Environmental Assessment for SE Report of "Longhorn Long Cut Mint"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

November 18, 2016

Table of Contents

This environmental assessment (EA) is for the market authorization of a smokeless tobacco moist snuff manufactured by "Swedish Match North America, Inc." Information presented in the EA is based on the submission referenced in Appendix 1, unless noted or referenced otherwise. This EA has been prepared in accordance to 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

Swedish Match North America, Inc.

2. Address

Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

3. Manufacturer

Swedish Match North America, Inc.

4. Description of Proposed Action

The proposed action is for FDA to issue a market authorization under section 910(a)(2) of the FD&C Act for the introduction of the new smokeless tobacco, Longhorn Long Cut Mint, in interstate commercial distribution in the U.S. The authorization is based on the finding that this new product is substantially equivalent to its predicate product that was on the market as of February 15, 2007.

4.1 Requested Action

Order finding the smokeless tobacco product, Longhorn Long Cut Mint, is substantially equivalent to the predicate product.

4.2 Need for Action

Swedish Match North America, Inc. wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the U.S. The applicant claimed that the new product differs only from the predicate product in product quantity (sec 910(a)(3)(A)(ii) of the FD&C Act), as described in the FDA guidance to industry issued on March 4, 2015.[1] After considering the SE Report (SE0011055), the Agency shall issue an order pursuant to section 910(a)(2) of the FD&C Act when finding the new product to differ from the predicate product in product quantity alone.

[1] FDA Guidance for Industry. Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions. Issued March 4, 2015. Available at: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf. Accessed on December 28, 2015.

4.3 Identification of the New Tobacco Product that is the Subject of the Proposed Action

4.3.1 Type of Tobacco Product

Smokeless tobacco product, moist snuff, loose

4.3.2 Product Name and Its Original STN

The name of the new product is listed below, along with the original submission tracking number (STN) and the name of the predicate product. See Appendix 1 for additional STNs associated with the new product and the predicate product.

STN	New Product	Predicate Product
SE0011055	Longhorn Long Cut Mint	Longhorn Long Cut Mint

4.3.3 Description of the Product Package

The packaging materials of the finished new product are identical to those of its predicate product. The new product packaging components consist of a can base with plastic lid. The assembled can is made out of a homopolymer polypropylene resin. Details of the package ingredients and weight of each packaging component for the new product are described in Confidential Appendices 3 and 4. Five cans are combined into a roll by wrapping them with a polyvinyl copolymer shrink film. Eighteen rolls are combined into a 90-can corrugated cardboard shipping case.

4.3.4 Location of Manufacturing

Swedish Match North America, Inc.
1121 Industrial Drive
Owensboro, KY 42301

4.3.5 Location of Use

Swedish Match North America Inc. intends to distribute and sell the new tobacco product to consumers in the U.S.

4.3.6 Location of Disposal

Once used the new tobacco product will be disposed of in municipal solid waste (MSW) landfills or as litter. Disposal of the packaging material following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The distribution of waste from disposal after use should correspond to the pattern of the product use.

4.4 Modification(s) Identified as Compared to the Predicate Product

The applicant claims that a change in product quantity (from 37.42 gram/can to 34.02 gram/can) is the only difference between the new product and its predicate product.

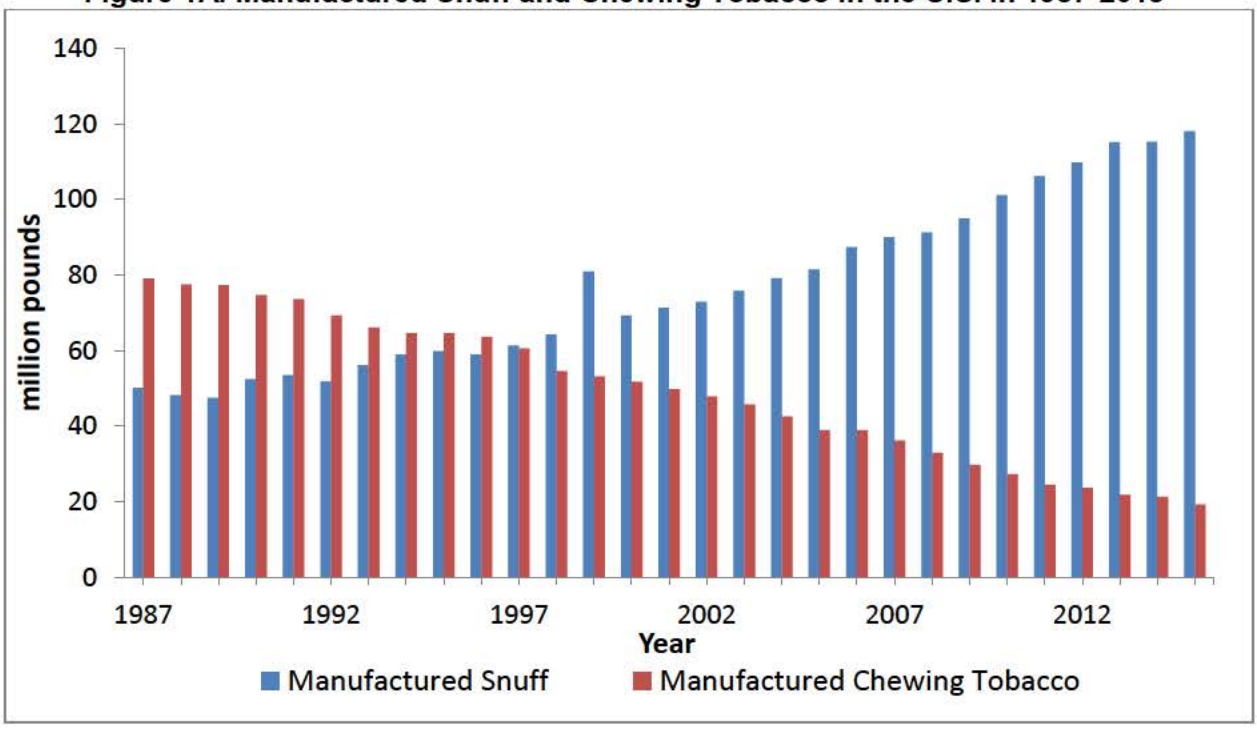
5. Environmental Introduction Due to the Proposed Action

5.1 Introduction as a Result of Manufacturing the New Tobacco Product

5.1.1 Tobacco Manufacture in the U.S. and Pollution Emission by Swedish Match North America's Owensboro (KY) Facility

Tobacco Manufacture and Tobacco Market Volumes. Smokeless tobacco products include moist snuff, chew, snus, dry snuff, and some dissolvable products. As of February 2014, a total of 73 tobacco establishments are registered under 915(c) of the FD&C Act. According to Tobacco Statistical Release Reports of the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), production of chewing tobacco decreased to 19 million pounds (8,618 tons) in 2015 from 79 million pounds (35,834 tons) in 1987, whereas snuff production increased to 118 million pounds (53,524 tons) in 2015 from 50 million pounds (22,680 tons) in 1987 (Figure 1A).[2] However, combined production remained almost constant and did not change over the years (Figure 1B). Of the 128.04 million pounds (58,078 tons) of all smokeless tobacco products that were sold in the U.S. in 2013, 104.5 million pounds (47,400 tons) was moist snuff.[3]

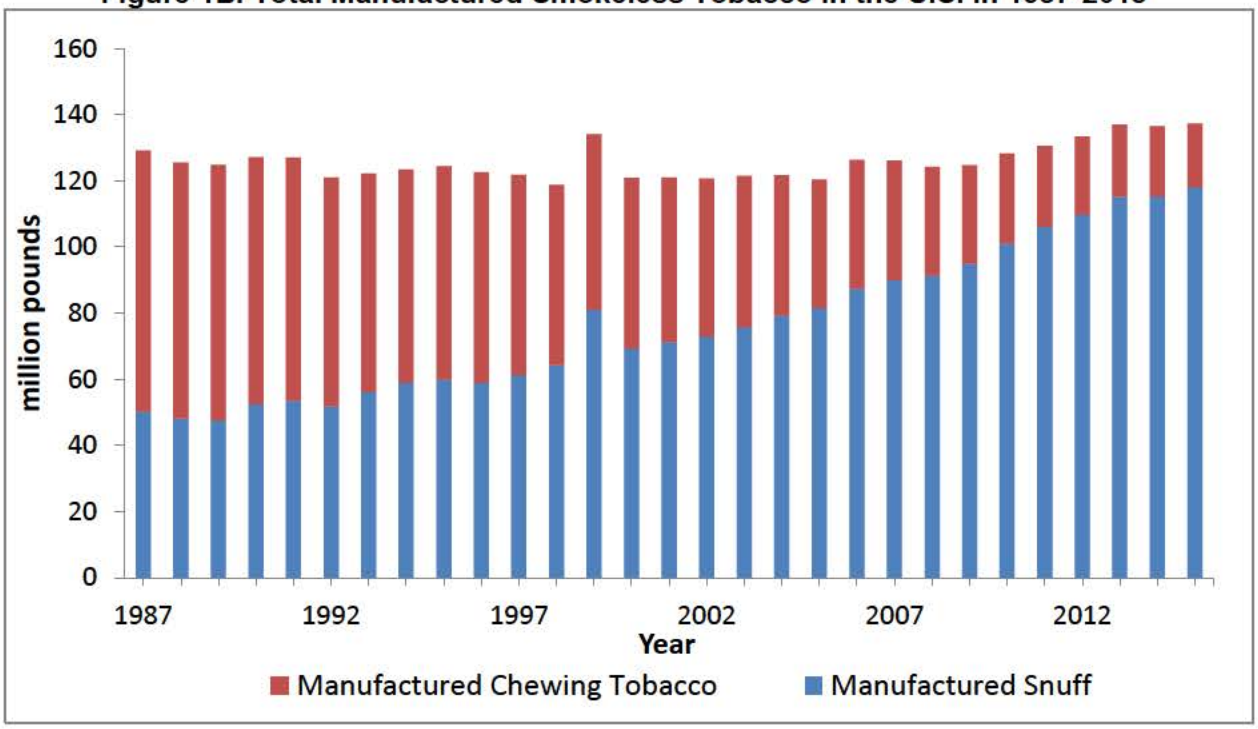
Figure 1A. Manufactured Snuff and Chewing Tobacco in the U.S. in 1987-2015[1]



[2] U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: https://ttb.gov/tobacco/tobacco-stats.shtml. Accessed May 16, 2016.

[3] Federal Trade Commission (March 2016). Federal Trade Commission Smokeless Tobacco Report for 2013. Available at https://www.ftc.gov/reports/federal-trade-commission-smokeless-tobacco-report-2013. Accessed May 17, 2016.

Figure 1B. Total Manufactured Smokeless Tobacco in the U.S. in 1987-2015[1]



Ammonia and Nicotine, Including Nicotine Salts from Tobacco Manufacturing Facilities. The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available.[4] In 2014, U.S. tobacco manufacturers released 438,000 pounds of ammonia and 255,000 pounds of nicotine and nicotine salts to the air[5]; no ammonia and 69,900 pounds of nicotine and nicotine salts to the land[6]; 167 pounds of ammonia and 276 pounds of nicotine and nicotine salts to the water[7]; and 28,653 pounds of ammonia and 84,843 pounds of nicotine and nicotine salts transferred to publicly owned treatment works (POTWs) or an off-site location.[8] A search in the TRI database found no record on toxic chemicals registered for Swedish Match North America, Inc.

[4] The estimation is done by using the Toxics Release Inventory (TRI), a dataset (http://www.epa.gov/tri/) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the U.S., including details on quantities of chemicals managed through disposal or other release, recycling, energy recovery or treatment. Data associated with the tobacco manufacturing industry is retrieved by using North American Industry Classification System (NAICS) codes beginning with 3122. Not all toxic release data of tobacco manufacturers are included in the database. The database includes information from any facility that (1) falls within a TRI-reportable industry sector or is federally-owned or operated; (2) has 10 or more full-time (or equivalent) employees; and (3) manufactures, processes or otherwise uses (MPOU) a TRI-listed chemical http://www.epa.gov/tri/trichemicals/listchanges/TRIListChangesUpdate11282011.pdf) in an amount above the TRI reporting threshold during a calendar year.

[5] http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=air_total_release

[6] http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=land_total_release

[7] http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=water_total_release

[8] http://oaspub.epa.gov/enviro/ef_metadata_html.tri_page?p_column_name=off_site_total_transfers

5.1.2 Environmental Introduction from Manufacturing the New Tobacco Product

Introduction from Manufacturing the New Product in the Proposed Action. The agency anticipates the waste generated as a result of manufacturing the new snuff product will be released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other smokeless tobacco products manufactured in the U.S. In addition, the new product will replace the predicate product (Appendix 1), which has been marketed in the U.S. since July 1, 2005, and compete with other currently marketed snuff products. Therefore, the agency does not foresee the introduction of the new product to notably affect the current manufacturing waste generated from the production of all smokeless tobacco products.

Based on information in the SE Report, the only difference between the new product and the predicate product is in product quantity. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new product.

The applicant provided the first- and fifth-year market volumes for the new product (Confidential Appendix 1). Comparing the projected market volume of the new product with the forecasted market volume of snuff manufactured in the U.S. in 2016 and 2020, the cumulative projected market volume of the new product is a small fraction of the total forecasted market volume in 2020 (Appendix 2 and Confidential Appendix 1). Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed.

Furthermore, the applicant provided information on the manufacturer's operating permit issued by the Kentucky Department of Environmental Protection (Confidential Appendix 2). The permit is applicable for air emission, storm water discharges, wastewater discharges, and solid and liquid waste. The permit expires in January 2020. The applicant stated that the facility complies with all requirements mentioned in the permit.

Global methane emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related methane emissions in the U.S., releasing an estimated 133.1 million metric tons of CO_2, accounting for approximately 18.2% of these emissions in 2014.[9] Methane is a potent greenhouse gas (GHG) that has a global warming potential of 28-36 times greater than CO_2, and it has an atmospheric life of about 12 years. EPA released a final rule stating an expectation of methane emission reduction by an estimated 334,000 metric tons, the equivalent of reducing 8.2 million metric tons of CO_2 in

[9] U.S. EPA. Landfill Methane Outreach Program. Available at http://www3.epa.gov/lmop/basic-info/index.html. Accessed September 16, 2016.

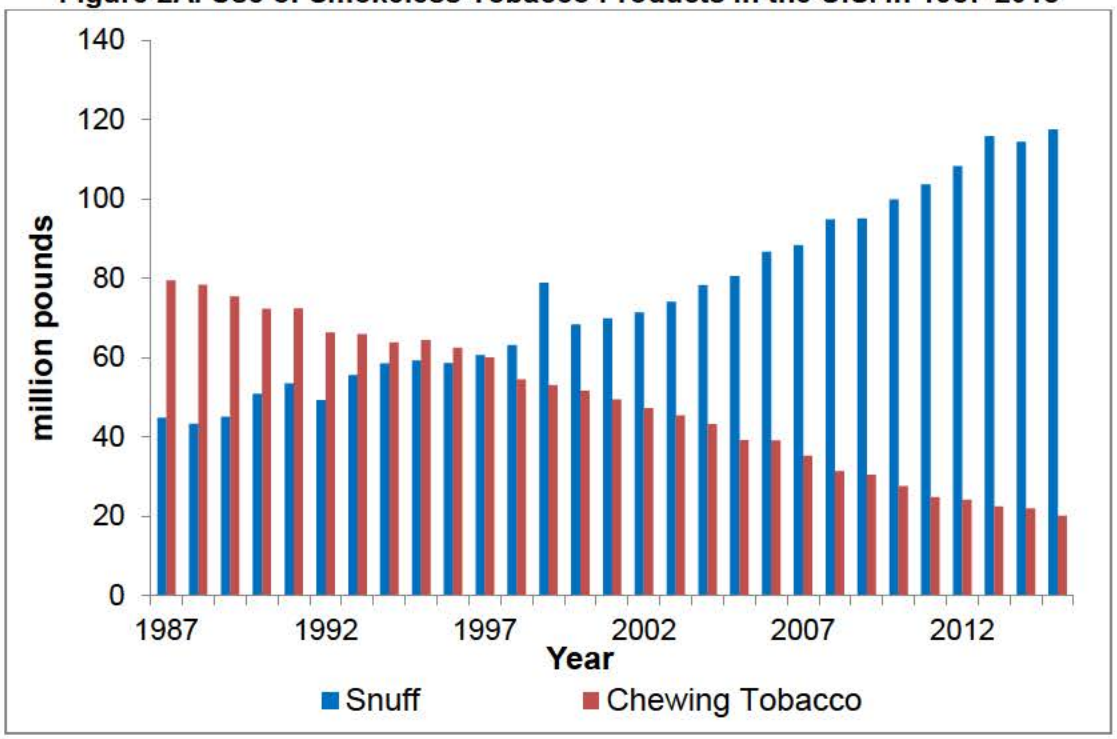
2025.[10] Because the new product will compete with other currently marketed smokeless products, no addition of GHG emissions is anticipated.[11]

5.2 Environmental Introduction as a Result of Use of the New Tobacco Product

5.2.1 Use of Total Smokeless Tobacco Products in the U.S.

According to the TTB statistical reports, the use of chewing tobacco in the U.S. decreased from 79 million pounds (35,833.8 tons) in 1987 to 20 million pounds (9,072 tons) in 2015, whereas the use of snuff increased from 45 million pounds (20,411.7 tons) in 1987 to 117 million pounds (53,070 tons) in 2015 (Figure 2A)[12]. However, total use of all smokeless products remained relatively unchanged (Figure 2B).

Figure 2A. Use of Smokeless Tobacco Products in the U.S. in 1987-2015

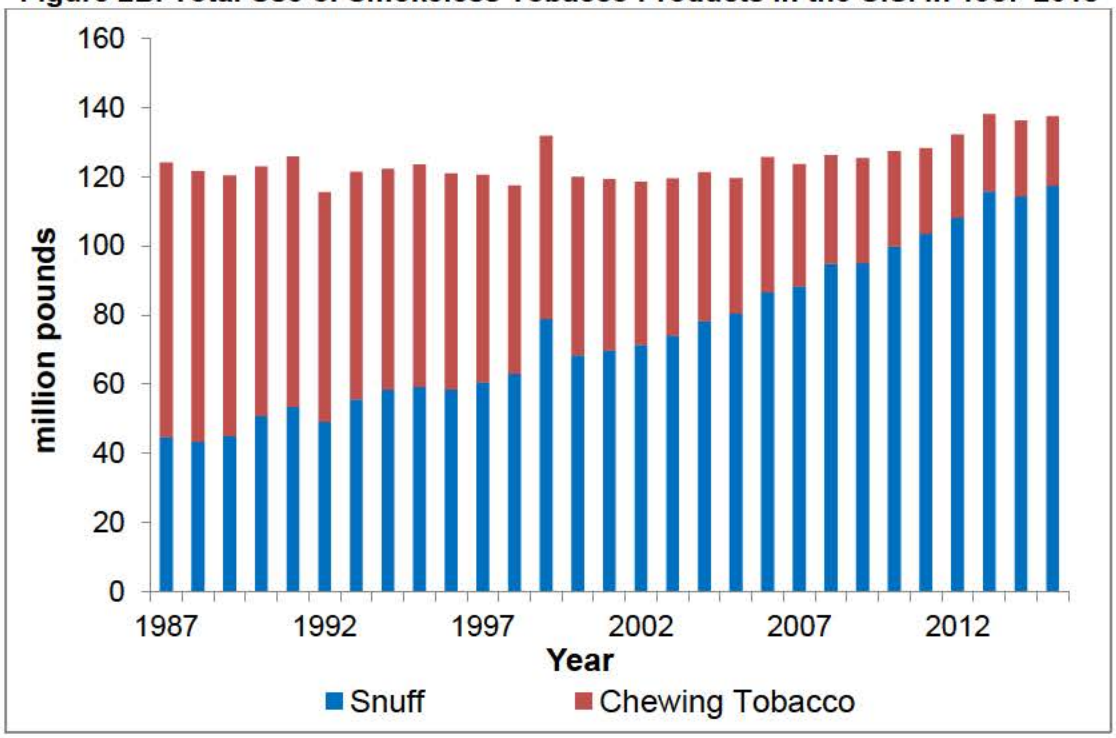


[10] U.S. EPA. Technology Transfer Network – Air Toxics Web Site. Rule and Implementation Information for Standards of Performance for Municipal Solid Waste Landfills. Docket #A-88-09. Available at https://www3.epa.gov/ttn/atw/landfill/landflpg.html. Accessed September 16, 2016.

[11] A qualitative analysis is recommended pursuant to the Council of Environmental Quality (CEQ) "Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews" when Agencies lack of tools, methodologies, or data inputs to qualify Greenhouse gas emission.

[12] U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed May 27, 2016.

Figure 2B. Total Use of Smokeless Tobacco Products in the U.S. in 1987-2015



5.2.2 Environmental Introduction from Use of the New Product

The Agency does not anticipate new substances to be released into the environment as a result of use of the new moist snuff product, relative to the substances released by the predicate product already on the market. As noted, the only difference between the predicate product and the new tobacco product is in product quantity. The new product is used in similar manner to the predicate product and other moist snuff products.

5.3 Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Product

The environmental consequences resulting from disposal following use of smokeless tobacco products are 1) disposal of packaging, 2) discarding of the used smokeless products, and 3) excretion of ingredients other than tobacco in smokeless products.

5.3.1 Disposal Following Use of Smokeless Tobacco

a) Disposal of Packaging Material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2013, approximately 254 million tons of trash was generated in the U.S., and roughly 87 million tons of this material was recycled and composted, equivalent to a 34.3% recycling rate (Figure 3 and 4). Plastics and paper and paperboard account for 13% and 27%, respectively, of the total MSW generated in 2013. Out of the MSW generated of each material, the

recovery was 9.2% (3 million tons) for plastics and 63% (43.4 million tons) for paper and paperboard. On average, 4.40 pounds per person of waste was generated, of which 1.51 pounds was recycled and composted in the U.S. in 2013.[13]

Figure 3. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960-2013

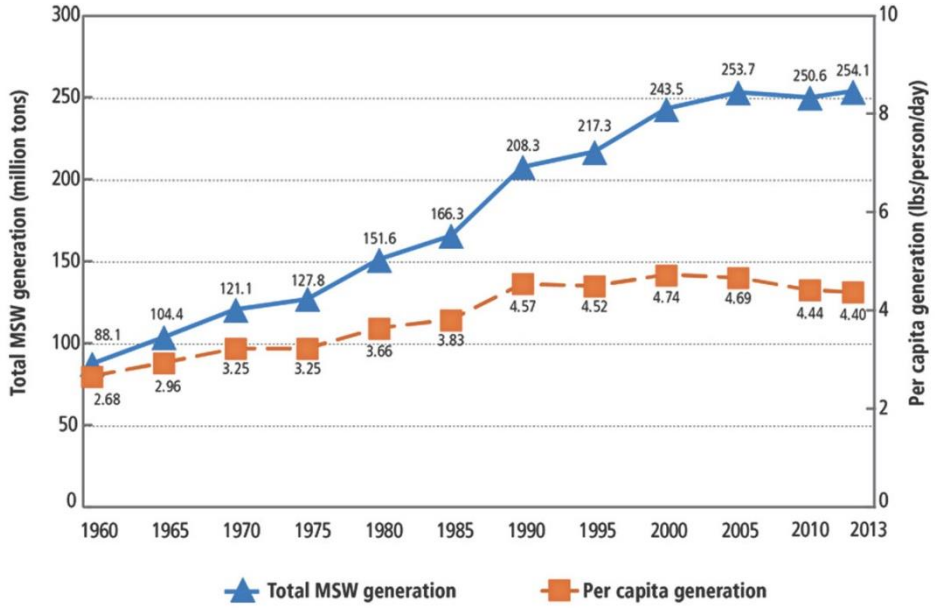
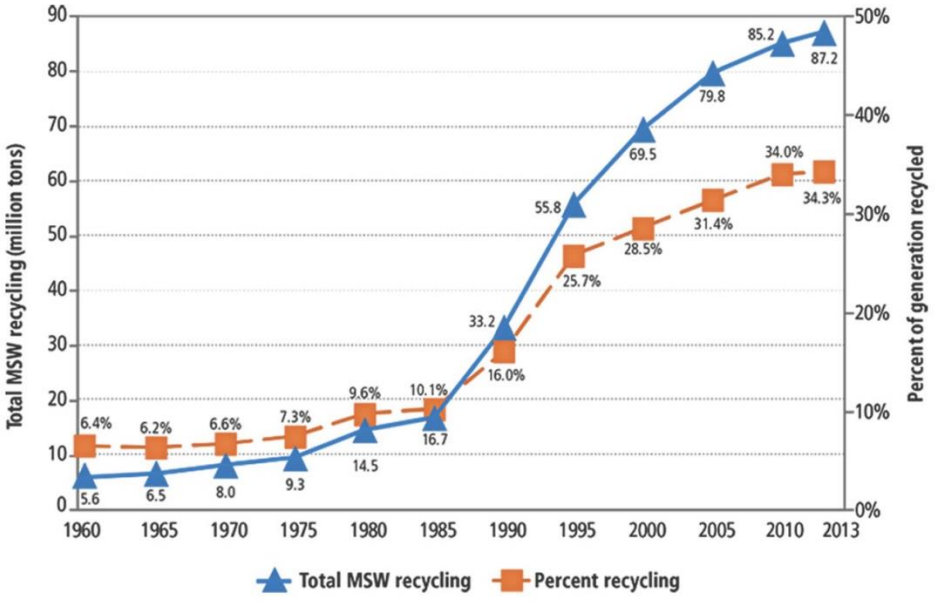


Figure 4. MSW Recycling Rates in the U.S., 1960-2013



[13] U.S. EPA. Materials and Waste Management in the United States Key Facts and Figures. Available at https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures. Accessed May 17, 2016.

b) Disposal of Used Smokeless Product Following Use

Used smokeless tobacco products are usually disposed of in MSW landfills or as litter. When discarded as litter, the spent product is likely to move by run-off to the ocean and eventually decompose. When discarded as MSW, the tobacco would enter landfills. The Agency utilized the historical data for use of smokeless tobacco products in the U.S. to forecast the future use of smokeless products and calculate the projected tobacco waste accordingly (Appendix 3). Assuming that all used smokeless or snuff products will be disposed of as MSW, the estimated waste of used smokeless or snuff products is a fraction of a percent of the total 254 million tons of projected MSW to be generated in the U.S (Table 1).

Table 1. Forecast of Waste of Used Smokeless Tobacco as Compared to Total MSW Forecast in the U.S.

Year of Marketing the New Product	Projected Use (Equivalent to Projected Waste) of Smokeless in the U.S. (Tons)[a]	Percent of Projected Waste of Smokeless to Total MSW Forecasted in the U.S. (%)[14]	Projected Use (Equivalent to Projected Waste) of Snuff in the U.S. (Tons)	Percent of Projected Waste of Snuff to Total MSW Forecasted in the U.S. (%)[12]
1st Year	64,748	0.025	56,397	0.022
5th Year	71,471	0.028	65,184	0.026

[a]See table in Appendix 3

c) Excretion of Ingredients Other than Tobacco in Smokeless Tobacco Products

In addition to the disposal of the product in MSWs or as litter, the users will excrete ingredients and constituents which are part of the smokeless product, as well as their metabolites, excluding the tobacco itself, into the waste stream. Smokeless tobacco products contain levels of toxicants and carcinogens comparable to those found in conventional cigarettes.[15] Studies have shown that nicotine metabolites can be detected in the excreted waste of smokeless tobacco users.[16,17,18] These metabolites

[14] Smokeless in percentage: 1st Year = (64,748/254,000,000) x 100% = 0.025%
5th Year = (71,471/254,000,000) x 100% = 0.028%
Snuff in percentage: 1st Year = (56,397/254,000,000) x 100% = 0.022%
5th Year = (65,184/254,000,000) x 100% = 0.026%

[15] Stepanov, I., Jensen, J., Hatsukami, D. and Hecht S.S. 2008. New and traditional smokeless tobacco: comparison of toxicant and carcinogen levels. Nicotine & Tobacco Research 10(2): 1773-1782.

[16] Hecht, S.S., Carmella, S.G., Ye, M., Le, K., Jensen, J.A., Zimmerman, C.L. and Hatsukami, D.K. 2002. Quantification of metabolites of 4-(methylnitrosamine)-1-(3-pyridyl)-1-butanone after cessation of smokeless tobacco use. Cancer Research 62: 129-134.

[17] Jacob, P., Yu, L., Shulgin, A.T. and Benowitz, N.L. 1999. Minor tobacco alkaloids as biomarkers for tobacco use: comparison of users of cigarettes, smokeless tobacco, cigars, and pipes. American Journal of Public Health 89(5): 731-736.

[18] Stepanov, I. and Hecht, S.S. 2005. Tobacco-specific nitrosamines and their pyridine-N-glucuronides in the urine of smokers and smokeless tobacco users. Cancer Epidemiology, Biomarkers & Prevention 14(4): 885-891.

and other constituents may enter the sewage system as components in human excreted waste, which is transferred to and treated at POTWs in the same manner as other wastewater. The excreted waste may also be digested by microbial systems in the home's septic system.

Recent efforts have been taken to detect and measure nicotine metabolites in wastewater, groundwater and surface waters.[19,20,21,22] Although, to date, some studies have demonstrated deleterious effects of nicotine exposure on zebrafish, such as abnormal neural and muscle development, and behavioral changes, these studies have not linked these effects directly to nicotine metabolites.[23,24] The ecotoxicological risks associated with nicotine metabolites are still largely unknown.

5.3.2 Environmental Introduction from Disposal Following Use of the New Product

The Agency believes that the disposal of the new product will be similar to the disposal conditions of other moist snuff products and any other smokeless tobacco products that are currently being marketed. After using the new product, the users may dispose of or recycle the packaging material. Users may also discard the spent product, which includes the tobacco and other ingredients, as discussed above, as MSW or litter.

a) Disposal of Paper Packaging Material

To determine the amount of waste due to disposal of paper and cardboard packaging material, the Agency used the projected volumes of marketing in the first and fifth years after issuance of an authorization order for the new product. The calculated waste of the paper and cardboard packaging materials of the new product was determined to be miniscule compared to the forecasted MSW to be generated in the U.S. (Confidential Appendix 3). In addition, paper components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

b) Disposal of Plastic Packaging Material

[19] Castiglioni, S., Senta, I., Borsotti, A., Davoli, E. and Zuccato, E. 2014. A novel approach for monitoring tobacco use in local communities by wastewater analysis. Tobacco Control 0: 1-5.

[20] Katz, B.G., Griffin, D.W. and Davis, J.H. 2009. Groundwater quality impacts from land application of treated municipal wastewater in a large karstic spring basin: chemical and microbiological indicators. Science of Total Environment 407: 2872-2886.

[21] Buerge, I.J., Kahle, M., Buser, H-R., Müller, M.D. and Poiger, T. 2008. Nicotine derivatives in wastewater and surface waters: application as chemical markers for domestic wastewater. Environmental Science & Technology 42: 6354-6360.

[22] Rodriguez-Alvarez, T., Rodil, R., Rico, M., Cela, R. and Quintana, J.B. 2014. Assessment of local tobacco consumption by liquid chromatography-tandem mass spectrometry sewage analysis of nicotine and its metabolites, cotinine and trans-3'-hydroxycotinine, after enzymatic deconjugation. Analytical Chemistry 86: 10274-10281.

[23] Stewart, A.M., Grossman, L., Collier, A.D., Echevarria, D.J. and Kalueff, A.V. 2015. Anxiogenic-like effects of chronic nicotine exposure in zebrafish. Pharmacology, Biochemistry and Behavior 139: 112-120.

[24] Klee, E.W., Ebbert, J.O., Schneider, H., Hurt, R.D. and Ekker S.C. 2011. Zebrafish for the study of the biological effects of nicotine. Nicotine & Tobacco Research 13(5): 301-312.

To determine the amount of waste due to disposal of plastic packaging material, the Agency used the projected volumes of marketing in the first and fifth years after issuance of an authorization order for the new product. The plastic packaging waste generated from the can base of the pouched products, can lids, and shrink film wrap is also a small fraction of the amount of forecasted MSW to be generated in the U.S. (Confidential Appendix 4). Furthermore, plastic components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

As previously discussed, because the new moist snuff product will compete with other similar smokeless tobacco products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfills is not anticipated due to the proposed action.

Because the waste generated from using the new product is expected to make up a negligible fraction of the total MSW, no additional control of greenhouse gas emissions is anticipated in the landfills.[25]

6. Fate of Materials Released into the Environment due to the Proposed Action

The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment because the new product is anticipated to be manufactured, used, and disposed of in the same way as other smokeless tobacco products, including moist snuff products. Therefore, the fate of any materials emitted to the environment is anticipated to be the same as any materials from other smokeless tobacco products, including moist snuff products, manufactured in the facility. No new types of material are anticipated to be emitted to the environment because the new product has identical properties to the predicate product and will be made using the same materials and processes as the predicate product.

7. Environmental Effects of New Materials Released into the Environment due to the Proposed Action

The applicant stated that the manufacturing operation is in compliance with all local, state and federal environmental laws. Therefore, cumulative introduction of materials released into the environment is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

Furthermore, as discussed above, the amounts of materials anticipated to enter the environment due to the manufacturing and use of the new product are small fractions when compared to that of the projected snuff manufactured and used in the U.S. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new product occupies a small fraction of the total forecasted MSWs in the U.S. Consequently, no new environmental effects are anticipated due to the new product.

8. Use of Resources and Energy

The new product will compete with other currently marketed smokeless products. When comparing the market volume projections with the forecasted total snuff market volumes in the U.S., the Agency found that the projected market volume of the new product is a small

[25] See Footnote #11.

fraction of the total forecasted market volume in 2020. Additionally, the applicant stated that all ingredients used to manufacture the new product are from sustainable sources. Accordingly, no additional use of resources and energy is anticipated.

9. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for the new product and its proposed used as moist snuff. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco product in the U.S. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products as many other similar smokeless tobacco products will continue to be marketed.

Alternative B (Proposed action): There is no substantial environmental effect due to the proposed action of authorizing the new product and associated manufacture, use, and disposal following use of the new tobacco product.

Therefore, the difference between the environmental impacts of these two alternatives is negligible, or non-existent.

11. List of Preparers

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment.

Preparers:

Catherine W. McCollum, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Biochemistry and Cell Biology
- Experience: 8 years in various scientific activities
- Expertise: NEPA analysis, environmental impact analysis, ecotoxicity

Smokeless Tobacco Projection Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Plant Molecular Biology and Virology
- Experience: 23 years in various scientific activities
- Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA implementation

Reviewers:

Hoshing Chang, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Biochemistry and M.S. in Environmental Science
- Experience: 8 years in NEPA practice

Expertise: Waste water treatment, environmental impact analysis

12. List of Agencies and Persons Consulted

Not applicable.

13. Appendix List

Appendix 1: Submission Tracking Number for the SE Report and Package Size of the New and Predicate Product and Related Amendments Covered Under this Environmental Assessment (EA)
Appendix 2: Forecast of Manufacturing Smokeless Tobacco Products in the U.S.
Appendix 3: Forecast of Use of Smokeless Tobacco Products in the U.S.

14. Confidential Appendix List

Confidential Appendix 1: The Fifth-Year Market Volume Projections of the New Product
Confidential Appendix 2: Manufacturer's Operating Permit for Swedish Match North America Owensboro Plant Issued by Kentucky Department for Environmental Protection
Confidential Appendix 3: The Fifth-Year Projections of Paper and Cardboard Waste of Packaging Materials Associated with Marketing the Product
Confidential Appendix 4: The Fifth-Year Projections of Plastic Waste of Packaging Materials Associated with Marketing the Product

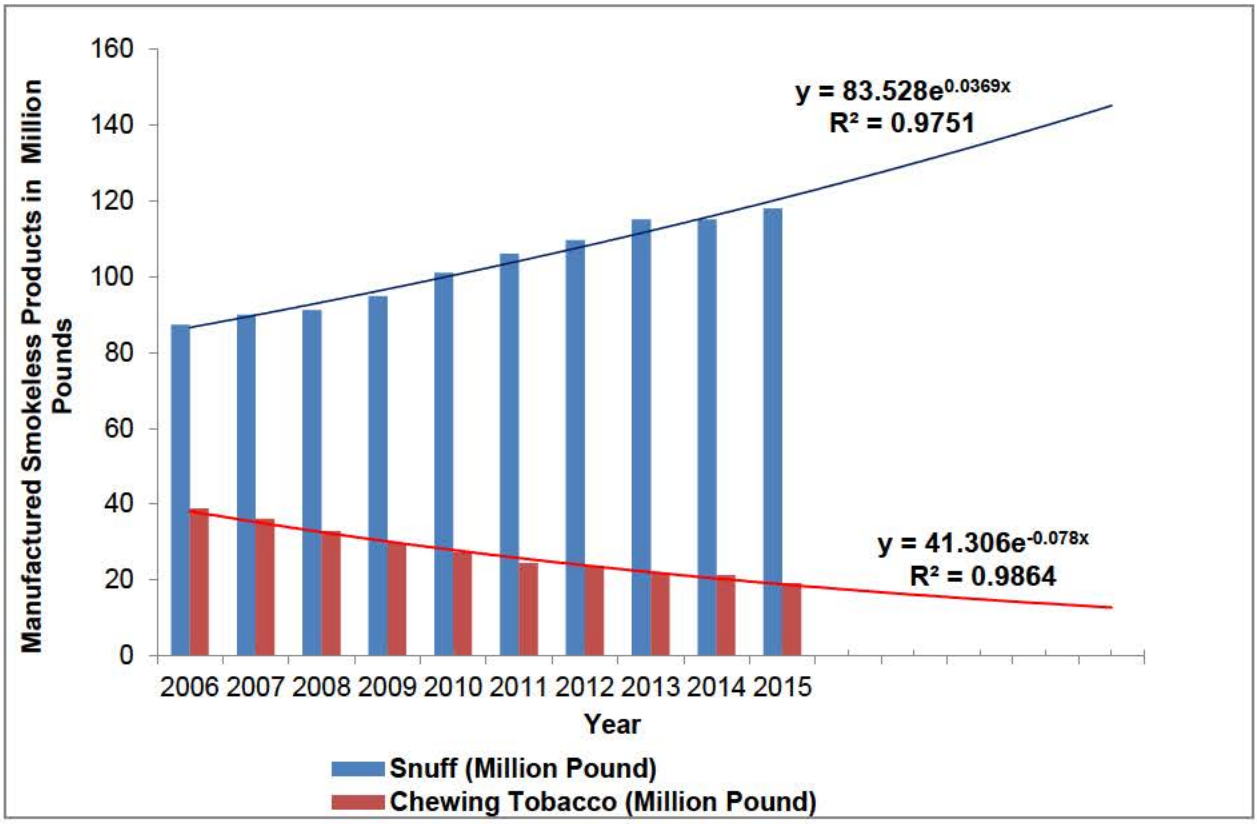
APPENDIX 1

Submission Tracking Number for the SE Report and Package Size of the New and Predicate Product and Related Amendments Covered Under this Environmental Assessment (EA)

STN	Product	Name	Package Size (Gram/Can)	Package Composition	Amendments
SE0011055	New	Longhorn Long Cut Mint	34.02	Plastic can and plastic lid	SE0011760, SE0013294
	Predicate	Longhorn Long Cut Mint	37.42	Plastic can and plastic lid	

APPENDIX 2
Forecast of Manufacturing Smokeless Tobacco in the U.S.

To evaluate the environmental impact of the proposed action due to manufacturing of the new product, historical data regarding use of smokeless tobacco from 2006 to 2015 was used to forecast the use of smokeless tobacco products[26]. This was achieved by using one best-fit exponential trend line with the R^2 value of 0.9751 and 0.9864 for snuff and chewing tobacco, respectively. Accordingly, the forecasted amounts of snuff and chewing tobacco in the U.S. are estimated to be 125 and 18 million pounds in 2016 and 145 and 13 million pounds in 2020, respectively.



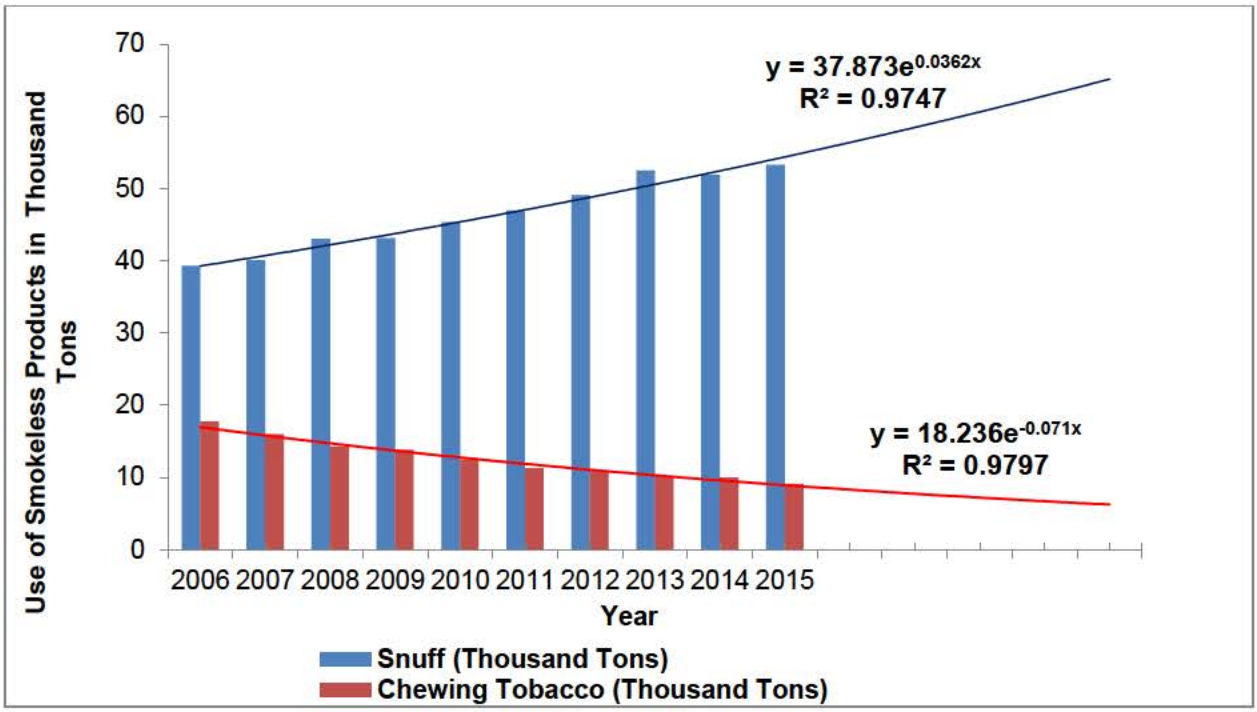
[26] Forecast trend lines extrapolated from TTB data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed May 27, 2016.

APPENDIX 3

Forecast of Use of Smokeless Tobacco Products in the U.S.

To evaluate the environmental impact of the proposed action due to use of the new products, the Agency utilized the historical data of use in 2006–2015 to forecast the use of smokeless tobacco products, chewing tobacco and snuff, in the U.S. This was achieved by using one best-fit exponential trend line with the R^2 value of 0.9747 for snuff and another best-fit exponential trend line with the R^2 value of 0.9797 for chewing tobacco.[27]

Using trend lines, the forecast of use of smokeless tobacco products in the U.S. was estimated mathematically.



Year[28]	Snuff Use (Tons)	Chewing Tobacco Use (Tons)	Total Smokeless Use (Tons)
1st Year (2016)	56,397	8,351	64,748
5th Year (2020)	65,184	6,287	71,471

[27] Forecast trend lines extrapolated from TTB data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed May 27, 2016.

[28] 1st Year (2015) in thousand tons: Snuff Use = (37.873)EXP(0.0362 x 11) = 56.397
Chewing Tobacco Use = (18.236)EXP(-0.071 x 11) = 8.351
Total Smokeless Use = Snuff Use + Chewing Tobacco Use = 64.748

5th Year (2020) in thousand tons: Snuff Use = (37.873)EXP(0.0362 x 15) = 65.184
Chewing Tobacco Use = (18.236)EXP(-0.071 x 15) = 6.287
Total Smokeless Use = Snuff Use + Chewing Tobacco Use = 71.471

CONFIDENTIAL APPENDIX 1

The Fifth-Year Market Volume Projections of the New Product

Product Name	Measure	5th-Year Market Volume Projection (FY2020 Fcst)
Longhorn Long Cut Mint	Units (cans)	(b) (4)
	Metric Tons*	
	US Tons	

*Units (cans) multiplied by net weight.

Note: Applicant provided FY2015 market volume but did not provide 1st-year market volume projection (FY2016).

We calculated the percent occupied in the projected 5th year of marketing of the new product using the equation below:

(b) (4)

Compared to the forecasted use of snuff in the U.S. for 2020, (b) (4) (see Appendix 3), the fifth-year market volume projection of the new product occupied (b) (4) of the forecasted market volume of the total snuff used in the U.S.

CONFIDENTIAL APPENDIX 2
Manufacturer's Operating Permit for Swedish Match North America Owensboro Plant Issued by Kentucky Department for Environmental Protection

Kentucky Title V
Proposed Operating Permit Number #V-14-019
Issued 1/14/2015, Expiring 1/14/2020

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

CONFIDENTIAL APPENDIX 3
The Fifth-Year Projection of Paper and Cardboard Waste of Packaging Materials Associated with Marketing the New Product

To analyze the environmental effects from paper and cardboard waste due to the proposed action, the Agency estimated the fifth-year weight of the projected paper waste (in tons) generated from disposal after use of the new product in 2020. Projected paper waste generation is the summation of the projected label waste and cardboard shipping case waste generation of the new product:

$$\sum_{i=1}^{1} A_i = \sum_{i=1}^{1} (B_i + C_i)$$

$$B_i = D_i \times E \times H$$

$$C_i = \frac{D_i}{F} \times G \times H$$

A_i: Projected paper waste generation of the new product (tons)
B_i: Projected paper label waste generation of the new product (tons)
C_i: Projected cardboard shipping case waste generation of the new product (tons)
D_i: Projected number of cans of the new product
E: Average weight of paper label (grams/can)
F: Number of cans per case
G: Average weight of cardboard shipping case (grams/case)
H: 1.10231 x 10^{-6} tons/gram

Product Name	G	F	E	D	C	B	A
Longhorn Long Cut Mint	(b) (4)						

Paper and Cardboard Waste. Estimation of generated total paper and cardboard waste is (b) (4) in the fifth year. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper and paperboard products at 63% in the U.S., according to the U.S. EPA[29]. Therefore, if 37% of the paper and cardboard waste is disposed of as waste based on the 2013 waste generation data in the U.S., the estimated cumulative paper and cardboard waste will be (b) (4) in the fifth year of marketing the product[30].

If the entire packaging paper and cardboard are disposed of as waste, in the worst case scenario, the project cumulative paper and cardboard waste in the fifth year of marketing the product is (b) (4). This is a negligible fraction of the 254 million tons of total waste reported in the U.S. in 2013.

[29] U.S. EPA. June 2015. Advancing sustainable materials management: Facts and Figures 2013. Available at: https://www.epa.gov/sites/production/files/2015-09/documents/2013_advncng_smm_rpt.pdf. Accessed May 31, 2016.
[30] (b) (4)

CONFIDENTIAL APPENDIX 4

The Fifth-Year Projections of Plastic Waste of Packaging Materials Associated with Marketing the Product

To analyze the environmental effects from plastic waste due to the proposed action, the Agency estimated the fifth-year weight of the projected packaging materials waste (in tons) that are generated from disposal after use of the new product in 2020. Projected plastic waste generation is the summation of the projected plastic can and plastic shrink film waste generation of the new product:

$$\sum_{i=1}^{1} A_i = \sum_{i=1}^{1} (B_i + C_i)$$

$$B_i = D_i \times E \times H$$

$$C_i = \frac{D_i}{F} \times G \times H$$

A_i: Projected plastic waste generation of the new product (tons)
B_i: Projected plastic can waste generation of the new product (tons)
C_i: Projected plastic shrink film waste generation of the new product (tons)
D_i: Projected number of cans of the new product
E: Average weight of assembled plastic can (grams/can)
F: Number of cans per case
G: Average weight of plastic shrink film (grams/case)
H: 1.10231 x 10^{-6} tons/gram

Product Name	G	F	E	D	C	B	A
Longhorn Long Cut Mint	(b) (4)						

Plastic Waste. Estimation for generated total plastic waste (can and shrink film) is (b) (4) in the fifth year. A portion of the generated plastic waste is likely to be recycled with an overall recycling rate for plastic products at 9.2% in the U.S., according to the U.S. EPA[31]. Therefore, if 90.2% of the plastic can and shrink film are disposed of as waste based on the 2013 waste generation data in the U.S., the estimated cumulative plastic waste will be (b) (4) in the fifth year of marketing the product[32].

If the entire packaging plastic is disposed of as waste, in the worst case scenario, the project cumulative plastic waste in the fifth year of marketing the product is (b) (4). This is a small fraction of the 254 million tons of total waste reported in the U.S. in 2013.

[31] U.S. EPA. June 2015. Advancing sustainable materials management: 2013 fact sheet. Available at: https://www.epa.gov/sites/production/files/2015-09/documents/2013_advncng_smm_fs.pdf. Accessed May 31, 2016.

[32] At (b) (4)