# Programmatic Environmental Assessment for Market Authorization of "General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Portion White Large, and General Wintergreen Portion White Large" Snus, Manufactured by Swedish Match North America, Inc. Found Substantially Equivalent to their Respective Predicate Products

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

August 20, 2015

## Table of Contents

This programmatic environmental assessment (PEA) is for the market authorizations of "General Loose, General Dry Mint Portion Original Mini General Portion Original Large, General Portion White Large, and General Wintergreen Portion White Large." Information presented in the PEA is based on the submissions 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 authorizations 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 of Applicant

Two James Center

1021 East Cary Street, Suite 1600

Richmond, VA23219

## 3 Name of Manufacturer

Swedish Match North America, Inc.

## 4 Description of the Proposed Action

The proposed action is for FDA to issue market authorizations under section 910(a)(2) of the FD&C Act for the introduction of new snus tobacco products "General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Portion White Large, and General Wintergreen Portion White Large". The agency has found the new smokeless tobacco products are substantially equivalent to their respective predicate products (see table 1) that were commercially marketed in the U.S. as of February 15, 2007.

### 4.1 Requested Action

Orders finding that the new products are substantially equivalent to the respective predicate products.

### 4.2 Need for Action

Swedish Match North America, Inc. wishes to introduce new snus products into interstate commerce distribution in the United States (U.S.) and submitted to FDA the referenced SE Reports to obtain market authorizations pursuant to section 910(a)(2) of the FD&C Act. The applicant claims that the new products are substantially equivalent to their respective predicate products, which were commercially marketed in the U.S. as of February 15, 2007 and therefore, are grandfathered tobacco products.

Swedish Match North America, Inc. also identified currently marketed provisional products that these new products will replace. A list of the new products, predicate grandfathered products, and provisional products with the associated STNs is provided in Appendix 2.

## 4.3 Identification of the New Tobacco Products that are Subject of the Proposed Action

### *4.3.1 Type of tobacco product*

Smokeless Tobacco –loose and portioned snus products

### *4.3.2 Names of the new tobacco products*

Names of the new products and their corresponding predicate products are listed in **Table 1** (Also see Appendix 1 for STNs associated with the new products and their respective predicate products).

**Table 1 Name of the New Products and Their Corresponding Predicate Products**

| STN | New Product | | Predicate Product | |
|---|---|---|---|---|
| | Name | Package Size | Name | Package Size |
| **SE0010524** | General Loose | 45 g | General Loose | 50 g |
| **SE0010525** | General Dry Mint Portion Original Mini | 6 g | Catch Dry Peppermint Portion Original Mini | 6 g |
| **SE0010526** | General Portion Original Large | 24 g | General Portion Original Large | 24 g |
| **SE0010532** | General Portion White Large | 24 g | General Portion White Large | 24 g |
| **SE0010533** | General Wintergreen Portion White Large | 24 g | General Wintergreen Portion White Large | 24 g |

### *4.3.3 Package description of the new and predicate products*

The packaging size of the finished new products and the predicate products are identical except for the General Loose product, which had a decrease in size as compared to its predicate product (Table 1). Likewise, the packaging components of the finished new products and the predicate products are identical and consist of a can base with plastic lid and wrapped in polypropylene plastic film. 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. Details of the package ingredients and weight of each packaging component for the new products and the predicate products are described in Confidential Appendix 1.

### *4.3.4 Location of manufacturing*

Swedish Match North Europe

Trollhättegatan 1

SE - 401 21 Göteborg, Swede

#### *4.3.5 Location of use*

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

#### *4.3.6 Location of disposal*

The distribution of the generated waste from 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 landfills or as litter.

### 4.4 Proposed Modifications in the New Products as Compared to the Predicate Products

The modifications in the new products from their corresponding predicate products include:

- 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).
- Additional or tightened specifications for design features such as pH, pouch width decrease and tightened range limit for the ingredients and packaging components.
- Modified plastic can design to provide more space for the used pouch receptacle in the lid of the can of pouched products. In addition, the can base height of the loose product was reduced.

The modifications in the new products as compared to their corresponding predicate products are described in Confidential Appendix 2.

## 5 Environmental Introduction Due to the Proposed Action

### 5.1 Environmental Introduction as a Result of Manufacturing the New Products

#### *5.1.1 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 snuff and dry snuff; and (iii) dissolvables, comprised of lozenges, sticks, strips, and orbs.[1] [2] Snus, also

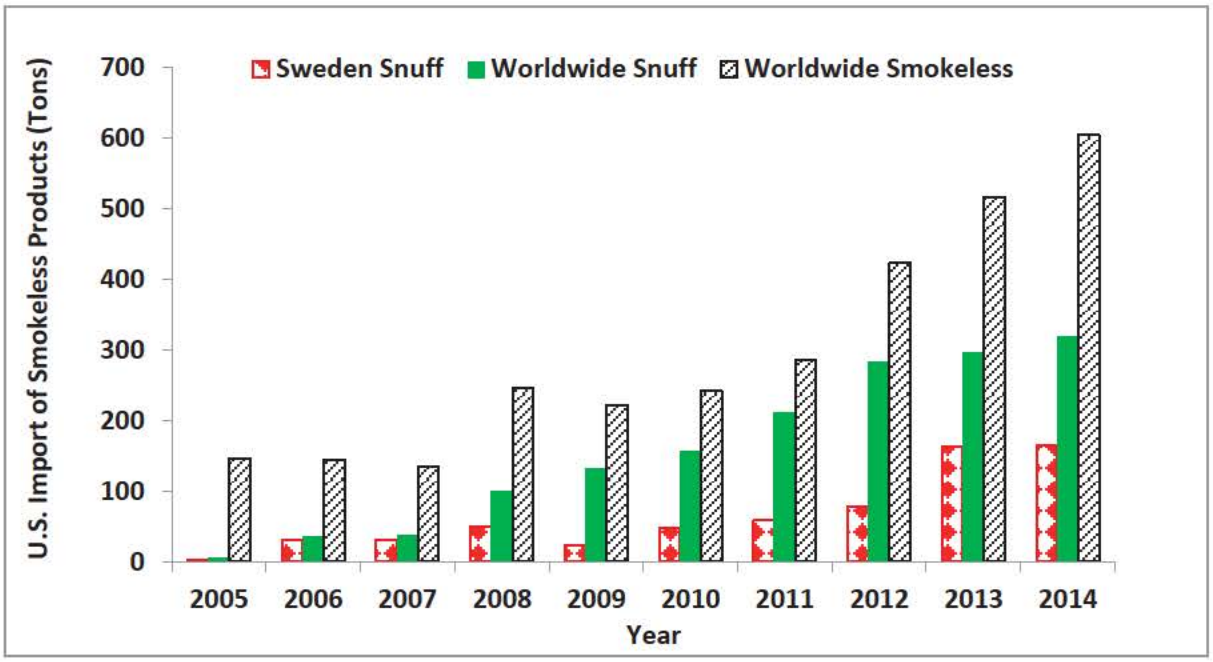
[1] World Health Organization. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 89: Smokeless Tobacco and Some Tobacco-Specific N-Nitrosamines. Lyon (France): World Health Organization, International Agency for Research on Cancer, 2007. Available at: http://monographs.iarc.fr/ENG/Monographs/vol89/mono89.pdf.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

[2] 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

called spitless, is a moist snuff of finely ground tobacco and is available in either a loose form or portioned form in sealed pouches.[3] [4]

Worldwide import of snuff into the U.S. increased at an estimated rate of 64 times during the past 10 years from 5 tons in 2005 to 319 tons in 2014. The U.S. import of snuff from Sweden, which also increased 33 times from 2.5 tons in 2005 to 165 tons in 2014 (Figure 1 and Figure 2), comprises 50% and 27% of the worldwide import of snuff and smokeless products, respectively, into the U.S.[5] [6]

**Figure 1 – U.S. Import of Smokeless Tobacco Products in 2005 – 2014** [5] [6]



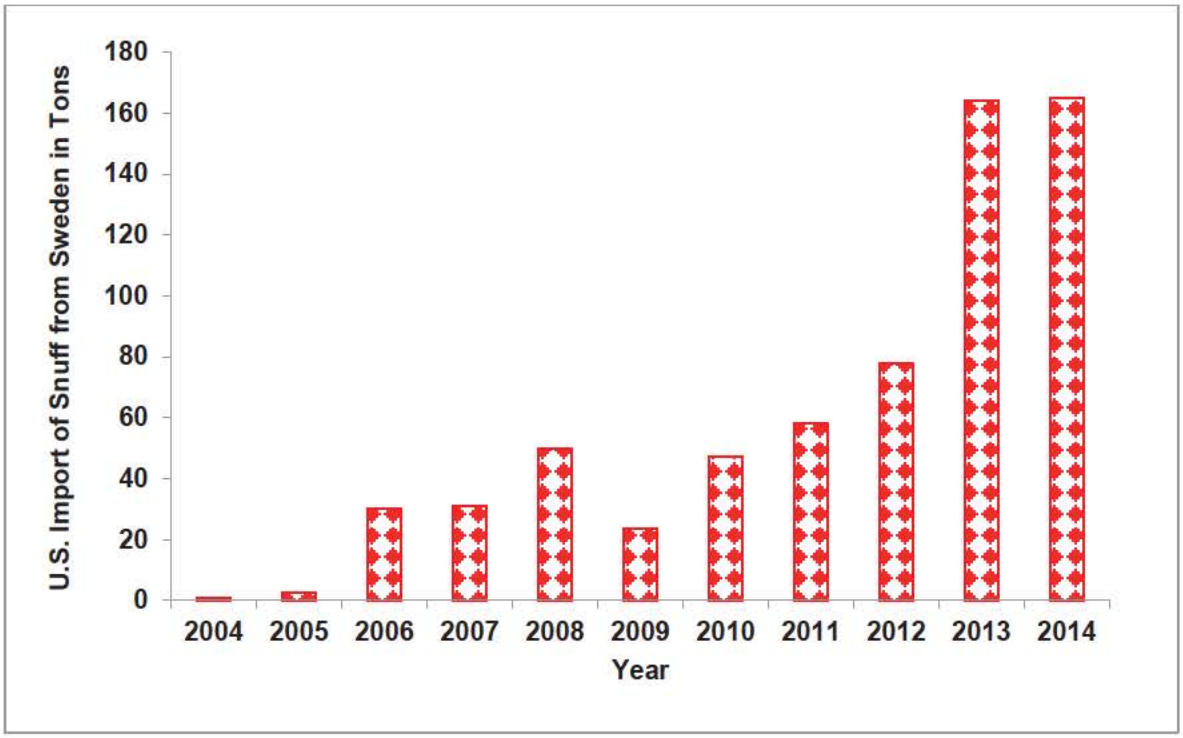

[3] Digard H, Errington G, Richter A and McAdam K. Patterns and behaviors of snus consumption in Sweden. *Nicotine & Tobacco Research*. 2009;11(10):1175-1181

[4] 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.

[5] 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

[6] 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 2 – U.S. Import of Snuff Tobacco from Sweden in 2005 – 2014**[5 6]




### *5.1.2 Environmental consequences from manufacturing the new tobacco products*

The agency anticipates the waste generated as a result of manufacturing the new snus products will 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. In addition, the new products will replace the provisional products that are currently being marketed and 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. The applicant stated that Swedish Match has two manufacturing facilities in Sweden, one in Gothenburg and one in Kungalv, and both facilities comply with environmental legislation of Gothenburg Environmental Agency and Kungalv Environmental Agency, respectively. These agencies review the respective facilities on an annual basis for compliance with the environmental legislation and ensure efficient energy consumption and no environmental leakages. Therefore, the agency does not anticipate any additional emissions to be released into the environment as a result of manufacturing the new product.

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 new products are authorized. 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 3). 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 (Table 3; Appendix 3). The individual and cumulative projected market volumes of the new products in the 1st, 5th, and 10th years of marketing the new products after issuance of the authorizations are anticipated to be a fraction of the forecasted worldwide import of smokeless products or snuff into the U.S. (Confidential Appendix 3 and Confidential Appendix 4). Additionally, the projected market volumes of the new products are a portion of the U.S. import forecast of snuff from Sweden. However, the predicate products are grandfathered products that are not currently being marketed, and the provisional products may remain on the market unless FDA finds the products not substantially equivalent (NSE) to a predicate product. Any forecast of snuff import from Sweden would encompass those of the provisional products, and, the new products will replace the provisional products that are currently being marketed. Therefore, the agency does not anticipate any additional new emissions to be released into the environment as a result of manufacturing the new product when considering future emissions.

Therefore, the introduction of released substances from manufacturing of the new products is negligible from the environmental viewpoint.

## 5.2 Environmental Introduction as a Result of Use of the New Tobacco Products

### *5.2.1 Use of smokeless tobacco products in the U.S.*

According to the statistical reports from 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).[7] While the trend of combined amount of use of smokeless tobacco products (chewing tobacco and snuff) in the U.S. during 1987 – 2010 remained relatively unchanged, there seemed to be a gradual increase in use of smokeless products from 54,296 tons in 2005 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.[8]

[7] 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.

[8] 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** [7]

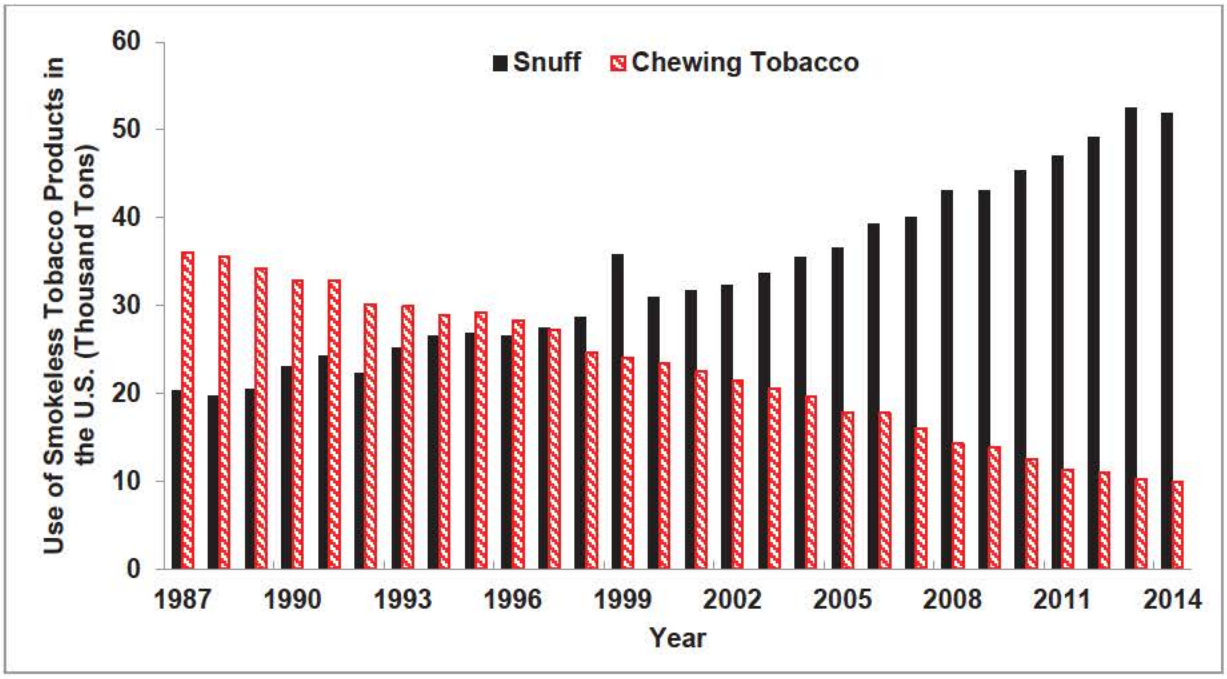
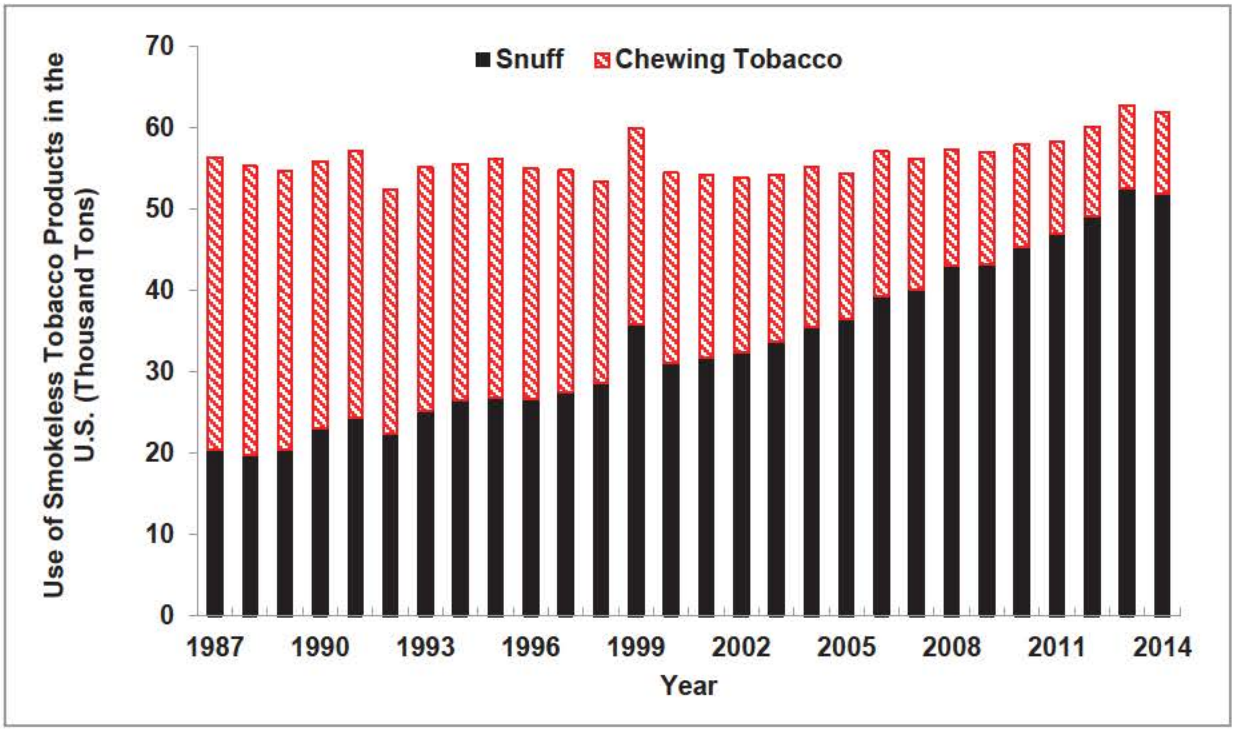



**Figure 3B – Use of Smokeless Tobacco Products in the U.S. in 1987 – 2014** [7]




### *5.2.2 Environmental consequences from use of the new products*

The new products are usually used in a manner similar to the predicate product and other smokeless tobacco products that are currently on the market. The ingredients used in the new products are used in other smokeless products and the modifications are

intended to reduce the amount of certain harmful and potentially harmful constituents (HPHC). 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 product already on the market or all other smokeless tobacco.

No economic models are available to the agency to predict the use of smokeless tobacco products 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 of use in 2005-2014 to forecast the use of smokeless tobacco products, chewing tobacco and snuff in the U.S. after the products are authorized. 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 4). Accordingly, the forecast of future use of smokeless products was estimated using mathematical prediction (Table 4; Appendix 4). The individual and cumulative projected market volumes in the 1$^{st}$ year, 5$^{th}$ year and 10$^{th}$ year 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 3 and Confidential Appendix 5). However, the new products are expected to replace the currently marketed provisional products. Therefore, 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 environmental viewpoint.

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

### *5.3.1 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 i) disposal of packaging material, ii) discarding the used tobacco, and iii) excretion by the user of other ingredients in smokeless tobacco.

**i. 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 percent recycling rate (Figure 4 and Figure 5).[9] 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

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

which, 1.51 pounds was recycled and composted in the U.S. in 2012. The recovery of 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** [9]

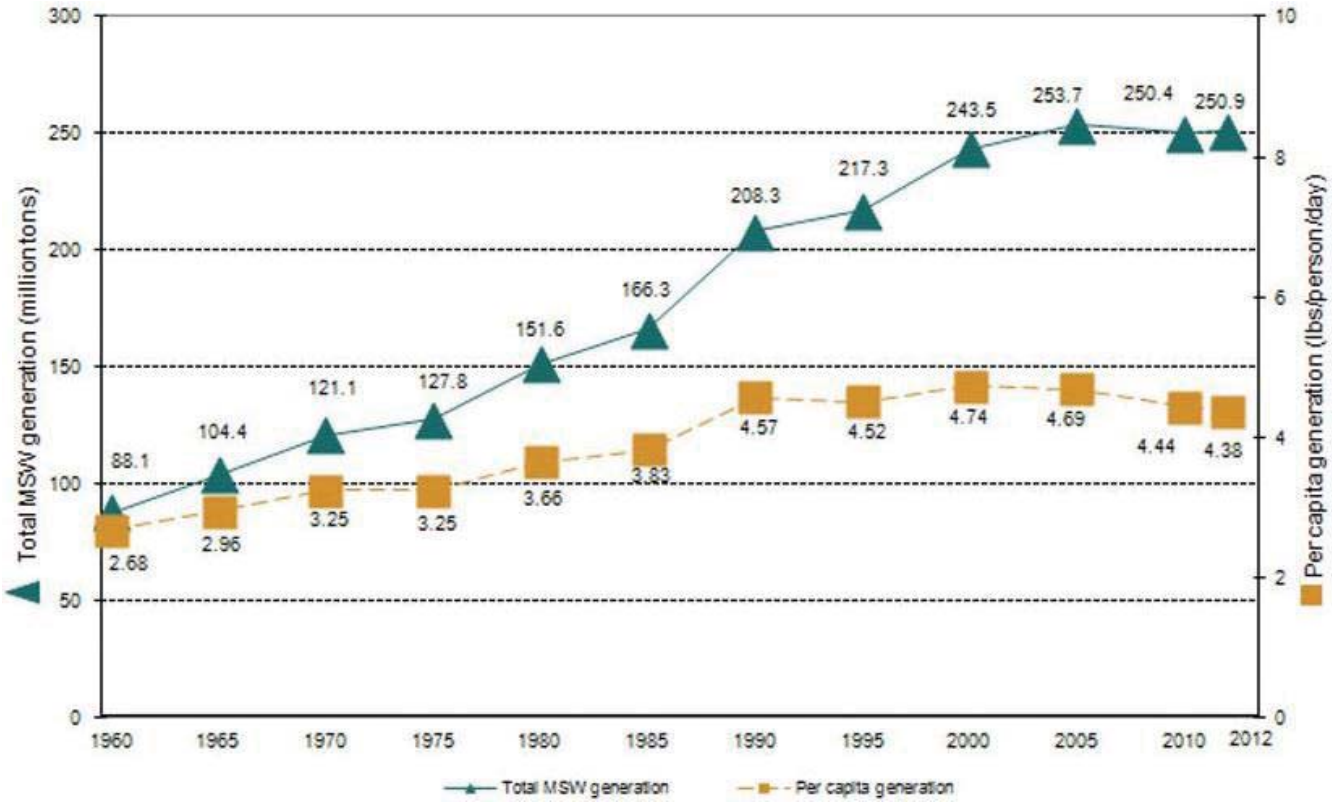
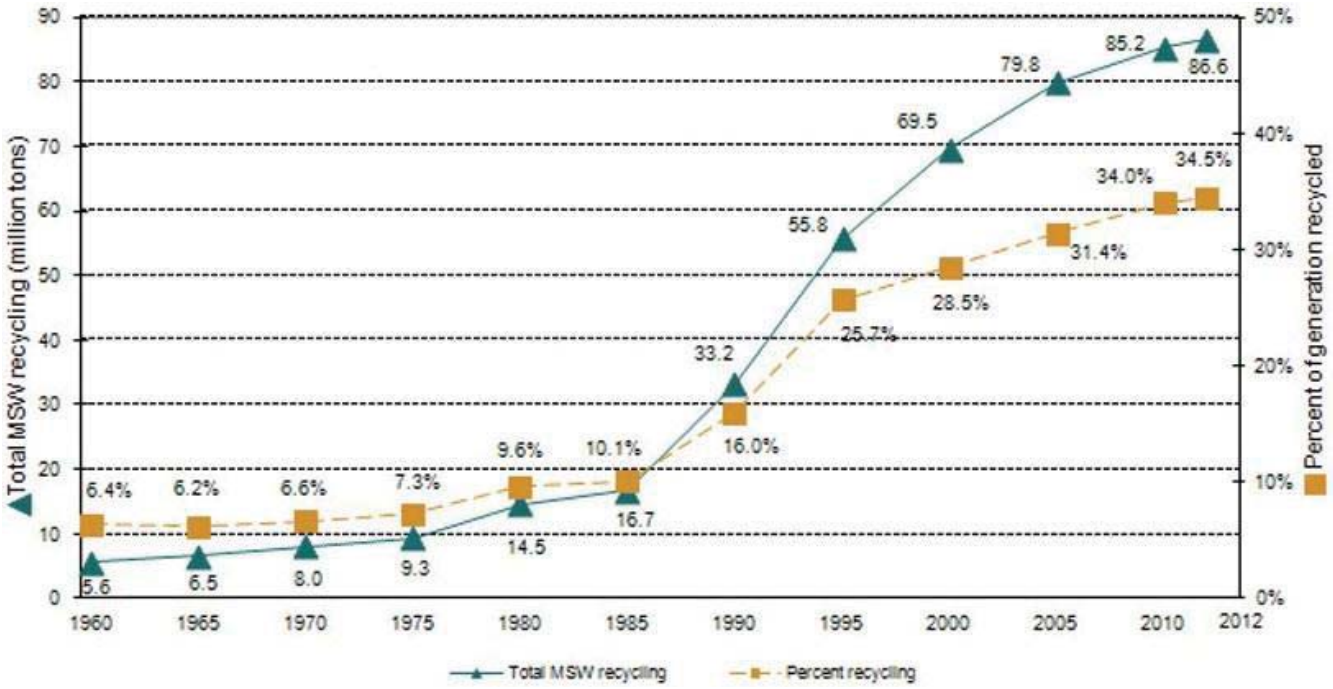


**Figure 5 – MSW Recycling Rates in the U.S.[9]**




### ii. Disposal of used tobacco

Consumers of smokeless products usually dispose the used tobacco 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 amount of disposed material usually depends on the amount of tobacco in the specified smokeless product, which typically constitutes 40%-45% of the product.[10] The agency utilized the historic data of 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 4). Assuming that all smokeless or snuff products that are used in the U.S. 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 the forecasted MSW to be generated in the U.S (Table 2). [11]

[10] Ramström LM. 2000. Snuff - An alternative nicotine delivery system. In: Nicotine and Public Health, eds Ferrence R, Slade J, Room R, and Pope M, 159-178. American Public Health Association.

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

**Table 2 Forecast of Waste Due to Use of Smokeless Tobacco as Compared to Total MSW Forecast in the U.S.[11]**

| Year | Projected Use (Equivalent to Projected Waste) of Smokeless in the U.S. (Tons) | 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 |

**iii. Excretion of other ingredients**

Excretion of the other ingredients of the used smokeless products might enter the sewer system as components in human waste, assuming all ingredients, other than tobacco, were ingested and no ingredients were metabolized. The excreted waste is anticipated to be digested by microbial systems in the home's septic system or treated in POTW.

### *5.3.2 Environmental consequences from disposal following use of the new products*

The agency believes that the disposal of the proposed new products resembles the disposal conditions of the predicate products, provisional products and any other smokeless tobacco products. The waste generated as a result of use of the new 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 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 smokeless products in the U.S. (Confidential Appendix 6).

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. According to the information presented in the SE Reports, the predicate products are not being marketed and the new products will replace the provisional products. In addition, the predicate products and the new products are packed similarly with minor differences related to packaging size of one product (Confidential Appendix 1). To determine the amount of waste from disposal of paper and plastic packaging material, the agency used the projected market volumes in the 1st, 5th and 10th year after the marketing authorization orders are issued for the new products (Confidential Appendix 7). The calculated waste of the cardboard packaging material of the can base of the new loose product is miniscule compared to the projected MSW to be generated in the U.S and 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 all new products, as well as pouch material, is negligible compared to the amount of projected MSW to be generated in the U.S. (Confidential Appendix 7).

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

## 6 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.

## 7 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 is not substantial.

## 8 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 respective 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 predicate product is not on the market and the new products will replace the currently marketed provisional products and the agency does not anticipate the market volume to be changed.

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

## 9 Mitigation

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

## 10 Alternative Actions

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

*Alternative B (Proposed action)*: There is virtually no environmental effect due to the proposed action of authorizing the new products and the associated manufacture, use, and disposal after use of the new tobacco products. Furthermore, the new products will replace the provisional product. Therefore, to issue market authorizations 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.

## 11 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

## 12 List of Appendix

Appendix 1 List of SE Reports and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

Appendix 2 List of SE Report Submission Tracking Number, Names of New, Predicate and Provisional Products, Submission Number and Date of Marketing Provisional Products, and Grandfathered Submission Number and Status Date

Appendix 3 Forecast of U.S. Import of Smokeless and Snuff Tobacco Products

Appendix 4 Forecast of Use of Smokeless Tobacco Products in the U.S.

## 13 List of Confidential Appendix

Confidential Appendix I – Detailed Description of Packaging Components of the New Products as Compared to the Predicate Products

Confidential Appendix 2 – Modifications in Ingredients and Constituents of the New Products as Compared to their Corresponding Predicate Products

Confidential Appendix 3 – Projected Market Volumes in the 1$^{st}$ Year, 5$^{th}$ Year and 10$^{h}$ Year of Marketing the New Products

Confidential Appendix 4 – Projected Market Volumes of the New Products as Compared to the Forecasted U.S. Import of Smokeless and Snuff Tobacco Products

Confidential Appendix 5 – Projected Market Volumes of the New Products as Compared to the Forecasted Use of Smokeless and Snuff Tobacco Products in the U.S.

Confidential Appendix 6 – Projected Waste Due to Use of the New Products

Confidential Appendix 7 – Projected Waste Due to Packaging Components of the New Products

## Appendix 1

## List of SE Reports and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

| Product Name | Original SE Report | Amendments |
|---|---|---|
| General Loose | SE0010524 | SE0010735; SE0010948, SE0011679, SE0011687 and SE001171 |
| General Dry Mint Portion Original Mini | SE0010525 | SE0010735; SE0010948, SE0011679, SE0011687 and SE001171 |
| General Portion Original Large | SE0010526 | SE0010735; SE0010948, SE0011679, SE0011687 and SE001171 |
| General Portion White Large | SE0010532 | SE0010735; SE0010948, SE0011679, SE0011687 and SE001171 |
| General Wintergreen Portion White Large | SE00533 | SE0010735; SE0010948, SE0011679, SE0011687 and SE001171 |

## Appendix2

## List of SE Report Submission Tracking Number, Names of New, Predicate and Provisional Products, Submission Number and Date of Marketing Provisional Products, and Grandfathered Submission Number and Status Date

| STN | Name of New Product | Name of Predicate Product | Name of Provisional Product | Submission # and as-of-Date of Marketing the Provisional Product | Grandfathered Submission # and Status Date |
|---|---|---|---|---|---|
| **SE0010524** | General Loose | General Loose | General Loose | SE0000140; July 23, 2010 | GF1300612; July 8, 2013 |
| **SE0010525** | General Dry Mint Portion Original Mini | Catch Dry Peppermint Portion Original Mini | General Dry Mint Portion Original Mini | SE0000139; March 7, 2011 | GF1300607; July 17, 2013 |
| **SE0010526** | General Portion Original Large | General Portion Original Large | General Portion Original Large | SE0000143; July 22, 2010 | GF1300613; July 24, 2013 |
| **SE0010532** | General Portion White Large | General Portion White Large | General Portion White Large | SE0000144; September 27, 2010 | GF1300614; July 17, 2013 |
| **SE0010533** | General Wintergreen Portion White Large | General Wintergreen Portion White Large | General Wintergreen Portion White Large | SE0000145; September 10, 2010 | GF1300615; July 17, 2013 |

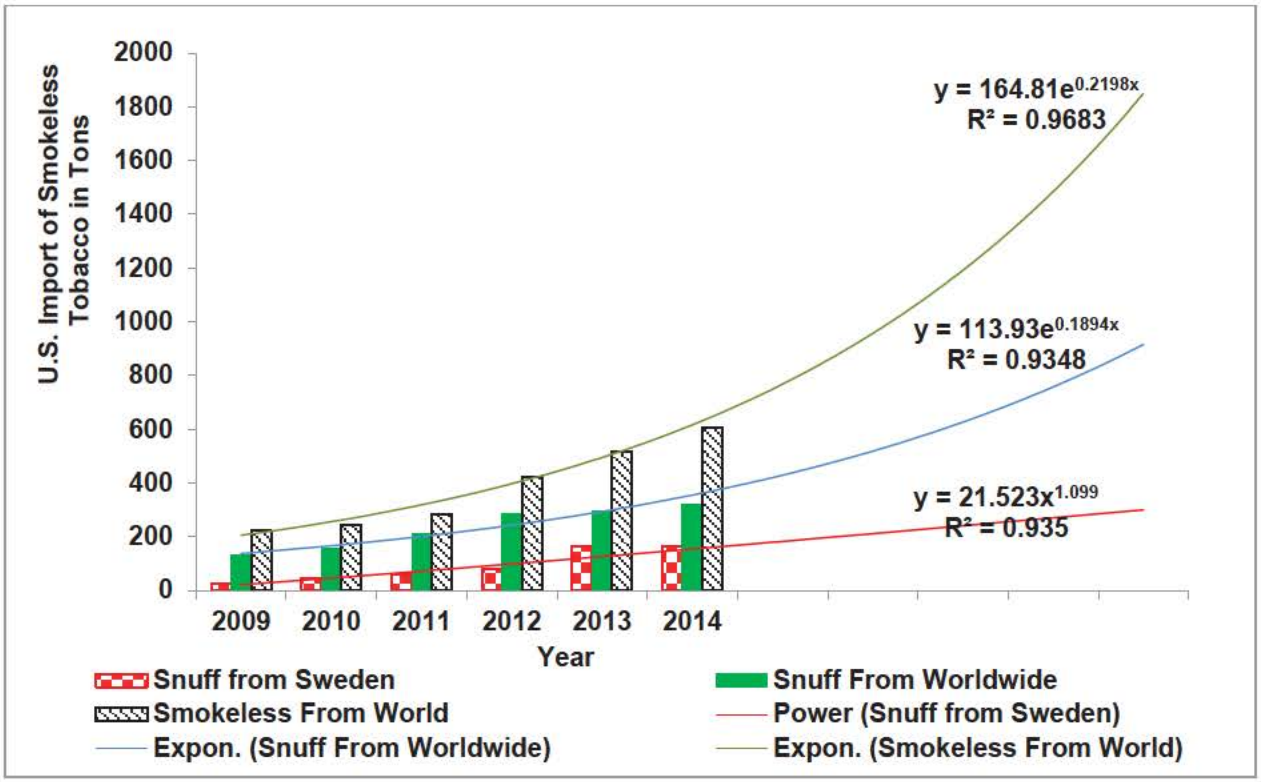
## Appendix 3

### Forecast of U.S. Import of Smokeless and Snuff 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 forecast of U.S. import of snuff and smokeless tobacco from worldwide and Sweden is calculated mathematically (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 [12]**

| Projected Year of Marketing the New Products | 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 |

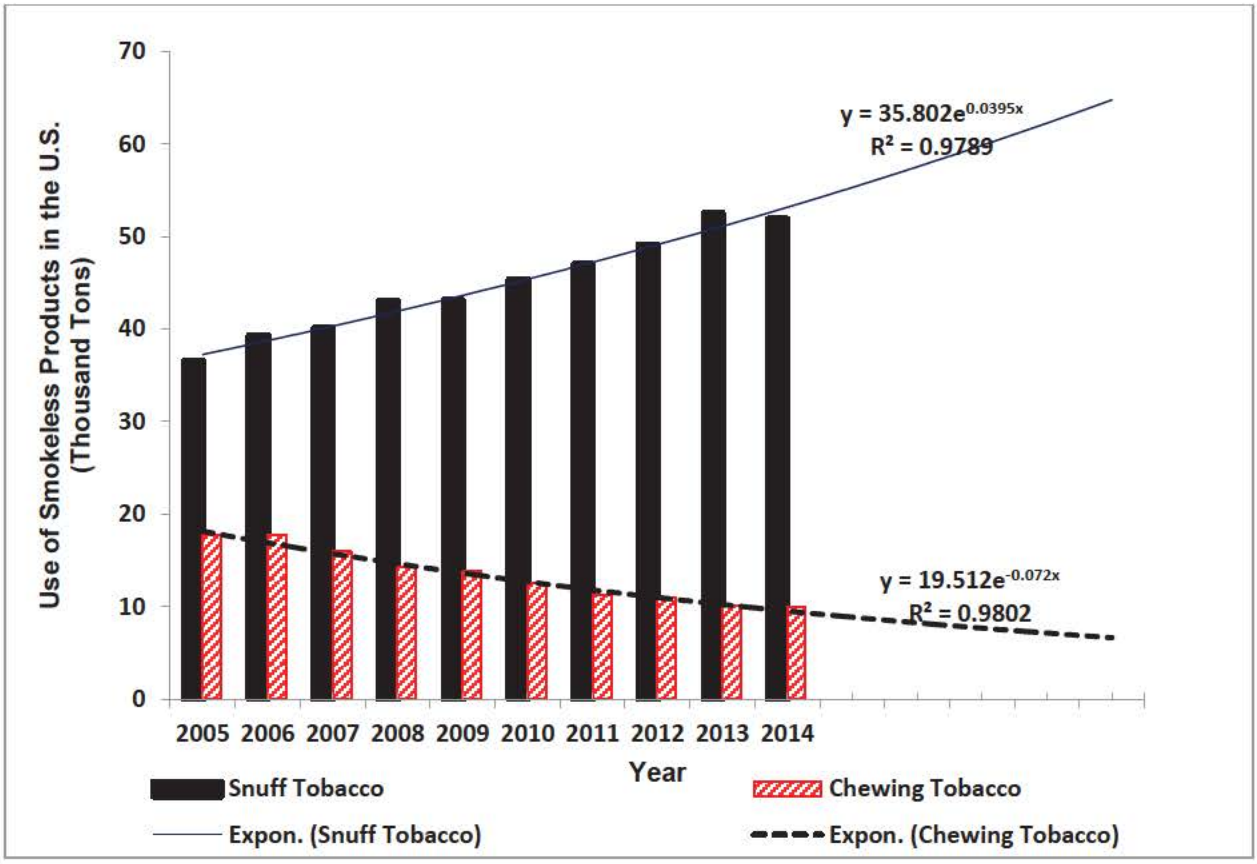
## Appendix 4

### 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 future 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).

Accordingly, the forecast of smokeless and snuff tobacco use in the U.S. is calculated mathematically (Table 4).

**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.[13]**

| 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 as Compared to the Predicate Products

| Component | SE0010524 | | SE0010525 | | SE0010526 | | SE0010532 | | SE0010533 | |
|---|---|---|---|---|---|---|---|---|---|---|
| | New | Predicate | New | Predicate | New | Predicate | New | Predicate | New | Predicate |
| Package Size (gram/Can) | 45 | 50 | 6 | 6 | 24 | 24 | 24 | 24 | 24 | 24 |
| Weight of Portion (gram/pouch) | Loose | Loose | 0.3 | 0.3 | 1 | 1 | 1 | 1 | 1 | 1 |
| Number of Pouches/Can | NA[14] | NA | 20 | 20 | 24 | 24 | 24 | 24 | 24 | 24 |
| Weight of Pouch Material (gram/Portion) | (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 | SE0010524 | | SE0010525 | | SE0010526 | | SE0010532 | | SE0010533 | |
|---|---|---|---|---|---|---|---|---|---|---|
| | New | Predicate | New | Predicate | New | Predicate | New | Predicate | New | Predicate |
| Weight of Can Base (gram/Can) | (b) (4) | | | | | | | | | |
| Weight of Lid (gram/Can) | | | | | | | | | | |
| Weight of Plastic Film (gram/Can) | | | | | | | | | | |

General Loose product (SE0010524) is contained in a waxed cardboard can base with plastic lid. The height of the can base for this product was also reduced as compared to its corresponding predicate product.

The pouched products; "General Dry Mint Portion Original Mini, General Portion Original Large, General Portion White Large, and General Wintergreen Portion White Large" are contained in a round plastic can base with a plastic lid. The plastic can design was modified to provide more space for the used pouch receptacle in the lid. The white pouch fabric is made of (b) (4) , (b) (4) r and (b) (4) . The pouches are arranged in the can of the new product versus a random fill in the predicate products to provide for a more accurate pouch count.

## Confidential Appendix 2

## Modifications in Ingredients and Constituents of the New Products as Compared to the Predicate Products[16] [17] [18] [19]

| STN | Modification | Amount (unit of measurement) | Quantity in the New Product | Quantity in the Predicate Product | Change (%) |
|---|---|---|---|---|---|
| SE0010524 | Ingredients | Tobacco Leaf – (b) (4) (mg/gm) | (b) (4) | | |
| | | Tobacco Leaf – (b) (4) (mg/gm) | | | |
| | | Tobacco Leaf – (b) (4) (mg/gm) | | | |
| | | (b) (4) | | | |
| | Constituents | Nicotine Content (mg/gm) | (b) (4) | | |
| | | Nicotine Free (mg/gm) | | | |
| | | Acetaldehyde (µg/gm) | | | |
| | | Arsenic (µg/gm) | | | |
| | | B[a]P (ng/gm) | | | |

[16] All other modifications in ingredients are at a concentration of less than (b) percent of the total weight of the finished product

[17] Replacing (b) (4) Flavor in the predicate product with (b) (4) Flavor in the new product resulted in the addition of five ingredients (b) (4) - (b) ) and the elimination of eight ingredients, as well as some increases or decreases in the quantities of other flavorings

[18] NP= Not present

[19] NA= Not applicable

| STN | Modification | Amount (unit of measurement) | Quantity in the New Product | Quantity in the Predicate Product | Change (%) |
|---|---|---|---|---|---|
| | | Cadmium (µg/gm) | (b) (4) | | |
| | | Crotonaldehyde (µg/gm) | | | |
| | | Formaldehyde (µg/gm) | | | |
| | | NNN (µg/gm) | | | |
| | | NNK (µg/gm) | | | |
| **SE0010525** | Ingredient | Tobacco Leaf – (b) (4) (b) (4) (mg/gm) | (b) (4) | | |
| | | Tobacco Leaf – (b) (4) (b) (4) (mg/gm) | | | |
| | | Tobacco Leaf – (b) (4) (mg/gm) | | | |
| | | (b) (4) | | | |
| | Constituents | Acetaldehyde (µg/gm) | (b) (4) | | |
| | | Nicotine Content (mg/gm) | | | |
| | | B[a]P (ng/gm) | | | |
| | | Cadmium (µg/gm) | | | |
| | | Crotonaldehyde (µg/gm) | | | |
| | | Formaldehyde (µg/gm) | | | |
| | | NNN (µg/gm) | | | |
| | | NNK (µg/gm) | | | |
| **SE0010526** | Ingredients | Tobacco Leaf – (b) (4) (b) (4) (mg/gm) | | | |
| | | Tobacco Leaf – (b) (4) (b) (4) (mg/gm) | | | |
| | | Tobacco Leaf – (b) (4) (mg/gm) | | | |
| | | (b) (4) Flavor (mg/gm) | | | |

| STN | Modification | Amount (unit of measurement) | Quantity in the New Product | Quantity in the Predicate Product | Change (%) |
|---|---|---|---|---|---|
| | | (b) (4) | | | |
| | Constituents | Nicotine Content (mg/gm) | | | |
| | | Nicotine Free (mg/gm) | | | |
| | | Acetaldehyde (µg/gm) | | | |
| | | Arsenic (µg/gm) | | | |
| | | B[a]P (ng/gm) | | | |
| | | Cadmium (µg/gm) | | | |
| | | Crotonaldehyde (µg/gm) | | | |
| | | Formaldehyde (µg/gm) | | | |
| | | NNN (µg/gm) | | | |
| | | NNK (µg/gm) | | | |
| **SE0010532** | Ingredients | Tobacco Leaf – (b) (4) (mg/gm) | (b) (4) | | |
| | | Tobacco Leaf – (b) (4) (mg/gm) | | | |
| | | Tobacco Leaf – (b) (4) (mg/gm) | | | |
| | | (b) (4) | | | |
| | Constituents | Nicotine Content (mg/gm) | | | |
| | | Nicotine Free (mg/gm) | | | |
| | | Acetaldehyde (µg/gm) | | | |
| | | Arsenic (µg/gm) | | | |

| STN | Modification | Amount (unit of measurement) | Quantity in the New Product | Quantity in the Predicate Product | Change (%) |
|---|---|---|---|---|---|
| | | B[a]P (ng/gm) | (b) (4) | | |
| | | Cadmium (µg/gm) | | | |
| | | Crotonaldehyde (µg/gm) | | | |
| | | Formaldehyde (µg/gm) | | | |
| | | NNN (µg/gm) | | | |
| | | NNK (µg/gm) | | | |
| **SE0010533** | Ingredients | Tobacco Leaf – (b) (4) (b) (4) (mg/gm) | (b) (4) | | |
| | | Tobacco Leaf – (b) (4) (b) (4) (mg/gm) | | | |
| | | Tobacco Leaf – (b) (4) (mg/gm) | | | |
| | | (b) (4) | | | |
| | Constituents | Nicotine Content (mg/gm) | (b) (4) | | |
| | | Nicotine Free (mg/gm) | | | |
| | | Acetaldehyde (µg/gm) | | | |
| | | B[a]P (ng/gm) | | | |
| | | Cadmium (µg/gm) | | | |
| | | Crotonaldehyde (µg/gm) | | | |
| | | Formaldehyde (µg/gm) | | | |
| | | NNN (µg/gm) | | | |
| | | NNK (µg/gm) | | | |

## Confidential Appendix 3

## Projected Market Volumes in the 1st Year, 5th Year and 10th Year 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 of market volume (Tons)

B= Projected number of manufactured cans

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

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

| STN | Projected Year of Marketing the New Products [a] | Projected Market Volume (# of Cans) | Weight of Product (gram/ Can) | Projected Market Volume (Grams) | Projected Market Volume (Tons) |
|---|---|---|---|---|---|
| SE0010524 | 1st Year | (b) (4) | | | |
| | 5th Year | | | | |
| | 10th Year | | | | |
| SE0010525 | 1st Year | | | | |
| | 5th Year | | | | |
| | 10th Year | | | | |
| SE0010526 | 1st Year | | | | |
| | 5th Year | | | | |
| | 10th Year | | | | |
| SE0010532 | 1st Year | | | | |
| | 5th Year | | | | |

| STN | Projected Year of Marketing the New Products [a] | Projected Market Volume (# of Cans) | Weight of Product (gram/ Can) | Projected Market Volume (Grams) | Projected Market Volume (Tons) |
|---|---|---|---|---|---|
| | 10th Year | (b) (4) | | | |
| SE0010533 | 1st Year | | | | |
| | 5th Year | | | | |
| | 10th Year | | | | |

[a] In the EAs contained in amendment SE0010948, dated March 16, 2015, the applicant provided projections of market volumes in the 1st year and 2nd year of marketing the new products after authorization is issued. Per FDA request dated April 14, 2015, the applicant provided projections of market volumes in the 1st year, 5th year and 10th year of marketing the new products in amendment SE0011687 quoting the same volumes for the 1st year that were presented in SE0010948 but specified the years 2019 and 2024 for 5th year and 10th year projections, respectively. For the purposes of this PEA, the projected market volumes provided by the applicant were compared to the forecasted volumes of 2016, 2020, and 2025.

A summary of the projected market volumes of the new products is presented in Table 5 below.

**Table 5 Summary of Market Volume Projections in Tons**

| STN | 1st Year Market Volume Projections | 5th Year | 10th Year |
|---|---|---|---|
| SE0010524 | (b) (4) | | |
| SE0010525 | | | |
| SE0010526 | | | |
| SE0010532 | | | |
| SE0010533 | | | |
| Total (Tons) | | | |

**Confidential Appendix 4**

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

| STN | Year | Projected Market Volume (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 U.S. Import of Snuff from Sweden (%) |
|---|---|---|---|---|---|---|---|---|
| **SE0010524** | 1st Year | (b) (4) | | | | | | |
| | 5th Year | | | | | | | |
| | 10th Year | | | | | | | |
| **SE0010525** | 1st Year | | | | | | | |
| | 5th Year | | | | | | | |
| | 10th Year | | | | | | | |
| **SE0010526** | 1st Year | | | | | | | |
| | 5th Year | | | | | | | |
| | 10th Year | | | | | | | |
| **SE0010532** | 1st Year | | | | | | | |
| | 5th Year | | | | | | | |
| | 10th Year | | | | | | | |

| STN | Year | Projected Market Volume (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 U.S. Import of Snuff from Sweden (%) |
|---|---|---|---|---|---|---|---|---|
| SE0010533 | 1st Year | (b) (4) | | | | | | |
| | 5th Year | | | | | | | |
| | 10th Year | | | | | | | |

**Confidential Appendix 5**

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

| STN | Projected Year of Marketing the New Products | Projected Market Volume of the New Product (Tons) | Forecast of Use of Smokeless in U.S. (Tons) | Percent of Projected Market Volume to Forecasted Use of Smokeless in U.S. (%) | Forecast of Use of Snuff in U.S. (Tons) | Percent of Projected Market Volume to Forecasted Use of Snuff in U.S. (%) |
|---|---|---|---|---|---|---|
| **SE0010524** | 1st Year | (b) (4) | | | | |
| | 5th Year | | | | | |
| | 10th Year | | | | | |
| **SE0010525** | 1st Year | | | | | |
| | 5th Year | | | | | |
| | 10th Year | | | | | |
| **SE0010526** | 1st Year | | | | | |
| | 5th Year | | | | | |
| | 10th Year | | | | | |
| **SE0010532** | 1st Year | | | | | |
| | 5th Year | | | | | |
| | 10th Year | | | | | |
| **SE0010533** | 1st Year | | | | | |

| STN | Projected Year of Marketing the New Products | Projected Market Volume of the New Product (Tons) | Forecast of Use of Smokeless in U.S. (Tons) | Percent of Projected Market Volume to Forecasted Use of Smokeless in U.S. (%) | Forecast of Use of Snuff in U.S. (Tons) | Percent of Projected Market Volume to Forecasted Use of Snuff in U.S. (%) |
|---|---|---|---|---|---|---|
| | 5th Year | (b) (4) | | | | |
| | 10th Year | | | | | |

The total projected market volume of the new products in the 1st year, 5th year, and 10th of issuance of the market authorization orders are a fraction of the forecasted snuff use in the same time frame.

## Confidential Appendix 6

## Projected Waste Due to Use of the New Products

The projected waste due to use of the finished product is the weight of the product minus the packaging components. Assuming that the entire product is disposed of as waste in the worst case scenario, the agency estimated the waste in tons of used product as follows:

A= B x C x D, where

A= Projected waste of disposed product (tons)

B= Projected number of manufactured cans

C= Weight of product in each can (grams/can)

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

| STN | 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 Used in the U.S. (%) | Percent of Projected Waste to Total Forecasted Waste of Snuff Used in the U.S. |
|---|---|---|---|---|---|---|
| **SE0010524** | 1st Year | (b) (4) | | | | |
| | 5th Year | | | | | |
| | 10th Year | | | | | |
| **SE0010525** | 1st Year | | | | | |
| | 5th Year | | | | | |
| | 10th Year | | | | | |
| **SE0010526** | 1st Year | | | | | |
| | 5th Year | | | | | |

| STN | 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 Used in the U.S. (%) | Percent of Projected Waste to Total Forecasted Waste of Snuff Used in the U.S. |
|---|---|---|---|---|---|---|
| | 10th Year | (b) (4) | | | | |
| SE0010532 | 1st Year | | | | | |
| | 5th Year | | | | | |
| | 10th Year | | | | | |
| SE0010533 | 1st Year | | | | | |
| | 5th Year | | | | | |
| | 10th Year | | | | | |

Assuming that the entire used products will be disposed of, the cumulative projected waste of new products in the 1st year, 5th year, and 10th year of marketing is (b) (4) , and (b) tons, respectively; a small fraction of the amount of forecast waste due to use of smokeless or snuff tobacco products in the U.S (See also Table 2 of this PEA).

## Confidential Appendix 7

## Projected Waste Due to Packaging Components of the New Products

The agency estimated the projected waste (in tons) of the 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 number of manufactured cans

C= Weight of the packaging component (grams/can)

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

| STN | 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 (Tons) |
|---|---|---|---|---|---|---|---|---|
| SE0010524 | 1st Year | (b) (4) | | | | | | |
| | 5th Year | | | | | | | |
| | 10th Year | | | | | | | |

| STN | Year | Projected Market Volume (# of Cans) | Weight of Plastic Can (Base & Lid) (gm/Can) | Projected Plastic Waste (Tons) | Weight of Shrink film (gram/Can) | Projected Film Waste (Tons) | Weight of Fabric Pouch (gram/Can) | Projected Pouch Fabric Waste (Tons) |
|---|---|---|---|---|---|---|---|---|
| SE0010525 | 1st Year | (b) (4) | | | | | | |
| | 5th Year | | | | | | | |

| STN | Year | Projected Market Volume (# of Cans) | Weight of Plastic Can (Base & Lid) (gm/Can) | Projected Plastic Waste (Tons) | Weight of Shrink film (gram/Can) | Projected Film Waste (Tons) | Weight of Fabric Pouch (gram/Can) | Projected Pouch Fabric Waste (Tons) |
|---|---|---|---|---|---|---|---|---|
| | 10th Year | (b) (4) | | | | | | |
| SE0010526 | 1st Year | | | | | | | |
| | 5th Year | | | | | | | |
| | 10th Year | | | | | | | |
| SE0010532 | 1st Year | | | | | | | |
| | 5th Year | | | | | | | |
| | 10th Year | | | | | | | |
| SE0010533 | 1st Year | | | | | | | |
| | 5th Year | | | | | | | |
| | 10th Year | | | | | | | |

A summary of the cumulative weight of packaging material is presented in Table 6 below

**Table 6 Cumulative Projected Waste of Packaging Material Generated From Use of the New Products**

| Projected Year of Marketing | Waste of Cardboard (Tons) | Waste of Polypropylene Plastic (Tons) | Waste of Fabric Pouch (Tons) |
|---|---|---|---|
| 1st Year | (b) (4) | | |
| 5th Year | | | |
| 10th Year | | | |

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