Programmatic Environmental Assessment for Market Authorization of "General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Classic Blend Portion White Large – 12 CT, General Mint Portion White Large, General Nordic Mint Portion White Large – 12 CT, General Portion White Large, and General Wintergreen Portion White Large" Snus, Manufactured by Swedish Match North America, Inc.

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

October 8, 2015

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This programmatic environmental assessment (PEA) is for market authorization orders for "General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Classic Blend Portion White Large – 12 CT, General Mint Portion White Large, General Nordic Mint Portion White Large – 12 CT, General Portion White Large, and General Wintergreen Portion White Large" Snus. Information presented in the PEA is based on the submissions listed in Appendix 1, unless noted or referenced otherwise. This PEA has been prepared in accordance with 21 CFR 25.40 in support of the market authorization orders under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

1 Name of Applicant

Swedish Match North America, Inc.

2 Address of Applicant

Two James Center

1021 East Cary Street, Suite 1600

Richmond, VA 23219

3 Name of Manufacturer

Swedish Match North America, Inc.

4 Background

Swedish Match North America (SMNA) submitted eight premarket tobacco product applications (PMTAs) [PM00000010-PM00000017] for new snus products to FDA seeking authorization under Section 910(b) of the FD&C Act. The applicant submitted the PMTAs in connection with the June 10, 2014 modified risk tobacco product applications (MRTPAs) for the same eight snus products requesting risk modification orders under Section 911(g) of the FD&C Act to change the statutory mandated health warning on the package labels and advertisements. Additionally, the applicant also submitted Substantial Equivalence (SE) Reports for the same eight snus products requesting the market authorizations under section 910(a)(2) of FD&C Act. The agency has issued a finding of no significant impact (FONSI)", dated August 20, 2015, for findings of substantial equivalence (SE) "General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Portion White Large, and General Wintergreen Portion White Large" under section 910(a)(2) of FD&C Act. The FONSI is supported by a PEA issued on the same date.

5 Description of the Proposed Action

The proposed action is for FDA to issue market authorization orders under section 910(c)(1)(A)(i) of the FD&C Act prior to marketing the new products listed in Table 1 (See below). The agency has found the new snus products may be introduced or delivered for introduction into interstate commerce. The applicant has demonstrated that the products meet the criteria for marketing authorization under the PMTA pathway under section 910 of the FD&C Act.[1]

[1] FDA's Draft Guidance for Industry on Applications for Premarket Review of New Tobacco Products

5.1 Requested Action

Orders finding that the new products may be introduced or delivered for introduction into interstate commerce under Section 910(b) of the FD&C Act.

5.2 Need for Action

SMNA wishes to introduce eight new snus products into interstate commerce distribution in the United States (U.S.) and submitted to FDA the "Premarket Review of New Tobacco Products (PMT)" applications referenced in Appendix 1 to obtain market authorizations pursuant to Section 910(b) of the FD&C Act.

Swedish Match North America, Inc. also identified currently marketed products (with the same names) that these new products will replace (See Section 6.1.2 if the PEA).

5.3 Identification of the New Tobacco Products that are Subject of the Proposed Action

5.3.1 Type of tobacco product

Smokeless Tobacco –loose and portioned snus products

5.3.2 Name of products

Product names are listed in Table 1.

Table 1 List of Product Names, STNs and their Package Size

STN	Product Name	Portion Size (g)	Number of Portions per can	Total Package Size (g)
PM0000010	General Loose	NA	NA	45
PM0000011	General Dry Mint Portion Original Mini	0.3	20	6
PM0000012	General Portion Original Large	1	24	24
PM0000013	General Classic Blend Portion White Large – 12 CT	0.9	12	10.8
PM0000014	General Mint Portion White Large	1	24	24
PM0000015	General Nordic Mint Portion White Large – 12 CT	0.9	12	10.8

issued in September 2011. Available at: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM273425.pdf. Accessed August 6, 2015.

STN	Product Name	Portion Size (g)	Number of Portions per can	Total Package Size (g)
PM0000016	General Portion White Large	1	24	24
PM0000017	General Wintergreen Portion White Large	1	24	24

5.3.3 Package description of the new products

The packaging components of the finished products are similar to that of the snus products that are currently being marketed, except for the package size. The packaging components of the finished products consist of a can base and plastic lid that are then wrapped in polypropylene plastic film wrap. The can base for the loose product is made of cardboard paper but the can base for the pouched products is made of polypropylene plastic. The lid for the portioned products provides spaces designed for disposal of the used pouches. The can of the products is round shape but the can for the "General Classic Blend Portion White Large" and "General Nordic Mint Portion White Large" products is of rectangular shape.

The package size of the finished products is listed in Table 1 and details of the package ingredients and weight of each packaging component are described in Confidential Appendix 1.

5.3.4 Location of manufacturing

Swedish Match North Europe

Trollhättegatan 1

SE - 401 21 Göteborg, Swede

5.3.5 Location of use

Swedish Match North America intends to distribute and sell the new products to consumers in the U.S. for use as smokeless tobacco.

5.3.6 Location of disposal

The distribution of the generated waste due to disposal after use should correspond to the pattern of product use. Disposed packaging materials will either enter the recycling stream or be disposed of in municipal solid waste (MSW) landfills or as litter. Waste of used tobacco is also disposed of in MSW or as litter.

5.4 Description of the New Products

Swedish snus is made mainly from air-dried tobacco varieties, various salts, flavoring, and moisture-preserving substances. According to the applications, the new products differ from other currently marketed smokeless tobacco products in several ways, including:

- Use of different quantities of tobacco blends
- Increase, decrease or replacement of certain ingredients

- Decrease or increase in quantity of certain harmful or potentially harmful constituents (HPHCs), such as the N'-Nitrosonornicotine (NNN), 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), acetaldehyde, crotonaldehyde, formaldehyde, and BaP
- Additional or tightened specifications for design features such as pH, pouch width decrease and tightened range limit for the ingredients and packaging components.

Additionally, the plastic can design provides space for the used pouch receptacle in the lid of the can of pouched products.

6 Environmental Introduction Due to the Proposed Action

6.1 Environmental Introduction as a Result of Manufacturing the New Products

6.1.1 Manufacturing conditions of smokeless tobacco products in the U.S.

Smokeless tobacco products include: (i) chewing tobacco, which includes loose leaf, plug, or twist, and may come in flavors; (ii) snuff, which includes moist or dry and can be loose, or in packets; and (iii) dissolvables, which includes lozenges, sticks, strips, and orbs.[2] [3] Snus, also called spitless, is a moist snuff of finely ground tobacco and is available in either loose form or portioned form in sealed pouches.[4] [5]

Worldwide import of snuff into the U.S. has shown a 64-fold increase during the past 10 years from 5 tons in 2005 to 319 tons in 2014. The U.S. import of snuff from Sweden also increased 33-fold, from 2.5 tons in 2005 to 165 tons in 2014 (Figure 1 and Figure 2). Products imported from Sweden comprise 50% and 27% of the worldwide import of snuff and smokeless tobacco, respectively, into the U.S.[6] [7]

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[2] World Health Organization. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 89: Smokeless Tobacco and Some Tobacco-Specific N-Nitrosamines. Lyon (France): World Health Organization, International Agency for Research on Cancer, 2007. Available at: http://monographs.iarc.fr/ENG/Monographs/vol89/mono89.pdf. Accessed June 20, 2015.

[3] U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012. Available at: http://www.cdc.gov/tobacco/data_statistics/sgr/2012/index.htm. Accessed June 20, 2015

[4] Digard H, Errington G, Richter A and McAdam K. Patterns and behaviors of snus consumption in Sweden. *Nicotine & Tobacco Research*. 2009;11(10):1175-1181

[5] Hatsukami DK1, Ebbert JO, Feuer RM, Stepanov I, Hecht SS. Changing smokeless tobacco products new tobacco-delivery systems. *Am J Prev Med*. 2007;33(6 Suppl):S368-S378

[6] United States Department of Agriculture (USDA). Foreign Agricultural Service (FAS). Global Agricultural Trade System (GATS). Available at: http://apps.fas.usda.gov/gats/default.aspx. Accessed on April 29, 2015

[7] Unit is defined by the United States International Trade Commission, available at: http://dataweb.usitc.gov/scripts/tariff_current.asp?Phase=List_items&lookfor=481310. Accessed on April 29, 2015

Figure 1 – U.S. Import of Smokeless Tobacco Products in 2005 – 2014 [67]

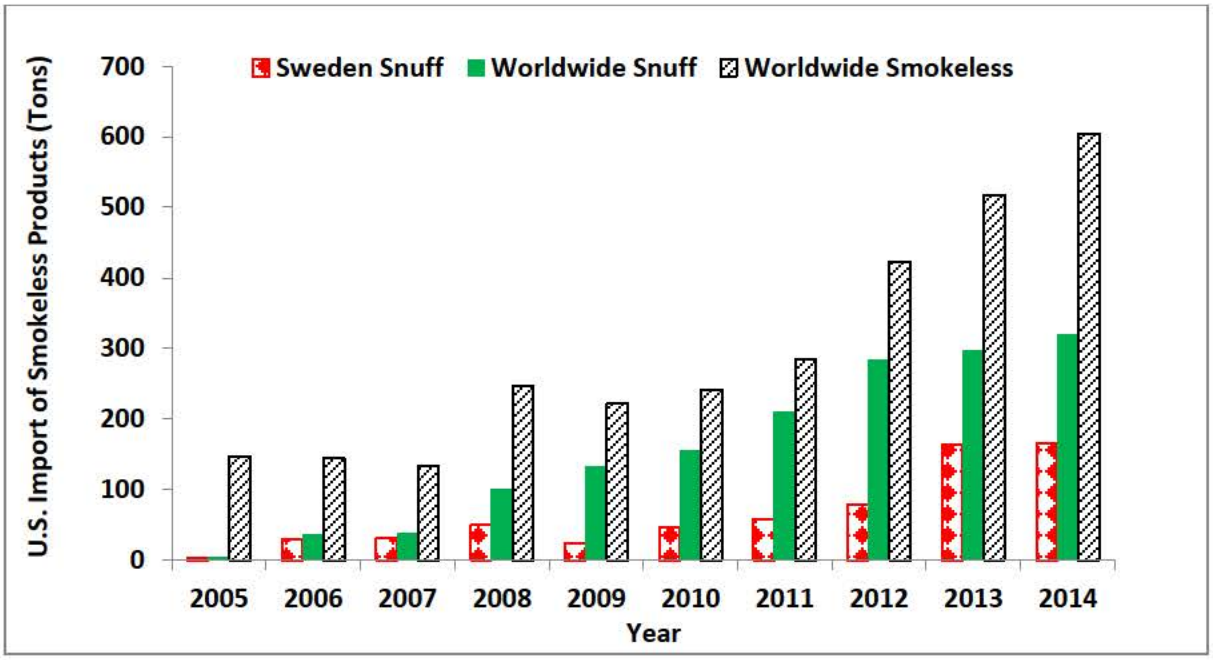
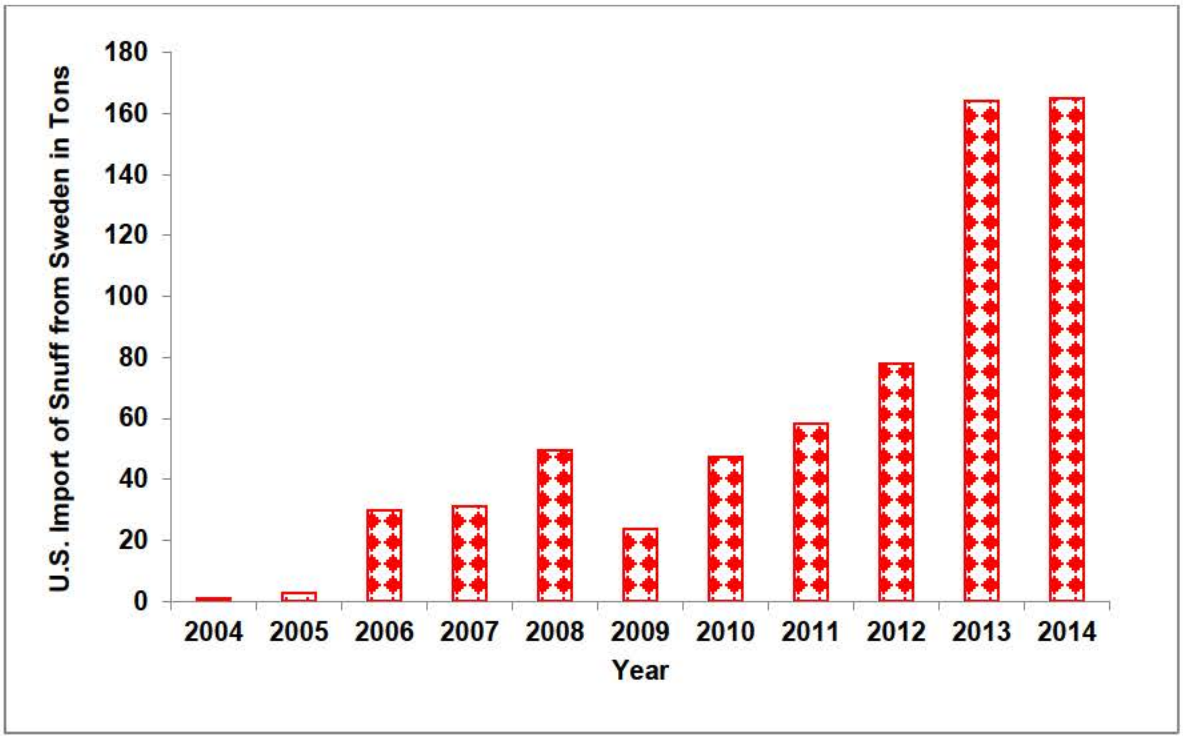


Figure 2 – U.S. Import of Snuff Tobacco from Sweden in 2005 – 2014 [67]



6.1.2 Environmental consequences from manufacturing the new tobacco products

The agency anticipates the waste generated as a result of manufacturing the new snus products to be released to the environment, transferred to publicly owned treatment works (POTW), 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 Sweden. Therefore, the agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated as a result of manufacturing the new products.

The new products will be manufactured in Sweden in two facilities that also manufacture other currently marketed snus products with the same names; one in Gothenburg and one in Kungalv. The applicant stated that both facilities comply with environmental legislation known as Miljobalken (1998:808) and are regulated by Gothenburg Environmental Agency and Kungalv Environmental Agency, respectively. According to the applicant, these agencies review the respective facilities on an annual basis for compliance with the environmental legislation to ensure efficient energy consumption and no environmental leakages. In addition, the new products are anticipated to replace the currently marketed snus products with same names, therefore, the agency does not anticipate any additional emissions to be released into the environment as a result of manufacturing the new products.

No economic models are available to the agency to forecast the manufacturing of smokeless or snuff products in Sweden or their import into the U.S. To evaluate the environmental impact of the proposed action due to the manufacture of the new products in Sweden, the agency utilized historic data from 2009-2014 to forecast the amount of smokeless tobacco products imported to the U.S. from Sweden if the authorization orders are issued. This was achieved by using a best-fit trendline, which includes; exponential with an R^2 value of 0.9683 for world smokeless import, exponential with an R^2 value of 0.9348 for world snuff import, and power with an R^2 value of 0.935 for Sweden snus import (See Appendix 2). A most accurate best-fit trendline is when the R^2 value is at or near 1. Accordingly, the forecast of future import of smokeless products was estimated using mathematical prediction (Appendix 2).

The applicant also submitted SE Reports (SE0010524-SE0010533, listed in Appendix 1) to obtain market authorizations pursuant to section 910(a)(2) of the FD&C Act for the same new products.The applicant also submitted Modified Risk Tobacco Product Applications (MRTPA) (MR0000020-MR0000029 listed in Appendix 1) to obtain market authorizations pursuant to section 911(g) of the FD&C Act for the same new products but with the applicant's proposed modifications of the package labels. The applicant indicated in the MRTPAs that the projected market volumes of the new products in the SE Reports and in the MRTPAs are the same. The applicant also indicated the lack of mathematical methods to forecast the difference in market volume projections due to the proposed changes to the package labels. As described in the SE Reports, the applicant indicated that these new products will replace currently marketed products with the same names.

The individual and cumulative projected market volumes of the new products in the 1st, 5th, and 10th years of issuing the PMTA authorizations are anticipated to be a fraction of the forecasted worldwide import of smokeless products or snuff into the U.S. (Confidential Appendix 2 and Confidential Appendix 3). Additionally, the projected market volumes of the new products are a portion of the U.S. import forecast of snuff tobacco from Sweden. However, as discussed, the new products are expected to replace the currently marketed products with the same names. Any forecast of snuff import from Sweden would encompass the currently marketed products and therefore, the agency expects that the forecast of snuff imports from Sweden will likely be the same after authorization.

It is worth noting that although the projected market volumes of all eight of these products are discussed in this PEA, the cumulative environmental effects due to the manufacturing of five of the eight were already evaluated and accounted for in the PEA for SE0010524-SE0010526 and SE0010532-SE0010533 reports.

Consequently, the agency does not foresee any additional emissions to be released into the environment due to the manufacturing of the new products. Therefore, the introduction of released substances due to manufacturing the new products is negligible from the environmental viewpoint.

6.2 Environmental Introduction as a Result of Use of the New Tobacco Products

6.2.1 Use of smokeless tobacco products in the U.S.

According to the statistical reports of the U.S. Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB), the use of snuff increased from 20,323 tons in 1987 to 51,884 tons in 2014, whereas the use of chewing tobacco in the U.S. decreased from 36,029 tons in 1987 to 9,965 tons in 2014 (Figure 3A).[8] While the combined use of smokeless tobacco products (snuff and chewing tobacco) in the U.S. remained relatively unchanged from 1987 to 2010, there seemed to be a gradual increase in use of smokeless products from 54,296 tons in 2009 to 61,849 tons in 2014 (Figure 3B).

Three companies, U.S. Smokeless Tobacco Company, American Snuff, and Swedish Match, account for nearly 90% of U.S. sales of smokeless tobacco.[9]

[8] 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 April 10, 2015.

[9] Centers for Disease Control and Prevention (CDC). Smoking and Tobacco Use – Economic Facts About U.S. Tobacco Production and Use. Available at: http://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/. Accessed April 20, 2015.

Figure 3A – Use of Smokeless Tobacco Products in the U.S. in 1987 – 2014 [8]

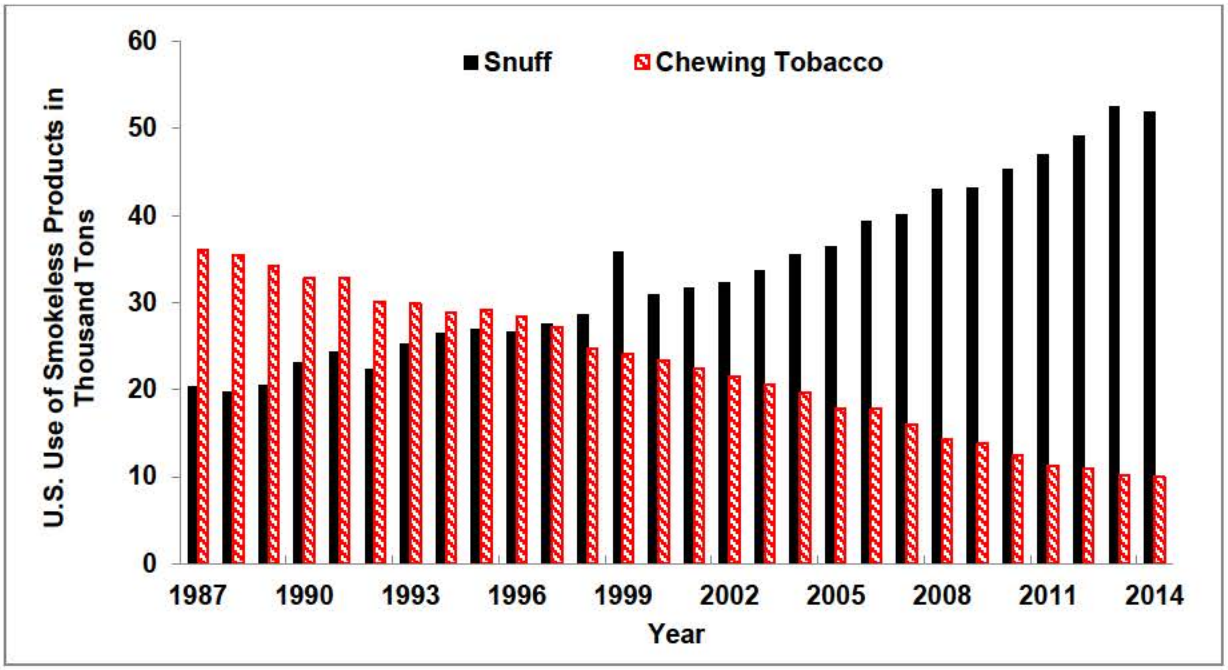
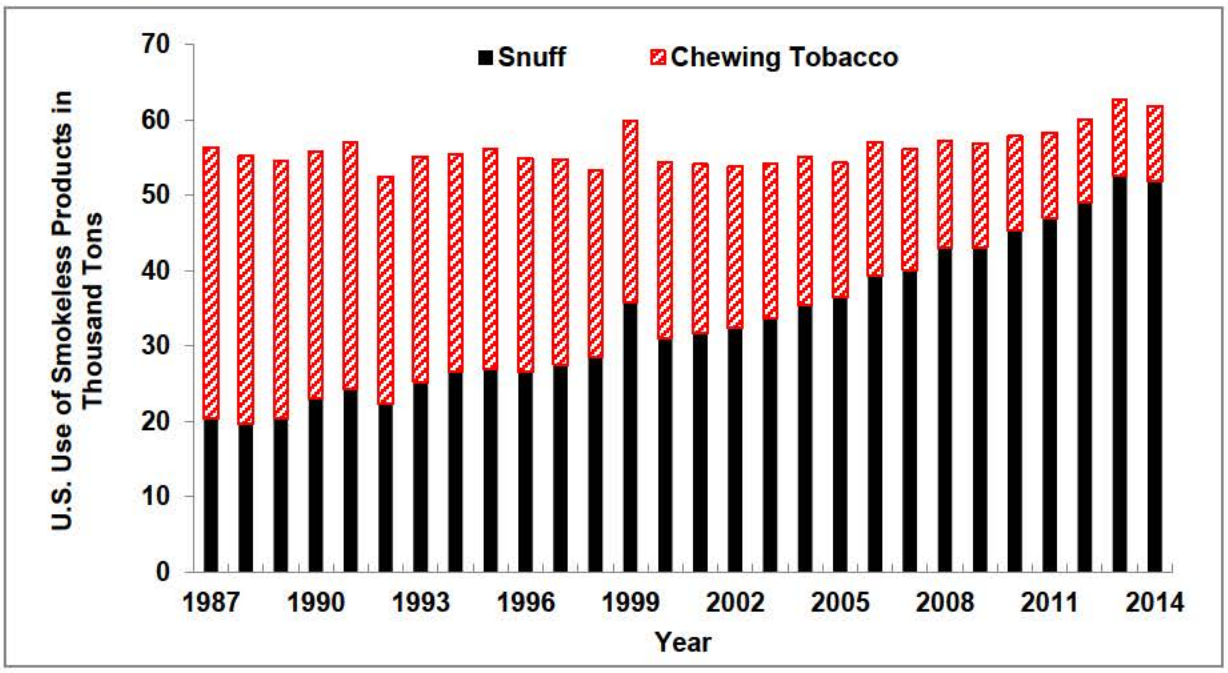


Figure 3B – Use of Smokeless Tobacco Products in the U.S. in 1987 – 2014 [8]



6.2.2 Environmental consequences from use of the new products

The new products are usually used in a manner similar to any other smokeless products that are currently on the market. The ingredients used in the new products are used in other smokeless products and the aim of the differences in the ingredients is to reduce the amount of certain HPHCs. Essentially, the agency does not anticipate new substances to be released into the environment as a result of use of the new products, in

comparison to the substances released by the smokeless products of the same name that are already on the market or all other smokeless tobacco.

No economic models are available to the agency to predict the use of smokeless or snuff in the U.S. To evaluate the environmental impact of the proposed action due to use of the new products, the agency utilized the historic data for use in 2005-2014 to forecast the amount of use of smokeless tobacco products and snuff in the U.S. after issuance of the authorizations. This was achieved by using one best-fit exponential trendline with the R^2 value of 0.9789 for snuff and another best-fit exponential trendline with the R^2 value of 0.9802 for chewing tobacco (See Appendix 3). Accordingly, the forecast of future use of smokeless products was estimated using a mathematical prediction (Appendix 3). The individual projected market volumes in the 1st, 5th and 10th years of marketing the new products make up a fraction of the total forecasted use of smokeless products or snuff in the U.S during the same time frame (See Confidential Appendix 2 and Confidential Appendix 4). However, as discussed, the new products are expected to replace products that are already on the market. In addition, the environmental introduction due to use of five of the eight products were accounted for and evaluated in the PEA for SE0010524-SE0010526 and SE0010532-SE0010533.

Consequently, the amount of release of material mass into the environment as a result of use of the new products is negligible compared to that of all smokeless tobacco products or snuff being used in the U.S. Therefore, the introduction of released substances from use of the new products is negligible from the environment viewpoint.

6.3 Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Products

6.3.1 Disposal following use of smokeless tobacco products in the U.S.

The environmental consequences of disposal following use of the smokeless tobacco products result from a) disposal of packaging material, b) discarding the used tobacco, and c) excretion of other ingredients in smokeless tobacco.

a. Disposal of packaging material:

Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2012, the amount of waste generated in the U.S. was approximately 251 million tons and approximately 87 million tons of this material was recycled and composted, equivalent to a 34.5% recycling rate (Figure 4 and Figure 5).[10] Visual examination of the waste trend indicates that the annual amount of generated waste for the upcoming years will more likely remain approximately close to that in 2012. On average, 4.38 pounds per person per day of waste was generated, of which 1.51 pounds was recycled and composted in the U.S. in 2012. The recovery of

[10] EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: http://www.epa.gov/waste/nonhaz/municipal/. Accessed April 20, 2015.

papers through recycling was about 70% and recovery for polypropylene waste was 30.8%.

Figure 4 – Municipal Solid Waste (MSW) Generation Rates in the U.S, 1960 – 2012 [10]

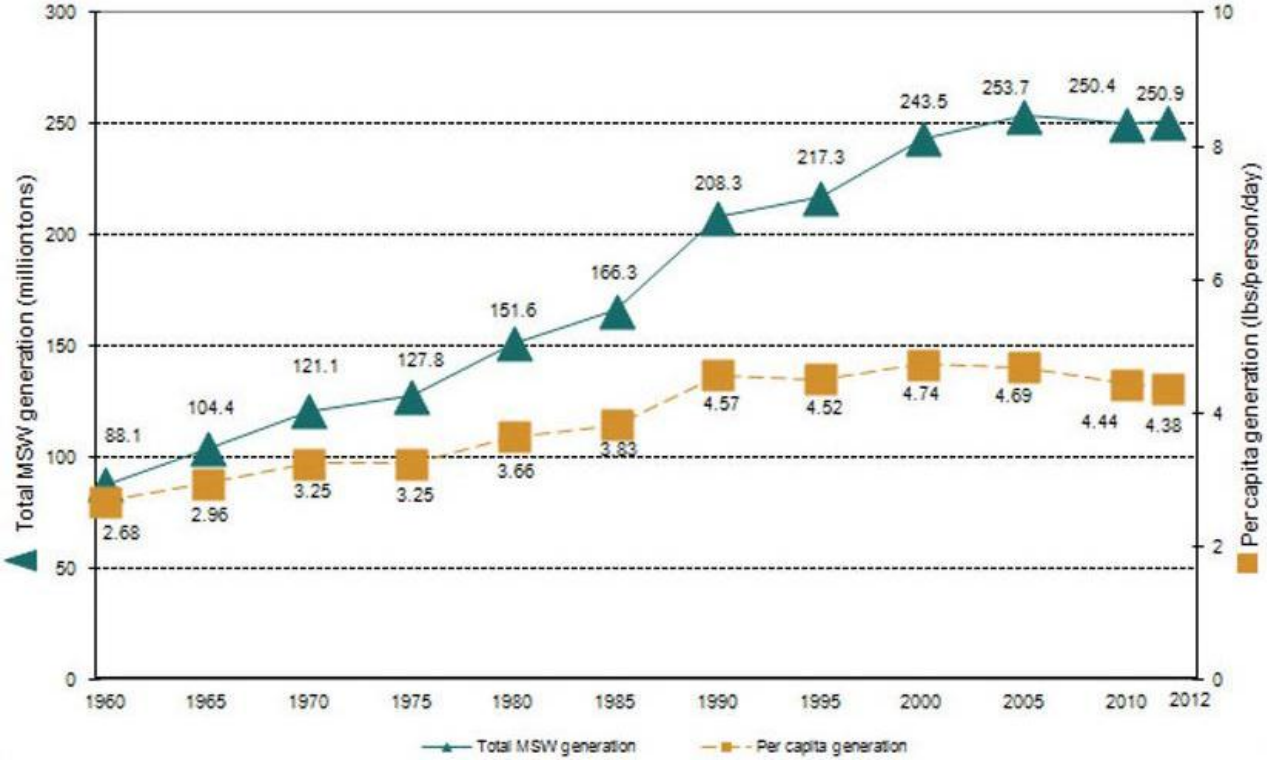
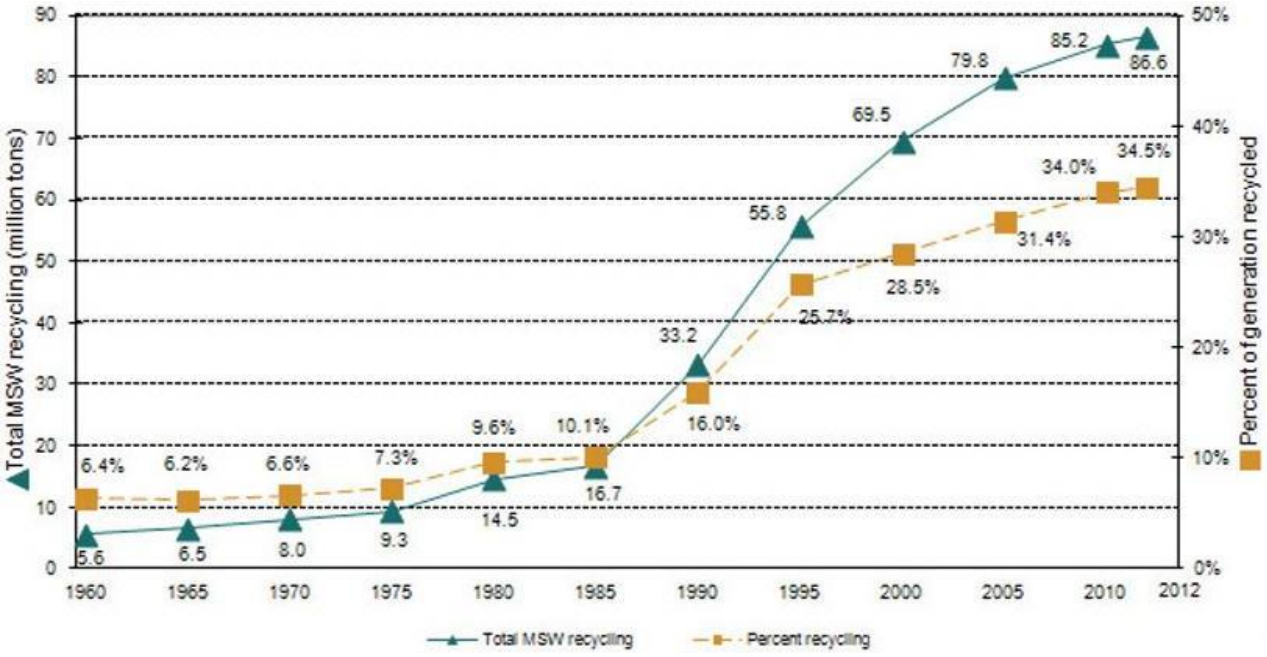


Figure 5 – MSW Recycling Rates in the U.S. [10]



b. Disposal of used tobacco

Used smokeless tobacco is usually disposed of in MSW landfills or as litter. When discarded as litter, the tobacco 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 historic 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 251 million tons of projected MSW to be generated in the U.S (Table 2). [11]

Table 2 Forecast of Waste of Used Smokeless Tobacco as Compared to Total MSW Forecast in the U.S.[12]

Year	Projected Use (Equivalent to Projected Waste) of Smokeless in the U.S. (Tons) [a]	Percent of Projected Waste of Smokeless to Total MSW Forecast in the U.S. (%)	Projected Use (Equivalent to Projected Waste) of Snuff in the U.S. (Tons)	Percent of Projected Waste of Snuff to Total MSW Forecast in the U.S. (%)
1st Year	65,736	0.026	57,512	0.023
5th Year	73,522	0.029	67,357	0.027
10th Year	86,366	0.034	82,064	0.033

[a]See Table 4 in Appendix 3

c. Excretion of product ingredients:

In addition to the disposal of the product in MSWs or as litter, there will also be excretion by the user of ingredients of the used smokeless products, which might enter the sewer system as components in human waste. The excreted waste is anticipated to be digested by microbial systems in the home's septic system or treated in POTW.

6.3.2 Environmental consequences from disposal following use of the new products

The agency believes that the disposal of the proposed products resembles the disposal conditions of the snus products and any other smokeless tobacco products that are currently being marketed. The waste generated as a result of use of the products 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 smokeless tobacco products used

[11] Based on trend of MSW reported in the referenced EPA report.

in the U.S. The projected tobacco waste due to use of the new products is a minute fraction of the forecasted tobacco waste generated due to use of the smokeless tobacco products (Confidential Appendix 5).

In the worst case scenario, the agency assumes that all packaging material of the new products will be disposed of as MSW. However, paper components are more likely to be recycled. To determine the amount of waste due to disposal of paper and plastic packaging material, the agency used the projected market volumes in the 1st, 5 h and 10th years after issuance of the authorization orders for the new products (Confidential Appendix 6). The calculated waste of the cardboard packaging material of the can base of the loose product was accounted for and calculated in the PEA for SE0010524 and determined to be miniscule compared to the forecasted MSW to be generated in the U.S.; at least a portion of the waste is likely to be recycled.

Likewise, the polypropylene waste generated from the can base of pouched products, can lids and film wrap of the new products, as well as pouch material is negligible compared to the amount of forecasted MSW to be generated in the U.S. (Confidential Appendix 6). Furthermore, the cumulative waste due to polypropylene packaging materials of the new loose and four of the pouched products (SE0010524-SE0010526 and SE0010532-SE0010533) and the pouch components of the four pouched products (SE0010525, SE0010526, SE0010532 and SE0010533) is accounted for in the PEA for these SE Reports. The projected additional plastic and pouch material waste due to the remaining three products are anticipated to be negligible compared to the amount of forecasted MSW to be generated in the U.S (Confidential Appendix 6).

Therefore, the introduction of released substances from disposal after use of the new products is negligible from the environmental viewpoint.

7 Cumulative Environmental Introduction Due to Past and Future Related Actions

As discussed, in addition to these eight PMT Applications, SMNA has also submitted ten SE Reports, SE0010524-SE0010533, listed in Appendix 1, to obtain market authorizations pursuant to section 910(a)(2) of the FD&C Act. In addition, concurrent with the SE Reports and PMT Applications, SMNA has submitted the MRTP Applications, MR0000020-MR0000029, also listed in Appendix 1, for the same snus products. The applicant also submitted SE Reports (SE00000138-SE00000145) to FDA for the eight provisional products that are currently marketed and will be replaced by the new products submitted in the SE Reports and the PMT Applications. Although the projected market volumes of all eight of the new products are discussed in this PEA, the cumulative environmental effects due to the manufacture, use and disposal after use of five of the eight were already evaluated and accounted for in the PEA for SE0010524-SE0010526 and SE0010532-SE0010533 reports. Consequently, the agency does not anticipate any additional emissions to be released into the environment as a result of its combined actions of issuing market authorizations for these five new products.

8 Fate of New Materials Released into the Environment Due to the Proposed Action

The introduction of released substances from manufacturing, use, and disposal after use of the new products is negligible from the environmental viewpoint. Therefore, no fate discussion is required.

9 Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

Because the amount of new materials anticipated to enter the environment due to the proposed action is negligible, the environmental effects of the materials released due to the manufacturing, use, and disposal following use of the new products are not substantial.

10 Use of Resources and Energy

Swedish Match has two manufacturing facilities in Sweden one in Gothenburg and one in Kungalv. According to the applicant, both facilities comply with environmental legislation known as Miljobalken (1998:808). The facilities are regulated by the Gothenburg Environmental Agency and Kungalv Environmental Agency, respectively, which review the corresponding facilities on an annual basis for compliance with the environmental legislation and ensure efficient energy consumption.

Based on information provided by the applicant, the projections of the market volume of the new products are a negligible fraction of the total smokeless tobacco products sold in the U.S. Furthermore, the new products will replace currently marketed products and the agency does not anticipate the market volume to be changed noticeably based on the provided information.

Accordingly, the additional use of resources and energy due to the proposed action is negligible.

11 Mitigation

During the review of the available data and information, the agency did not identify adverse environmental effects due to the manufacture, use, and disposal after use of the new products as proposed. Therefore, no mitigation measures are discussed.

12 Alternative Actions

Alternative A (No-action alternative): The no-action alternative is to not issue the market authorization orders. The environmental impact of this action would not noticeably change the existing condition of the manufacturing, use, and disposal from use of the smokeless products since snus products, as well as many other smokeless tobacco products, will continue to be marketed in the U.S.

Alternative B (Proposed action): There are virtually no environmental effects due to the proposed action of issuing the market authorization orders and the associated manufacture, use, and disposal after use of the new tobacco products. Furthermore, the new products are intended to replace products that are being marketed and used in the U.S. To issue market authorization orders for the new products would not change the environment noticeably. The environmental effects from the proposed action are expected to be approximately the same as that related to the no action alternative.

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

13 List of Preparers

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

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Years of Experience: 22 years in various scientific activities

Expertise: NEPA Analysis, Environmental Risk Assessment, Evidence-Based Assessment of Health Technologies

14 List of Appendix

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Appendix 3	Forecast of Use of Smokeless Tobacco Products in the U.S.

15 List of Confidential Appendix

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Confidential Appendix 3	Projected Market Volumes of the New Products as Compared to the Forecasted Import of Smokeless and Snuff Tobacco Products to U.S.
Confidential Appendix 4	Projected Market Volumes of the New Products as Compared to the Forecasted Use of Smokeless and Snuff Tobacco in the U.S.
Confidential Appendix 5	Projected Waste Due to Use of the New Products
Confidential Appendix 6	Projected Waste Due to Packaging Components of the New Products

APPENDIX 1

List of PMT Applications and Related Submissions and Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

Product Name	STN	Related MRTP	Related SE	Amendments
General Loose	PM0000010	MR0000020	SE0010524	PM0000018; PM0000026; PM0000027; MR0000030; MR0000031; MR0000032; MR0000033; MR0000035; MR0000036; MR0000038; MR0000039; MR0000041; MR0000042; MR0000044; MR0000045
General Dry Mint Portion Original Mini	PM0000011	MR0000021	SE0010525	PM0000019; PM0000026; PM0000027; PM0000029; MR0000030; MR0000031; MR0000032; MR0000033; MR0000035; MR0000036; MR0000038; MR0000039; MR0000041; MR0000042; MR0000044; MR0000045
General Portion Original Large	PM0000012	MR0000022	SE0010526	PM0000020; PM0000026; PM0000027; PM0000029; MR0000030; MR0000031; MR0000032; MR0000033; MR0000035; MR0000036; MR0000038; MR0000039; MR0000041; MR0000042; MR0000044; MR0000045
General Classic Blend Portion White Large – 12 CT	PM0000013	MR0000024	SE0010528	PM0000021; PM0000026; PM0000027; PM0000029; MR0000030; MR0000031; MR0000032; MR0000033; MR0000035; MR0000036; MR0000038; MR0000039; MR0000041; MR0000042; MR0000044; MR0000045
General Mint Portion White Large	PM0000014	MR0000025	SE0010529	PM0000022; PM0000026; PM0000027; PM0000029; MR0000030; MR0000031; MR0000032; MR0000033;

				MR0000035; MR0000036; MR0000038; MR0000039; MR0000041; MR0000042; MR0000044; MR0000045
General Nordic Mint Portion White Large – 12 CT	PM0000015	MR0000027	SE0010531	PM0000023; PM0000026; PM0000027; PM0000029; MR0000030; MR0000031; MR0000032; MR0000033; MR0000035; MR0000036; MR0000038; MR0000039; MR0000041; MR0000042; MR0000044; MR0000045
General Portion White Large	PM0000016	MR000028	SE0010532	PM0000024; PM0000026; PM0000027; PM0000029; MR0000030; MR0000031; MR0000032; MR0000033; MR0000035; MR0000036; MR0000038; MR0000039; MR0000041; MR0000042; MR0000044; MR0000045
General Wintergreen Portion White Large	PM0000017	MR0000029	SE0010533	PM0000025; PM0000026; PM0000027; PM0000029; MR0000030; MR0000031; MR0000032; MR0000033; MR0000035; MR0000036; MR0000038; MR0000039; MR0000041; MR0000042; MR0000044; MR0000045

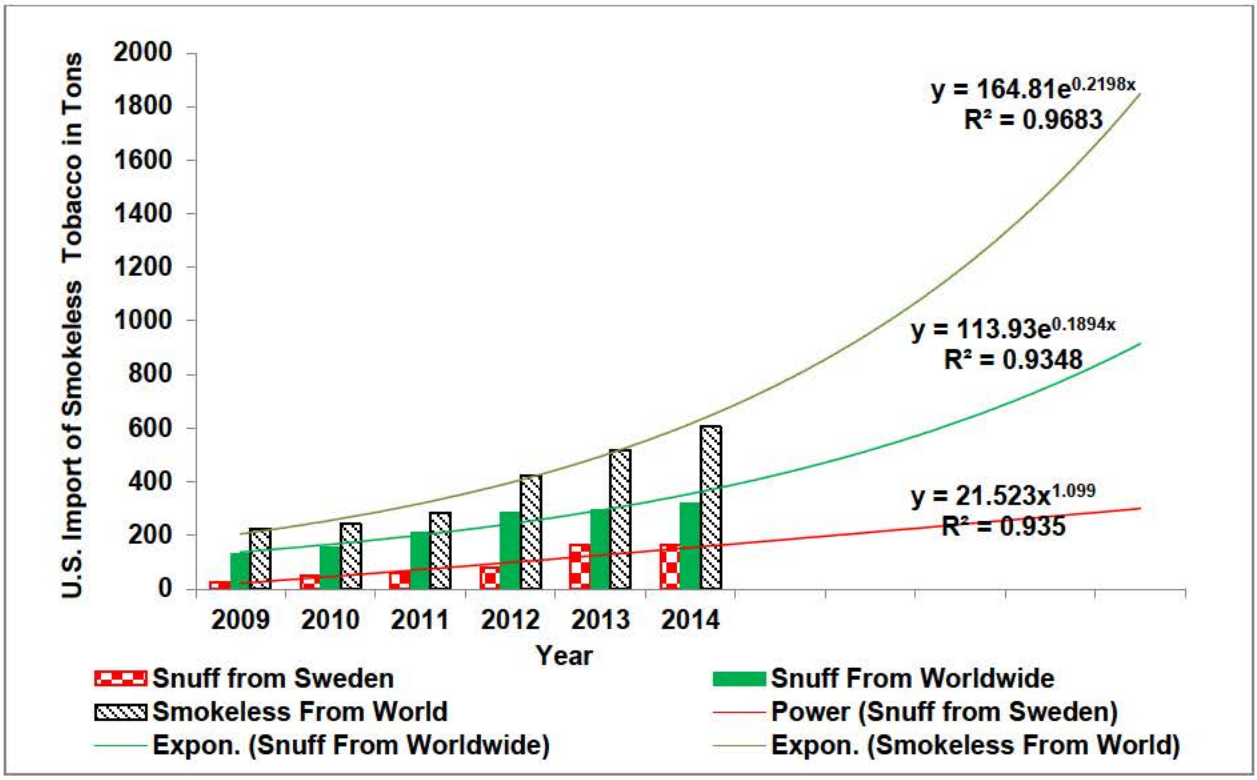
Appendix 2

Forecast of U.S. Import of Smokeless Tobacco Products

To evaluate the environmental impact of the proposed action due to manufacturing the new products in Sweden, the agency utilized the historic data of U.S. import of smokeless products from Sweden and worldwide during 2009-2014 to forecast the future import of smokeless tobacco products. This was achieved by using a best-fit trendline of; exponential with an R^2 value of 0.9683 for world smokeless import, exponential with an R^2 value of 0.9348 for world snuff import, and power with an R^2 value of 0.9348 for Sweden snus import. A most accurate best-fit trendline is when the R^2 value is at or near 1 (Figure 6).

Accordingly, the information from these best-fit trendlines were used to mathematically estimate the forecast of U.S. import of snuff and smokeless tobacco (Table 3).

Figure 6 – Forecast of U.S. Import of Smokeless Tobacco Products[12]



[12] Based on United States Department of Agriculture (USDA). Foreign Agricultural Service (FAS). Global Agricultural Trade System (GATS). Available at: http://apps.fas.usda.gov/gats/default.aspx. Accessed on April 29, 20

Table 3 Forecast of U.S. Import of Smokeless and Snuff Products from Worldwide and Sweden [13]

Year	U.S. Import of Smokeless from Worldwide (Tons)	U.S. Import of Snuff from Worldwide (Tons)	U.S. Import of Snuff from Sweden (Tons)
1st Year	956	518	212
5th Year	2,304	1,106	330
10th Year	6,915	2,851	484

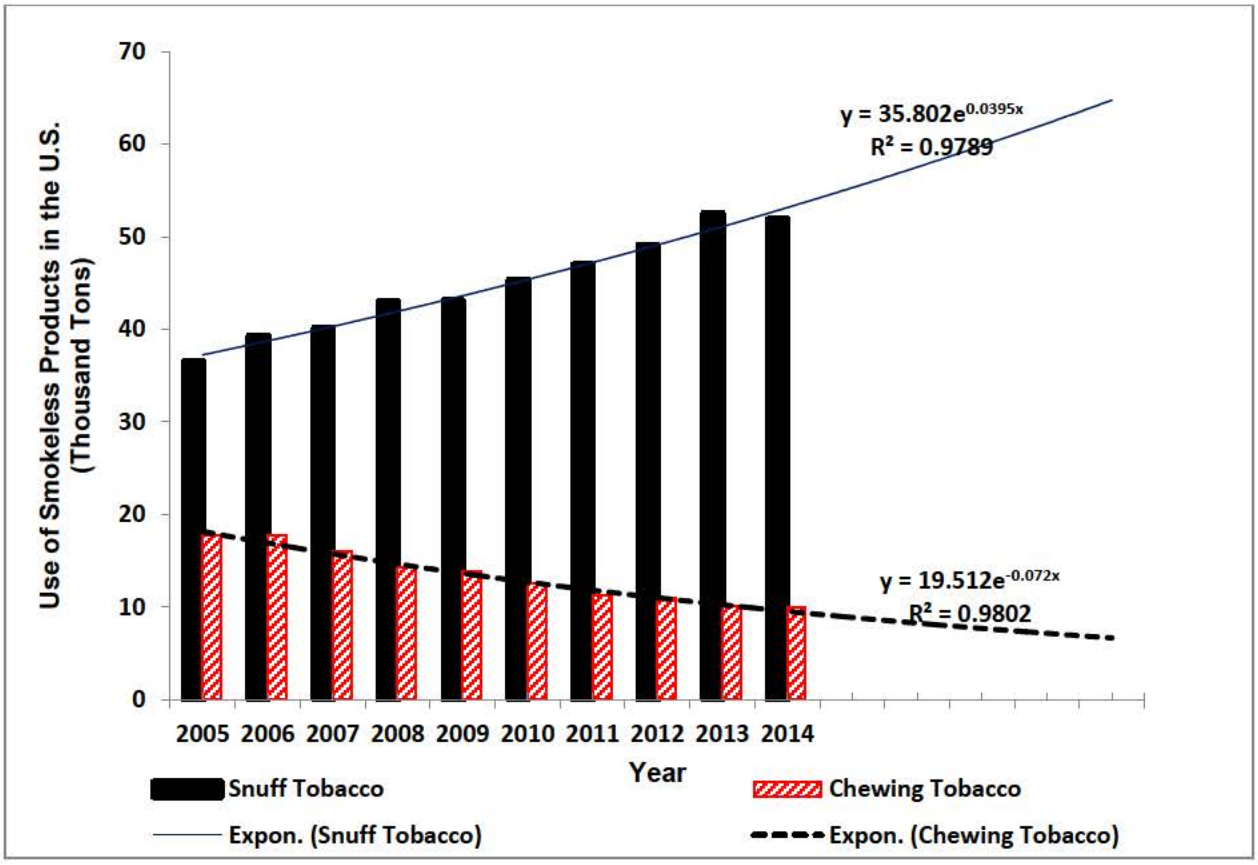
Appendix 3

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 historic data of use in 2005 – 2014 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 trendline with the R^2 value of 0.9789 for snuff and another best-fit exponential trendline with the R^2 value of 0.9802 for chewing tobacco (Figure 7).

Utilizing trendlines, the forecast of use of smokeless products in the U.S. was estimated mathematically (Table 3).

Figure 7 Forecast of Use of Smokeless Tobacco Products in the U.S.[13]



[13] Based on TTB data

Table 4 Forecast of Use of Smokeless Products in the U.S. [14]

Year	Snuff Use (Tons)	Chewing Tobacco Use (Tons)	Total Smokeless Use (Tons)
1st Year	57,512	8,224	65,736
5th Year	67,357	6,166	73,523
10th Year	82,064	4,302	86,366

Confidential Appendix 1

Detailed Description of the Packaging Components of the New Products

Component	PM0000010	PM0000011	PM0000012	PM0000013	PM0000014	PM0000015	PM0000016	PM0000017
Package Size (gram/Can)	45	6	24	10.8	24	10.8	24	24
Weight of Portion (gram/pouch)	Loose	0.3	1	0.9	1	0.9	1	1
Number of Pouches/Can	NA[14]	20	24	12	24	12	24	24
Weight of Pouch Material (gram/Portion)	(b)(4)	(b)(4)						
Weight of Pouch Material (gram/Can)[15]								

[14] NA= Not applicable

[15] The weight of pouch material in each can is calculated as follows:

A= B x C, where

A= Weight of pouch material in each can (gram/can)

B= Weight of Pouch material for each portion (gm/pouch)

C= Number of pouches in each can

Component	PM0000010	PM0000011	PM0000012	PM0000013	PM0000014	PM0000015	PM0000016	PM0000017
Weight of Can Base (gram/Can)	(b)(4)							
Weight of Lid (gram/Can)								
Weight of Plastic Film (gram/Can)								

General Loose product (PM0000010) is contained in a waxed cardboard can base with a polypropylene plastic lid. The can base and lid materials of the pouched products are also made of polypropylene resin. The cans are wrapped in shrink wrap made of polypropylene resin. The pouched products; "General Classic Blend Portion White Large – 12 CT and General Nordic Mint Portion White Large – 12 CT" are contained in a rectangular plastic can base, whereas all other pouched products are in round cans. The can lid of the pouched products also serves as a receptacle for the used tobacco waste. The white pouch fabric is made of (b) (4) .

Confidential Appendix 2

Projected Market Volumes in the 1st, 5th and 10th Years of Marketing the New Products

The agency calculated the forecast of market volume of the new products after issuance of market authorizations as follows:

A= B x C / D, where

A= Forecast market volume (Tons)

B= Projected number of manufactured cans

C= Weight of the new product (grams/can)

D= 10^{-6} (tons/gram)

STN[a]	Projected Year of Marketing the New Products[b]	Projected Market Volume (# of Cans)	Weight of Product (gram/ Can)	Projected Market Volume (Grams)	Projected Market Volume (Tons)
PM0000010	1st Year	(b) (4)			
	5th Year				
	10th Year				
PM0000011	1st Year				
	5th Year				
	10th Year				
PM0000012	1st Year				
	5th Year				
	10th Year				
PM0000013	1st Year				
	5th Year				

STN[a]	Projected Year of Marketing the New Products[b]	Projected Market Volume (# of Cans)	Weight of Product (gram/ Can)	Projected Market Volume (Grams)	Projected Market Volume (Tons)
	10th Year	(b) (4)			
PM0000014	1st Year				
	5th Year				
	10th Year				
PM0000015	1st Year				
	5th Year				
	10th Year				
PM0000016	1st Year				
	5th Year				
	10th Year				
PM0000017	1st Year				
	5th Year				
	10th Year				

[a]Also see Appendix 1for the corresponding MRTP STNs. These are the STNs that contained the market volume information.

[b]The PMT Applications reference the EAs that are contained in the corresponding MRTP Application and amendments. In the EAs contained in the MRTP Application dated June 10, 2014, the applicant provided projections of market volumes in the 1st year and 2nd year of marketing the modified products after an order would be issued. So, the 1st year could be 2015.

In response to an FDA request regarding the SE Reports, dated April 14, 2015 (SE0011687), the applicant provided projections of market volumes in the 1st, 5th and 10th years of marketing the products quoting the same volumes for the 1st year that were presented in the MRTP Application but specified the 5th year to be 2019 and the 10th year to be 2024. Back calculating using

these years, that would mean the applicant is considiering 2015 as the 1st year of marketing.. However, the 1st year could be 2016 as the submissions were received in 2015.

In the applicant's response to another FDA request for information (MR0000042 dated May 22, 2015) to FDA, the applicant stated that the projected market volume provided for the SE Reports and the MRTP Aapplications correspond to years 5 and 10, 2019 and 2024, respectively. So, as discussed above, the 1st year could be 2015 because of the back calculation using 2019 and 2024 as the 5th and 10th years, respectively. However, the 1st year could be 2016 because of the submission date being 2015.

It is clear from the PMT Applications, MRTP Applications, and SE Reports, the applicant considers the 5th year to be 2019 and the 10th year to be 2024. It appears that the years the applicant deems the 5th and 10 h years are dependent on when the applications were prepared, and the applicant's projections are based on the 1st year being 2015. However based on the timing of the receipt of the PMT Applications, the review of these submissions and the potential timing of any marketing authorizations, the first year of marketing the new products could be 2016. For the purpose of this PEA, the projected market volumes provided by the applicant were compared to the forecasted volumes of 2016, 2020, and 2025.

The cumulative projected market volumes of the products that are covered in the PMT Applications and those covered in the SE Reports are presented in the table below.

Cumulative Market Volume Projections of the New Products in Tons			
STN	**1st Year**	**5th Year**	**10th Year**
Projected market volume of all new products (Tons) from the table above in this Appendix	(b) (4)		
Projected market volume of new products accounted for in the PEA of SE Reports SE0010524 – SE0010526 and SE0010532 – SE0010533			
Projected market volume of the 3 remaining pouched new products (Tons)			

Confidential Appendix 3

Projected Market Volumes of the New Products as Compared to the Forecasted U.S. Import of Smokeless and Snuff Tobacco Products

STN[a]	Year	Projected Market Volume of New Products (Tons)	Forecast of Worldwide Import of Smokeless to U.S. (Tons)	Percent of Projected Market Volume to Forecasted Worldwide Import of Smokeless to U.S. (%)	Forecast of Worldwide Import of Snuff to U.S. (Tons)	Percent of Projected Market Volume to Forecasted Worldwide Import of Snuff to U.S. (%)	Forecast of U.S. Import of Snuff from Sweden (Tons)	Percent of Projected Market Volume to Forecasted Import of Snuff from Sweden to U.S. (%)
PM0000010	1st Year	(b) (4)						
	5th Year							
	10th Year							
PM0000011	1st Year							
	5th Year							
	10th Year							
PM0000012	1st Year							
	5th Year							
	10th Year							
PM0000013	1st Year							
	5th Year							
	10th Year							

STN[a]	Year	Projected Market Volume of New Products (Tons)	Forecast of Worldwide Import of Smokeless to U.S. (Tons)	Percent of Projected Market Volume to Forecasted Worldwide Import of Smokeless to U.S. (%)	Forecast of Worldwide Import of Snuff to U.S. (Tons)	Percent of Projected Market Volume to Forecasted Worldwide Import of Snuff to U.S. (%)	Forecast of U.S. Import of Snuff from Sweden (Tons)	Percent of Projected Market Volume to Forecasted Import of Snuff from Sweden to U.S. (%)
PM0000014	1st Year	(b) (4)						
	5th Year							
	10th Year							
PM0000015	1st Year							
	5th Year							
	10th Year							
PM0000016	1st Year							
	5th Year							
	10th Year							
PM0000017	1st Year							
	5th Year							
	10th Year							

[a]Also see Appendix 1for the corresponding MRTP STNs. These are the STNs that contained the market volume information.

Based on these calculations, the projected market volume of each of the new products is a fraction of the forecasted market volume of all smokeless imported to the U.S, all snuf imported to the U.S., and all snuff imported to the U.S. from Sweden.

Confidential Appendix 4

Projected Market Volumes of the New Products as Compared to the Forecasted Use of Smokeless and Snuff Tobacco in the U.S.

STN[a]	Year	Projected Market Volume of the New Product (Tons)	Forecast of Use of Smokeless in U.S. (Tons)	Percent of Projected Market Volume to Forecasted Smokeless Use in U.S. (%)	Forecast of Use of Snuff in U.S. (Tons)	Percent of Projected Market Volume to Forecasted Snuff Use in U.S. (%)
PM0000010	1st Year	(b) (4)				
	5th Year					
	10th Year					
PM0000011	1st Year					
	5th Year					
	10th Year					
PM0000012	1st Year					
	5th Year					
	10th Year					
PM0000013	1st Year					
	5th Year					
	10th Year					
PM0000014	1st Year					

STN[a]	Year	Projected Market Volume of the New Product (Tons)	Forecast of Use of Smokeless in U.S. (Tons)	Percent of Projected Market Volume to Forecasted Smokeless Use in U.S. (%)	Forecast of Use of Snuff in U.S. (Tons)	Percent of Projected Market Volume to Forecasted Snuff Use in U.S. (%)
	5th Year	(b) (4)				
	10th Year					
PM0000015	1st Year					
	5th Year					
	10th Year					
PM0000016	1st Year					
	5th Year					
	10th Year					
PM0000017	1st Year					
	5th Year					
	10th Year					

[a]Also see Appendix 1for the corresponding MRTP STNs. These are the STNs that contained the market volume information.

The total combined projected market volumes of (b) (4) and (b) (4) of the new products in the 1st, 5th, and 10th years after issuance of the authorization orders, respectively, are estimated to be a fraction of the (b) (4), and (b) (4) (b) (4) of the forecasted use of snuff in the U.S. within the same time frame. Additionally, the projected market volumes of five of the eight products were already accounted for, and their environmental impact was evaluated, in the PEA for SE0010524-SE0010526 and SE0010532-SE0010533.

Based on these calculations, the projected market volume of each of the new products is a fraction of the forecasted smokeless and snuff use in the U.S. in the 1st, 5th, and 10th years after issuances of the marketing authorizations.

Confidential Appendix 5

Projected Waste Due to Use of the New Products

The projected waste due to use of the finished product is the weight of the products used by the consumers (i.e, total package size). Assuming that the entire product is disposed of in the worst case scenario, the agency estimated the waste in tons of used products as follows:

A= B x C x D, where

A= Projected waste of disposed tobacco (tons)

B= Projected market volume (number of manufactured cans)

C= Weight of tobacco product in each can (i.e., total package size; grams/can)

D= 10^{-6} (tons/gram)

STN[a]	Year	Projected Market Volume (# of cans)	Product Size (gm/can)	Projected Waste of Used Product (Tons)	Percent of Projected Waste to Total Forecasted Waste of Smokeless in U.S. (%)[b]	Percent of Projected Waste to Total Forecasted Waste of Snuff in the U.S. (%)
PM0000010	1st Year	(b) (4)				
	5th Year					
	10h Year					
PM0000011	1st Year					
	5th Year					
	10h Year					
PM0000012	1st Year					
	5th Year					
	10h Year					

STN[a]	Year	Projected Market Volume (# of cans)	Product Size (gm/can)	Projected Waste of Used Product (Tons)	Percent of Projected Waste to Total Forecasted Waste of Smokeless in U.S. (%)[b]	Percent of Projected Waste to Total Forecasted Waste of Snuff in the U.S. (%)
PM0000013	1st Year	(b) (4)				
	5th Year					
	10h Year					
PM0000014	1st Year					
	5th Year					
	10h Year					
PM0000015	1st Year					
	5th Year					
	10h Year					
PM0000016	1st Year					
	5th Year					
	10h Year					
PM0000017	1st Year					
	5th Year					
	10h Year					

[a]Also see Appendix 1for the corresponding MRTP STNs. These are the STNs that contained the market volume information.

[b]See Table 4, Appendix 3, assuming that the entire product is disposed of in the worst case scenario

The cumulative projected waste disposed of as litter after use of all of the new products in the 1st year, 5th year, and 10th year of marketing is summarized in the table below.

Cumulative Projected Waste Due to Use of the New Products in Tons			
	1st Year Projected Waste	5th Year Projected Product Waste	10th Year Projected Product Waste
Projected waste of all new products (Tons) from the table above in this Appendix	(b) (4)		
Projected waste of new products accounted for in the PEA of SE Reports SE0010524 – SE0010526 and SE0010532 – SE0010533			
Projected waste of the 3 remaining pouched new products (Tons)			

The cumulative projected waste of snuff products in the 1st year, 5th year and 10th year of issuance of the orders is a minute fraction of the forecasted 251 million tons of waste to be generated in the U.S.

Confidential Appendix 6

Projected Waste Due to Packaging Components of the New Products

The agency calculated the forecast of waste (in tons) of packaging components generated from disposal after use of the new products as follows:

A= B x C x D, where

A= Projected waste of the packaging component (tons)

B= Projected market volume (number of manufactured cans)

C= Weight of the packaging component (grams/can) (base, lid, film, can or pouch)

D= 10^{-6} (tons/gram)

STN[a]	Year	Projected Market Volume (Number of Cans)	Weight of Cardboard Can Base (gm/Can)	Projected Cardboard Waste (Tons)	Weight of Plastic Lid (gm/Can)	Projected Plastic Waste (Tons)	Weight of Plastic film (gm/Can)	Projected Waste of Plastic Film
PM0000010	1st Year	(b) (4)						
	5th Year							
	10th Year							

STN[a]	Year	Projected Market Volume (# of Cans)	Weight of Plastic Can (Base & Lid) (gm/Can)	Projected Plastic Waste (Tons)	Weight of Plastic Shrink film (gram/Can)	Projected Film Waste (Tons)	Weight of Fabric Pouch (gram/Can)	Projected Pouch Fabric Waste (Tons)
PM0000011	1st Year	(b) (4)						
	5th Year							
	10th Year							
PM0000012	1st Year							
	5th Year							
	10th Year							
PM0000013	1st Year							
	5th Year							
	10th Year							
PM0000014	1st Year							
	5th Year							
	10th Year							
PM0000015	1st Year							
	5th Year							
	10th Year							
PM0000016	1st Year							
	5th Year							
	10th Year							
PM0000017	1st Year							

STN[a]	Year	Projected Market Volume (# of Cans)	Weight of Plastic Can (Base & Lid) (gm/Can)	Projected Plastic Waste (Tons)	Weight of Plastic Shrink film (gram/Can)	Projected Film Waste (Tons)	Weight of Fabric Pouch (gram/Can)	Projected Pouch Fabric Waste (Tons)
	5th Year	(b) (4)						
	10th Year							

[a]Also see Appendix 1for the corresponding MRTP STNs. These are the STNs that contained the market volume information.

The cumulative projected waste of the packaging components is presented in the table below.

Cumulative Projected Waste Due to Packaging Components of the New Products			
Year	Waste of Cardboard (Tons)	Waste of Plastic (Tons)	Waste of Fabric Pouch (Tons)
1st year			
All products[a]	(b) (4)		
Products Evaluated in SE Reports			
5th Year			
All products[a]	(b) (4)		
Products Evaluated in SE Reports			
10th Year			
All products[a]	(b) (4)		
Products Evaluated in SE Reports			

[a]Information relevant to all new products in this PEA is obtained from the table above in this appendix.

Assuming that the entire packaging material is disposed of as waste in the worst case scenario, the cumulative projected waste of cardboard paper and fabric pouch material in the 1st, 5th and 10th years of issuing the PMT orders is a fraction of the 251 million tons of the forecasted waste based on the EPA 2012 trend report of waste in the U.S. Furthermore, a portion of the generated paper waste is likely to be recycled. Likewise, the cumulative projected waste of polypropylene plastic packaging components is a small fraction of the forecasted MSW in the U.S.

Additionally, the projected waste of the cardboard packaging material of the new loose product was already accounted for and evaluated in the PEA for SE0010524, whereas the projected waste of polypropylene waste and pouch material due to use of the loose and four pouched products in the 1st year, 5th year, and 10th of issuance of the authorization orders were already accounted for in EAs for SE0010524-SE0010526 and SE0010532-SE0010533.