Programmatic Environmental Assessment for Marketing Orders for New Combusted, Filtered Cigarettes Manufactured by Philip Morris USA, Inc.

Prepared by Center for Tobacco Products,
U.S. Food and Drug Administration

June 26, 2020

Table of Contents

1. Applicant and Manufacturer Information

Applicant Name:	Altria Client Services LLC
Applicant Address:	2325 Bells Road Richmond, VA 23234
Manufacturer Name:	Philip Morris USA, Inc.
Product Manufacturing Address:	3601 Commerce Road Richmond, VA 23234

2. Product Information

New Product Names, Submission Tracking Numbers (STNs), and Predicate Product Names

STN	New Tobacco Product Name	Predicate Tobacco Product Name
SE0015685	Marlboro Menthol Special Select Box	Marlboro Menthol Special Select Box
SE0015693	Marlboro Menthol Special Select Box	Marlboro Menthol Special Select Box
SE0015686	Marlboro Menthol Special Select 100's Box	Marlboro Menthol Special Select 100's Box
SE0015694	Marlboro Menthol Special Select 100's Box	Marlboro Menthol Special Select 100's Box
SE0015687	Marlboro Menthol Box	Marlboro Menthol Box
SE0015688	Marlboro Menthol Black Special Blend Box	Marlboro Menthol Box
SE0015689	Marlboro Black Label Box	Marlboro Black Label Box
SE0015703	Marlboro Black Label Box	Marlboro Black Label Box
SE0015690	Marlboro Red Label 100's Box	Marlboro Red Label 100's Box
SE0015691	Merit Blue Pack 100's Box	Merit Blue Pack 100's Box
SE0015692	Marlboro Red Label Box	Marlboro Red Label Box

Product Identification

Product Category	Cigarettes
Product Sub-Category	Combusted Filtered
Number of Products per Retail Unit	Twenty cigarettes per pack with ten packs per paperboard carton and 60 cartons per shipping case.
Product Package	The packaging materials consist of paperboard hard packs with inner frames. The hard packs have inner foils, polypropylene outer wraps, polypropylene tear tapes, paperboard cartons and corrugated paperboard shipping cases.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco products substantially equivalent to the corresponding

predicate tobacco products. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency eleven substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue the marketing orders if the new tobacco products are found substantially equivalent to the corresponding predicate tobacco products. The predicate tobacco products were previously found substantially equivalent and received marketing orders.

The new tobacco products differ from the corresponding predicate tobacco products in changes in cigarette paper, filter components, and tipping adhesive (Confidential Appendix 1).

4. Alternative to the Proposed Actions

The no action alternative is FDA does not issue marketing orders for the new tobacco products.

5. Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the New tobacco products

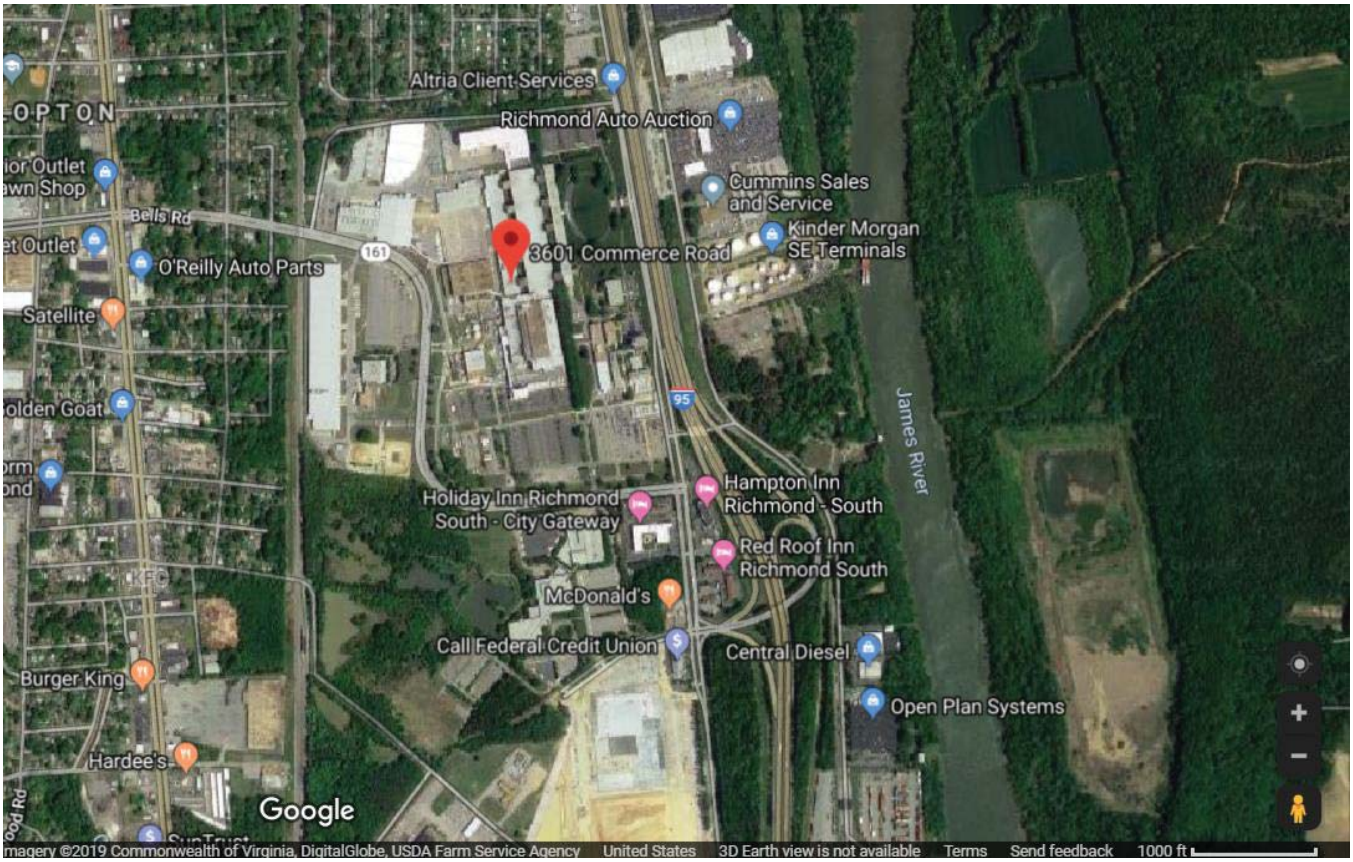
The Agency considered potential impacts that may be affected by manufacturing the new tobacco products and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- The production of the new tobacco products will replace production of other cigarettes currently being manufactured at the same facility.
- The applicant stated that the new and predicate tobacco products would not be simultaneously manufactured if the new tobacco products receive marketing orders.
- No facility expansion or new construction is expected due to manufacturing the new tobacco products.
- No net increase in the facility production is expected due to manufacturing the new tobacco products.

5.1 Affected Environment

The new and predicate tobacco products are manufactured at 3601 Commerce Road, Richmond, VA (Figure 1).

Figure 1. Location of the Manufacturing Facility



The manufacturing facility is surrounded by a residential development across a road to the north; a two-lane divided road and an interstate freeway (I-95) to the east; two hotels, a fast food restaurant, and a gas station at the southeast corner; undeveloped forested land and a petroleum product pumping station and delivery terminal to the south; and a railroad to the west with a spur into the manufacturing facility.[1] The facility is located in the James River watershed, which occupies the central portion of Virginia and covers 24% of total land area of the state of Virginia.[2,3] Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area.[4]

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[1] Google. 2019. Map of 3601 Commerce Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. July 19, 2019.

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

[3] 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 July 19, 2019.

[4] Ibid.

5.2 Air Quality

The Agency does not anticipate that manufacturing the new tobacco products would lead to release of new chemicals into the air. The applicant stated that manufacturing the new tobacco products is not expected to result in changes in air emissions; accordingly, the applicant concluded that manufacturing the new tobacco products would not require revised or new air permits.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new tobacco products would cause any new chemicals to be discharged into the water. The new tobacco products are intended to replace similar tobacco products currently manufactured at the facility. The applicant stated that manufacturing the new tobacco products is not expected to result in changes in wastewater discharge and therefore, would not require revised or new wastewater discharge permits.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new tobacco products would lead to changes in soil, land use, or zoning. No facility expansion or new construction due to manufacturing the new tobacco products would be expected. Therefore, no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use would be anticipated.

5.5 Biological Resources

The Agency does not anticipate manufacturing the new tobacco products would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA). The applicant stated that manufacturing the new tobacco products will not require expansion of the facility. The applicant reviewed the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps. According to the maps, three threatened species (two plants, and one 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).[5,6] However, the applicant stated that none of these species are found near the manufacturing facility. The Agency searched the U.S. FWS maps and verified the accuracy of the listed species.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with the Clean Air Act, the Clean Water Act and the Resource Conservation and Recovery Act. The manufacturing facility is registered for waste generation under EPA ID# VAD000819466. The applicant provided detailed information for the following air emission and wastewater permits:

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[5] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/endangered/. Accessed July 19, 2019.

[6] Critical habitat maps available at: https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449 Accessed July 19, 2019.

(1) Air permits: Title V Air Permit number PRO50076 and a Stationary Source Permit, issued in accordance with applicable U.S. Environmental Protection Agency (EPA) and Virginia Department of Environmental Quality (VA DEQ) regulations.
(2) Wastewater permit: Industrial User Permit number 2149 from the local publicly owned treatment works (POTW) 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 applicant stated that the facility submits regular discharge monitoring reports to VA DEQ.

The Agency's search of EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations at the facility.[7]

The applicant stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

5.7 Socioeconomics and Environmental Justice

No changes in socioeconomics are anticipated due to manufacturing the new tobacco products. The Agency does not anticipate any impacts on employment, revenue, or taxes because the new tobacco products are intended to replace similar tobacco products currently manufactured at the facility.

No changes in impacts on environmental justice are anticipated. The applicant stated that no new air or waste water permits would be required and no facility expansion would occur due to manufacturing the new tobacco products. Also, as discussed, the emissions and discharges from the facility are not expected to change because of manufacturing the new tobacco products. Thus, though 2010 U.S. Census and American Community Survey data show that 77% of the population within a three-mile radius of the manufacturing facility is minority,[8] no disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new tobacco products.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new tobacco products would notably affect the current manufacturing waste generated from the facility production of all combusted, filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new tobacco products would be released to the environment, transferred to a POTW, and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility or from any other combusted, filtered cigarettes manufactured in the United States.

[7] EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000869793. Accessed October 18, 2019.

[8] EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: https://echo.epa.gov/detailed-facility-report?fid=110000869793. Accessed July 19, 2019.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new tobacco products and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.

5.10 Cumulative Impacts

The Agency does not anticipate the proposed action would incrementally increase or change the chemicals released to the air from the facility due to the tobacco manufacturing. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2018, Philip Morris USA manufacturing facility in Richmond, Virginia released 10,313 pounds of nicotine and nicotine salts to air but released no other hazardous air pollutants at reportable levels (Table 1). Nicotine and nicotine salts have known adverse developmental effects. The applicant stated that the facility does not anticipate any future increased production beyond its current permitted capacity and therefore, a revised or new air permit would not be required. The TRI database search did not show that the Philip Morris USA manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Philip Morris USA Facility in 2018

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			122,530
Energy Recovery			0
Treated			94,266
Subtotal Waste Managed			*216,796*
On-site Release	Air	Ammonia	0
		Nicotine and Nicotine Salts	10,313
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-site Release			35,528
Subtotal Waste Released			*45,841*
Total Production-Related Waste			**262,637**

The applicant does not anticipate manufacturing the new tobacco products would require a revised or new wastewater permit.

5.11 Impacts of the No-Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of manufacturing cigarettes, as many similar tobacco products would continue to be marketed in the United States.

6. Potential Environmental Impacts of the Proposed Actions and Alternative – Use of the New Tobacco Products

The Agency evaluated potential impacts to resources in the environment that may be affected by use of the new tobacco products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new tobacco products (Confidential Appendix 2) and the documented decline in cigarette use in the United States.

6.1 Affected Environment

The affected environment includes human and natural environments in the United States; the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

6.2 Air Quality

The Agency does not anticipate new chemicals would be released into the environment as a result of use of the new tobacco products, relative to chemicals released into the environment due to use of other cigarettes already on the market, because (1) the combustion products from the new tobacco products would be released in the same manner as the combustion products of other marketed cigarettes, (2) the new tobacco products are expected to compete with or replace other currently marketed cigarettes and (3) the ingredients in the new tobacco products are used in other currently marketed tobacco products.

6.3 Environmental Justice

No new emissions are expected due to use of the new tobacco products. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.4 Cumulative Impacts

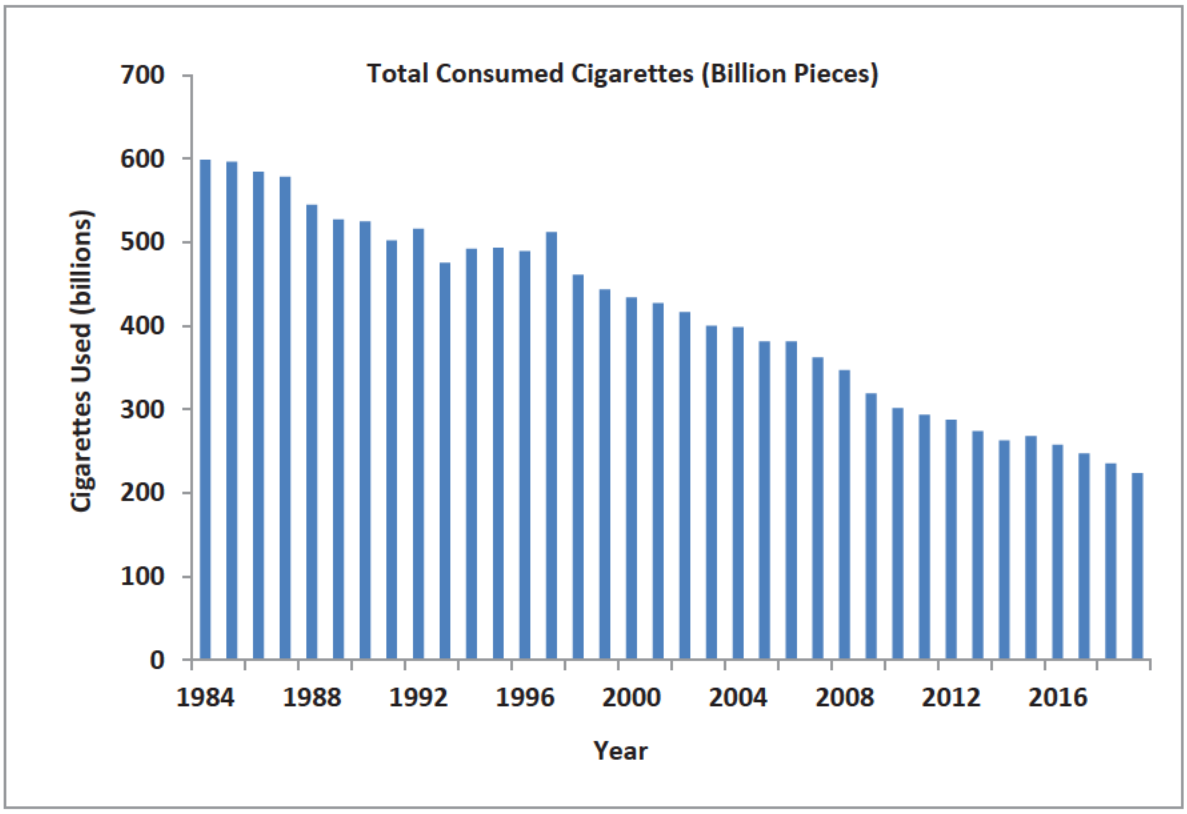
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigarettes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke (THS). These pollutants coexist in a mixture in the environment alongside SHS (Burton, 2011; Matt et al., 2011).

There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). 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% (U.S. Department of Health and Human Services, 2014).
- 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. Such exposure can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).
- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

However, use of cigarettes in the United States is declining according to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).[9] This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. Exposure to SHS declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010 as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

Figure 2. Use of Cigarettes in the United States, 1984 – 2019



As of March 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2020). Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

[9] U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: https://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed July 19, 2019.

6.5 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of cigarettes, as many similar tobacco products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Actions and Alternative – Disposal of the New Tobacco Products

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new tobacco products. The Agency found no significant impacts based on publicly available information such as the documented continuous decline in use of cigarettes in the United States, and the applicant's submitted information, including the projected market volumes for the new tobacco products.

7.1 Affected Environment

The affected environment includes human and natural environments in the United States; the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

7.2 Air Quality

The Agency does not anticipate disposal of the new tobacco products or the packaging material would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the cigarette butts of the new tobacco products. The chemicals in the cigarette butts are commonly used in other currently marketed cigarettes. Because the new tobacco products are anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new tobacco products would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new tobacco products are anticipated to be the same as any materials from other cigarettes disposed of in the United States.

No changes in air quality from disposal of the packaging materials in the new tobacco products would be expected because (1) the paper and plastic components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

7.3 Water Resources

No changes in impacts on water resources are expected due to disposal of the cigarette butts from the new tobacco products because the chemicals in the new tobacco products are the same or similar to chemicals in the currently marketed cigarettes. The new tobacco products would replace similar products currently on the market.

7.4 Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species, or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. Although disposal of smoldering cigarettes has been implicated in many fire incidents,[10, 11] the disposal of the new tobacco products is not expected to change the fire frequency because (1) the disposal of the new tobacco products would be similar to the disposal of cigarettes that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigarettes being disposed of as the new tobacco products are anticipated to replace similar marketed cigarettes.

7.5 Solid Waste

The Agency does not foresee the introduction of the new tobacco products would notably affect the current cigarette butt waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new tobacco products would be handled in the same manner as any other waste generated from any other combusted, filtered cigarettes manufactured in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 2) and a portion of those would be littered.

7.6 Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new tobacco products. The waste generated due to disposal of the new tobacco products is expected to be handled in the same manner as the waste generated from other cigarettes in the United States. No new emissions are expected due to disposal of the new tobacco products; therefore, there would be no new disproportionate impacts on minority or low-income populations.

7.7 Cumulative Impacts

A major existing environmental consequence of the use of the new tobacco products as well as other conventional cigarettes is littering of discarded cigarette filters or butts, which can persist in the environment (Novotny and Zhao, 1999). Cigarette butts are among the most common forms of litter found on beaches (Claereboudt, 2004; Smith et al., 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson et al., 2014), roads, and streets (Healton et al., 2011; Patel et al., 2013). Cigarette butts have been found at densities averaging more than four cigarette butts per meter squared of urban environments (Seco Pon and Becherucci, 2012).

Compounds in cigarette butts can leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigarette butts due to air emissions is not well studied. The chemicals in cigarette butts can be the original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the

[10] National Fire Protection Association. The smoking-material fire problem. Available at: https://www.nfpa.org/News-and-Research/Fire-statistics-and-reports/Fire-statistics/Fire-causes/Smoking-Materials. Accessed August 16, 2018.

[11] UC Davis Health News. Available at: https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763. Accessed August 16, 2018.

cigarette butts. Airborne emissions from cigarette butts after disposal depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco fillers, number of puffs, and the mass transfer behavior of combustion products along the cigarette.[12]

However, the cumulative impacts from cigarette butts are declining because the use of cigarettes in the United States is declining.

7.8 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of disposal of cigarettes and cigarette packaging, as many other similar tobacco products would continue to be marketed in the United States.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment (PEA):

Preparer:

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

Reviewer:

Gregory G. Gagliano, M.S., Center for Tobacco Products
- Education: M.S. in Environmental Science
- Experience: Thirty-seven years in environmental compliance and analysis
- Expertise: Environmental toxicology, risk assessment, regulatory compliance, NEPA analysis

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2006.

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Wilson N, Oliver J, Thomson G. Smoking close to others and butt littering at stops: Pilot observational study. *PeerJ*. 2014;2:e272.

Yao T, Sun HY, Wang Y, Lightwood J, Max W. Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*. 2016;*131:*357-366.

CONFIDENTIAL APPENDIX 1

Comparison of the New Tobacco Products to the Corresponding Predicate Tobacco Products

STN	Change from Predicate Product
SE0015685 SE0015693	Cigarette paper - Minor changes in the material composition of the cigarette paper with increased total levels of (b) (4) Tipping adhesive - Addition of (b) (4)
SE0015685 SE0015693	Cigarette paper - Minor changes in the material composition of the cigarette paper with increased total levels of total (b) (4) Tipping adhesive - Addition of (b) (4)
SE0015687	Cigarette seam adhesive – Minor changes in the composition with addition of (b) (4), and (b) (4). Deletion of (b) (4)
SE0015688 SE0015690 SE0015692	Cigarette seam adhesive – Minor changes in the composition with addition of (b) (4), and (b) (4). Deletion of (b) (4) Tipping Adhesive – Addition of (b) (4)
SE0015689 SE0015703	Monogram ink – minor decrease in material composition Cigarette seam adhesive - Minor changes in the composition with addition of (b) (4), and (b) (4) Deletion of (b) (4)
SE0015691	Cigarette paper – Minor changes in the material composition of the cigarette paper with increased total levels of (b) (4) Plug wrap – Deletion of (b) (4) and (b) (4) Addition of (b) (4) and (b) (4) Tipping adhesive - Addition of (b) (4)

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections for the New Tobacco Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Tobacco Products

First- and fifth-year market volume projections for the new tobacco products were compared to the total forecasted use of cigarettes in the United States.[13] The projected use of the new tobacco products in the first and fifth years of marketing account for about (b) (4) and (b) (4) of the forecasted cigarette use in the United States, respectively. In addition, the applicant stated that the new tobacco products would replace similar tobacco products currently on the market.

STN	Projected Market Volume			
	First-Year		Fifth-Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[14]	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[15]
SE0015685	(b) (4)			
SE0015693				
SE0015686				
SE0015694				
SE0015687				
SE0015688				
SE0015689				
SE0015703				
SE0015690				
SE0015691				
SE0015692				
Total				

[13] The Agency used historical data regarding total use of cigarettes from 2002 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R^2 value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 228.66 billion cigarettes in the first year and 205.02 billion cigarettes in the fifth year of marketing the new products.

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

[15] Ibid.