



# Environmental Assessment ZYN (all SKUs)

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Environmental Assessment for Marketing Orders for Twenty New Non-Combusted, Smoke-free, Spit-free and Tobacco leaf-free, Nicotine Pouches that contain nicotine salt derived from tobacco and are produced by Swedish Match

[Författare]

**10 July 2019**

**Version 1**


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 products, ZYN (All SKUs), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco products in interstate commerce in the United States (“U.S.”).

## SUMMARY

Swedish Match's ZYN tobacco-free nicotine pouch provides a smoke-free, spit-free and tobacco leaf-free experience. ZYN contains nicotine that is derived from tobacco leaves and ingredients suitable for use in foods. It comes in ten (10) flavors: cool mint, wintergreen, cinnamon, peppermint, spearmint, citrus, smooth, chill, fresh and coffee. All flavors are available in two nicotine strengths: 3 milligrams or 6 milligrams. All flavors are packaged in a child-resistant round can.

ZYN is produced in two Swedish Match factories. The principal manufacturing facility is in the United States in Owensboro, Kentucky. A supplementary, manufacturing facility is in Kungälv, Sweden. The manufacturing facilities produce ZYN 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, and all other features. Except for a difference in manufacturing location and the suppliers of two chemically identical additives, the new products are otherwise identical.

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 (ALL SKUs), manufactured by Swedish Match. The applicant wishes to continue commercially distributing the new tobacco products in interstate commerce in the United States ("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. A Finding of No Significant Impact ("FONSI") by FDA is warranted for this environmental assessment of the new products. Additionally, the net positive benefit from the introduction of the new products into the U.S. market is further substantiated: manufacturing the new product would likely 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.

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68 **I. APPLICANT AND MANUFACTURER INFORMATION**

<b>Applicant/Submitter Name:</b>	Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Swedish Match USA Inc.
<b>Applicant/Submitter Address:</b>	Two James Center 1021 East Cary Street Suite 1600 Richmond, VA 23219
<b>Primary Product Manufacturing Name and Address</b>	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301
<b>Secondary Product Manufacturing Name and Address:</b>	Swedish Match North Europe Rollsbovagen 45 SE-441 17 Kungälv, Sweden

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70 **II. PRODUCT INFORMATION**

71 **A. Identification of the Products**

72 New Product Trade Names and Strength, Applicant Unique ID number by Manufacturing  
73 Location

74

<b>New Product Trade Names &amp; Strength</b>	<b>SM Unique ID no. (KY) Stock-Keeping Unit ("SKU"): ID#</b>	<b>SM Unique ID no. (Kungälv)</b>
ZYN Cool Mint 3mg	900510	8105
ZYN Cool Mint 6mg	900520	8106
ZYN Peppermint 3mg	901510	8107
ZYN Peppermint 6mg	901520	8108
ZYN Spearmint 3mg	902510	8109
ZYN Spearmint 6mg	902520	8110
ZYN Wintergreen 3mg	903510	8111
ZYN Wintergreen 6mg	903520	8112
ZYN Citrus 3mg	907510	8122
ZYN Citrus 6mg	907520	8123
ZYN Coffee 3mg	904510	8124
ZYN Coffee 6mg	904520	8125
ZYN Cinnamon 3mg	906510	8128
ZYN Cinnamon 6mg	906520	8129

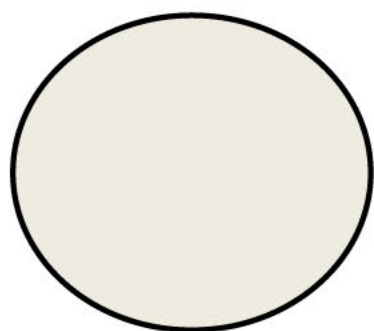
ZYN Smooth 3mg	914510	8134
ZYN Smooth 6mg	914520	8135
ZYN Chill 3mg	920510	8136
ZYN Chill 6mg	920520	8137
ZYN Fresh 3mg	921510	8140
ZYN Fresh 6 mg	921520	8141

## B. Description of the Products

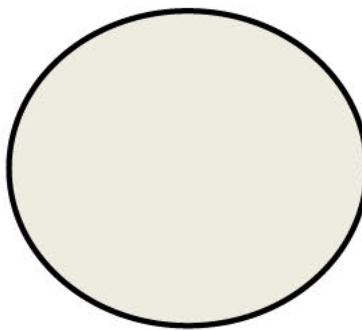
The new products are portioned pouched tobacco products within the deemed “other tobacco product” sub-category. The new products are comprised of nicotine salts, extracted from tobacco leaves, as well as ingredients approved for use in foods, and are tobacco-free. The portion weight for each pouch is 0.4 g; each can contains 15 pouches and the net can weight is 6 g (0.21 oz). As a reminder, the information in this section is confidential and should not be placed in a public Environmental Assessment document.

The new product’s application has been submitted under the premarket tobacco product application (PMTA) pathway. The new products are currently marketed pursuant to FDA’s “Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule.” In this document, published August 2017 and revised March 2019, FDA extended the timeline for manufactures to submit tobacco product review applications for 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 products, to August 8, 2022. Subsequently, the deadline extension was modified so that applications are due in May 2020.

The new products are 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 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. These packaging materials are approved for safe use as an indirect or direct food contact material.

The Packaging Material Description, Ingredients, Dimensions, Regulatory Authority for Food Contact Materials, Weight per Selling Unit (g), and Supplier Information are found in the Confidential Appendix to the Environmental Assessment ([see Table CA.1](#) 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 products ([see Table CA.2](#) in the Confidential Appendix to the Environmental Assessment). As a reminder, this information is confidential and should not be placed in a public Environmental Assessment document.



### **III. DESCRIPTION OF PROPOSED ACTIONS**

#### **A. Purpose of and need for action**

The proposed actions, requested by the applicant, are for FDA to issue marketing orders finding the “deemed” new tobacco products 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 products in interstate commerce in the United States (“U.S.”). The Agency shall issue marketing orders if, after considering the application submitted by the applicant, the new products are found appropriate for the protection of public health.

#### **B. Location of Use**

The new products will be manufactured primarily at Swedish Match’s facility in Owensboro, KY, with support from Swedish Match’s facility in Kungälv, Sweden. The new products will be sold to adult consumers at a variety of retail establishments and consumed primarily in homes and automobiles. The new products will be widely distributed and use of the new products 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 products, 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 2009 update regarding municipal solid waste in the United States, about 54.3% of municipal solid waste was land disposed, 11.9% was combusted, and 33.8% was recovered (recycled and composted). The types of environments present at and adjacent to these disposal locations will not differ for the new products.

#### **D. Alternative to the Proposed Actions**

Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, alternatives to the proposed action are not proposed.

### **IV. ENVIRONMENTAL ISSUES**

#### **A. Introduction of Products into the Environment**

Swedish Match’s sustainability strategy emphasizes six areas – public health, ethical business practices, equal opportunity, greenhouse gases, waste, and child labor, which are material to our

Company as a whole, and in the long term. Our vision of a world without cigarettes is central to our sustainability strategy and how we contribute to making the world a better place. Offering tobacco consumers alternative products to cigarettes is at the core of what we do.

The new products are intended to compete with cigarettes and other statutory tobacco products positioned at the more harmful end of the continuum of risk. Based on the findings of Swedish Match's patterns of use consumer research, we expect certain tobacco product users to cease using – or substantially reduce the amount they use of – tobacco products from other categories, including combustible cigarettes, moist snuff tobacco, or chewing tobacco. This likelihood would 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.

## **1. As a Result of Manufacture and Transport**

The new products are manufactured at the facility addresses listed in [Section I](#) of this document, above. The new products are 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 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 manufacturing locations are in compliance with all environmental laws today and there is minimal 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 products, or from the production of the new products. The plant-based materials or ingredients used in the new products are purchased from agricultural commodities on the existing market and other materials or ingredients are synthetic, artificial, or



190 inorganic. No rare or protected flora or fauna are used as materials or ingredients in the new  
191 products.

192 There are no anticipated adverse effects on any endangered species, or the critical habitat of the  
193 species identified under CITES (“Convention on International Trade on Endangered Species”) and  
194 ESA (“Endangered Species Act”) due to: (i) the materials used to manufacture the new  
195 products; (ii) the manufacturing process itself; and (iii) the disposal of the new products.

196 Swedish Match’s Owensboro, KY facility is the primary producer of the new products. This  
197 facility has historically made smokeless tobacco products (e.g., chewing tobacco, moist snuff  
198 tobacco, plug tobacco). Production of the aforementioned statutory tobacco products was not,  
199 and will not be, affected by the manufacturing of the new products at the Owensboro facility.  
200 The Owensboro facility will manufacture the new products and continue to manufacture the  
201 already existing statutory tobacco products.

202 Compliance of environmental laws is audited by local government agencies. Swedish Match’s  
203 production site is classified as a manufacturing establishment. The Owensboro production  
204 facility producing the new products is certified according to ISO 9001: 2015 by SAI Global and  
205 ISO 14001: 2015 by SAI Global.

206 Manufacturing the new products resulted in an expansion of the Owensboro manufacturing  
207 facility. No expansion of the Kungälv manufacturing facility regarding the new products for the  
208 US market has occurred or is planned.

209 The portion of the Owensboro manufacturing facility dedicated to producing the new products is  
210 a combination of remodeled internal space and new external facilities. The minor expansion  
211 includes the following:

- 212 • 19,200 square foot internal packaging area remodeled within the existing facility;
- 213 • 36,000 square foot new process expansion;
- 214 • 2,100 square foot new ethanol storage building.

215  
216 The expansion to the Owensboro facility was conducted on the existing Swedish Match campus  
217 located in Daviess County. The construction site on the Swedish Match Owensboro campus was  
218 not occupied by wildlife. The Owensboro facility is located in an area of significant industrial  
219 development and not within or near critical habitat for any endangered or threatened species.  
220 According to the U.S. Fish and Wildlife Service’s Environmental Conservation Online System,  
221 the only threatened or endangered species potentially present in Daviess County are the Indiana  
222 bat (*Myotis sodalis*), Gray bat (*Myotis grisescens*), and Northern Long-Eared Bat (*Myotis*  
223 *septentrionalis*). Critical habitat has not been designated for the Gray and Northern Long-Eared  
224 Bats. The only critical habitat in Kentucky for the Indiana bat consist of caves, outside of  
225 Daviess County.

Manufacturing the new products 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 products, generally, and to handle additional ethanol and nicotine waste, specifically.

Ethanol:

Ethanol (190 Proof) is used in the new products manufacturing process as a carrier and is removed through evaporation. During processing, the ethanol is evaporated away, leaving only residual quantity of max 1.0%, with no technical effect on 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:

(b) (4)

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<sup>1</sup> (b) (4)

(b) (4)

Swedish Match intends for the new product to compete with cigarettes and tobacco products at the most harmful end of the continuum of risk. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of these tobacco product categories to switch to the new products or substitute their products out for the new products. 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. 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.

Swedish Match has ongoing sustainability initiatives on which the company focuses. These initiatives, approved by the Swedish Match board of directors, and aligning with the 2016 Paris Agreement within the United Nations Framework Convention on Climate Change (UNFCCC), include categories devoted specifically to waste and greenhouse gas emissions.<sup>2</sup> One target

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<sup>2</sup> Swedish Match's sustainability initiatives can be accessed via the company's home page: <https://www.swedishmatch.com/Sustainability/>

remains to keep waste volumes constant, even with increased production. Another target is to increase recycling/recovery while decreasing reliance on landfills. A third target is 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 increased production at the Owensboro facility due to the new products, the facility would maintain these target goals.

It is reasonable to conclude that, though there are new environmental controls introduced to the manufacturing facility to accommodate production of the new products, the production of the new product would result in the overall transition of more tobacco users away from the most harmful of tobacco products. Additionally, the manufacturing 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.4.1](#) 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 products 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 products from the state of Kentucky, on 2/25/2018 (permit # (b) (4)).

#### 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 products resulted in an expansion of existing waste/sanitary water discharge. Manufacturing the new products 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.

Socioeconomics and Environmental Justice.

No significant changes on socioeconomics are anticipated due to manufacturing the new products. Manufacturing the new products would result in additional employment.<sup>3</sup>

No changes in impacts on environmental justice are anticipated. As illustrated in the Enforcement and Compliance History Online (ECHO) database,<sup>4</sup> which summarizes the demographic information regarding the community surrounding the Owensboro facility (in a 3 mile radius) based on the 2010 U.S. Census and American Community Survey data, minorities make up 16% of the population and the facility is not located on an Indian reservation. White residents make up approximately 86% of the population. Thus, no impacts to environmental justice populations would occur as a result of manufacturing the new products.

Manufacturing the new products should not result in new or increased compounds being emitted from the manufacturing of the new products at the Owensboro the facility. Release of new chemicals (i.e., (b) (4)) into the environment due to manufacturing the new products is not anticipated due to the proposed action. Additives used in the manufacture of the new products 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 products 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.

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 CA.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 products projections cannot be viewed in a vacuum. Although Swedish Match sales of the new products 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

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<sup>3</sup> [https://www.messenger-inquirer.com/news/local/swedish-match-unveiling-m-expansion/article\\_86fbddac-c044-5a44-a0e2-78f3dd574f5c.html](https://www.messenger-inquirer.com/news/local/swedish-match-unveiling-m-expansion/article_86fbddac-c044-5a44-a0e2-78f3dd574f5c.html)

<sup>4</sup> <https://echo.epa.gov/detailed-facility-report?fid=110013765559>



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 products would not impede the expected continual decline in the production of these statutory tobacco products at the Owensboro facility. Swedish Match intends for the new products to compete with cigarettes and tobacco products at the most harmful end of the continuum of risk. Accordingly, following receipt of a marketing order, Swedish Match expects certain smokers and users of these tobacco product categories to switch to the new products or substitute their products out for the new products. 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.

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.

There may be a net increase in manufacturing due to the new products. 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: Total Waste Generation at Owensboro Facility (2020 – 2024)<sup>5</sup>

Year	2020	2021	2022	2023	2024
Waste (metric tons)	(b) (4)				

Table 1.1, above, provides estimates based on the assumption that the facility would generate (b) (4) metric tons in waste in Year 1 (2020). Further, tobacco products (metric tons) other than the new products are the overriding cause of the total waste produced at the facility and would decline at a rate of (b) (4)

This forecast takes into account;

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<sup>5</sup> (t)= Metric tons



(b) (4)

Manufacturing the new products 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, (b) (4), who generates its power from two coal-fired generating units. Swedish Match purchases its natural gas from a local municipal supplier, (b) (4).

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<sup>6</sup>

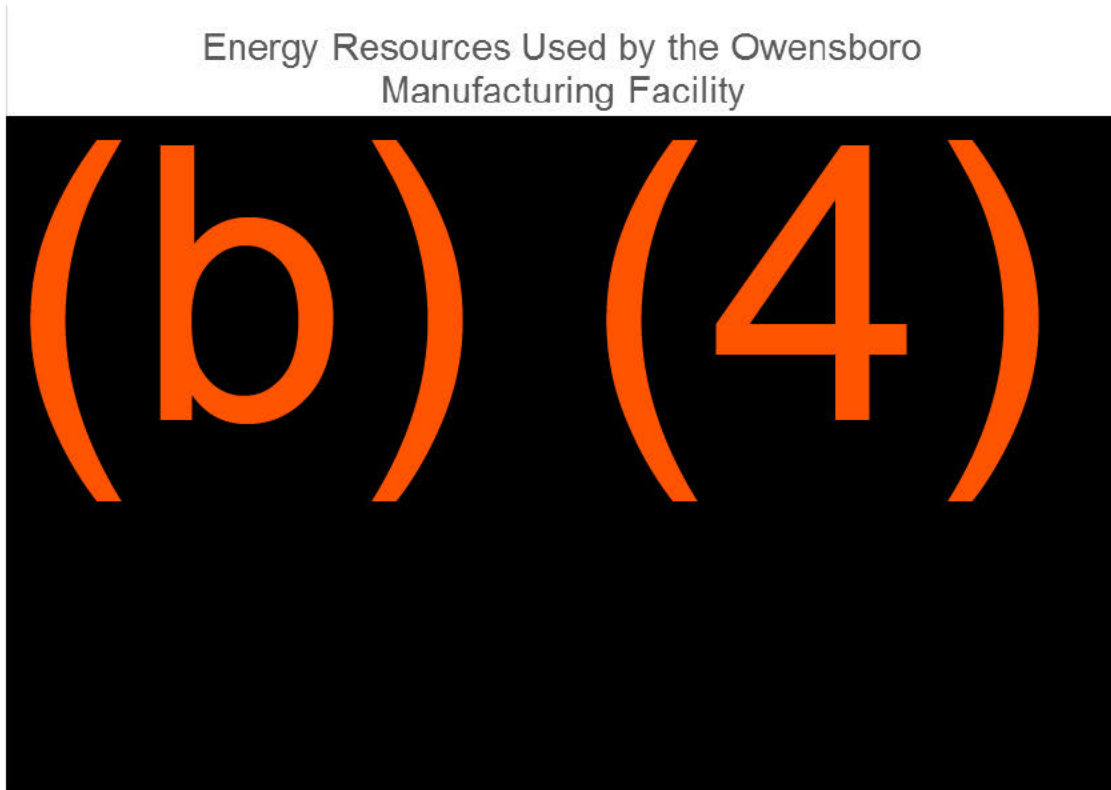


Table 1.2: Energy Resources Used by the Owensboro Manufacturing Facility (2007 – 2017)

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

<sup>6</sup> (MW-h) =Megawatt-Hour

production of the new products, waste generated is expected to fall approximately (b) (4) annually. Energy use is expected to experience similar declines.

Manufacturing the new products is not expected to impact greenhouse gas (GHG) emissions. As noted above, Swedish Match has outlined ongoing sustainability initiatives which directly impact the energy resources used by the Owensboro manufacturing facility. These initiatives, approved by the Swedish Match board of directors, and aligning with the 2016 Paris Agreement within the United Nations Framework Convention on Climate Change (UNFCCC), include categories devoted specifically to waste and greenhouse gas emissions.<sup>7</sup> Most applicable to this section 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 products, 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 CA.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 products, or from the production of the new products. The plant-based materials or ingredients used in the new products 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 products.
- 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 products; (ii) the manufacturing process itself; (iii) the disposal of the new products.
- There will not be an expansion of the manufacturing facility regarding the new products. Swedish Match produces the new products both for US and non-US markets in the production facility, with US production representing less than 3% of total production. Therefore, Swedish Match can confidently state that an PMTA order and production generally from new products will not result in expansion or give rise to any additional environmental impacts.

Furthermore, Regarding the Kungälv facility:

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<sup>7</sup> Swedish Match's sustainability initiatives can be accessed via the company's home page: <https://www.swedishmatch.com/Sustainability/>

- Manufacturing due to the new products 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 products.
- Manufacturing the new products 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 products would not require any additional environmental controls.
- Manufacturing the new products would not impact greenhouse gas (GHG) emissions.
- Manufacturing the new products would not result in a net increase of energy use at the manufacturing location.

The Kungälv facility uses gas, electricity and district heat as energy sources. The Green electricity (with no contribution to CO<sub>2</sub> emissions) represents >75% of the total, gas <10% and district heat about 20%.

Swedish Match objectives are to reduce the total use of energy and to use fossil-free energy sources by the end of year 2021 at the latest. [See Table 1.4](#)

Table 1.4 Total Energy Resources by the Kungälv Manufacturing Facility

Energy	2017	2018	2019	2020	2021
KWh/produced can	(b) (4)				

(b) (4)

Multiple manufacturing facilities withstanding, none of the Environmental effects of manufacturing or transport are expected to result in environmental effects that would significantly<sup>8</sup> affect the quality of the human environment. Accordingly, (a) a Finding of No Significant Impact (FONSI) for the new product's application remains warranted, and (b) the new product remains appropriate for the protection of the public health.

<sup>8</sup> Swedish Match uses the term "significantly" as defined at 40 CFR 1508.27.

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## 2. As a Result of Use

500 The new product will be used similarly to other portioned tobacco products, including smokeless  
501 tobacco/chewing tobacco products (e.g., moist snuff, snus). No environmental effects of  
502 disposal of used product and “spit” generated during product use are anticipated. When the  
503 pouch has been consumed by the consumer practically none of the contents of the pouch will  
504 remain. Contents of the pouch dissolve during consumption and will gradually be extracted from  
505 the pouch during consumption and should not result in spitting. The use of the new product  
506 would result in the direct introduction of little or no change in the complexity of the ingredients  
507 nor any of the other ingredients into the environment because these ingredients are consumed  
508 during use.

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510 The new tobacco products characteristics are similar to other portioned smokeless tobacco  
511 products in the market. Thus, consumer perceptions of harm and addictiveness should not be  
512 affected. Further, as a reminder to FDA, there is a high likelihood that certain tobacco product  
513 users will cease using – or substantially reduce the amount they use of – cigarettes, moist snuff,  
514 or chewing tobacco based upon Swedish Match’s consumer research. This likelihood would  
515 result in a corresponding effect on the materials associated with the production, manufacture,  
516 transport, and disposal after use of these tobacco products.

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## 3. As a Result of Disposal

519 The new product and any associated waste will be disposed of by the end user in the same  
520 manner as similarly marketed portioned tobacco products or tobacco product categories (e.g.,  
521 moist snuff, snus). The new product’s container is not intended for repeat use. Disposal by the  
522 ultimate consumer of plastic cans, used product, and any other waste material will be by re-  
523 cycling or conventional rubbish disposal and, therefore, primarily by sanitary landfill or  
524 incineration. There is a high likelihood that certain tobacco product users will cease using – or  
525 substantially reduce the amount they use of – cigarettes, moist snuff, or chewing tobacco. This  
526 likelihood would result in a corresponding effect on the materials associated with the production,  
527 manufacture, transport, and disposal after use of these tobacco products. The proposed action  
528 may result in an increased product sale. However, this increase is expected to be offset by the  
529 reduction in the use of other tobacco products as adult consumers on the more harmful end of the  
530 continuum of risk switch completely to the new product or substitute their more harmful tobacco  
531 product with the new product. Moreover, by 2024, all SKUs of the new product combined are  
532 expected to comprise approximately 3% of the total smokeless tobacco sales (measured in  
533 pounds of smokeless tobacco) in the United States, and waste from the product will make up a  
534 very small portion of total municipal solid waste. Further, each individual SKU of the new  
535 products represents less than 1% of the 131.43 million pounds of smokeless tobacco sold in the  
536 U.S. per 2016 FTC Smokeless Tobacco Report. It will not significantly alter the emissions from  
537 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 products are expected to enter into the environment in extremely small, negligible,<sup>9</sup> 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 these products 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). This literature review identified a continuum of environmental harm arising from the waste of tobacco products, with the post-use remains of combustible cigarettes (e.g., cigarette filters or "butts") clearly and overwhelmingly representing the primary waste not just among tobacco products but for all consumer waste products. Concerns were also raised for the post-consumer use technological remnants (e.g., batteries, liquid cartridges, coils, hard plastic outer shell) of vapor products. The category of "Other tobacco products" and similarly pouched tobacco product categories, like smokeless tobacco, were not discussed in this light. Given the potential effects of post-consumer cigarette and vapor waste on the environment, we would like to remind FDA that the new products are not cigarettes or vapor products and the new products are not contained in anything akin to a cigarette butt or a vapor shell (e.g., "cigalike" or tank).

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 products, or smokeless tobacco generally. Further, the available research assessing the external environmental impact of tobacco products has focused on combustible cigarettes, while not addressing any potential impact from "other tobacco products," or smokeless tobacco products generally. The available research assessed indoor and outdoor pollution occurring from smoking cigarettes, both from the constituents of the smoke (e.g. second hand smoke; third hand smoke) and the waste products of

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<sup>9</sup> EPA defines negligible as <5000 tons of municipal solid waste (see Table 1) in Advancing Sustainable Materials Management: Facts and Figures 2014 found at [https://www.epa.gov/sites/production/files/2016-11/documents/2014\\_smmfactsheet\\_508.pdf](https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf), accessed July 11, 2017. Each of the new product represents approximately less than 50% of EPA's threshold for negligible tons of solid waste.



cigarette consumption (e.g. “butts, packages, cellophane wrappers, and cartons” discarded either in waste disposal or in the natural environment itself) (Novotny and Zhao, 1999: 75 – 76). Novotny and Slaughter (2014: 208) summarized two studies substantiating that “most” cigarette users (74.1% of smokers; 76.6% of smokers) littered their cigarette butts. The butts represent up to 38% of items picked up in international coastal and urban clean-ups (Novotny and Slaughter, 2014: 208). Additional concern expressed by the World Health Organization (2017: 28) relates to the possibility that the technological components connected to e-cigarettes and “Heat Not Burn” products may become the cigarette butts of the future. None of the aforementioned authors extrapolated from these results and applied them to the context of “other tobacco products,” or smokeless tobacco generally.

To that end, Swedish Match does not find any correlation between the post-consumer waste of the new products with that of the “estimated 4.5 trillion” discarded cigarette butts worldwide (Novotny and Slaughter, 2014: 208). There is also no alignment between the magnitude or manner by which compounds are emitted from the disposal following use of cigarettes relative to the new products. Further, there is a likelihood, as illustrated by the consumer behavior studies, that a net change in tobacco product use behavior would increase the presence of the new product-related materials (through manufacture, disposal, and use), yet also reduce materials associated with other tobacco product categories, like cigarettes. Accordingly, the new products 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 materials connected to the use and disposal of other, far more prevalent, tobacco product categories. This type of significant environmental impact 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 products, 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 products are 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 Indiana bat (*Myotis sodalis*), Gray bat (*Myotis grisescens*), and Northern Long-Eared Bat (*Myotis septentrionalis*). 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.

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 products

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 products are 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 Indiana bat (*Myotis sodalis*), Gray bat (*Myotis grisescens*), and Northern Long-Eared Bat (*Myotis septentrionalis*) as the only threatened or endangered species potentially present in Daviess County. Critical habitat has not been designated for the Gray or Northern Long-Eared Bats, and 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 products.

(iii) No effects on species or critical habitat are anticipated from disposal of the new products. The new products are 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 products and their ingredients require the use of natural resources such as petroleum products and coal. However, the new products 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**

Based on current information, Swedish Match has not identified any adverse environmental effects associated with the proposed action. Therefore, alternatives to the proposed action are not proposed.

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**VIII. REFERENCES**

686 Novotny and Slaughter (2014): Tobacco Product Waste: An Environmental Approach to Reduce  
687 Tobacco Consumption. Current Environment Health Report. 1:208-216.

688 Novotny and Zhao (1999): Tobacco Control. 8:75-80.

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694 **IX. AGENCIES AND PERSONS CONSULTED**

695 N/A  
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699    **X.       CONFIDENTIAL APPENDIX (CA)**

700    The information in the following confidential appendixes (CA) is confidential and should not be  
701    placed in a public Environmental Assessment document.

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