Programmatic Environmental Assessment for Marketing Orders for Philip Morris USA Inc. "Marlboro Soft Pack, Marlboro Menthol Box, and Marlboro Box"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

April 19, 2018

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This programmatic environmental assessment (PEA) is for marketing orders for three combusted, filtered cigarettes manufactured by Philip Morris USA Inc. 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 with 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

Philip Morris USA Inc.

2. Address

2325 Bells Road
Richmond, VA 23234

3. Manufacturer

Philip Morris USA Manufacturing Center

4. Description of Proposed Actions

The proposed actions are for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of combusted, filtered cigarettes into interstate commerce for commercial distribution in the United States. This authorization is based on the finding that the new products are substantially equivalent to the corresponding predicate products. The predicate products are grandfathered products, GF1200100, GF1200098, and GF1200090, and FDA confirmed eligibility on October 5, 2017. The applicant claimed that the predicate products are not currently manufactured or marketed.

4.1 Requested Action

The applicant requests that FDA issue orders finding the listed tobacco products are substantially equivalent to the corresponding predicate products.

4.2 Need for Action

Philip Morris USA Inc. wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the United States. The differences between the new and corresponding predicate products are in the removal of an ingredient from the tipping paper ink and tipping paper ink extender; and differences in the composition of the tipping paper ink and tipping paper ink extender. The applicant claims the new products do not raise different questions of public health (sec 910(a)(3)(A)(ii) of the FD&C Act). After considering the substantial equivalence (SE) reports, the Agency shall issue orders under the provisions of sections 910 and 905(j) of the FD&C Act when finding the new products to be substantially equivalent to the corresponding predicate products.

4.3 Identification of the New Tobacco Products that are the Subjects of the Proposed Actions

4.3.1 Type of Tobacco Products

Combusted, filtered cigarettes

4.3.2 Product Names and STNs

STN	New Product	Predicate Product	Predicate STN
SE0014279	Marlboro Soft Pack	Marlboro Soft Pack	GF1200100
SE0014280	Marlboro Menthol Box	Marlboro Menthol Box	GF1200098
SE0014281	Marlboro Box	Marlboro Box	GF1200090

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

4.3.3 Description of the Product Package

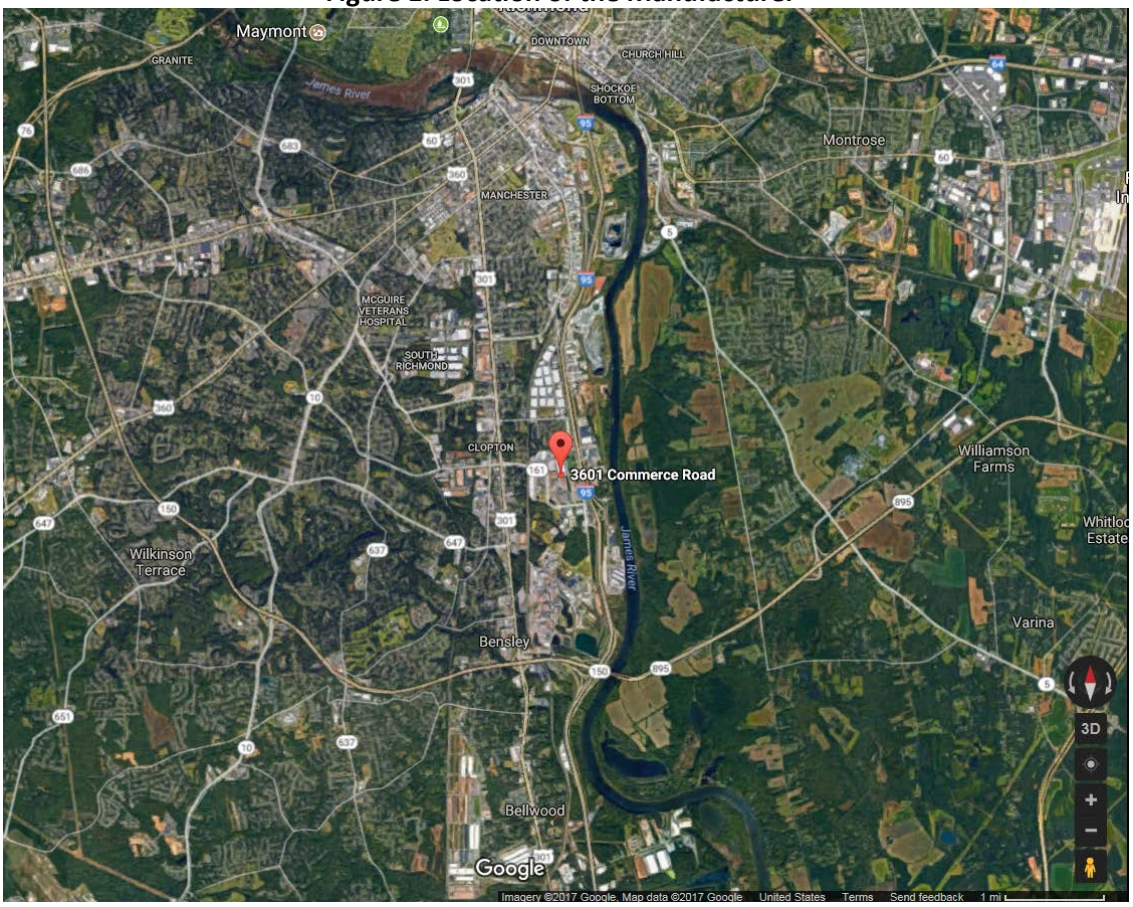
The new products' packaging consists of cartons, box (hard pack), label (soft pack), innerframe, foil, overwrap film, tear tape, and closures.

4.3.4 Location of Manufacturing

Philip Morris USA Manufacturing Center
3601 Commerce Road
Richmond, VA 23234

The facility is in Richmond, VA, bounded by the James River to the east and north, US 64 to the north, state road 150 to the south, and surrounded by industrial land (Figure 1).

Figure 1. Location of the Manufacturer[1]



4.3.5 Location of Use

Philip Morris USA Inc. 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 landfills as municipal solid waste (MSW) or as litter in the same manner as the corresponding predicate products and any other combusted, filtered cigarettes. Disposal of the packaging materials will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates the distribution of waste will correspond to the pattern of the product use.

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

The differences between the new and corresponding predicate products are differences are in the removal of an ingredient from the tipping paper ink and tipping paper ink extender; and differences in the composition of the tipping paper ink and tipping paper ink extender. Details of product changes are described in Confidential Appendix 1.

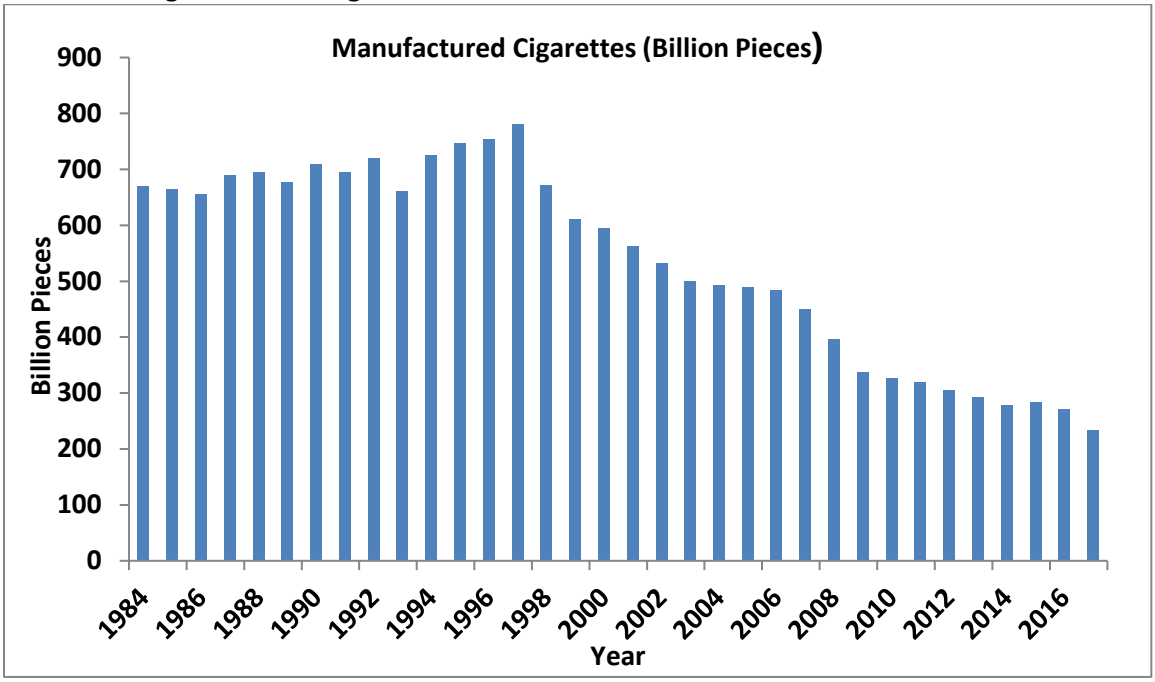
[1] Manufacturer address via Google Map. Accessed October 2, 2017.

5. Potential Environmental Impacts Due to the Proposed Actions

5.1. Potential Environmental Impacts Due to Manufacturing the New Products

As of January 2018, a total of 3227 tobacco production establishments are registered under 915(c) of the FD&C Act.[2] These manufacturers produced 233 billion cigarettes (11.7 billion packs of 20 cigarettes each) in 2017 with a decline starting in 1997 (Figure 2) [1].

Figure 2. Total Cigarettes Manufactured in the United States 1984-2017



The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available.[3] In 2015, U.S. tobacco manufacturers released 475,000 pounds of ammonia and 280,000 pounds of nicotine and nicotine salts to the air; 9,564 pounds of ammonia and 313,765 pounds of nicotine and nicotine salts to landfill; 220 pounds of ammonia and 279 pounds of nicotine and nicotine salts to the surface water; and 19,550 pounds of ammonia and 83,384 pounds of nicotine and nicotine salts transferred to publicly owned treatment works (POTWs) or an off-site location. In 2016, the Philip Morris USA Richmond facility released 20,347 pounds of ammonia and 11,671 pounds of nicotine and nicotine salts to the air; no ammonia, nicotine, or nicotine salts to the

[2] 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 January 12, 2018.

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

land or water; and 2,483 pounds of ammonia and 84,422 pounds of nicotine and nicotine salts transferred to POTWs.[4]

The Agency anticipates the waste generated as a result of manufacturing the new combusted, filtered cigarettes will be released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other combusted, filtered cigarettes manufactured in the United States. The applicant stated that the new products will also compete with other currently marketed combusted, filtered cigarettes. No expansion of the manufacturing facility is anticipated for manufacturing the new products. Therefore, the Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the production of all combusted, filtered cigarettes.

The differences between the new and corresponding predicate products are in the removal of an ingredient from the tipping paper ink and tipping paper ink extender; and differences in the composition of the tipping paper ink and tipping paper ink extender. However, the components are similar to those of the corresponding predicate products and other cigarettes currently on the market. Therefore, the Agency does not anticipate any new type of emissions to be released into the environment as a result of manufacturing the new products.

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 of the new products, historical data regarding the manufacture of cigarettes in the United States from 2007 to 2017 was used to forecast the manufacture of cigarettes.[5] This was achieved by using one best-fit exponential trend line with the R^2 value of 0.9448 (Figure 3). Accordingly, the forecasted number of all cigarettes to be manufactured in the United States is estimated to be 222 billion pieces in 2018 and 191 billion pieces in 2022. The number of all cigarettes manufactured in the United States was 233 billion pieces in 2017.

Comparing the projected market volumes of the new products with the forecasted manufacture of all cigarettes in the United States, in 2018 and 2022, the projected market volumes of the new products are small fractions of the total projected number of cigarettes to be manufactured in 2018 and 2022 (Figure 3 and Confidential Appendix 3). Additionally, the applicant stated that manufacturing the new products will not require any new equipment or expansion of the current manufacturing facility. Therefore, no new control practices of air emission, water discharge, or solid waste disposal are needed.

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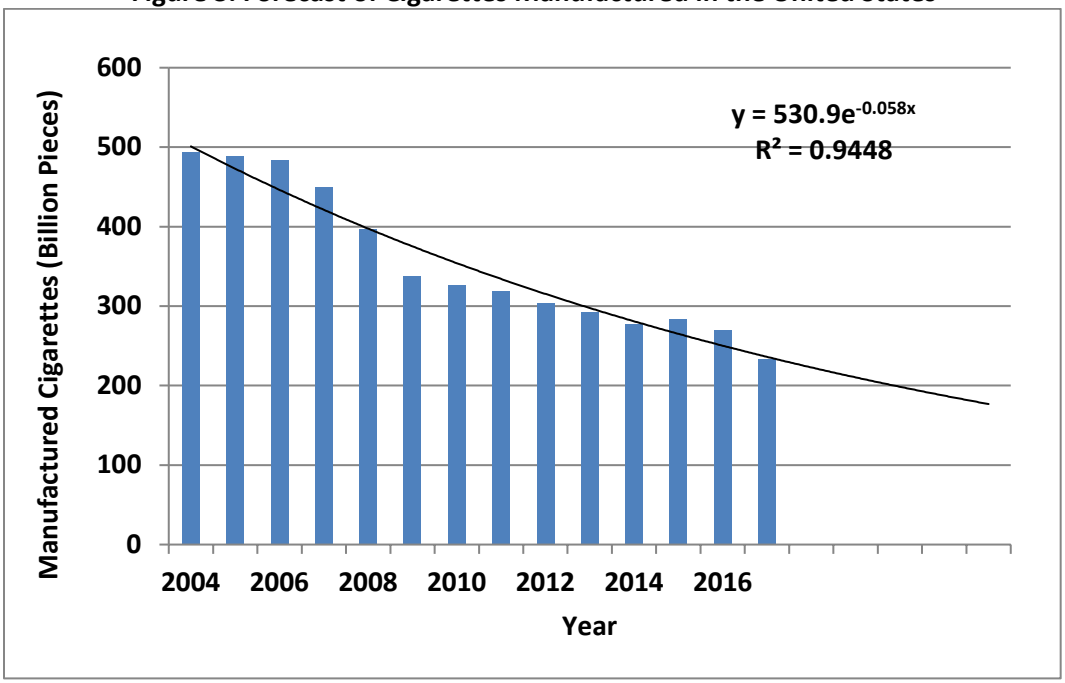
[4] The estimation is done by using the Toxics Release Inventory (TRI), a dataset (http://www.epa.gov/tri/) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the U.S., including details on quantities of chemicals managed through disposal or other release, recycling, energy recovery or treatment. Data associated with the tobacco manufacturing industry is retrieved by using North American Industry Classification System (NAICS) codes beginning with 3122. Not all toxic release data of tobacco manufacturers are included in the database. The database includes information from any facility that (1) falls within a TRI-reportable industry sector or is federally-owned or operated; (2) has 10 or more full-time (or equivalent) employees; and (3) manufactures, processes or otherwise uses (MPOU) a TRI-listed chemical https://www.epa.gov/sites/production/files/documents/TRIListChangesUpdate11282011.pdf) in an amount above the TRI reporting threshold during a calendar year. Search performed January 17, 2018.

[5] Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau: Statistical Report – Tobacco for November 2017. Reported on January 10, 2018. Available at: https://www.ttb.gov/statistics/2017/201711tobacco.pdf. Accessed on January 18, 2017.

Figure 3. Forecast of Cigarettes Manufactured in the United States

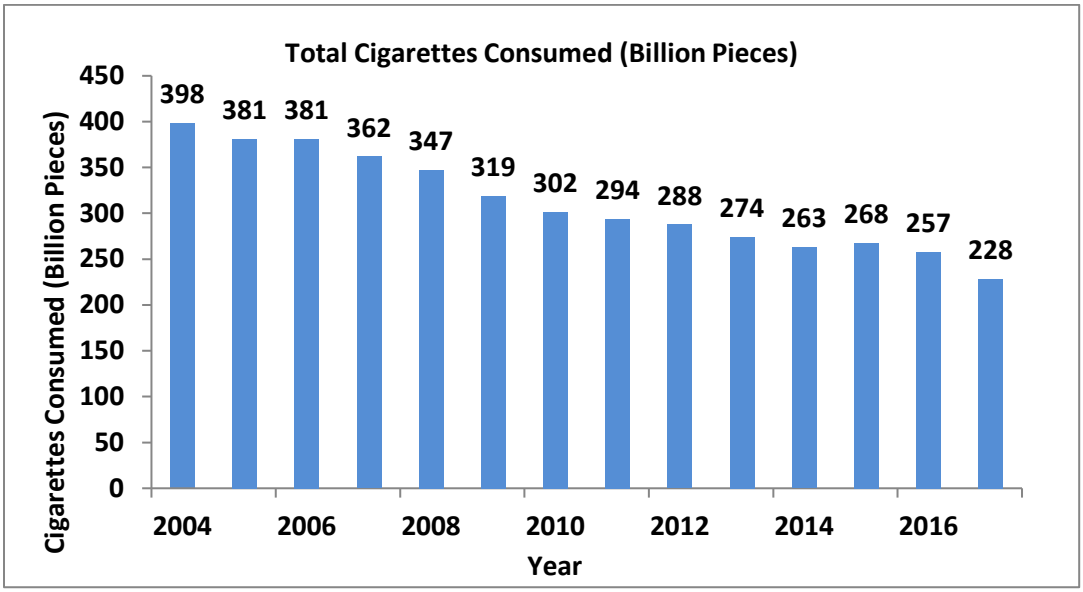


The applicant stated that they are in compliance with all federal, state, and local environmental regulations and provided information on the manufacturering facility's air and wastewater permits. The applicant holds a Federal Operating Permit (PRO50076) for air emissions and an Industrial User Permit (2149) for wastewater pretreatment from the local POTWs.

5.2. Potential Environmental Introduction Due to Use of the New Products

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of cigarettes in the United States decreased from 398 billion in 2004 to 228 billion in 2017 (Figure 4) [1, 2].

Figure 4. Use of Cigarettes in the United States in 2004-2017



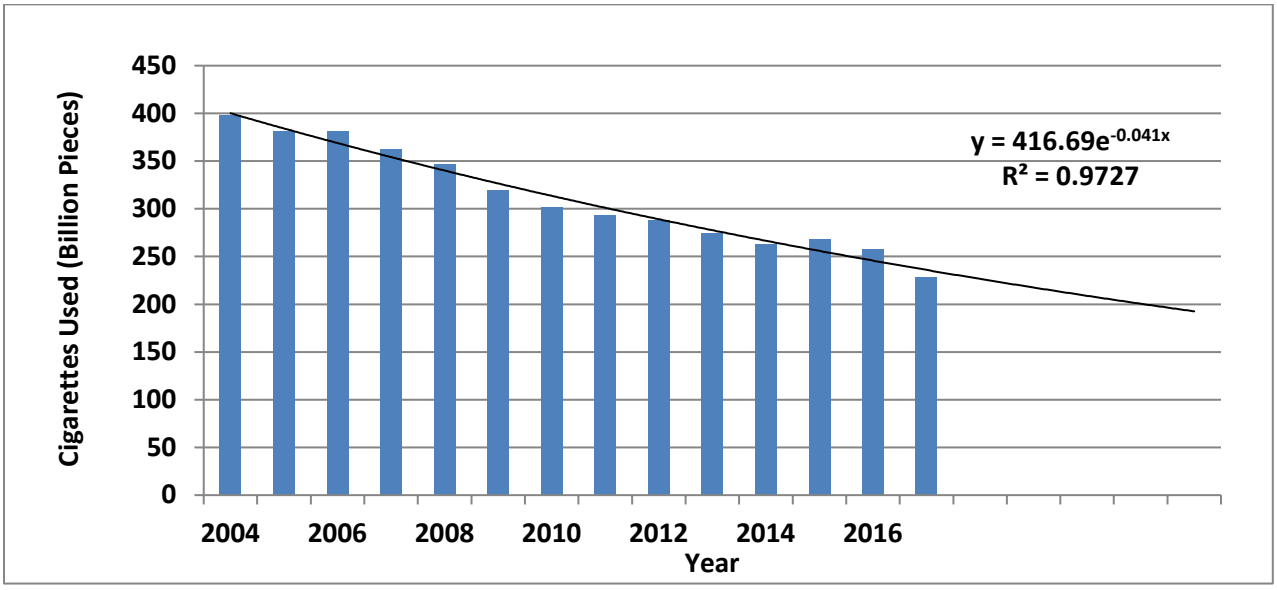
The Agency does not anticipate new substances to be released into the environment as a result of use of the new products, relative to the substances released by the corresponding predicate products, and other cigarettes already on the market. As noted, the only differences between the new and corresponding predicate products are in the removal of an ingredient from the tipping paper ink and tipping paper ink extender; and differences in the composition of the tipping paper ink and tipping paper ink extender. When burned, cigarettes release tobacco smoke to the environment, referred to as secondhand smoke. There is no safe level of exposure to secondhand smoke [3, 4]. Even low levels of secondhand smoke can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30%[5].
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness [3, 4].
- Secondhand smoke causes more than 40,000 deaths a year [5].

To evaluate the environmental impact of the proposed actions due to use of the new products, historical data regarding total use of cigarettes from 2004 to 2017 was employed to mathematically estimate the forecast of the total number of cigarettes used in the United States.[6] Using a best-fit exponential trend line with the R^2 value of 0.9727, the number of cigarettes forecasted to be used in the United States is estimated to be 225.28 billion in 2018 and 191.20 billion in 2022 (Figure 5). Comparing the projected market volume of the new products with the forecasted use of all cigarettes produced in the United States, in 2018 and 2022, the projected market volume of the new products are small fractions of the total projected use in 2018 and 2022 (Figure 5 and Confidential Appendix 4)

[6] Forecast trend lines extrapolated from TTB data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed January 18, 2018.

Figure 5. Projected Use of Cigarettes in the United States in the First and Fifth Year of Marketing the New Products



The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment due to use based on the changes in the new products compared to the predicate products and because the components changed are similar to those of the corresponding predicate product and other cigarettes currently on the market. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes.

5.3. Potential Environmental Impacts Due to Disposal of the New Tobacco Product

The environmental consequences from disposal of combusted, filtered cigarettes are associated with disposal of packaging and discarding the used cigarette products. The Agency believes that the disposal of the new products will be the same as the disposal of other combusted, filtered cigarettes that are currently being marketed. After using the new product, the users may recycle the packaging material or dispose of it as MSW or litter. Used cigarettes, consisting of cigarette butts,[7] are usually disposed of as MSW or litter.

Packaging disposal and properly discarded used products contribute to using landfill capacity and air emissions from landfills. Improperly discarded used products generate litter.

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 cigarette products, can be informative about the disposal of cigarette packing materials. Specifically, in 2014, approximately 258.46 million tons (U.S.

[7] Cigarette butt is defined in this PEA as cigarette paper containing remainder tobacco that is disposed of after the product is used. The cigarette butt may or may not also include a filter.

short tons in section 5.3 of the EA, unless specified) 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 (Figure 6 and 7) . Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014[6]. 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 [6]. Figure 8 shows the overlap of MSW that is paper or paperboard, as well as container and packaging material. These are the types of materials that will be disposed of from the new product packaging.

Figure 6. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014

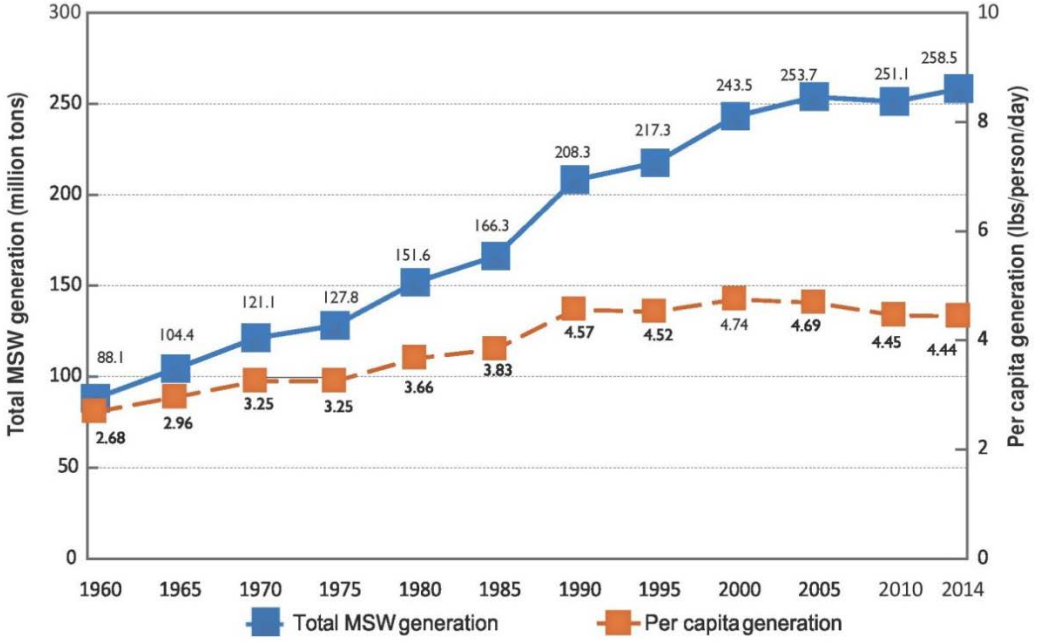


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 7. MSW Recycling Rates in the United States, 1960-2014

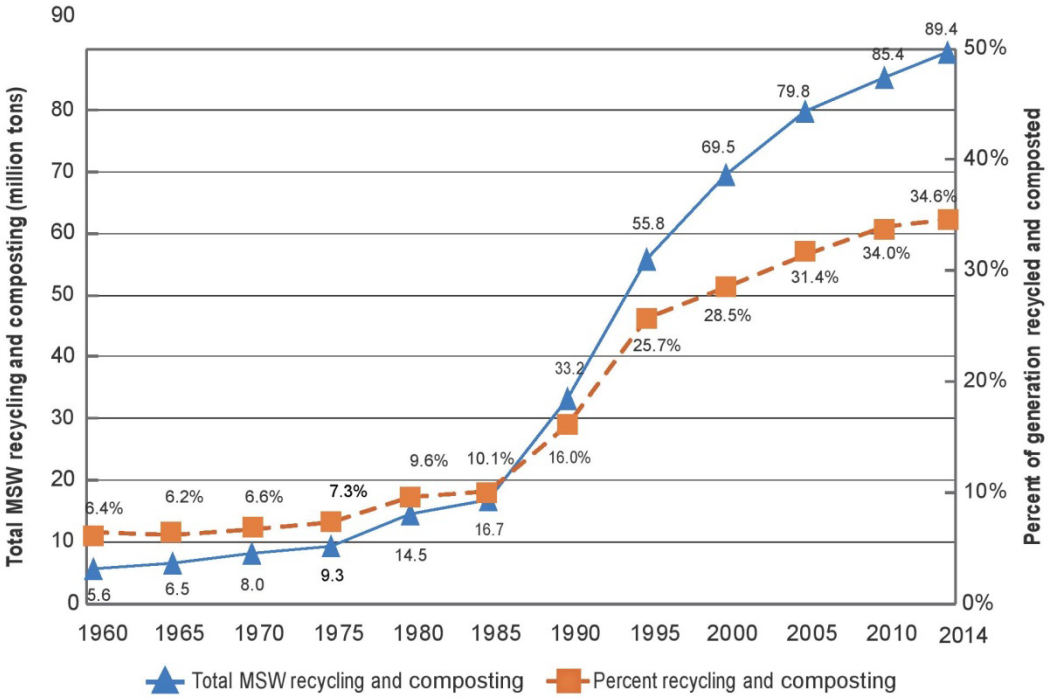
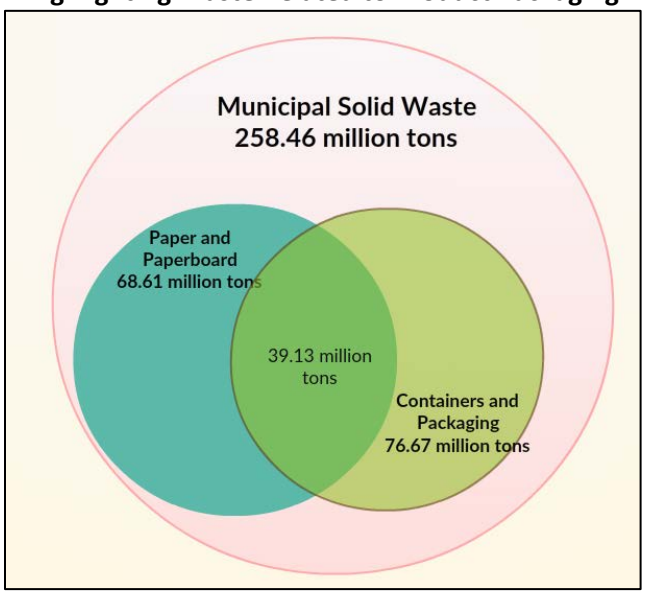


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 8. Overview of Contents of Municipal Solid Waste: Highlighting Waste Related to Product Packaging



The Agency believes that the disposal of the new products will be the same as the disposal conditions of other cigarettes that are currently being marketed. After using the new products, users may dispose of or recycle the packaging materials. Users may also discard the combusted cigarettes and filters, as discussed above, as MSW or litter.

To determine the amount of waste due to disposal of packaging materials and product materials, 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 and product 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). In addition, paper components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

As previously discussed, because the applicant stated that the new products will compete with other similar 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.

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment due to disposal of the packaging materials. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from the disposal of the packaging material of other cigarettes marketed in the United States.

5.3.2. Discarding Used Cigarettes

Cigarette butt waste may have an end-of-life-cycle scenario as either managed or unmanaged waste.

Managed waste is handled by an organized solid waste collection and management system. For the managed waste, 80.4% by weight enters landfills, and the remaining 19.6% by weight is incinerated for energy recovery [7]. The Agency used the projected market volumes for the first and fifth years of marketing to estimate the waste from discarding used products (cigarette butts). The estimated waste from cigarette butt disposal as MSW would be miniscule compared to the total MSW forecasted to be discarded in the United States (Confidential Appendix 5). The new combusted, filtered cigarette products will compete with other similar combusted filtered cigarette products on the market; the estimates described above and detailed in Confidential Appendix 5 indicate a negligible contribution to the total MSW in the United States. Because of these points, construction of new solid waste landfills or incinerators is not anticipated due to disposal of used products under the proposed actions.

Unmanaged waste consists of littered cigarette butts. The environmental effects of cigarette butt litter have been summarized in the publicly available literature as follows [8]:

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide… The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste... Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Introducing the new products into the U.S. market is not expected to increase the nationwide use of combusted filtered cigarettes; instead, they would compete for market share with existing products. Thus, authorizing the new products is not expected to affect the overall level of cigarette butt litter in the United States, but may displace the level of litter from other cigarette products.

6. Use of Resources and Energy

The applicant stated that there will be no change in how the new products are manufactured compared to the corresponding predicate products. The same raw materials and energy will be used to manufacture the new products compared to the corresponding predicate products and the applicant does not anticipate any increased energy or resource needs to manufacture the new products. The applicant stated that the proposed actions will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total cigarette volumes in the United States, the Agency found that the projected market volumes of the new products are small fractions of the total forecasted cigarette market volume in 2018 and 2022. Because the applicant stated that the new products will compete with other similar cigarettes, no increase of overall cigarette market volume and no net increase of energy use will be expected from the proposed actions. The applicant stated that no adverse effects to endangered or threatened species or critical habitat are expected from manufacturing the new products.

7. Mitigation

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

8. Alternatives to the Proposed Actions

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 many similar tobacco products would continue to be marketed.

Alternative B (Proposed actions): 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 (Confidential Appendices 2-6).

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 programmatic environmental assessment.

<u>Preparer:</u>

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology
Experience: 4 years in various scientific activities
Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reveiwer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry
Experience: 9 years in FDA-related NEPA review
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 for the New and Corresponding Predicate Products Covered Under this Programmatic Environmental Assessment (PEA)

12. Confidential Appendix List

Confidential Appendix 1: Comparison of the New and Corresponding Predicate Products
Confidential Appendix 2: The First-, and Fifth-Year Market Volume Projections for the New Products
Confidential Appendix 3: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Manufactured in the United States
Confidential Appendix 4: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Used in the United States
Confidential Appendix 5: Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products

13. References

1. *U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau, Tobacco Statistics*. Available from: https://www.ttb.gov/statistics/2017/201710tobacco.pdf Accessed January 17, 2018.
2. *Centers for Disease Control and Prevention, Economic Facts about Tobacco Production and Use*. Available from: http://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/ Accessed January 17, 2018.
3. *U.S. Department of Health and Human Services, The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General.* 2006: Atlanta, GA.
4. *U.S. Department of Health and Human Services, The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet)*. 2006: Atlanta, GA.

5. *U.S. Department of Health and Human Services, The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General*. 2014: Atlanta, GA.
6. *U. S, Environmental Protection Agency EPA, Materials and Waste Management in the United States Key Facts and Figures.*; Available from: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures Accessed January 17, 2018.
7. Agency, E.P., *Advancing Sustainable Materials Management: 2014 Fact Sheet*. 2016.
8. Novotny, T.E., et al., *The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption.* Bull World Health Organ, 2015. **93**(12): p. 877-80.
9. *Advancing Sustainable Materials Management: Facts and Figures*. U.S. Environmental Protection Agency web site, 2016a.

APPENDIX 1

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

New and Corresponding Predicate Product Information				
STN	**New Product**	**Predicate Product**	**Predicate STN**	**Amendments**
SE0014279	Marlboro Soft Pack	Marlboro Soft Pack	GF1200100	SE0014474
SE0014280	Marlboro Menthol Box	Marlboro Menthol Box	GF1200098	SE0014474
SE0014281	Marlboro Box	Marlboro Box	GF1200090	SE0014474

CONFIDENTIAL APPENDIX 1

Comparison of the New and Corresponding Predicate Products

STN	Modification	
SE0014279	Deletion of (b) (4)	from tipping paper ink and tipping paper ink extender
SE0014280	Deletion of (b) (4)	from tipping paper ink and tipping paper ink extender
SE0014281	Deletion of (b) (4)	from tipping paper ink and tipping paper ink extender

CONFIDENTIAL APPENDIX 2

The First- and Fifth-Year Market Volume Projections for the New Products

STN	Product Name	Market Volume	
		First-Year (Cigarettes)	Fifth-Year (Cigarettes)
SE0014279	Marlboro Soft Pack	(b) (4)	
SE0014280	Marlboro Menthol Box		
SE0014281	Marlboro Box		
	Total		

CONFIDENTIAL APPENDIX 3

Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total Cigarettes Manufactured in the United States

The share of the new products projected to occupy the U. S. market was determined by comparing the first- and fifth-year projected market volumes of the new products (Confidential Appendix 2) to the forecasted manufacture of cigarettes in the United States. The percent of the total cigarette market occupied in the projected first and fifth year of marketing of the new products was calculated using the equations below.

$$\text{First Year Market Occupation of New Products (\%)} = \frac{\text{First-Year Market Volume Projection (\# of cigarettes)}}{\text{Forecasted Manufacture of cigarettes in the U.S. for 2018 (\# of cigarettes)}} \times 100\%$$

$$\text{Fifth Year Market Occupation of New Products (\%)} = \frac{\text{Fifth-Year Market Volume Projection (\# of cigarettes)}}{\text{Forecasted Manufacture of cigarettes in the U.S. for 2022 (\# of cigarettes)}} \times 100\%$$

STN	Product Name	Market Volume			
		First-Year		Fifth-Year	
		Cigarettes	% Cigarette Market[a]	Cigarettes	% Cigarette Market[b]
SE0014279	Marlboro Soft Pack	(b) (4)			
SE0014280	Marlboro Menthol Box				
SE0014281	Marlboro Box				
Total					

Comparing the projected market volume of the new products with the number of all cigarettes projected to be manufactured in the United States in 2018 and 2022, the projected market volume of the new products is approximately (b) (4) of the total number of cigarettes projected to be manufactured in 2018 and (b) (4) of the projected m for 2022.

[a] Forecasted manufacture of cigarettes in the United States for 2018 (# of cigarettes) - 222,421,377,496

[b] Forecasted manufacture of cigarettes in the United States for 2022 (# of cigarettes) - 191,204,309,590

CONFIDENTIAL APPENDIX 4

Comparison of the First- and Fifth-Year Market Volume Projections for the New Product with Total Cigarettes Used in the United States

The share of the new products projected to occupy the U. S. market was determined by comparing the first- and fifth-year projected market volumes of the new products (Confidential Appendix 2) to the forecasted use of cigarettes in the United States. The percent of the total cigarette market occupied in the projected first and fifth year of marketing of the new products was calculated using the equations below:

$$\text{First Year Market Occupation of New Products (\%)} = \frac{\text{First-Year Market Volume Projection (\# of cigarettes)}}{\text{Forecasted Use of cigarettes in the U.S. for 2018 (\# of cigarettes)}} \times 100\%$$

$$\text{Fifth Year Market Occupation of New Products (\%)} = \frac{\text{Fifth-Year Market Volume Projection (\# of cigarettes)}}{\text{Forecasted Use of cigarettes in the U.S. for 2022 (\# of cigarettes)}} \times 100\%$$

STN	Product Name	Market Volume			
		First-Year		Fifth-Year	
		Cigarettes	% Cigarette Market[c]	Cigarettes	% Cigarette Market[d]
SE0014279	Marlboro Soft Pack	(b) (4)			
SE0014280	Marlboro Menthol Box				
SE0014281	Marlboro Box				
	Total				

Comparing the projected market volume of the new products with the projected use of all cigarettes produced in the United States in 2018 and 2022, the projected market volume of the new products is approximately (b) (4) of the total projected cigarette use in 2018 and (b) (4) of the projected use for 2022.

[c] Forecasted use of cigarettes in the United States for 2018 (# of cigarettes) - 225,279,654,666

[d] Forecasted use of cigarettes in the United States for 2022 (# of cigarettes) - 191,204,309,590

CONFIDENTIAL APPENDIX 5

Projected Product and Packaging Waste from Disposal as Municipal Solid Waste after Use

To analyze the environmental effects from the disposal of the new products as MSW in landfills or incinerators, the Agency estimated the weights of the non-recycled waste that would be generated from disposal of the used products (cigarette butts) and product packaging in the first and fifth years of marketing. Projected used product and packaging waste is the sum of the cigarette butt and the paper, cardboard, plastic, and mixed materials specific to the packaging for each product as follows:

$$\sum_{i=1}^{8} A_i \text{ (tons)} = \sum_{i=1}^{8} (B_i + C_i + D_i + E_i)$$

$$B_i\text{(tons)} = F \times G_i\ (ounces) \times H_i\ (cigarettes) \times \frac{pound}{16\ ounces} \times \frac{ton}{2{,}000\ pounds}$$

$$C_i\text{(tons)} = H_i\ (cigarettes) \times \left[\frac{I_i\ (grams)}{20\ cigarettes} + \frac{J_i\ (grams)}{200\ cigarettes} + \frac{K_i\ (grams)}{12{,}000\ cigarettes}\right] \times L \times \frac{ton}{907{,}184.74\ grams}$$

$$D_i\text{(tons)} = H_i\ (cigarettes) \times \frac{M_i\ (grams)}{20\ cigarettes} \times N \times \frac{ton}{907{,}184.74\ grams}$$

$$E_i\text{(tons)} = H_i\ (cigarettes) \times \frac{O_i\ (grams)}{20\ cigarettes} \times \frac{ton}{907{,}184.74\ grams}$$

$$G_i\text{(ounces)} = [P_i\ (milligrams) + Q_i\ (milligrams) + R_i\ (milligrams)] \times \frac{ounce}{28{,}350\ milligrams}$$

$$H_i\ (ounces) = \frac{J\ (millimeters)}{K_i\ (millimeters)} \times \left(\frac{0.0325\ ounces\ RYO\ tobacco}{cigarette\text{-}equivalent} + \frac{L_i\ (ounces)}{cigarette\text{-}equivalent}\right)$$

$$R_i\text{(milligrams)} = [(S_i + T_i)\ (milligrams)] \times \frac{(U_i - V_i)\ (millimeters)}{W_i\ (millimeters)}$$

A_i = total cigarette butt and packaging waste generated by the new products (tons)

B_i = cigarette butts generated by the used products (tons)

C_i = cardboard and paper waste generated by the packaging for the new products (tons)

D_i = plastic waste generated by the packaging for the new products (tons)

E_i = mixed and other materials waste generated by the packaging for the new products (tons)

F = fraction of cigarette butts disposed of in MSW = 0.66 (34% are littered)

G_i = weight per cigarette butt (ounces)

H_i = market volume projection (cigarettes)

I_i = pack (grams)

J_i = carton (grams)

K_i = shipping box (grams)

L = fraction of cardboard paper waste not recycled = 1 - 0.647 = 0.353 (U.S. EPA 2016a)

M_i = polypropylene shrink-wrap (grams)

N = fraction of polypropylene not recycled = 1 - 0.008 = 0.992 (U.S. EPA 2016a)

O_i = foil pack liner (grams)

P_i = filter + plug wrap (milligrams)

Q_i = tipping paper (milligrams)

R_i = cigarette paper in cigarette butt + tobacco rod filler in cigarette butt (milligrams)

S_i = cigarette paper in cigarette (milligrams)

T_i = tobacco rod filler in cigarette (milligrams)

U_i = cigarette butt length (millimeters). For filtered cigarettes: the greatest of 23 mm, length of filter + 8 mm, or length of overwrap + 3 mm, from draft 2015 revisions to ISO 3308 intense smoking regimen (Section 7.2.1). For unfiltered cigarettes: 27 mm, from ISO 15592-3:2008(E).

V_i = filter length (millimeters)

W_i = cigarette rod length (millimeters)

The product packaging elements are disposed of as MSW or recycled, and the cigarette butts are disposed of as MSW or litter. The Agency estimated the amount of MSW that would be disposed of in landfills or incinerated, after accounting for portions of the paper and plastic packaging being recycled at rates of 64.7% for paper and cardboard products and 0.8% for polypropylene plastic products[9]. The total estimated MSW generated from the new products is (b) (4) and (b) (4) tons (b) (4) and (b) (4) metric tons) in the first and fifth years of marketing, respectively. This is a negligible fraction (b) (4) to (b) (4) of the 192,080,000 tons (174,250,000 metric tons) of total MSW generated and not recycled in the United States in 2014.

	STN	W	V	U	T	S	R	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
First-Year	SE0014279	63	21	31	743	46.8	125.4	23.6	136.6	1.19	0.992	0.34	0.353	611	18.58	1.51	(b) (4)	0.010	0.66	(b) (4)				
	SE0014280	62	21	31	720	45.4	123.5	23.6	136.6	0.90	0.992	0.30	0.353	638	19.39	5.65	(b) (4)	0.010	0.66					
	SE0014281	60	19	31	707	44.6	150.3	22.7	127.7	0.90	0.992	0.30	0.353	626	18.96	5.65	(b) (4)	0.011	0.66					
	Subtotal, MSW from disposal of new products after use (tons)																							(b) (4)
	Total MSW disposed of (not recycled) in U.S. (2014) (tons)																							(b) (4)
	MSW from product disposal as a % of total MSW disposed of in U.S.																							(b) (4)
Fifth-Year	STN	W	V	U	T	S	R	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
	SE0014279	63	21	31	743	46.8	125.4	23.6	136.6	1.19	0.992	0.34	0.353	611	18.58	1.51	(b) (4)	0.010	0.66	(b) (4)				
	SE0014280	62	21	31	720	45.4	123.5	23.6	136.6	0.90	0.992	0.30	0.353	638	19.39	5.65	(b) (4)	0.010	0.66					
	SE0014281	60	19	31	707	44.6	150.3	22.7	127.7	0.90	0.992	0.30	0.353	626	18.96	5.65	(b) (4)	0.011	0.66					
	Subtotal, MSW from disposal of new products after use (tons)																							(b) (4)
	Total MSW disposed of (not recycled) in U.S. (2014) (tons)																							(b) (4)
	MSW from product disposal as a % of total MSW disposed of in U.S.																							(b) (4)