Programmatic Environmental Assessment for Marketing Orders for Philip Morris USA Inc. "Marlboro Soft Pack, Marlboro 100's Soft Pack, and Marlboro 100's Box"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

May 21, 2018

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This programmatic environmental assessment (PEA) is for marketing orders for six 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 of Applicant

2325 Bells Road
Richmond, Virginia 23234

3. Manufacturer

Philip Morris USA Manufacturing Center

4. Description of the 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 six combusted, filtered cigarettes into interstate commerce for commercial distribution in the United States. These marketing orders are based on the finding that the new products are substantially equivalent to the corresponding predicate products that were on the market as of February 15, 2007.

4.1. Requested Actions

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

4.2. Need for Actions

Philip Morris USA Inc. wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the United States and submitted to FDA six substantial equivalence (SE) reports to obtain marketing orders.

After considering the SE Reports, the Agency shall issue marketing orders under the provisions of sections 910 and 905(j) of the FD&C Act when finding the new products are substantially equivalent to the corresponding predicate products.

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

4.3.1. Type of Tobacco Products

Combusted, filtered cigarette

4.3.2. Product Names and the Submission Tracking Numbers (STN)

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

STN*	New Product	Predicate Product[1]
SE0013909	Marlboro Soft Pack	Marlboro Soft Pack (2007)
SE0013910	Marlboro 100's Soft Pack	Marlboro 100's Box (2007)
SE0013911	Marlboro 100's Box	Marlboro 100's Box (2007)
SE0014710	Marlboro Soft Pack	Marlboro Soft Pack (2007)
SE0014711	Marlboro 100's Soft Pack	Marlboro 100's Box (2007)
SE0014712	Marlboro 100's Box	Marlboro 100's Box (2007)
* Products in SE0013909-SE0013911 and in SE0014710-SE0014712 are identical except for the presence of alternative filter tow		

4.3.3. Description of the Products' Package

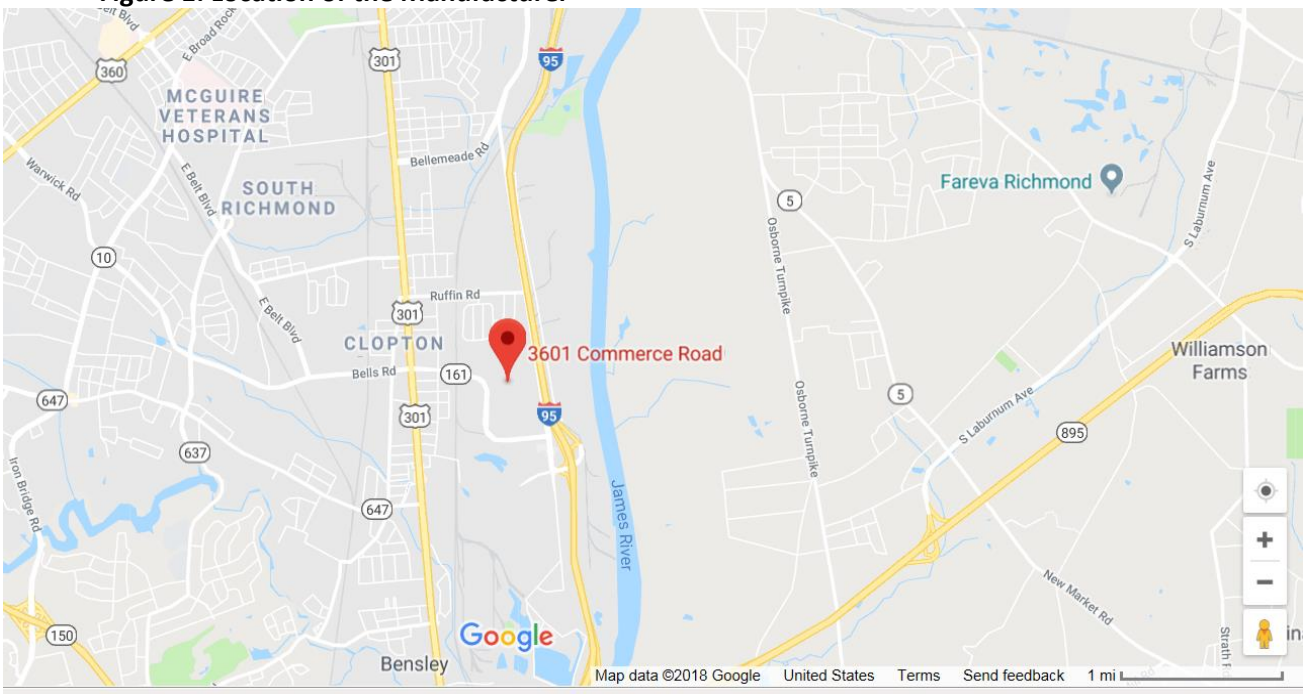
The packaging materials of the finished new products are identical in composition and weight to those of the corresponding predicate products, except for SE001910 (from hard box to a soft pack). The packaging of the new products consists of cardboard box and inner frame paper for the hard pack, paper label and closure for the soft pack, and a foil inner liner, plastic film overlap with plastic tear tape, and cardboard carton for both hard box and soft pack.

4.3.4. Location of Manufacturing

The manufacturer, Philip Morris USA Inc. is located at 3601 Commerce Road in Richmond, Virginia in the United States (Figure 1).

[1] The (2007) is not part of the product name but is used to distinguish the new product from the corresponding predicate product.

Figure 1. Location of the Manufacturer[2]



The facility is located within the James River watershed, which occupies the central portion of Virginia and covers approximately 10,265 square miles (24% of total land area of the state of Virginia).[3] [4] Land use within the watershed is predominantly forest (65%), with agriculture and farming accounting for approximately 19% and urbanized area of 12%. [5]

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

The new 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 cigarettes. Disposal of the used

[2] Manufacturer address via Google Map. Accessed March 12, 2018.

[3] A watershed is an area of land where all bodies of water, such as; surface water from lakes, streams, reservoirs and wetlands, the underlying ground water, and rainfall, drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. See https://water.usgs.gov/edu/watershed.html and http://www.dcr.virginia.gov/soil-and-water/document/wshedguideb2b.pdf.

[4] Virginia Department of Environmental Quality. Available at: http://deq.state.va.us/Portals/0/DEQ/Water/SWRP/App%20B%20James%20River%20Basin%20Summary.pdf. Accessed April 17, 2018

[5] See Virginia Department of Conservation and Recreation at: http://www.dcr.virginia.gov/soil-and-water/wsheds.

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 from disposal after use will correspond to the pattern of products use.

4.4. Modification(s) Identified as Compared to the Corresponding Predicate Products

The differences between the new and the corresponding predicate products are in the changes in product design, tobacco blends, cigarette paper and ingredients of the monogram ink for the new products, in addition to a change in packaging for SE0013910 from a hard box to a soft pack packaging (Confidential Appendix 1).

5. Potential Environmental Impacts Due to the Proposed Actions

5.1 Potential Environmental Impacts Due to Manufacturing the New Products

The Agency considered potential environmental impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency's gathered information and the applicant's submitted information. The Agency utilized data reported in the U.S. EPA's Toxic Release Inventory (TRI) database to search for the chemical waste released by the facility.[6] In 2016, Philip Morris USA manufacturing facility in Richmond, Virginia released 20,347 pounds ammonia and 11,671 pounds 'nicotine and nicotine salts' to air and transferred 2,483 ammonia and 86,420 pounds 'nicotine and nicotine salts' to an off-site location or publicly owned treatment works (POTWs) (Table 1).[7] The TRI database search did not show that Philip Morris USA manufacturing facility disposed of, treated, or released into the environment any other toxicants at or above the reportable levels.

[6] 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.

[7] U.S. Environmental Protection Agency (EPA). *TRI Data Form R & A Download*. Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched on March 7, 2018.

Table 1 Chemical Waste Associated with Manufacturing Tobacco Products at the Facility

Chemical Name	Air Release (Pound)	Land Release (Pound)	Water Release (Pound)	On-Site Release* (Pound)	On-Site Treated (Pound)	Off-Site Total Releaser† (Pound)
Ammonia	20,347	0	0	20,347	5,088	3,978
Nicotine & Nicotine Salts	11,671	0	0	11,671	105,627	201,890

* Total on-site release includes air release, land release, water release, on-site recycling, and on-site energy recovery

† Off-site total release includes disposal, energy recovery, POTWs, off-site recycling and off-site treatment

The Agency anticipates the waste generated due to manufacturing the new products will be released to the environment, transferred to POTW, and disposed of in landfills in the same manner as any other 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 compete with, or replace, other currently marketed cigarettes and will not add to the total volume of cigarettes sold in the United States. 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 products and the corresponding predicate products are in the product design, tobacco blends, cigarette paper and ingredients of the monogram ink for the new products. However, the tobacco blend, cigarette paper and packaging material of the new products are similar to other cigarettes manufactured at the facility. Consequently, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of the proposed actions.

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations, including Clean Air Act, Clean Water Act and the Resource Conservation and Recovery Act, and other environmental regulations. The facility is registered for waste generate under EPA ID# VAD000819466 and permitted to manufacture cigarettes at a level above the current and future year projections for cigarette manufacturing, including the new products. The applicant provided detailed information for the following air emission and waste generation permits:

(1) Air permits: Title V Air Permit number PRO50076 and a Stationary Source Permit, issued in accordance with applicable U.S. EPA and Virginia Department of Environmental Quality (VA DEQ) regulations. These air permits contain the methods used to control air emissions at the manufacturing facility.

(2) An Industrial User Permit number 2149 (i.e., wastewater pretreatment permit) from the local POTW facility in the City of Richmond. The permit requires compliance with the relevant effluent limitations (40 C.F.R. §§ 400 – 699) to ensure the wastewater is of a certain quality for effective treatment at the POTW facility. The facility is required to submit regular 'Discharge Monitoring

Reports' to VA DEQ regularly detailing its compliance with the applicable water quality standards.

Accordingly, manufacturing the new products will not require a revised or new air or wastewater permits and introduction of materials released into the environment is not expected to exceed the allowed amount to be released to the environment under relevant environmental laws. 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 applicant noted that the manufacturing facility has an environmental management system (EMS) designed to ensure environmental sustainability and compliance with good agricultural practice for tobacco farming. The applicant further noted that the facility complies with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). The applicant consulted the U.S. Fish and Wildlife Services (U.S. FWS) critical habitat and endangered species maps. According to the maps, three threatened species, two plants, and the northern long-eared bat, and one endangered freshwater mussel species are listed in the city of Richmond and the bordering counties (Henrico and Chesterfield Counties).[8] [9] The applicants confirmed that these threatened or endangered species are not known to be in the vicinity of the manufacturing facility. Accordingly, the Agency does not anticipate manufacturing the new products to jeopardize the continued existence of any endangered species, nor result in the destruction or adverse modification of the habitat of any such species identified under the ESA.

5.2 Potential Environmental Impacts Due to Use of the New Products

The Agency considered the potential environmental impacts to the environmental resources that may be affected by use of the new products. The Agency found no significant impacts based on gathered information and the applicant's submitted information, including market volumes for the new and predicate products, and the decline in cigarette use in the United States.

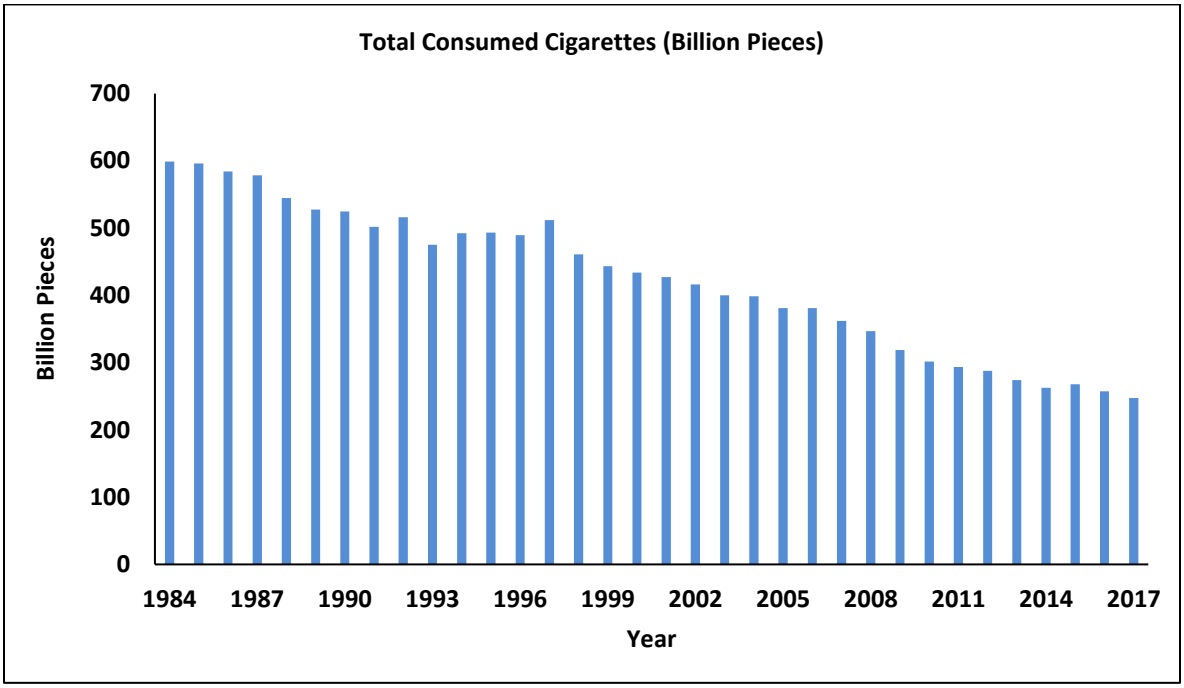
According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of cigarettes in the United States decreased from 512.02 billion cigarettes in 1997 to 247.19 billion cigarettes in 2017 (Figure 4).[10]

[8] U.S. Fish and Wildlife Services U.S. FWS), available at: https://www.fws.gov/endangered/.

[9] Critical habitat map available at: https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449

[10] U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: https://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed March 7, 2018.

Figure 4. Use of Cigarettes in the United States, 1984 – 2016



When burned, cigarettes produce environmental tobacco smoke (ETS) or secondhand smoke (SHS). There is no safe level of exposure to SHS [1, 2]. Even low levels of SHS 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% [3].
- Exposure to SHS 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 [1, 2].
- SHS causes more than 40,000 deaths a year [3].

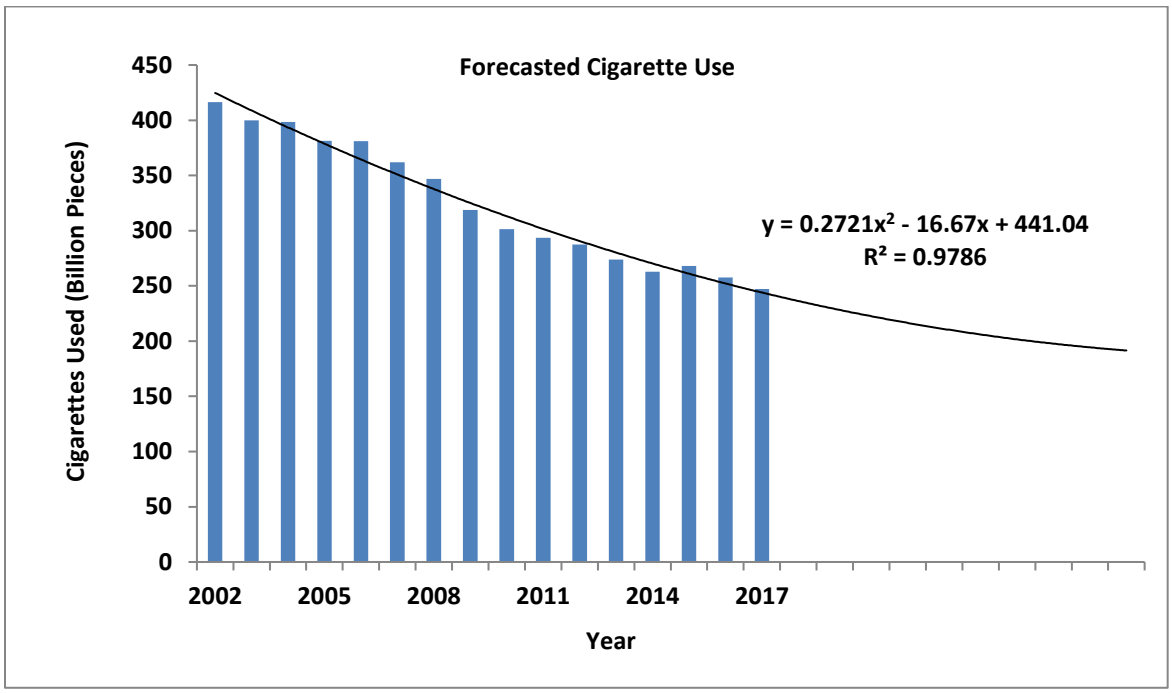
Historical data regarding total use of cigarettes from 2002 to 2017 was employed to mathematically estimate the forecast of the total amount of cigarettes used in the United States.[11] Using the best-fit trend line with an R^2 value of 0.9786, the forecasted number of cigarettes that will be used in the United States is estimated at 236.26 billion cigarettes and 210.92 billion cigarettes are forecasted to be used in the first year and fifth year of marketing the new products, respectively (Figure 5). [12] [13]

[11] See footnote 9.

[12] Projected first-year billion pieces of cigarettes = $(0.2721\ X\ (17)^2) - (16.67\ \mathrm{X}\ 17) + 441.04$

[13] Projected fifth-year billion pieces of cigarettes = $(0.2721\ X\ (21)^2) - (16.67\ \mathrm{X}\ 21) + 441.04$

Figure 5. Forecasted Use of Cigarettes in the United States, 2002-2017



The projected market volumes of the new products in the first and fifth year of marketing occupy a small percentage of the total projected estimate of use of cigarette in the United States (Confidential Appendix 2).

Based on the changes between the new and corresponding predicate products outlined in section 4.4, the Agency does not anticipate new substances to be released into the environment as a result of use of the new cigarettes, relative to the substances released by the predicate products, and other cigarettes already on the market. Because (1) the combustion products from the new products will be released in the same manner to the combustion products of the predicate products and other marketed cigarettes, and (2) the new products are expected to compete with, or replace, other currently marketed cigarettes, the Agency does not expect that new types of combustion products or net addition of greenhouse gas (GHG) emissions will be associated with use of the new products.

5.3 Potential Environmental Impacts Due to Disposal of the New 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 cigarette products, can be informative about the disposal of cigarette packaging materials. Specifically, according to the U.S. EPA, approximately 258.46 million tons of waste was generated in the United States in 2014, and approximately 89.4 million tons of

this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 6 and 7).[14] Paper and paperboard accounted 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%), of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW, 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. On average, 4.4 pounds of waste was generated per person in the United States, of which 2.1 pounds was recycled, composted, or combusted for energy recovery [4].

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

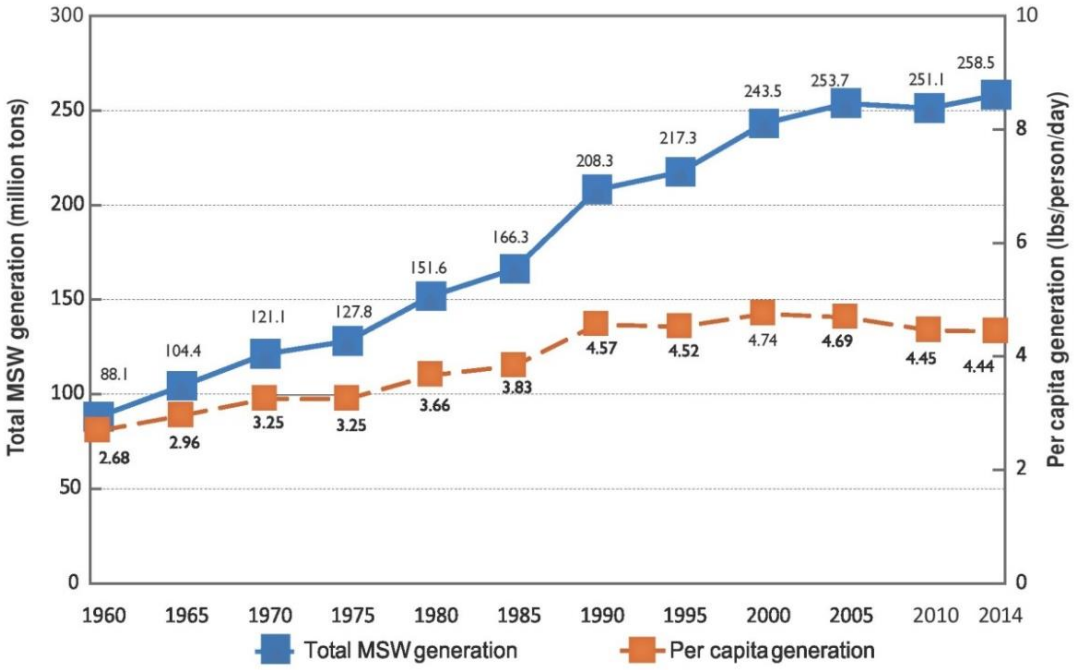


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

[14] The "ton" unit in section 5.3.1 is U.S. short ton, unless specified otherwise

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

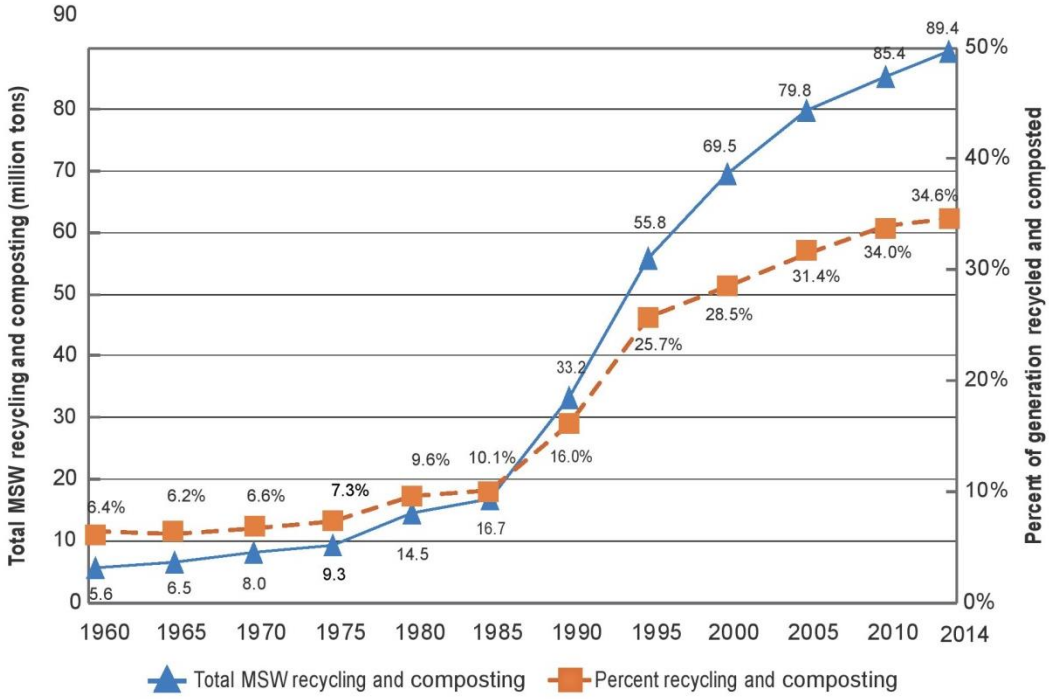


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

To calculate the amount of waste from disposal of the packaging material and products material, the Agency used the first- and fifth-year projected volumes of marketing the new products after issuance of the marketing orders for the new products (Confidential Appendix 3). The calculated cumulative waste of the packaging material is a fraction of the forecasted MSW that would be generated in the United States. In addition, because paper components and plastic wrap are more likely to be recycled, at least a portion of the packaging waste is likely to be recycled.

Construction of new POTWs or landfills is not anticipated due to the proposed actions. The Agency has reached this determination because (1) the new products will compete with, or replace, other similar products on the market, and (2) the waste generated will be a miniscule fraction of the total MSW generated in the United States.

The Agency does not anticipate the proposed actions to lead to the release of new chemicals into the environment due to disposal of the products' packaging material. The components and the chemicals that will be released from the disposal of the new products packaging are commonly released by similar packaging materials that are already disposed of in the United States. Therefore, the fate of any

materials emitted is anticipated to be the same as any materials from other packaging cigarettes manufactured in the facility.

5.3.2 Disposal of Cigarettes Following Use

Used cigarettes are usually disposed of in MSW landfills or as litter. When discarded as MSW, the products would enter landfills. When discarded as litter, cigarette butts are likely to move by run-off to the ocean.

Cigarette butts constitute the major existing environmental consequence of the use of combusted filtered cigarettes. Evidence has shown that cigarette butts are the most prevalent items discarded into roads and streets in urban areas. Once dumped onto city streets, they move through the storm drains to streams, into the ocean, and back onto the beaches, while leaching toxicants, including arsenic, lead, nicotine and ethyl phenol, into the aquatic environment and soil along the way [5]. Discarded filters are found to be the most collected item in beach clean-ups and litter surveys. An estimated 30% of the total waste (by count) on U.S. shorelines, waterways, and land is cigarette butt waste [6].

Introducing the new products into the U.S. market is not expected to increase the nationwide use of cigarettes; instead the new products will compete with, or replace, other similar cigarettes on the market. Therefore, issuing marketing orders for the new products is not expected to affect the overall level of cigarette butt litter in the United States. The Agency used the projected market volumes for the first and fifth years of marketing the new products to estimate the waste from disposal of cigarette butts as MSW (Confidential Appendix 4). The estimated waste of cigarette butts is miniscule compared to the total forecasted MSW disposal in the United States. Construction of new solid waste landfills or incinerators is not anticipated due to disposal of used products under the proposed actions because; (1) the estimated waste of cigarette butts is a negligible contribution to U.S. MSW and (2) the new products will not lead to increased use of cigarettes.

While littered cigarette butts remain as an environmental concern, the Agency does not anticipate the proposed actions to lead to the release of new chemicals into the environment due to disposal of the new products. The components and the chemicals that will be released from disposal of the new products are commonly released by similar products that are already disposed of in the United States. Therefore, the Agency does not anticipate the disposal of the new products to cause the release of new chemicals into the environment.

6. Use of Resources and Energy

Based on the SE Reports, 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 predicate products and the applicant does not anticipate any increased energy or resource needs to manufacture the new products. The applicant stated that the manufacture, use, and disposal of the new and predicate products is not expected to

jeopardize the continued existence of any endangered species, nor result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA.

The applicant confirmed 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 a small portion of the total forecasted cigarette market volumes in 2018 and 2022. Because 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.

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 were developed.

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 following use 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 issuing marketing orders for the new products and the associated manufacture, use, and disposal of the new tobacco products.

9. List of Preparers:

The following individuals were primarily responsible for preparing and reviewing this environmental assessment:

Preparer:

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

Education: Ph.D. in Plant Molecular Biology and Virology
Experience: 25 years in various scientific activities, including 7 years in NEPA practice
Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

Reviewer:

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

Education: Ph.D. in Biochemistry and M.S. in Environmental Science
Experience: 10 years in NEPA practice
Expertise: Waste water treatment, environmental impact analysis

10. List of Agencies and Persons Consulted

Not applicable.

11. Appendix List

Appendix 1: Submission Tracking Numbers for the SE Reports for the New Products, the Corresponding Predicate Products, and Related Amendments Covered Under this PEA

12. Confidential Appendix

Confidential Appendix 1: Proposed Modifications in the New Products as Compared to the Corresponding Predicate Products

Confidential Appendix 2: First- and Fifth-Year Market Volume Projections of the New and Currently Marketed Products and Percentage of Cigarette Use in the United States Occupied by the Products

Confidential Appendix 3: 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 Health and Human Services. 2006. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.
2. U.S. Department of Health and Human Services. 2006. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.
3. U.S. Department of Health and Human Services. 2014. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta, GA.
4. U.S. Environmental Protection Agency. (2016). Advancing Sustainable Material Management: Facts and Figures. Retrieved from https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf. Accessed March 7, 2018.
5. Moriwaki, H., Kitajima, S., Katahira, K. (2009). Waste on the roadside, 'poi-sute' waste: Its distribution and elution potential of pollutants into environment. *Waste Management*, 29, 1192-1197.
6. Novotny, T.E., Bialous, S.A., Burt, L., Curtis, C., da Costa, V.L., Iqtidar, S.U., Liu, Y., Pujari, S., Tursan d'Espaignet, E. (2015). The environmental and health impacts of tobacco agriculture, cigarette

manufacture and consumption. *Bull World Health Organ*, 93(12), 877-880.

APPENDIX 1

Submission Tracking Numbers for the SE Reports for the New Products, the Corresponding Predicate Products, and Related Amendments Covered Under this PEA

STN	New Product	Predicate Product	STN of Predicate Product	Amendments
SE0013909	Marlboro Soft Pack	Marlboro Soft Pack	GF1200100	SE0013990 SE0014195 SE0014392 SE0014549 SE0014647
SE0014710				
SE0013910	Marlboro 100's Soft Pack	Marlboro 100's Box	GF1200088	SE0013990 SE0014195 SE0014392 SE0014549 SE0014647
SE0014711				
SE0013911	Marlboro 100's Box	Marlboro 100's Box	GF1200088	SE0013985 SE0013990 SE0014195 SE0014392 SE0014549 SE0014647
SE0014712				

CONFIDENTIAL APPENDIX 1

Proposed Modifications in the New Products as Compared to the Corresponding Predicate Products

STN	Component	Modification
SE0013909 SE0014710	Cigarette Paper	An increase in band width (9.1%) A decrease in band porosity (3.7%)
	Tobacco Blend	A decrease in tobacco filler mass (1.6%) An increase in the (b) (4) (b) (4)
	Tobacco Filler	An increase in (b) (4) A decrease in (b) (4) (b) (4)
	Product design	A decrease in cigarette length (1.2%)
	Ink	A decrease in (b) (4) monogram ink
SE0013910 SE0014711	Package	Changed to a soft pack from the hard box in the corresponding predicate product
SE0013910 SE0013911 SE0014711 SE0014712	Cigarette Paper	An increase in cigarette paper band width (9.1%) A decrease in cigarette paper band porosity (3.1%)
	Tobacco Blend	An increase in the (b) (4)
	Tobacco Filler	An increase in (b) (4) A decrease in (b) (4) (b) (4)
	Ink	A decrease in (b) (4) monogram ink

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections of the New and Currently Marketed Products and Percentage of Cigarette Use in the United States Occupied by the Products

STN	Production of Currently Marketed Product* (Pieces)	First-Year Projected Volume (Pieces)	Fifth-Year Projected Volume (Pieces)
SE0013909	(b) (4)		
SE0014710			
SE0013910			
SE0014711			
SE0013911			
SE0014712			
Total Projected Volumes			
Current and Projected Use of Cigarettes in United States[15]			
Percentage of Market Occupation of the New Products Based on Total Cigarettes Used in the United States (%)[16]			

* The applicant stated that the new products and the currently marketed products differ only in the use of an alternate cigarette paper for the purposes of (b) (4) .

The current and projected market volumes of the new products in the first and fifth year of marketing comprise a small percentage of the current and estimated future use of cigarettes in the United States.

[15] See section 5.2

[16] $\textit{Projected Market Occupation of the New Product in the United States}\ (\%) = \frac{\text{Projected Market Volume of the New Products (cigarette } \textit{pieces})}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} x\ 100\%$

CONFIDENTIAL APPENDIX 3

Projected Waste of Packaging Material and Cigarette Butts in the First and Fifth Year of Marketing the New Products

To analyze the environmental effects from total waste due to the proposed actions, the Agency estimated the projected weight of the packaging and product materials waste (in metric tons) that would be generated from disposal of the new products in the first year- and fifth year after issuance of the marketing orders for the new products. Projected waste generation is a summation of the projected waste of packaging components (i.e. waste of cardboard shipping containers, waste of paperboard cartons, and paper components, foil inner liner and plastic wrap of the retail pack/box) and cigarette butts of the new products:

$\sum_{i=1}^{3} A_i = \sum_{i=1}^{3} (B_i + C_i + D_i + E_i + F_i + G_i)$	A_i: Projected total waste generation of the product (metric tons)
$B_i = \frac{H_i}{I} \times (J_i + K_i) \times Y$	B_i: Projected waste generation of the paper components of pack/box of the new product (metric tons)
$C_i = \frac{H_i}{I} \times L_i \times Y$	C_i: Projected waste generation of the foil inner liner of the new product (metric tons)
$D_i = \frac{H_i}{I} \times (M_i + N) \times Y$	D_i: Projected waste generation of the plastic wrap of the new product (metric tons)
$E_i = \frac{H_i}{(I\ X\ O)} \times P_i \times Y$	E_i: Projected waste generation of the paperboard carton of the new product (metric tons)
$F_i = \frac{H_i}{(I\ X\ O\ X\ Q)} \times R_i \times Y$	F_i: Projected waste generation of the cardboard shipping case of the new product (metric tons)
$G_i = H_i \times S_i \times T_i \times Y$	G_i: Projected waste generation of cigarette butts of the new product (metric tons)
$T_i = \frac{U}{V_i}$	H_i: Projected market volume of the new product (number of individual cigarettes; also see Confidential Appendix 2) I: Number of cigarettes per soft pack = 20 J_i: Weight of the paper container (label paper for soft pack or paperboard for the box) (grams) K_i: Weight of the paper closure for soft pack or the paper inner liner (box) (grams) L_i: Weight of the foil inner liner for the soft pack/box (grams) M_i: Weight of the outer plastic wrap (grams) N: Weight of the plastic teat tape (grams) O: Number of packs/boxes per carton = 10 P_i: Weight of empty paperboard carton (grams) Q: Number of cartons per shipping case = 60 R_i: Weight of empty cardboard shipping container (grams) S_i: Weight of cigarette (gram) T_i: Cigarette butt length U: Cigarette butt ratio [17] V_i: Length of cigarette (millimeter) Y: 1.0 x 10^{-6} metric tons/gram

[17] ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed of as solid waste following use.

a) **Projected Waste of Packaging Material**

Projected packaging waste is calculated as below:

	STN	H_i	O	J_i	K_i	B_i	I	Pi	E_i	Q	R_i	F_i	Total Paper Waste	L_i	C_i	M_i	N	D_i
First-Year	SE0013909	(b) (4)																
	SE0014710																	
	SE0013910																	
	SE0014711																	
	SE0013911																	
	SE0014712																	
	Total																	
Fifth-Year	SE0013909																	
	SE0014710																	
	SE0013910																	
	SE0014711																	
	SE0013911																	
	SE0014712																	
	Total																	

If all the projected packaging waste generated from use of the new products is disposed of in landfills, the projected cumulative paper waste generated in the first and fifth years of marketing the new products (variables B + E + F) would be (b) (4) metric tons and (b) (4) metric tons, respectively. This is a negligible percentage (b) (4)) of the 258.46 million tons (equivalent to 234.47 million metric tons) of total waste reported in the United States in 2014.[18] A portion of the generated cardboard waste is likely to be recycled, with an overall recycling rate for paper and paperboard products of 64.7% in the United States. If 64.7% of the paper packaging material is recycled and the rest (35.3%) is disposed of as waste, the estimated total paper waste disposed of in landfills will be decreased to (b) (4) metric tons (0.353 × (b) (4) metric tons) in the first year and (b) (4) metric tons (0.353 × (b) (4) metric tons) in the fifth year of marketing the new products.

The projected foil waste (variable C) of (b) (4) metric tons in the first year, and (b) (4) metric tons in the fifth year of marketing the new products is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014. Likewise, the projected

[18] EPA. Advancing Sustainable Materials Management: Facts and Figures Report. Available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report (accessed October 24, 2017).

plastic waste (variable D) of (b) (4) metric tons in the first year, and (b) (4) metric tons in the fifth year of marketing the new products is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.

b) Projected Waste of Cigarette Butts

Projected waste of disposed cigarette butts is calculated as below:

Projected Year	STN	*Market Volume (Pieces)* H_i	*Weight of Cigarette (gram)* S_i	*Length of Cigarette (mm)* V_i	*Cigarette Butt Waste (Tons)* F_i
First-Year	SE0013909	(b) (4)			
	SE0014710				
	SE0013910				
	SE0014711				
	SE0013911				
	SE0014712				
	Total				
Fifth-Year	SE0013909				
	SE0014710				
	SE0013910				
	SE0014711				
	SE0013911				
	SE0014712				
	Total				

If all the projected cigarette butt waste generated from use of the new products is disposed of in landfills, the projected waste of (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new products will be a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.