

**Programmatic Environmental Assessment for Marketing  
Orders for U.S. Smokeless Tobacco Company LLC's  
"Copenhagen Bold Wintergreen Flavor Packs (1.55g)" and  
"Copenhagen Bold Wintergreen Flavor Packs (2.0g)"**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

June 4, 2018

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This programmatic environmental assessment (PEA) is for the marketing orders for two smokeless tobacco moist snuff products manufactured by U.S. Smokeless Tobacco Company LLC. Information presented in the PEA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This PEA has been prepared in accordance to 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

#### **1. Name of Applicant**

U.S. Smokeless Tobacco Company LLC

#### **2. Address**

2325 Bells Road  
Richmond, VA 23235

#### **3. Manufacturer**

U.S. Smokeless Tobacco Company LLC

#### **4. Description of Proposed Actions**

These proposed actions are for FDA to issue marketing orders under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of the smokeless tobacco, Copenhagen Bold Wintergreen Flavor Packs (1.55g) and Copenhagen Bold Wintergreen Flavor Packs (2.0g), into interstate commerce for commercial distribution in the United States. The marketing orders are based on the finding that these new products are substantially equivalent to a single predicate product that was on the market as of February 15, 2007. The applicant intends to market the new and predicate products simultaneously after receiving marketing orders for the new products.

##### **4.1 Requested Actions**

Orders finding the listed tobacco products are substantially equivalent to the predicate product.

##### **4.2 Need for Actions**

U.S. Smokeless Tobacco Company LLC wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the United States. The new products have different characteristics than the predicate product, but the different characteristics do not raise different questions of public health (sec. 910(a)(3)(A)(ii)). After considering the substantial equivalence (SE) reports (SE0012626, SE0012633), the Agency shall issue marketing orders pursuant to section 910(a)(2) of the FD&C Act when finding the new products to be substantially equivalent to the predicate product.

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

###### **4.3.1 Type of Tobacco Product**

Smokeless tobacco product; loose, moist snuff

#### **4.3.2 Product Names and Their Original Submission Tracking Numbers (STNs)**

The names of the new products are listed below, along with the original submission tracking numbers (STNs) and the name of the single predicate product. See Appendix 1 for additional STNs associated with the new products and the predicate product.

STN	New Product	Predicate Product
SE0012626	Copenhagen Bold Wintergreen Flavor Packs (1.55g)	Skoal Pouches Wintergreen
SE0012633	Copenhagen Bold Wintergreen Flavor Packs (2.0g)	Skoal Pouches Wintergreen

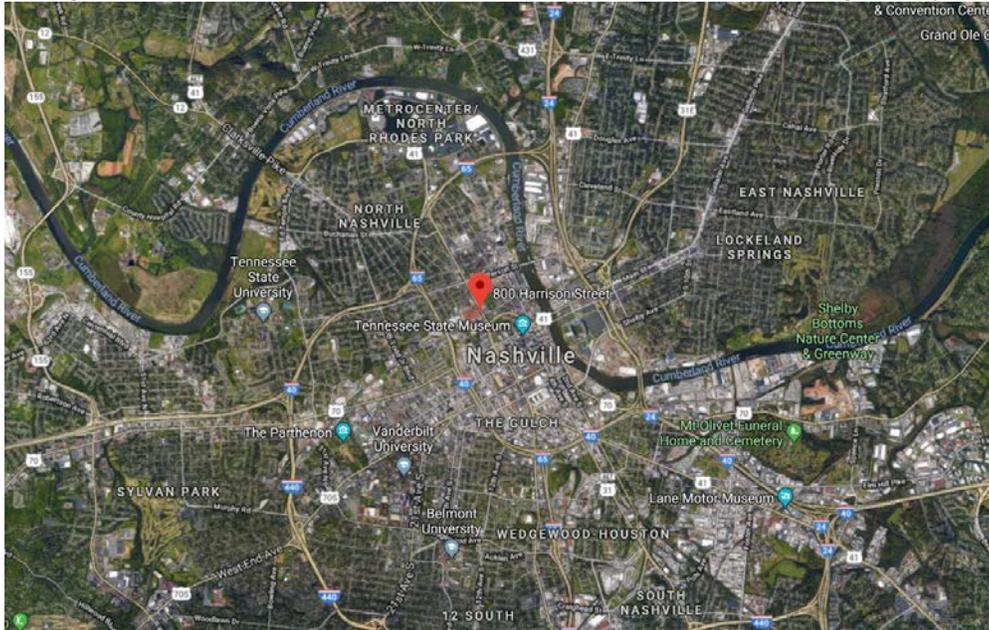
#### **4.3.3 Description of the Product Package**

The new products are packaged in individual cans that are shrink-wrapped into log rolls of five cans per roll and placed 18 log rolls to a shipping case. The new products may be purchased at retail in individual cans or in five-can log rolls. Details of the package components and weights of each packaging component for the new products are described in Confidential Appendix 5.

#### **4.3.4 Location of Manufacturing**

The manufacturer of the moist snuff smokeless tobacco is located at 800 Harrison Street, Nashville, TN 37203 (Figure 1).

**Figure 1.** Location of the Smokeless Tobacco Product Manufacturing Facility<sup>1</sup>



#### **4.3.5 Location of Use**

U.S. Smokeless Tobacco Company, LLC intends to distribute and sell the new tobacco products to consumers in the United States.

#### **4.3.6 Location of Disposal**

Once used, the new tobacco products will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as the predicate product and any other loose, moist snuff smokeless tobacco products. Disposal of the packaging materials will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates that the distribution of waste from disposal will correspond to the pattern of the product use.

#### **4.4 Modification(s) Identified as Compared to the Predicate Products**

The new products and the predicate product differ in composition, ingredients, and tobacco and nicotine content. Details of product and packaging changes are described in Confidential Appendix 1.

### **5. Potential Environmental Impacts Due to the Proposed Actions**

#### **5.1 Potential Environmental Impacts Due to Manufacturing the New Products**

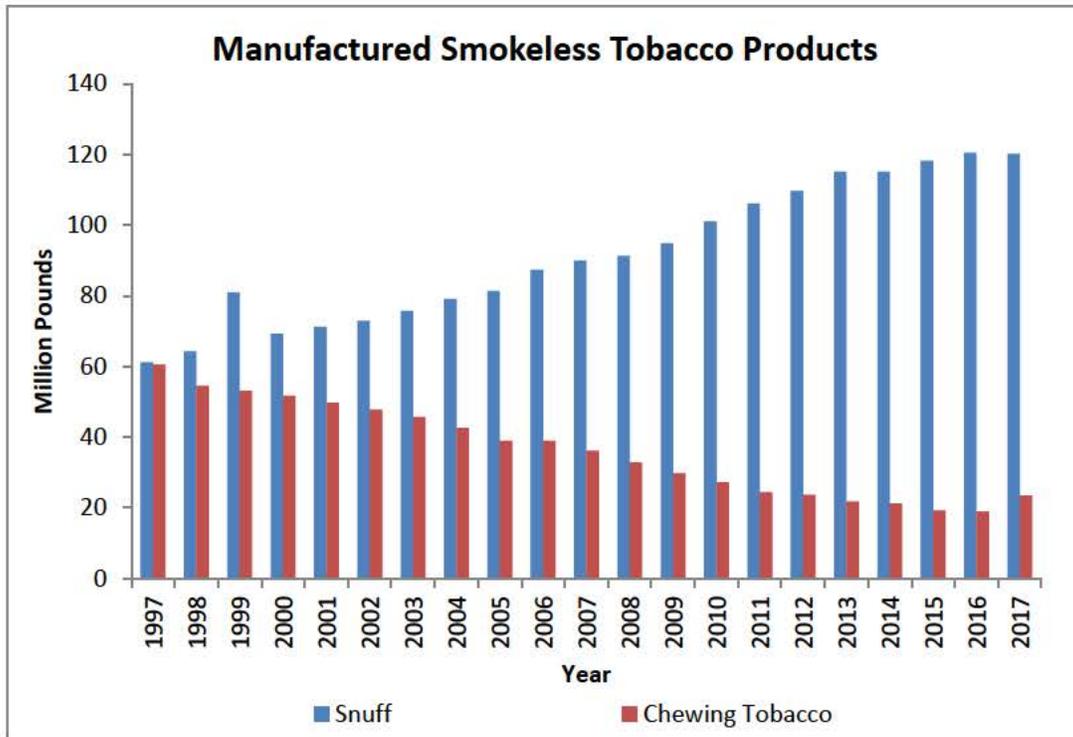
The Tobacco Control Act defines smokeless tobacco products as any tobacco products that consist of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity. As of

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<sup>1</sup> Manufacturer address via Google Map. Accessed February 20, 2018.

January 2018, a total of 2,524 tobacco establishments are registered under 915(c) of the FD&C Act.<sup>2</sup> According to Tobacco Statistical Release reports of the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), the production of chewing tobacco decreased from 61 million pounds in 1997 to 23 million pounds in 2017, whereas snuff production increased from 61 million pounds in 1997 to 120 million pounds in 2017 (Figure 2).<sup>3</sup> The combined manufacture of total smokeless products has remained relatively constant with a slight increase from 122 million pounds in 1997 to 143.7 million pounds in 2017 (Figure 3).

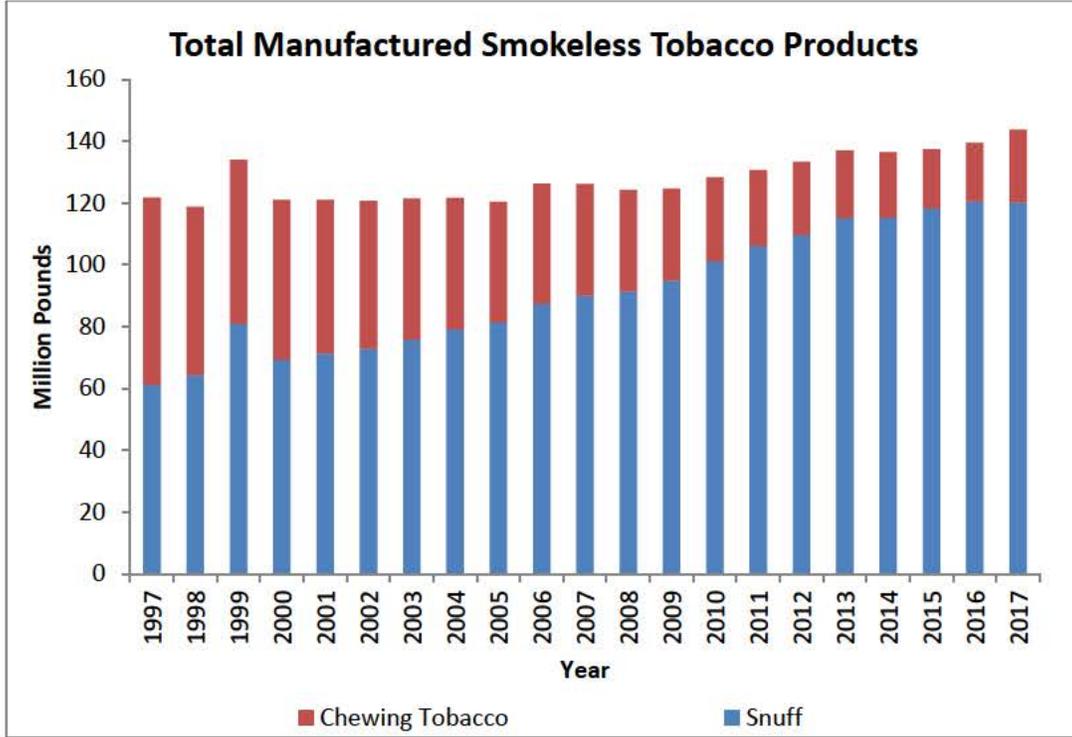
**Figure 2. Manufactured Snuff and Chewing Tobacco in the United States in 1997-2017**



<sup>2</sup> Based on FDA’s Establishment Registration & Tobacco Product Listing Database. Available at <https://www.accessdata.fda.gov/scripts/ctpocerl/index.cfm?action=main.home>. Accessed March 18, 2018.

<sup>3</sup> U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 18, 2018.

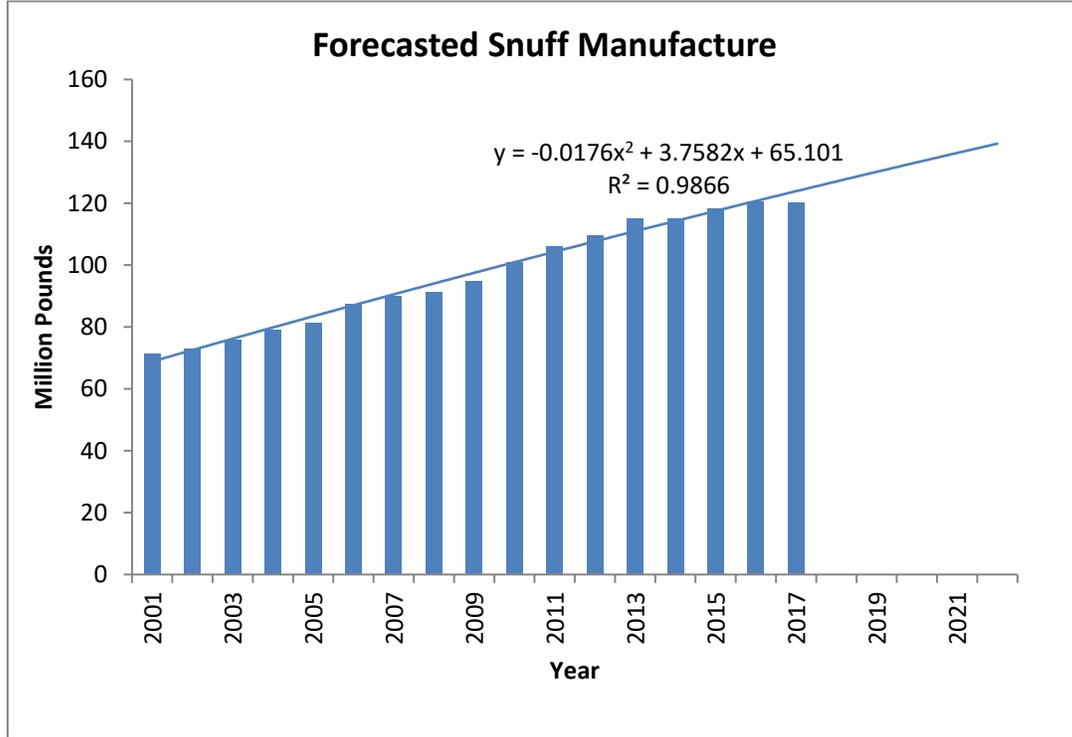
Figure 3. Total Manufactured Smokeless Tobacco in the United States in 1997-2017



The applicant provided the first- and fifth-year market volume projections for the new products (Confidential Appendix 2). To evaluate the environmental impact of the proposed actions due to manufacturing the new products, historical data regarding the manufacture of smokeless tobacco products in the United States from 2001 to 2017 was used to forecast the manufacture of snuff. This was achieved by using best-fit 2<sup>nd</sup> order polynomial trend lines with the R<sup>2</sup> values of 0.986 and 0.976, respectively, for snuff and chewing tobacco.<sup>4</sup> Accordingly, the forecasted amount snuff to be manufactured in the United States is estimated to be 124 million pounds in 2018 and 136 million pounds in 2022 (Figure 4).

<sup>4</sup> Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed on March 18, 2018. The first and fifth year projected market volumes are assumed to be 2018 and 2022, respectively.

Figure 4. Forecast of Snuff Manufactured in the United States



Comparing the projected market volumes of the new products with the forecasted market volume of snuff in 2018 and 2022, the projected market volumes of the new products is a small fraction of the total forecasted market volume for snuff in 2018 and 2022 (Figure 4 and Confidential Appendices 2 and 3). Additionally, the applicant stated that manufacturing the new products would not result in an increase in overall permitted manufacturing capacity at the manufacturing facility, and that any net increase in production volume associated with the new products would be nominal. Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new products. The applicant stated that the manufacturing facility does not dispose of waste on-site, and all waste generated from manufacturing the new products will be accommodated by existing waste management and storage practices. The applicant also stated that the nature of the waste generated from manufacturing the new products is not expected to change and therefore no additional disposal resources (e.g., landfills or recycling centers) are anticipated.

The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available. Per TRI database, in 2016, the U.S. Smokeless Tobacco Company Nashville facility released 154 pounds of nicotine and nicotine salts to the air and 68,479 pounds of nicotine and nicotine salts were transferred off-site for landfill disposal and waste management.

The applicant stated that manufacturing the new products will not result in emissions of new compounds or increases in the current emissions due to the predicate or other smokeless tobacco products. Additionally, the applicant stated that no material changes in solid waste generation are expected from manufacturing the new products. Furthermore, the applicant stated that manufacturing the new products would not result in changes in wastewater discharges from the manufacturing facility

or require additional environmental controls. The applicant also stated that the facility is in compliance with current federal and state air and wastewater permits, and that manufacturing the new products would not result in revised or new permits.

## 5.2 Potential Environmental Impacts Due to Use of the New Tobacco Products

According to the TTB Statistical Release reports, the use of snuff in the United States increased from 61 million pounds in 1997 to 119 million pounds in 2017 (Figure 5) (U.S. Dept of Treasury Alcohol and Tobacco Tax and Trade Bureau, 2018).

To evaluate the environmental impact of the proposed actions due to the use of the new products, the Agency analyzed historical use data for 2001-2017 to forecast the future use of snuff in the United States. This was achieved by using best-fit 2<sup>nd</sup> order polynomial trend lines with the R<sup>2</sup> values of 0.987 and 0.992, respectively, for snuff and chewing tobacco.<sup>5</sup> Accordingly, the forecasted amount of snuff to be used in the United States is estimated to be 122.5 million pounds in 2018 and 133.5 million pounds in 2022 (Figure 6).

Figure 5. Consumption of Snuff Tobacco in the United States in 1997-2017

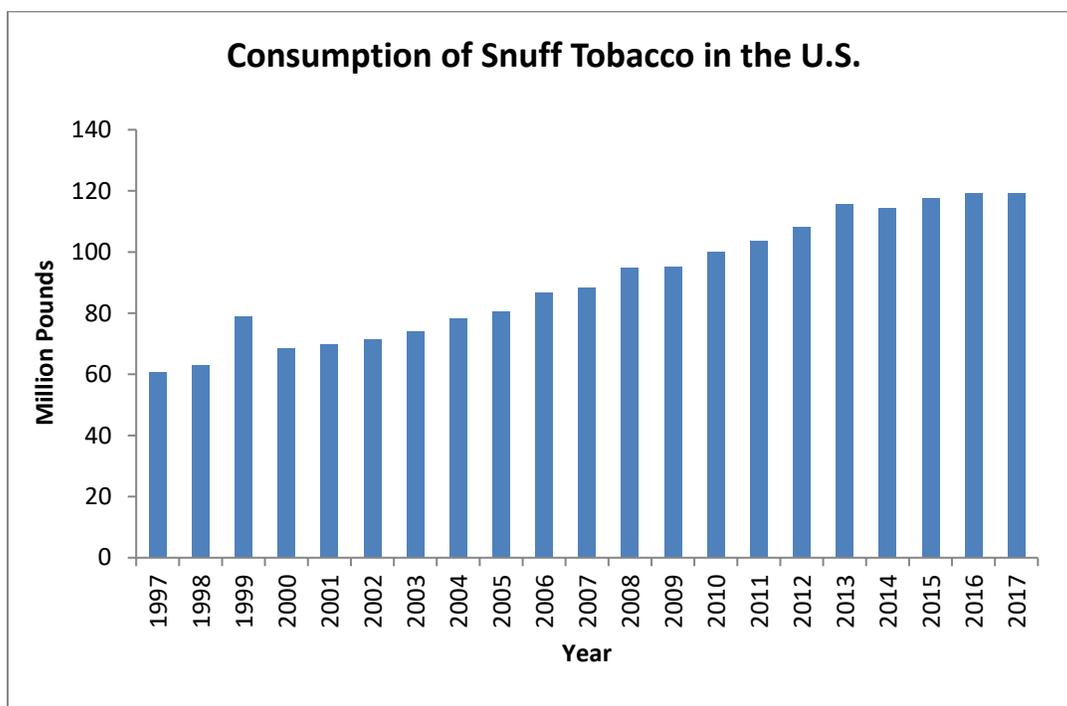
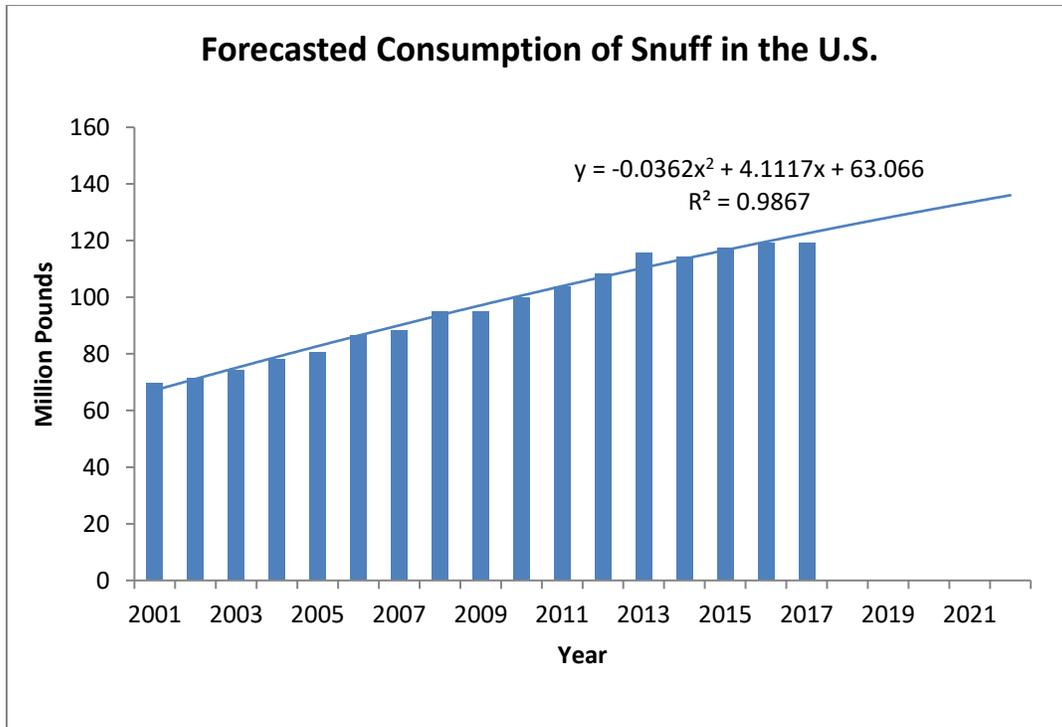


Figure 6. Forecasted Consumption of Snuff in the United States

<sup>5</sup> Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed on January 9, 2018. Note: 2017 annual TTB values have not been released. Since the SE Report was received in 2017, the first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.



Because the new products are expected to compete with similar smokeless tobacco products on the market, the Agency anticipates minimal or no net increase in the use of all smokeless tobacco products (Confidential Appendix 4). Additionally, the new products are used in the same manner as the predicate product and other moist snuff products. Subsequently, the Agency does not anticipate new substances to be released into the environment from the use of the new smokeless tobacco products, relative to the substances released by similar tobacco products already on the market.

### 5.3 Potential Environmental Impacts Due to Disposal of the New Tobacco Products

The environmental consequences resulting from the disposal of smokeless tobacco products are due to a) disposal of packaging material, b) discarding of the used smokeless tobacco products, and c) users' excretion of ingredients other than tobacco in smokeless products.

#### 5.3.1 Disposal of Packaging Material

Disposal of the packaging materials would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the United States, including details about disposal of materials comparable to those used in smokeless tobacco products, can be informative about the disposal of packaging materials associated with smokeless tobacco products. In 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the United States, and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 7 and 8). Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), out of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW generated, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with

energy recovery. Of the total metal MSW generated, specifically steel at 17.69 million tons, 5.84 million tons (33.0%) was recycled, 9.83 million tons (55.6%) was disposed of in landfills, and 2.02 million tons (11.4%) was combusted with energy recovery. Of the total plastic MSW generated at 33.25 million tons, 3.17 million tons (9.5%) was recycled, 25.10 million tons (75.5%) was disposed of in landfills, and 4.98 million tons (15.0%) was combusted with energy recovery. On average, 4.4 pounds per person of waste was generated, of which 2.1 pounds was recycled, composted, or combusted for energy recovery in the United States in 2014 (U.S. Environmental Protection Agency, 2016).

**Figure 7. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014**

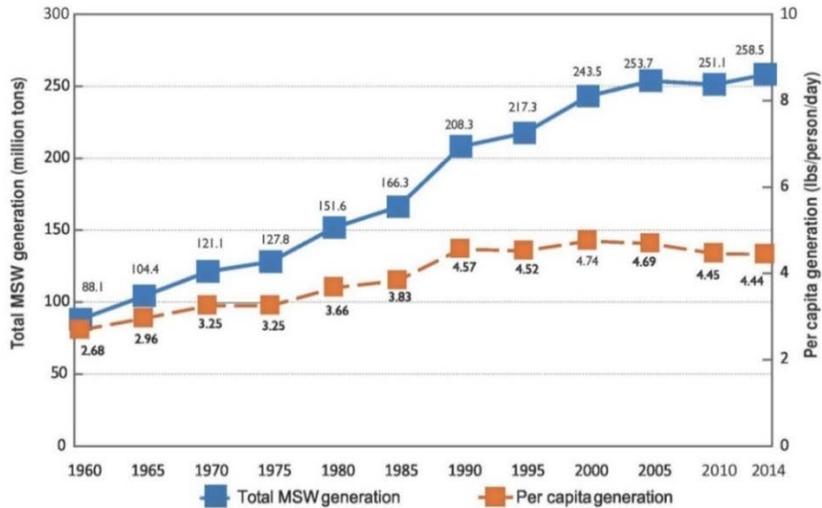


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

**Figure 8. MSW Recycling Rates in the United States, 1960-2014**

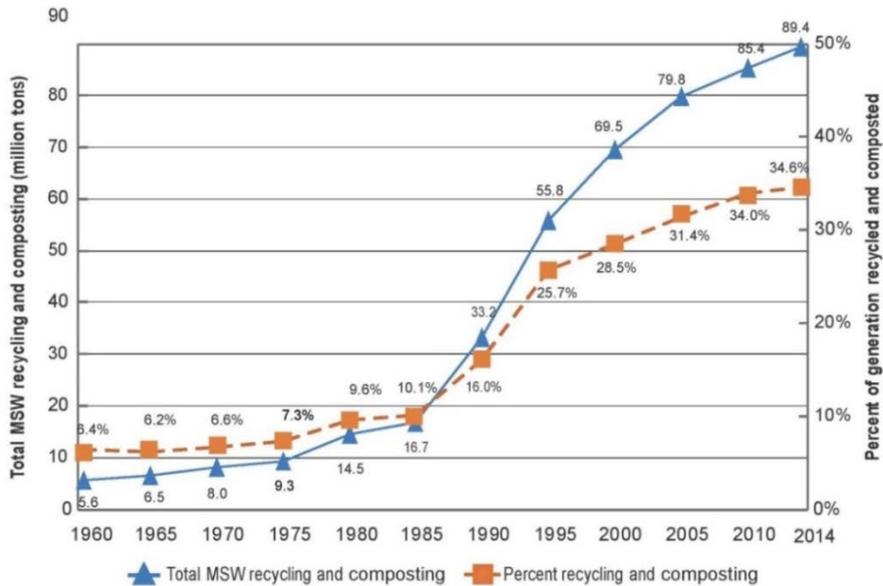


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the packaging materials associated with the new products will be to the same as the disposal conditions of similar smokeless tobacco products that are currently being

marketed. After using the new products, users may recycle or dispose of the packaging material as MSW or litter.

To determine the amount of waste due to disposal of the packaging material, the Agency used the projected market volumes in the first and fifth years after issuance of marketing orders for the new products. The calculated waste of the packaging materials of the new products were determined to be miniscule compared to the forecasted MSW to be generated in the United States (Confidential Appendix 5).

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

### 5.3.2 Discarding of the Used Smokeless Tobacco Products

Used smokeless tobacco products are usually disposed of in MSW landfills or as litter. When discarded as litter, the used product is likely to move by run-off to the ocean. When discarded as MSW, the tobacco would enter landfills. The Agency utilized the historical data for use of smokeless tobacco products in the United States to forecast the future use of smokeless products and calculate the projected tobacco waste accordingly (Figures 5 and 6 in Section 5.2). If all used smokeless products are disposed of as MSW, the estimated waste of used smokeless is a miniscule fraction of a percent of the total 258.46 million tons) of projected MSW to be generated in the United States (Table 1) (U.S. Environmental Protection Agency, 2016).

**Table 1. Forecast of Waste Generated from Used Smokeless Tobacco Products as Compared to Total MSW Forecast in the United States**

Year*	Total U.S. Smokeless Tobacco Products (million pounds)	Total Smokeless Tobacco Products as a Percent of Total MSW in the United States		
2017	137.6	0.0266%		
First Year (2018)	140.5	0.0272%		
Fifth Year (2022)	148.2	0.0287%		

\*The first and fifth years of marketing are assumed to be 2018 and 2022.

Introducing the new products into the U.S. market is not expected to increase the nationwide use of smokeless tobacco; instead, they would compete for market share with existing similar tobacco products. Therefore, marketing orders for the new products are not expected to affect the overall level of smokeless tobacco waste in the United States.

### 5.3.3 Users' Excretion of Ingredients other than Tobacco in Smokeless Products

In addition to the disposal of the products in MSW or as litter, chemicals, non-tobacco ingredients, or their metabolites, can be excreted by the user into the waste stream. Studies have shown that nicotine metabolites can be detected in excreted waste of smokeless tobacco users (Hecht, 2002; Jacob, 1999;

Stepanov I. a., 2005). These metabolites and other chemicals may enter the sewage system as components in human excreted waste, which is transferred to and treated at POTWs in the same manner as other wastewater. The excreted waste may also be digested by microbial systems in the home's septic system.

Efforts to detect and measure nicotine metabolites in wastewater, groundwater and surface waters are currently underway (Castiglioni, 2014; Katz, 2009; Buerge, 2008; Rodriguez-Alvarez, 2014). Although, to date, some studies have demonstrated deleterious effects of nicotine exposure on zebrafish, such as abnormal neural and muscle development, and behavioral changes, these studies have not linked these effects directly to nicotine metabolites (Stewart, 2015; Klee, 2011). The ecotoxicological risks associated with nicotine metabolites are still unknown. Therefore, marketing orders for the new products are not expected to affect the overall excretory waste produced by users in the United States.

## **6. Use of Resources and Energy**

The applicant stated that manufacturing the new products would not result in a significant net increase of energy usage at the manufacturing facility. Furthermore, because the new products will compete with similar currently marketed smokeless tobacco products, additional greenhouse gas (GHG) emissions are not anticipated from the proposed actions. The applicant provided evidence that the manufacturing facility is not within or in close proximity to a known critical habitat of a threatened or endangered species as listed by the Endangered Species Act (ESA). The applicant also stated that none of the materials or ingredients used to manufacture the new products originate from threatened or endangered species as defined by the U.S. Fish and Wildlife Service and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

## **7. Mitigation**

During the review of the available data and information, the Agency did not identify adverse environmental effects for manufacturing, use, and disposal of the new products. Therefore, no mitigation measures are discussed.

## **8. Alternatives to the Proposed Action**

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

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

## **9. List of Preparers**

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

Preparer:

Dilip Venugopal, Ph.D., Center for Tobacco Products  
Education: M.S. in Ecology and Ph.D. in Entomology  
Experience: 16 years in various scientific activities  
Expertise: NEPA analysis, environmental impact analysis and risk assessment, applied ecology, geo-statistics

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products  
Education: M.S. in Environmental Science and Ph.D. in Biochemistry  
Experience: 9 years in NEPA practice  
Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

**10. List of Agencies and Persons Consulted**

Not applicable.

**11. Appendix List**

Appendix 1: Submission Tracking Numbers for the SE Reports and Related Amendments and Package Sizes of the New and Predicate Products Covered Under this Programmatic Environmental Assessment (PEA)

**12. Confidential Appendix List**

Confidential Appendix 1: Modifications between the New Products and the Predicate Product  
Confidential Appendix 2: The First- and Fifth-Year Market Volume Projections of the New and Predicate Products  
Confidential Appendix 3: Comparison of the First- and Fifth-Year Market Volume Projections for the New and Predicate Products with Total Smokeless Tobacco and Snuff Products Manufactured in the United States  
Confidential Appendix 4: Comparison of the First- and Fifth-Year Market Volume Projections for the New and Predicate Products with Total Smokeless Tobacco and Snuff Products Used in the United States  
Confidential Appendix 5: The First- and Fifth-Year Projection of Waste of Packaging Materials Associated with Marketing the New and Predicate Products

**13. References**

Buerge, I. K.-R. (2008). Nicotine derivatives in wastewater and surface waters: application as chemical markers for domestic wastewater. *Environmental Science & Technology*, 42: 6354-6360.

Castiglioni, S. S. (2014). A novel approach for monitoring tobacco use in local communities by wastewater analysis. *Tobacco Control*, 0: 1-5.

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**APPENDIX 1**

**Submission Tracking Numbers for the SE Reports and Related Amendments and Package Sizes of the  
New and Predicate Products Covered Under this Programmatic Environmental Assessment (PEA)**

STN	Product Name	Product	Packaging Size			Amendments
			Grams/Can	Cans per Shrink-Wrapped Log Roll	Log Rolls per Shipping Case	
SE0012626	Copenhagen Bold Wintergreen Flavor Packs (1.55g)	New	23.25	5	18	SE0013794 SE0014032 SE0014643 SE0014748
SE0012633	Copenhagen Bold Wintergreen Flavor Packs (2g)	New	24	5	18	
GF1200229	Skool Pouches Wintergreen (1.55g)	Predicate	23.25	N/A	N/A	

**CONFIDENTIAL APPENDIX 1**  
**Modifications between the New Products and the Predicate Product**

STN	Component/ Ingredient	Unit of Measure	New	Predicate
SE0012626	Tobacco Cut	N/A	(b) (4)	
	(b) (4)	mg/gram		
	(b) (4)	mg/gram		
	(b) (4)	mg/gram		
	Pouch Material	mg/gram	Lower limit: 8.7 Target: N/A Upper limit: 17.4	Lower limit: 19.29 Target: 20.3 Upper limit: 21.32
	Pouch Thickness	mcg	N/A	Lower limit: 50 Target: 55 Upper limit: 60
	Pouch Basis Weight	g/m <sup>2</sup>	Lower limit: 15 Target: N/A Upper limit: 30	Lower limit: 15.5 Target: 16.5 Upper limit: 17.5
	Pouch Fiber Component	N/A	(b) (4)	
	Calculated Free Nicotine	mg/gram	(b) (4)	
	(b) (4)	mg/gram		
		mg/gram		
	mg/gram			

STN	Component/ Ingredient	Unit of Measure	New	Predicate
	(b) (4)			
			(b) (4)	N/A
SE0012633	Final Portion Weight	mg/portion	Lower limit: 1700 Target: 2000 Upper limit: 2300	Lower limit: 1331 Target: 1550 Upper limit: 1769
	Tobacco Cut	N/A	(b) (4)	(b) (4)
	Pouch Material	mg/gram	Lower limit: 8.7 Target: N/A Upper limit: 17.4	Lower limit: 19.29 Target: 20.3 Upper limit: 21.32
	Pouch Thickness	mcg	N/A	Lower limit: 50 Target: 55 Upper limit: 60
	Pouch Basis Weight	g/m <sup>2</sup>	Lower limit: 15 Target: N/A Upper limit: 30	Lower limit: 15.5 Target: 16.5 Upper limit: 17.5
	Pouch Fiber Component	N/A	(b) (4)	
	Calculated Free Nicotine	mg/gram	(b) (4)	
		mg/gram		
		mg/gram		

STN	Component/ Ingredient	Unit of Measure	New	Predicate
	(b) (4)	mg/gram	(b) (4)	N/A
	(b) (4)	mg/gram	(b) (4)	(b) (4)
	(b) (4)	mg/gram	(b) (4)	N/A
	(b) (4)	mg/gram	(b) (4)	(b) (4)
	(b) (4)	mg/gram	(b) (4)	(b) (4)
	(b) (4)	mg/gram	(b) (4)	(b) (4)
	(b) (4)	mg/gram	(b) (4)	(b) (4)
	(b) (4)	mg/gram	(b) (4)	N/A

**CONFIDENTIAL APPENDIX 2**

**The First- and Fifth-Year Market Volume Projections of the New and Predicate Products**

STN	Unit	First-Year Market Volume	Fifth-Year Market Volume
SE0012626	Kilograms	(b) (4)	
	Pounds		
	Metric Tons		
SE0012633	Kilograms		
	Pounds		
	Metric Tons		
GF1200229 (Predicate)	Kilograms		
	Pounds		
	Metric Tons		

**CONFIDENTIAL APPENDIX 3**

**Comparison of the First- and Fifth-Year Market Volume Projections for the New and Predicate Products with Total Smokeless Tobacco and Snuff Products Manufactured in the United States**

The portion of the U.S. commercial markets of manufactured smokeless tobacco and snuff that will be held by the new products during the first and fifth years after issuance of the marketing orders was determined by comparing the projected market volumes of the new and predicate products to the forecasted manufacture of total smokeless tobacco and snuff in the United States (Figure 4 and Confidential Appendix 2). The percent of the total smokeless tobacco and snuff markets occupied in the projected first and fifth year of marketing of the new and predicate products was calculated using the equations below.<sup>6</sup>

First Year Market Occupation of Products (%)

$$= \frac{\text{First-Year Market Volume Projection}}{\text{Forecasted Manufacture of Smokeless or Snuff in the U.S. for 2018}} \times 100\%$$

Fifth Year Market Occupation of Products (%)

$$= \frac{\text{Fifth-Year Market Volume Projection}}{\text{Forecasted Manufacture of Smokeless or Snuff in the U.S. for 2022}} \times 100\%$$

STN	Year	Forecasted Manufacture of Total Smokeless Tobacco in the United States <sup>7</sup> (Pounds)	Forecasted Manufacture of Snuff in the United States <sup>9</sup> (Pounds)	Projected Market Volume of Products <sup>8</sup> (Pounds)	Projected Smokeless Market Occupation of Products (%)	Projected Snuff Market Occupation of Products (%)
SE0012626	First	143,722,969	(b) (4)	(b) (4)		
	Fifth	154,968,400				
SE0012633	First	143,722,969				
	Fifth	154,968,400				
GF1200229 (Predicate)	First	143,722,969				
	Fifth	154,968,400				

<sup>6</sup> The first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.

<sup>7</sup> See Figure 4.

<sup>8</sup> See Confidential Appendix 2.

**CONFIDENTIAL APPENDIX 4**

**Comparison of the First- and Fifth-Year Market Volume Projections for the New and Predicate Products with Total Smokeless Tobacco and Snuff Products Used in the United States**

The portion of smokeless tobacco products and snuff used by consumers in the United States that will be attributed to the new products was determined by comparing the projected market volumes of the new and predicate products to the forecasted use of total smokeless tobacco and snuff in the United States (Figure 6, and Confidential Appendix 2). The percent of the total smokeless tobacco and snuff used in the projected first and fifth years of marketing for the new and predicate products was calculated using the equations below.<sup>9</sup>

First Year Market Occupation of Products (%)

$$= \frac{\text{First-Year Market Volume Projection}}{\text{Forecasted Use of Smokeless or Snuff in the U.S. for 2018}} \times 100\%$$

Fifth Year Market Occupation of New Products (%)

$$= \frac{\text{Fifth-Year Market Volume Projection}}{\text{Forecasted Use of Smokeless or Snuff in the U.S. for 2022}} \times 100\%$$

STN	Year	Forecasted Use of Total Smokeless Tobacco in the United States <sup>10</sup> (Pounds)	Forecasted Use of Snuff in the United States <sup>9</sup> (Pounds)	Projected Market Volume of Products <sup>11</sup> (Pounds)	Projected Smokeless Market Occupation of Products (%)	Projected Snuff Market Occupation of Products (%)
SE0012626	First	140,492,800	(b) (4)	(b) (4)		
	Fifth	148,150,800				
SE0012633	First	140,492,800				
	Fifth	148,150,800				
GF1200229 (Predicate)	First	140,492,800				
	Fifth	148,150,800				

<sup>9</sup> The first- and fifth-year projected market volumes are assumed to be 2018 and 2022, respectively.

<sup>10</sup> See Figure 6.

<sup>11</sup> See Confidential Appendix 2.

### CONFIDENTIAL APPENDIX 5

To analyze the environmental effects from waste due to the proposed actions, the Agency estimated the first- and fifth-year weights of the projected packaging materials wastes (in metric tons) that are generated from disposal of the new products in 2018 and 2022. Projected total waste is the summation of the projected paper, plastic, and metal waste generation of the product. Projected total paper waste is the summation of the projected recyclable (shipping case) and non-recyclable (coated paper side label) paper waste generation of the product. Projected total plastic waste is the summation of the projected recyclable (can bottom) and non-recyclable (shrink wrap) plastic waste generation of the product.

$$\sum_{i=1}^3 A_i = \sum_{i=1}^3 (B_i + C_i + D_i)$$

$$B_i = \sum_{i=1}^3 (G_i + H_i)$$

$$C_i = \sum_{i=1}^3 (E_i + F_i)$$

$$D_i = J_i \times M \times Z$$

$$E_i = J_i \times N \times Z$$

$$F_i = \frac{J_i}{K} \times P \times Z$$

$$G_i = \frac{J_i}{I_i \times H_i} \times Q \times Z$$

$$H_i = J_i \times O \times Z$$

$A_i$ : Projected total waste generation of the product (metric tons)

$B_i$ : Projected paper waste generation of the product (metric tons)

$C_i$ : Projected plastic waste generation of the product (metric tons)

$D_i$ : Projected metal waste of the product (metric tons)

$E_i$ : Projected recyclable plastic waste generation of the product (metric tons)

$F_i$ : Projected non-recyclable plastic waste generation of the product (metric tons)

$G_i$ : Projected recyclable paper waste generation of the product (metric tons)

$H_i$ : Projected non-recyclable paper waste generation of the product (metric tons)

$I_i$ : Projected market volume of the product (pounds)

$J_i$ : Number of individual units (each unit comprises of one can bottom, one can lid, and one coated side label)

$K$ : Number of individual units per log roll

$L$ : Number of log rolls per shipping case

$M$ : Weight of metal (tin-plated steel) can lid (grams)

$N$ : Weight of plastic (polypropylene) can bottom (grams)

$O$ : Weight of coated paper side label (grams)

$P$ : Weight of plastic shrink wrap (grams)

$Q$ : Weight of shipping case (grams)

$Z$ :  $1.0 \times 10^{-6}$  metric tons/gram

STN	Year	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C-plast	B-paper	A	
SE0012626	First	196	2.08	0.34	8.98	6.82	18	5	16799975	(b) (4)									
	Fifth	196	2.08	0.34	8.98	6.82	18	5	25299957										
SE0012633	First	196	2.08	0.34	8.98	6.82	18	5	20999949										
	Fifth	196	2.08	0.34	8.98	6.82	18	5	31624945										
GF1200229 (Predicate)	First	196	2.08	0.34	8.98	6.82	18	5	780510										
	Fifth	196	2.08	0.34	8.98	6.82	18	5	640472										
																	(b) (4)		
																	TOTAL FIRST YEAR	(b) (4)	
																	TOTAL FIFTH YEAR	(b) (4)	

**Total Waste.** The shipping case is disposed of, recycled, or both, as paper waste; the coated paper side label is disposed of as waste or litter. Estimation of generated total paper waste for SE0012626 is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year, and for SE0012633 is (b) (4) and (b) (4) metric tons for first and fifth years, respectively. A portion of the shipping case waste is likely to be recycled; there is an overall recycling rate for paper products of 64.7% in the United States, according to U.S. EPA (U.S. Environmental Protection Agency, 2016). Therefore, if 100% of the coated paper side label and 35.3% of the shipping cases are disposed of as waste based on the 2014 waste generation data in the United States, the estimated cumulative paper waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new product.<sup>12</sup> The plastic can bottom is disposed of, recycled, or both, as plastic waste; the shrink wrap is disposed of as waste or litter. Estimation of generated total plastic waste for SE0012626 is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year, and for SE0012633 is (b) (4) and (b) (4) metric tons for first and fifth years, respectively. A portion of the plastic can bottom is likely to be recycled; there is an overall recycling rate for plastic products of 9.5% in the United States (U.S. Environmental Protection Agency, 2016). Therefore, if 100% of the shrink wrap and 90.5% of the plastic can bottoms are disposed of as waste based on the 2014 waste generation data in the United States, the estimated cumulative plastic waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new product.<sup>13</sup> The metal can lid is disposed of, recycled, or both as metal waste. Estimation of generated total metal waste for

<sup>12</sup> At 35.3% disposal rate as paper waste (on shipping cases) for the 1<sup>st</sup> Year, (b) (4)

<sup>13</sup> At 90.5% disposal rate as plastic waste (on can bottoms) for the 1<sup>st</sup> Year, (b) (4)

SE0012626 is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year, and for SE0012633 is (b) (4) and (b) (4) metric tons for first and fifth years, respectively. A portion of the metal can lid is likely to be recycled; there is an overall recycling rate for metal products of 33.0% in the United States (U.S. Environmental Protection Agency, 2016). Therefore, if 67.0% of the metal can lids are disposed of as waste based on the 2014 waste generation data in the United States, the estimated cumulative metal waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new product.<sup>14</sup>

The conservative approach of assuming disposal of the entire packaging as waste, the paper, plastic, and metal components, the projected cumulative paper and plastic waste for the new and predicate products in the first and fifth years of marketing the new products is (b) (4) metric tons and (b) (4) metric tons, respectively, for the two new products and the predicate product. This is a negligible fraction (b) (4) of the 234.47 million metric tons of total waste reported in the United States in 2014.

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<sup>14</sup> At 67.0% disposal rate as metal waste (on can lids) for the 1<sup>st</sup> Year, (b) (4)