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

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

March 13, 2020

Table of Contents

Table	of Conte	ents	2			
1.	Applicar	nt and Manufacturer Information	3			
2.	Product	Information	3			
3.	The Need for the Proposed Actions					
4.	Alternat	ives to the Proposed Actions	4			
5.	Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the					
	New F	Products	4			
	5.1	Affected Environment	4			
	5.2	Air Quality	6			
	5.3	Water Resources	6			
	5.4	Soil, Land Use, and Zoning	6			
	5.5	Biological Resources	6			
	5.6	Regulatory Compliance				
	5.7	Socioeconomics and Environmental Justice	8			
	5.8	Solid Waste and Hazardous Materials				
	5.9	Floodplains, Wetlands, and Coastal Zones	8			
	5.10	Cumulative Impacts	8			
	5.11	Impacts from No-Action Alternative	9			
6.	Potentia	Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New				
	Produ	Products9				
	6.1	Affected Environment	9			
	6.2	Air Quality	9			
	6.3	Environmental Justice	10			
	6.4	Cumulative Impacts	10			
	6.5	Impacts from No-Action Alternative	11			
7.	Potentia	al Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the Ne	ew			
	Produ	cts	11			
	7.1	Affected Environment	11			
	7.2	Air Quality	11			
	7.3	Water Resources	12			
	7.4	Biological Resources	12			
	7.5	Solid Waste	12			
	7.6	Socioeconomics and Environmental Justice	13			
	7.7	Cumulative Impacts	13			
	7.8	Impacts from No-Action Alternative	13			
8.	List of P	reparers	13			
9.	A Listing of Agencies and Persons Consulted					
10.	Referen	ces	14			
CONI	FIDENTIA	L APPENDIX 1	16			
Com	parison o	f the New Products to the Predicate Product	16			
		L APPENDIX 2				
First-	and Fifth	n-Year Market Volume Projections for the New Products and Percentage of Cigarette U	lse			
	in the	United States Projected to be Attributed to the New Products	17			

1. Applicant and Manufacturer Information

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

2. Product Information

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

STN	New Product Name	Predicate Product Name	
SE0015664	Marlboro Special Select (Red Pack) Box	Marlboro Special Select (Red Pack) Box	
SE0015665	Marlboro Special Select (Gold Pack) Box	Marlboro Lights Soft Pack	
SE0015666	Marlboro Special Select (Red Pack) 100's Box	Marlboro Special Select (Red Pack) 100's Box	
SE0015667	Marlboro Menthol Black Special Blend 100's Box (Tipping Paper 1)	Marlboro Menthol Black Special Blend 100's Box (Tipping Paper 1)	
SE0015668	Marlboro Special Select (Gold Pack) 100's Box	Marlboro Lights 100's Soft Pack	
SE0015671	Marlboro Menthol Black Special Blend 100's Box (Tipping Paper 2)	Marlboro Menthol Black Special Blend 100's Box (Tipping Paper 2)	
SE0015672	Marlboro Menthol Black Special Blend 100's Box (Tipping Paper 3)	Marlboro Menthol Black Special Blend 100's Box (Tipping Paper 3)	

Product Identification

Product Category	Cigarettes		
Product Subcategory	Combusted filtered		
Product Number per	Twenty cigarettes per pack with ten packs per carton and 60 cartons per		
Retail Unit	shipping case.		
	The packaging materials consist of a foil laminated to paper inner foil,		
Product Package	paperboard innerframe, paperboard hard pack, polypropylene outer wrap		
	film, paperboard carton, and corrugated paperboard shipping case.		

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, is 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 predicate 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 substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the corresponding predicate products. Two of the corresponding predicate

products were previously found substantially equivalent. Six of the corresponding predicate products are grandfathered products commercially marketed in the United States as of February 15, 2007.

The new products differ from the corresponding predicate products in composition of the cigarette seam adhesive, tipping adhesive, and packaging (Confidential Appendix 1).

4. Alternatives 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 Products

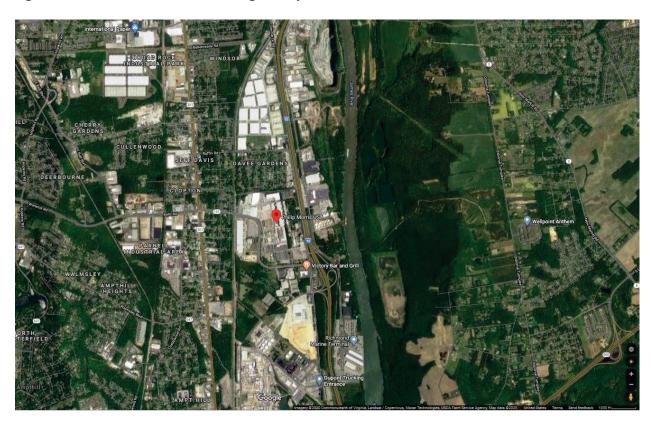
The Agency considered potential environmental impacts that may be affected by manufacturing the new products and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- The new and predicate products would not be marketed simultaneously upon receiving marketing orders for the new products.
- Production of the new products would replace production of other cigarettes currently manufactured at the facility.
- No facility expansion is expected due to manufacturing the new products.
- No increase in the facility production beyond the current permitted production capacity is expected due to manufacturing the new products.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products would be manufactured at 3601 Commerce Road, Richmond, VA 23234 (Figure 1).

Figure 1. Location of the Manufacturing Facility¹



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; banks, hotels, fast food restaurants, 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.²

¹ Google. 2019. Map of 3601 Commerce Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. March 3, 2020.

² Ibid

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.^{3,4} Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area.⁵

5.2 Air Quality

The Agency does not anticipate that manufacturing the new products would lead to release of any new chemicals or new type of emissions into the environment. The applicant stated that manufacturing the new products is not expected to require any additional environmental controls. Accordingly, the applicant concluded that manufacturing the new products would not require a revised or new air permit.

5.3 Water Resources

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

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products would lead to changes in soil, land use, or zoning. The applicant stated that there would be no expected facility expansion due to manufacturing the new products. Therefore, no zone changes 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 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 there are no plans of expanding the facility production beyond its current permitted level. The applicant reviewed the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps.

The U.S. FWS identifies one mammal, two flowering plants, and two freshwater mussel species as being present in Henrico and Chesterfield Counties bordering Richmond, Virginia.

³ 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 https://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 March 3, 2020.

⁵ Ibid.

Table 1. Species Identified by USFWS in Henrico and Chesterfield Counties⁶

Species	Status	
Northern long-eared bat (Myotis septentrionalis)	Threatened	
Sensitive joint-vetch (Aeschynomene virginica)	Threatened	
Swamp pink (Helonias bullata)	Threatened	
James spinymussel (Pleurobema collina)	Endangered	
Atlantic pigtoe (Fusconaia masoni)	Proposed Threatened	

The proposed actions do not require expansion of the manufacturing facility, and the listed species are not found in the immediate vicinity of the facility. Therefore, no impacts to protected species or their potential habitat are anticipated.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations, including 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:

- (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 CFR 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 the EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations for the manufacturing facility.⁸

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

⁶ U.S. Fish and Wildlife Service (U.S. FWS), available at: https://www.fws.gov/endangered/. Accessed March 3, 2020.

⁷ Critical habitat map available at: https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449. Accessed March 3, 2020.

⁸ EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000869793. Accessed March 3, 2020.

5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment, revenue, or taxes because the new 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 the future year projections of cigarette production at the facility, including the new products, are within the existing permitted manufacturing capacity and would not require facility expansion. Also, as discussed, the emissions and discharges from the facility are not expected to change because of manufacturing the new products. Thus, though 2010 U.S. Census and American Community Survey data show that 80% of the population within a three-mile radius of the manufacturing facility is minority, 9 no disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new products. In addition, the facility is not located within a Native American reservation.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new 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 products would be handled in the same manner as any other waste generated from any other products manufactured in the same facility.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new 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 actions to 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, and 35,528 pounds of nicotine and nicotine and salts off-site (Table 2). 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

⁹ EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: https://echo.epa.gov/detailed-facility-report?fid=110000869793. Accessed March 3, 2020.

¹⁰ U.S. Environmental Protection Agency (EPA). TRI Data https://enviro.epa.gov/facts/tri/ef-facilities/#/Release/23234PHLLP3601C. Accessed on March 3, 2020.

¹¹ EPA. myRight-to-Know, available at: https://myrtk.epa.gov/info. The site allows for searching the industrial facilities that manage toxic waste chemicals by entering the facility address and clicking on the facility location on the map. Accessed January 28, 2020.

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

Production-Related V	Chemical Mass (Pounds)		
R	Recycled		
Energ	Energy Recovery		
	Treated		
Subtotal	Subtotal Waste Managed		
On-site Release	Ammonia	0	
On-site Release	Nicotine and Nicotine Salts	10,313	
Off-site Release	Ammonia	0	
OII-site Release	Nicotine and Nicotine Salts	35,528	
Subtotal	45,841		
Total Produc	262,637		

The applicant does not anticipate manufacturing the new products would require a revised or new air or waste water permits.

5.11 Impacts from 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 manufactured at the same facility.

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

The Agency considered potential impacts to resources in the environment that may be affected by use of the new 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 (Confidential Appendix 2) for the new products 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 because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

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 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 products would be

released in the same manner as the combustion products of other marketed cigarettes, (2) the new products are expected to compete with or replace other currently marketed cigarettes, so the Agency does not expect that new or increased air emissions would be associated with use of the new products and (3) the ingredients in the new products are used in other currently marketed tobacco products.

6.3 Environmental Justice

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

6.4 Cumulative Impacts

Impacts from use of combusted tobacco products include health effects to both non-users and users. When using cigarettes, the users inhale and exhale smoke. Non-users may also inhale smoke, known as secondhand smoke (SHS). Furthermore, particles emitted by smoking may remain on surfaces, be reemitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants: referred to as thirdhand smoke (THS). These pollutants coexist in mixtures in the environment alongside SHS (Burton, 2011; Matt et al., 2011).

There is no safe level of exposure to SHS (DHHS, 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% (DHHS, 2006a and 2006b).
- 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 (DHHS, 2006a and 2006b).
- SHS causes more than 40,000 deaths per year (DHHS, 2014).

However, the use of cigarettes in the United States is declining as shown in Figure 2 (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2018). Declining cigarette use is likely 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%) as 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. Additionally, SHS exposure 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).

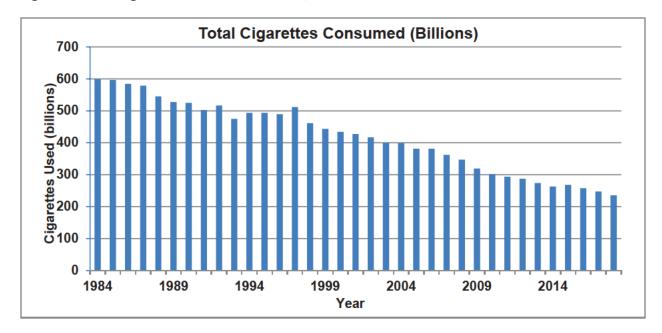


Figure 2. Use of Cigarettes in the United States, 1984 – 2018

As of March 2019, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2019). Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

6.5 Impacts from 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 used in the United States.

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

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new 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 products.

7.1 Affected Environment

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

7.2 Air Quality

The Agency does not anticipate disposal of the new 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 products. The chemicals in the cigarette butts are commonly used in other currently marketed cigarettes. Because the new products are anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new 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 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 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 tobacco products.

7.3 Water Resources

No changes in any impacts on water resources are expected due to disposal of the cigarette butts and packaging from the new products because the chemicals in the new products are like chemicals in currently marketed cigarettes. Furthermore, the new products would compete with or replace other cigarettes 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, ^{12, 13} the disposal of the new products is not expected to change the fire frequency because (1) the disposal of the new products would be the same as 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 products are anticipated to replace similar marketed cigarettes.

7.5 Solid Waste

The Agency does not foresee that the introduction of the new products would noticeably affect the current cigarette butt waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new 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 combusted, filtered cigarettes 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.

¹² 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 January 28, 2020.

¹³ UC Davis Health News. Available at: https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763. Accessed January 28, 2020.

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 products. The waste generated due to disposal of the new 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 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 products as well as other conventional cigarettes is littering of discarded cigarette filters or butts (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 (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 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.¹⁴

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

7.8 Impacts from 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:

Bria J. Martin, B.S., Center for Tobacco Products Education: B.S. in Biological Sciences

¹⁴ NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed January 28, 2020.

Experience: Three years in various scientific activities

Expertise: NEPA analysis, forestry, ecology and evolutionary studies

Reviewer:

Gregory 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

American Lung Association. 2018. Smokefree Air Laws. www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html (updated March 8, 2019). Accessed March 3, 2020.

Burton B. Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Enviro Health Perspectives*. 2011;119(2):A70-A74.

Becherucci ME, Pon JPS. What is left behind when the lights go off? Comparing the abundance and composition of litter in urban areas with different intensity of nightlife use in Mar del Plata, Argentina. *Waste Management*. 2014;34(8):1351-1355.

Claereboudt MR. Shore litter along sandy beaches of the Gulf of Oman. *Marine Pollution Bulletin*. 2004;49(9-10):770-777.

Healton CG., Cummings KM, O'Connor RJ, Novotny TE. Butt really? The environmental impact of cigarettes. *Tobacco Control*. 2011;20(suppl. 1): i1.

Homa DM, Neff LJ, King BA, Caraballo RS, Bunnell RE, Babb SD, Garrett BE, Sosnoff CS, Wang L. Vital signs: Disparities in nonsmokers' exposure to secondhand smoke — United States, 1999–2012. *MMWR Morb Mortal Wkly Rep.* 2015;64(4), 103-108.

Kadir AA, Sarani NA. Cigarette butts pollution and environmental impact – A review. *Appl Mechanics and Materials*. 2015;773-774:1106-1110.

Matt GE, Quintana PJE, Destaillats H, Gundel LA, Sleiman M, Singer BC, Jacob P, Benowitz N, Winickoff JP, Rehan V, Talbot P, Schick SF, Samet J, Wang Y, Hang B, Martins-Green M, Pankow JF, Hovell ME. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Enviro Health Perspectives*. 2011;119(9):1218-1226.

Novotny TE, Zhao, F. Consumption and production waste: Another externality of tobacco use. *Tobacco Control*. 1999;8(1):75-80.

Patel V, Thomson GW, Wilson, N. Cigarette butt littering in city streets: A new methodology for studying

and results. Tobacco Control. 2013;22(1):59-62.

Seco Pon JP, Becherucci ME. Spatial and temporal variations of urban litter in Mar del Plata, the major coastal city of Argentina. *Waste Management*. 2102;32(2):343-348.

Smith CJ, Livingston SD, Doolittle DJ. An international literature survey of "IARC Group 1 carcinogens" reported in mainstream cigarette smoke. *Food and Chem Toxicol*. 1997;35(10-11):1107-1130.

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.

U.S. Department of Health and Human Services. 2006a. 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.

U.S. Department of Health and Human Services. 2006b. 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.

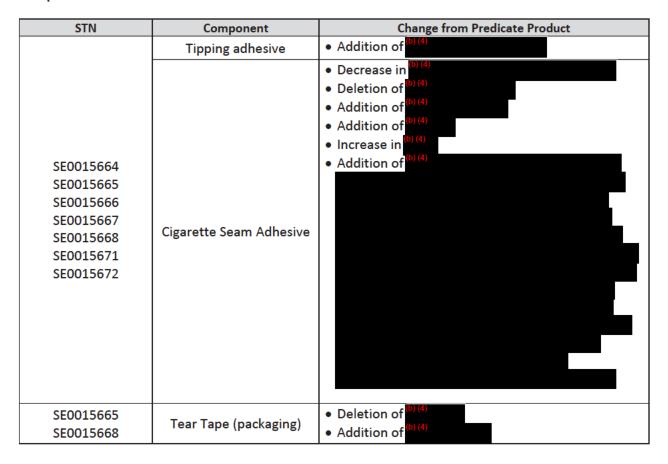
U.S. Environmental Protection Agency. (2018). Advancing Sustainable Materials Management: Facts and Figures.

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 Products to the Predicate Product



not present in SE0015666

CONFIDENTIAL APPENDIX 2

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

First- and fifth-year market volume projections for the new products were compared to the total forecasted use of cigarettes in the United States. The projected use of the new products in the first- and fifth-year of marketing account for about respectively, of the forecasted cigarette use in the United States. The applicant stated the predicate products would not be marketed simultaneously if marketing orders were issued for the new products. In addition, the applicant stated that the new products would compete with or replace similar tobacco products currently on the market.

	Projected Market Volume				
	Current-Year	First-Year		Fifth-Year	
STN	Predicate	New Product	New Product as a	New Product	New Product as a
	Product	(# of	Percent of Total	(# of Cigarettes)	Percent of Total
	(# of Cigarettes)	Cigarettes)	Cigarettes Used ¹⁷		Cigarettes Used ¹⁸
SE0015664	(b) (4)				
SE0015665					
SE0015666					
SE0015667					
SE0015668					
SE0015671					
SE0015672					
Total					

¹⁶ 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 R² value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 228.657 billion cigarettes in the first year and 205.021 billion cigarettes in the fifth year of marketing the new products.

 $^{^{17}}$ Projected Market Occupation of the New Products in the United States (%)= $\frac{\text{Projected Market Volume of the New Product (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} x \ 100$

¹⁸ Ibid