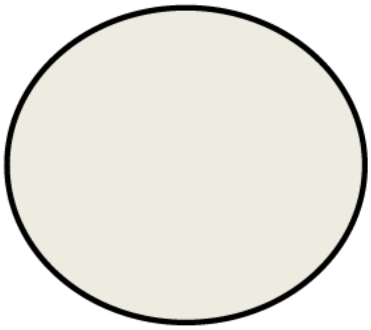


One (1) lid



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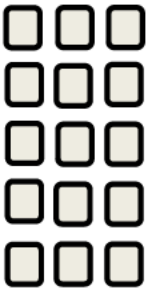

Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

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Basis weight	g/m^2	29	26	41
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Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

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Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000608

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	SMOOTH 6MG Year 1 (2	SMOOTH 6MG ear 5 (2024)
				can me (individual selling unit)	can volume (individ
				(b) (4) [redacted]	
				Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29		
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4) [redacted]

46 **B.** CA.2: Market Volume Projections: New Product

47 Table CA.2: New Product Projected Volume:

48

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Smooth 6 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

49

50 **C.** CA.3: Evidence of Manufacturing Facility Compliance with Regulations

51 **1.** Owensboro, Kentucky Facility

52 **Applicable Emission Requirements:**

53 • The Owensboro, Kentucky facility is currently permitted by and in compliance with:
54 Kentucky Title V
55 Proposed Operating Permit Number #V-20-006[2]
56 Issued 8/2/2020, Expiring 8/2/2025
57 • The following table reflects the breadth of permits that the Owensboro Plant has for
58 monitoring and controlling emissions as provided by state and local authorities. Swedish
59 Match is in compliance of all requirements listed in Table CA.3 below.
60

61 Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

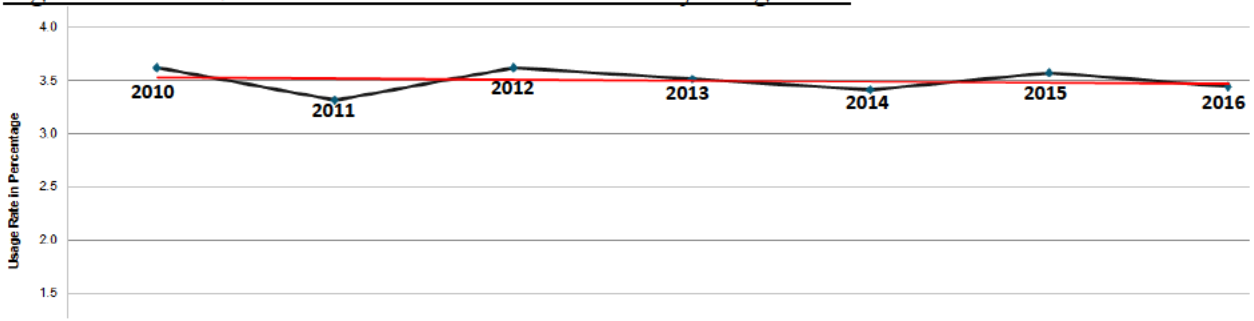
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

1 **Confidential Appendix to the Environmental Assessment**
2 **for the ZYN Spearmint (3 mg)[1] New Product**

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Spearmint (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

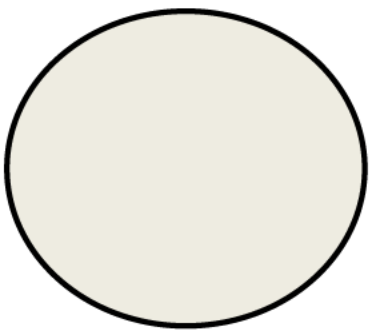
[1] The new product name is ZYN Spearmint. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Spearmint product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Spearmint (3 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

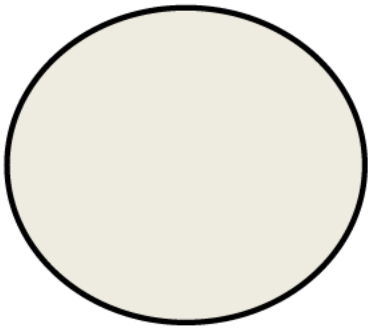
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

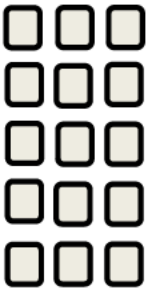
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

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The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000597

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	SPEARMINT 3MG Year 1 (2 ear 5 (2024) can me (individual selling unit) can volume (individ g) (b) (4) Waste Load Estimates in metric tonnes	SPEARMINT 3MG Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29		
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7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4)

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Spearmint 3 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

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[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

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	Non-hazardous solid plant waste to local landfill	No permit required

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Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

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D. CA.4: Forecasted Sales Volumes in other Products

Although sales of the new product are forecasted to increase through 2024 and are produced at the Owensboro facility, in addition to other statutory tobacco products, sales of these other statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf chewing tobacco) over time.

Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

[1]Based on an assumed (b) (4) in product produced per fiscal year.

Swedish Match estimates that the waste generated from statutory tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons).

The projected total tobacco products produced at the Owensboro facility, including the deemed new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

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144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
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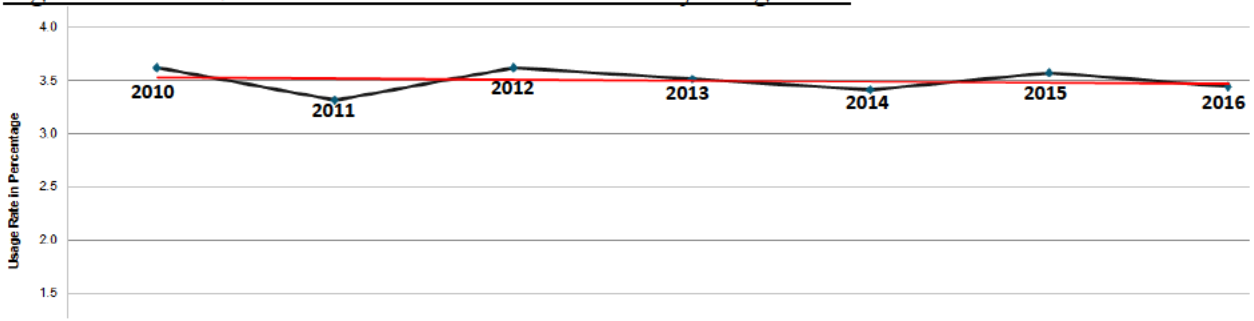
Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

Confidential Appendix to the Environmental Assessment for the ZYN Spearmint (6 mg)[1] New Product

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Spearmint (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

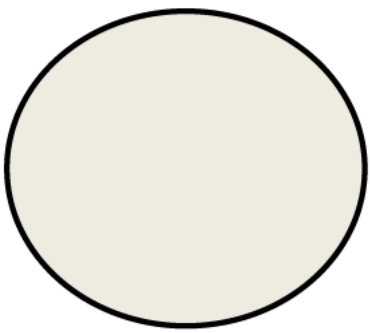
[1] The new product name is ZYN Spearmint. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Spearmint product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Spearmint (6 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

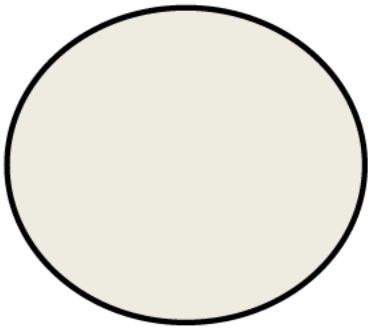
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

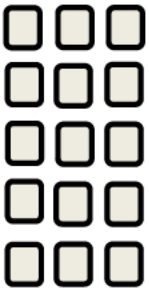
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000598

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	SPEARMINT 6MG Year 1 (2 ear 5 (2024) can me (individual selling unit) can volume (individ g) (b) (4) Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can base (with ring installed)	70 mm can	11.29		
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

(b) (4)

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Spearmint 6 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

Air emissions – Odor and other air emissions are regulated and audited by the authorities at least once a year. Swedish Match has installed equipment for incineration of the extracted air from the plants to reduce and avoid un-wanted air emissions.

Waste and hazardous waste – In Sweden it is prohibited to send process waste to landfill. All process waste is incinerated with energy recovery by municipality waste treatment suppliers. Swedish Match has a close cooperation with the waste treatment-supplier in Gothenburg to make sure that waste is treated correctly and to improve sorting and reducing the waste.

Chemicals - The use of chemicals are regulated by "*Kemikalieinspektionen*" (*Swedish Chemicals Agency*) who stipulates what chemicals that are allowed and requirements for exchanging chemicals to more environment- friendly chemicals when possible. Swedish Match works with a company, (b) (4) [redacted] to ensure compliance for both regulatory compliance, environment improvements and work safety.

Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

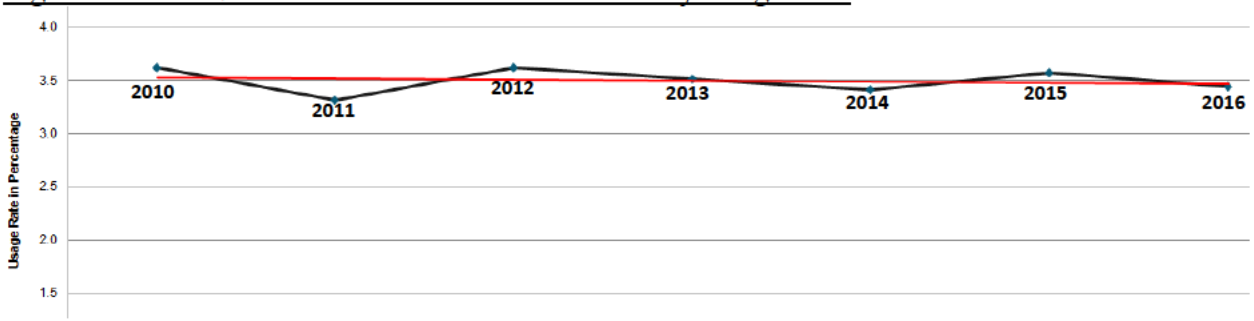
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

Confidential Appendix to the Environmental Assessment for the ZYN Wintergreen (3 mg)[1] New Product

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Wintergreen (3 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

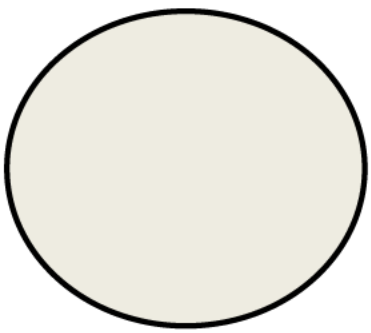
[1] The new product name is ZYN Wintergreen. It contains 3 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Wintergreen product with 6 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Wintergreen (3 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

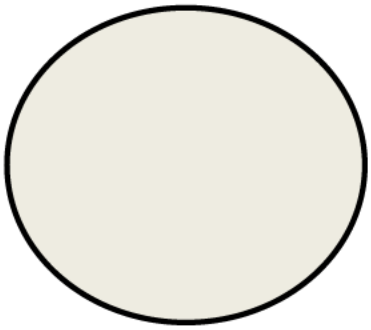
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

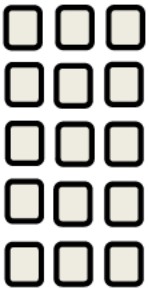
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, (b) (4) [redacted] Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000599

Estimated municipal solid waste loads for individual packaging material components

Item #	Item Name	OWENSBORO Material Description	OWENSBORO Weight Per Individual Selling Unit (g)	WINTERGREEN 3MG Year 1 (2 ... ear 5 (2024)	
				can ... me (individual selling unit)	can volume (individ ...
				(b) (4) [redacted]	
				Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29	[redacted]	
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
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6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Wintergreen 3 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
	KPDES Stormwater Program	401 KAR Chapter 5:050 - 080
	Groundwater Protection Plans	401 KAR Chapter 5:037
	Stormwater Permit	401 KAR Chapter 5
Wastewater Discharges	**Waste Water Requirements - Owensboro, Kentucky Factory**	
	Wastewater	Chapter 26 Article V Owensboro (KY) Municipal Code
	Sewer Permit	
	Pretreatment Standards	40 CFR 403
Solid and Liquid Waste	**Waste Requirements - Owensboro, Kentucky Factory**	
	Identification and Listing of Hazardous Waste	401 KAR Chapter 31
	Standards Applicable to Generators of Hazardous Waste	401 KAR Chapter 32
	Hazardous Waste Permitting Process	401 KAR Chapter 38
	Hazardous Waste Fees	401 KAR Chapter 39
	Standards for Used Oil Generators	401 KAR 44
	Registration for Hazardous Waste	401 KAR Chapter 38
	Non-hazardous solid plant waste to local landfill	No permit required

2. Kungälv Facility

Sweden has one of the world's most ambitious programs to improve environmental aspects and there are a lot of national laws and regulations for companies to comply with. Different environmental impacts are regulated and audited by different authorities and the most important ones are:

Waste water - *Svenskt Vatten (Swedish Water)* has a standard named "*Råd vid mottagande av avloppsvatten från industri och annan verksamhet*" ("advice at receiving waste water from industry or other business"), also called P95. In this standard BOD, COD and heavy metals have stipulated limits. Therefore, Swedish Match has sedimentation tanks and other equipment for adjustments of the waste water to comply with these regulations.

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Compliance of environment laws is audited by the Swedish government represented by each municipality (Miljöenheten Göteborg och Kungälv, *Environmental Unit Gothenburg and Kungälv*). Swedish Match's' production sites are classified as plants producing food products consisting of only vegetable raw materials and are therefore regarded as quite harmless business with a frequent audit time of 20 hours a year. Last audit was on the February 5, 2019 and no big issues were noticed. Notes from these audits can be provided at request.

The production facility producing the new product is certified according to ISO 14001 and awareness and compliance of laws and regulations are audited by an external auditor (DNV[3]) once a year and by internal auditors twice a year. During these audits the improvements of all environment aspects are reviewed.

[3] DNV GL is an accredited certification body. They certify the compliance of companies according to a third-party standard, such as ISO 9001 (quality management system) or ISO 14001 (environmental management system).

106 **D.** CA.4: Forecasted Sales Volumes in other Products

107 Although sales of the new product are forecasted to increase through 2024 and are produced at
108 the Owensboro facility, in addition to other statutory tobacco products, sales of these other
109 statutory tobacco products produced in the same factory are forecasted to decline (e.g., loose leaf
110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

116 Swedish Match estimates that the waste generated from statutory tobacco products manufactured
117 at the Owensboro facility would represent a (b) (4) (metric tons).

118 The projected total tobacco products produced at the Owensboro facility, including the deemed
119 new product, is represented in Table CA.4.2 and Figure CA.4.3, below.

120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
135 the following:

136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

141 Figure CA.5.1: Waste Generation at Owensboro Facility[5]
142

143
144
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146 This decline was due, primarily, to the flat or declining sales associated with the statutory
147 products produced at the facility in the past decade: loose leaf chewing tobacco (e.g., Red Man),
148 moist snuff tobacco (e.g., Timber Wolf), and plug tobacco (e.g., Union Standard). These are all
149 tobacco product categories that, on a national level, are experiencing flat or declining sales. The
150 most current usage rate data comes from the recently released 2017 National Health Information
151 Survey (NHIS).[6] This survey reported that 2.1% of Americans were current smokeless tobacco
152 users (note: "smokeless tobacco" was a general category including chewing tobacco, snuff, dip,
153 snus, and dissolvable). A significant decline ($p < 0.05$) was reported for smokeless tobacco
154 products between the years 2016 – 2017. These findings were similar to those of the National

[4] (t)= Metric tons

[5] (t) = Metric Tons

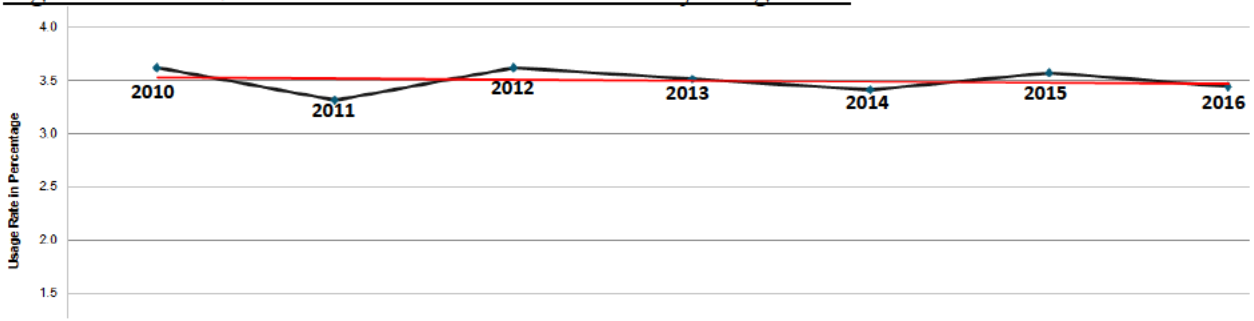
[6] https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html contains a summary of the report. The full report can be found in the latest compelling volume of CDC's Morbidity and Mortality Weekly Report (MMWR) at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a2.htm?s_cid=mm6744a2_w (accessed 11/9/2018).

Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate (b) (4) [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

[7] In order to estimate the monthly usage rate of smokeless tobacco, NSDUH asked respondents the following questions:

- Now think about the past 30 days, that is, from **[DATEFILL]** up to and including today. During the past 30 days, have you used "smokeless" tobacco, even once?
- During the past 30 days, that is, since **[DATEFILL]**, on how many **days** did you use "smokeless" tobacco?
- What is your **best estimate** of the number of days you used "smokeless" tobacco during the past 30 days?

these statutory smokeless tobacco products. Frankly, we would expect the rate of these declines to continually increase year-over-year.

The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4).

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

Confidential Appendix to the Environmental Assessment for the ZYN Wintergreen (6 mg)[1] New Product

Confidential Appendix to the Environmental Assessment for a Marketing Order for New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouch that contains nicotine salt derived from tobacco and is produced by Swedish Match

Prepared by Swedish Match USA, Inc.

September 24, 2020

This Confidential Appendix to the environmental assessment has been prepared in accordance with 21 C.F.R. §25.40, the Food and Drug Administration ("FDA" or "Agency")'s regulations implementing the National Environmental Policy Act of 1969 ("NEPA"), as part of a submission under Section 910(b) of the Food, Drug, and Cosmetic Act ("FD&C Act"). The Agency action under consideration, proposed by the applicant, is the premarket tobacco product application ("PMTA") for the deemed tobacco product, ZYN Wintergreen (6 mg), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco product in interstate commerce in the United States ("U.S.").

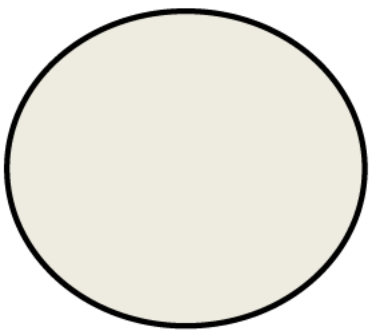
[1] The new product name is ZYN Wintergreen. It contains 6 mg of nicotine. To assist FDA's evaluation of this application, and to differentiate between the new product and the application featuring the ZYN Wintergreen product with 3 mg of nicotine, Swedish Match has placed the nicotine strength beside the product name: e.g., ZYN Wintergreen (6 mg.). The nicotine strength is not part of the name of the new product.

I. CONFIDENTIAL APPENDIX (CA)

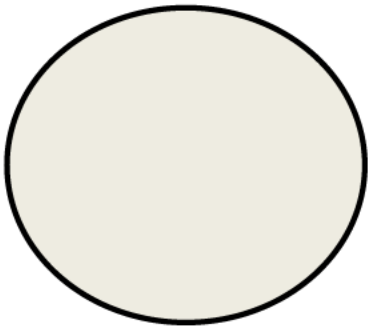
The information in the following confidential appendixes (CA) is confidential and should not be placed in a public Environmental Assessment document.

A. CA.1: Packaging Characteristics

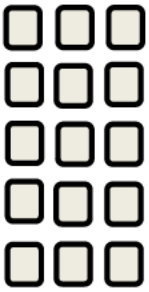
The new product is packaged in a two-piece, white, child resistant container manufactured out of recyclable polypropylene resin. Each container holds fifteen (15) individual 0.4 g pouches. The pouch materials, [redacted]. Five (5) cans are combined in a "sleeve" by wrapping them in a polyethylene shrink wrap film and placed in a corrugated shipping box.



One (1) lid



One (1) base



Fifteen (15) pouches

The pouch paper material type and its specifications are identified in Table CA.1, below:

Table CA.1: New Product Packaging Information

Component: Pouch Wrapping Material	---	---	---	---
Basis weight	g/m^2	29	26	41
Air permeability	$L/m^2/s$	4500	1700	5100
Thickness	mm	0.20	0.15	0.39

The container and the lid of the new "other tobacco product" products are composed of recyclable polypropylene resin with the resin identification code "5" contained within the Universal Recycling Symbol stamped into each respective component:

(image not to scale)

The packaging material is composed of recyclable material. The semi-gloss material as well as the water-based inks and varnishes are acceptable in the standard recycling process.

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The packaging material description, ingredients, dimensions, regulatory authority, weight per selling unit (g), and supplier information are found in Table CA.1.2, below. The more general packaging material weights are followed by estimates specific to the new product (in metric tonnes).

Table CA.1.2: New Product Packaging Material Information:

- General Information: See attached

Section Path	F. Product Environmental Assessment
Document File Name	File Name: f-environmental-assessment-package-materials.xlsx

- Information Specific to the New Product:

PM0000600

Estimated municipal solid waste loads for individual packaging material components

				WINTERGREEN 6MG	WINTERGREEN 6MG
				Year 1 (2	ear 5 (2024)
				can me (individual selling unit)	can volume (individ g)
		OWENSBORO	OWENSBORO	(b) (4) [redacted]	
Item #	Item Name	Material Description	Weight Per Individual Selling Unit (g)	Waste Load Estimates in metric tonnes	Waste Load Estimates in metric tonnes
		ZYN	ZYN		
		Currently in Market	Currently in Market		
		0.21 oz can (6 g)	0.21 oz can (6 g)		
1	Can Base (with ring installed)	70 mm can	11.29	(b) (4) [redacted]	
2	Can Lid	70 mm flat lid	4.90		
3	Top Label	Top Label - 70mm can	0.33		
4	Side Label	Side label - 70mm can	0.35		
5	Bottom Label	Bottom Label - 70mm can	0.26		
6	Shrink Wrap (Film)	Shrink film - can roll (5 can roll)	0.18		
7	Shrink Wrap Label	5-can roll label	0.07		
8	Case	Shipping Case (90 - cans per case)	2.14		
9	Case Tape	Clear Carton Sealing Tape	0.03		
	TOTAL		19.56		

B. CA.2: Market Volume Projections: New Product

Table CA.2: New Product Projected Volume:

Brand/SubBrand	Measure	Projected Volume	
		Year 1 (2020)	Year 5 (2024)
ZYN Wintergreen 6 MG	Units (pounds)	(b) (4) [redacted]	
	Metric Tons		

C. CA.3: Evidence of Manufacturing Facility Compliance with Regulations

1. Owensboro, Kentucky Facility

Applicable Emission Requirements:

- The Owensboro, Kentucky facility is currently permitted by and in compliance with:
  Kentucky Title V
  Proposed Operating Permit Number #V-20-006[2]
  Issued 8/2/2020, Expiring 8/2/2025
- The following table reflects the breadth of permits that the Owensboro Plant has for monitoring and controlling emissions as provided by state and local authorities. Swedish Match is in compliance of all requirements listed in Table CA.3 below.

Table CA.3: Table of Applicable Emission Requirements

[2] Swedish Match submitted the renewal for this permit 10/13/2019. This permit renewal was submitted at least six (6) months prior to the date of expiration as the Commonwealth of Kentucky Energy and Environment Cabinet Department for Environmental Protection Division for Air Quality allows for permitted facilities to continue to operate past their Kentucky Title V expiration date until the renewal permit is issued or denied by the Division (e.g., see 401 KAR 52:020, Section 12).

ASPECT	REQUIREMENT	CITATION/SOURCE
Air Emissions	**Air Quality Requirements – Owensboro, Kentucky Factory**	
	Title V Permit	401 KAR Chapter 52:020
	Title V	401 KAR Chapter 52
Storm Water Discharges	**Storm Water Requirements - Owensboro, Kentucky Factory**	
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110 chewing tobacco) over time.

111

112 Table CA.4.1: Projected Statutory Tobacco Products Produced at Owensboro Facility - 2020 -
113 2024:

Category	Measure	2020	2021	2022	2023	2024
Loose Leaf	Units (pounds)	(b) (4)				
	Metric Tons					
Plug	Units (pounds)					
	Metric Tons					
Moist Snuff	Units (pounds)					
	Metric Tons					
Other (NTC)	Units (pounds)					
	Metric Tons					
Total	Units (pounds)					
	Metric Tons					

114 [1]Based on an assumed (b) (4) in product produced per fiscal year.

115

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120

121 Table CA.4.2: Projected Total Tobacco Products Produced at Owensboro Facility - 2020 - 2024:

		2020	2021	2022	2023	2024
Total Forecast (including new product)	Units (pounds)	(b) (4)				
	Metric Tons					

122

Figure CA.4.1: Projected Total Tobacco Products (Pounds) Produced at Owensboro Facility – 2020 – 2024:

(b) (4)

As outlined in Figure CA.4.1, above, Swedish Match forecasts that the waste generated from the production of all statutory and deemed tobacco products manufactured at the Owensboro facility would represent a (b) (4) (metric tons) from Year 1 to Year 5.

132 **E.** CA.5: Facility Waste Generation

133 As demonstrated in Table CA.5.1 and Figure CA.5.1, below, the "trendline" for the recent
134 history of waste generation of all statutory tobacco products at the Owensboro facility has been
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136

137 Table CA.5.1: Waste Generation at Owensboro Facility (2009 – 2017)[4]
138

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Waste (t)	(b) (4) [redacted]								

139
140

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145

146 This decline was due, primarily, to the flat or declining sales associated with the statutory
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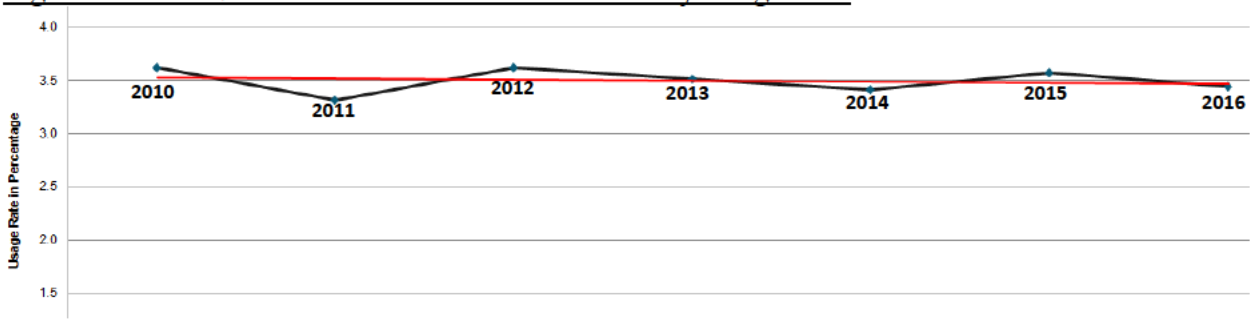
Survey on Drug Use and Health (NSDUH). To illustrate a linear trend line for this category, Swedish Match used data from NSDUH, tracking the responses of monthly users of smokeless tobacco who are 18 and older, to record their usage rate (in percentage)[7] (see Table CA.5.2 and Figure CA.5.2, below).

Table CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate (%)

Year	2010	2011	2012	2013	2014	2015	2016
Usage Rate	3.6	3.3	3.6	3.5	3.4	3.6	3.4

Figure CA.5.2: NSDUH Smokeless Tobacco Monthly Usage Rate



The red line in Figure CA.5.2 represents the estimated linear trend line for the 2010 - 2016 timeframe for all 18 and higher adult smokeless tobacco users. This trend line indicates that the past month usage rate for smokeless tobacco use is flat or slightly declining. Swedish Match's quarterly reports for 2019 also demonstrate a continuation of these sales declines. For example, in the report for the first quarter of 2019, Swedish Match reported an 8% decline in chewing tobacco for the quarter, compared to first quarter 2018, a decline that is typical for this tobacco product category. Moist snuff tobacco also declined sharply (a -11% decline compared to first quarter 2018). We expect these declines to continue during the next five years, the time frame aligned with the first- and fifth-year sales figures discussed in the context of the new product's environmental assessment.

There is an approximate [redacted] in the amount of waste generated associated with the production of these smokeless tobacco products at the Owensboro facility. As these smokeless tobacco products are expected to remain declining sales over the next five years (2020 – 2024), the forecasted time frame presented in the confidential appendix to the environmental assessment, we would not expect to see an increase in waste generated from the production of

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The above figures, the continued decline of these smokeless tobacco categories, and the decline of waste generation during the 2009 – 2017 timeframe, all contributed to the most current waste generation figures. Reasonably, any increase in waste generation at the Owensboro facility as a result of the proposed action would be offset by a reduction from all the other products produced at the facility.

For the forecasted period over the next five years, 2020 – 2024, the period covered by this environmental assessment, we expect to see an offset of the decline of the waste generated at the facility due to the production of the new product.

We estimated waste generation for the next five years (2020 – 2024) in the following table:

Table CA.5.3: Waste Generation at Owensboro Facility (2020 – 2024)[8]

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4) [redacted]				

Table CA.5.3 provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020) and that the amount of tobacco products (metric tons) produced at the facility would decline at a rate of (b) (4)

F. CA.6: Consumer Research Summary

In accordance with the recommendations found in FDA's PMTA Draft Guidance, Swedish Match conducted perceptions and behavior research among users of the new product. Based on the findings of this research, consumer use patterns of the new product, as compared to that of tobacco products on the most harmful end of the continuum of risk, may impact sales forecasts, as well as expectations regarding manufacturing. Certain tobacco product users may change their pattern of use regarding cigarettes, moist snuff, or chewing tobacco. This may result in a corresponding effect on the materials associated with the production, manufacture, transport, and disposal after use of these tobacco products.

[8] (t)= Metric tons

	Nicotine content (mg/g)
Wintergreen 3 mg	(b) (4)
Wintergreen 6 mg	
Spearmint 3 mg	
Spearmint 6 mg	
Cool mint 3 mg	
Cool mint 6 mg	
Cinnamon 3 mg	
Cinnamon 6 mg	
Peppermint 3 mg	
Peppermint 6 mg	
Fresh 3 mg	
Fresh 6 mg	
Citrus 3 mg	
Citrus 6 mg	
Chill 3 mg	
Chill 6 mg	
Coffee 3 mg	
Coffee 6 mg	
Smooth 3 mg	
Smooth 6 mg	

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]