Programmatic Environmental Assessment for Four Exemption Requests by R.J. Reynolds Tobacco Company

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

September 24, 2018

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1. Applicant and Manufacturer Information

Applicant Name:	R.J Reynolds Tobacco Company
Applicant Address:	401 North Main Street Winston-Salem, North Carolina 27101
Manufacturer Name:	R.J. Reynolds Tobacco Company
Product Manufacturing Address:	7855 King-Tobaccoville Road Tobaccoville, North Carolina 27050

2. Product Information

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

New Product Name	STN	Original Product Name
Newport Non-Menthol Box	EX0000251	Newport Menthol Box
Newport Non-Menthol Box 100s	EX0000252	Newport Menthol Box 100s
Newport Non-Menthol Box	EX0000253	Newport Menthol Box
Newport Non-Menthol Box 100s	EX0000254	Newport Menthol Box 100s

Product Identification

Product Type	Cigarette
Product Subtype	Combusted, filtered
Product Quantity per Retail Unit	Twenty cigarettes per pack with ten packs per carton.
Product Package	The packaging materials consist of a foil inner liner, inner frame paper, paper board box, and polypropylene outer wrap

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the introduction of four combusted, filtered cigarettes into interstate commerce for commercial distribution in the United States. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if: (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products an exemption from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant

may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained an exemption from demonstrating substantial equivalence.

The new products, as compared to the corresponding original products, are modified by minor changes in ingredients, the cigarette paper, the tipping paper, and the monogram ink on the cigarette barrel (Confidential Appendix 1).

4. Alternative to the Proposed Actions

The no-action alternative is FDA does not issue exemptions from demonstrating substantial equivalence for marketing orders for the new tobacco products.

5. Potential Environmental Impacts of the Proposed Actions and Alternative – Manufacturing the New Products

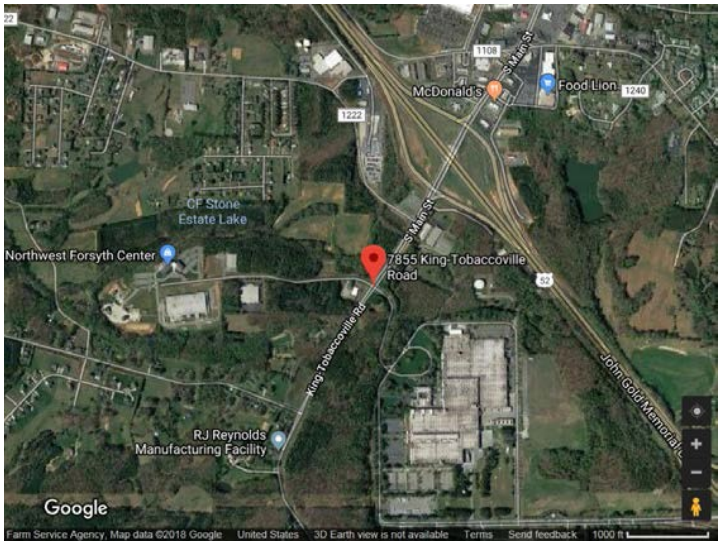
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- Components of the proposed cigarette papers and tipping papers are commonly used in other products manufactured at the facility and used throughout the cigarette industry.
- The new products would not be commercially marketed simultaneously with the original products if marketing orders are granted for the new products.
- The new products are intended to compete with and eventually replace similar tobacco products currently manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new products.

5.1 Affected Environment

The new products would be manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturer



The manufacturing facility is in Forsyth County, NC in Headwaters Muddy Creek watershed, hydrologic unit code 03040101, which is the largest of the Yadkin River tributaries.[1,2] The facility is surrounded by woodlands and is bounded by the city of King, NC to the north; US 52 (a four-lane, divided highway) to the east; and mixed use residential, commercial, and agricultural land to the south and west.

The affected environment includes human and natural environments surrounding the facility.

5.2 Air Quality

The Agency does not anticipate any new chemicals or new type of emissions would be released into the environment due to manufacturing the new products. The applicant stated that manufacturing the new products is not expected to result in changes in air emissions; accordingly, the applicant concluded that manufacturing the new products would not require any additional environmental controls for air emissions.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into the water. The new products are intended to replace similar tobacco products currently manufactured at the facility. The applicant also stated that manufacturing the new products would not require any additional environmental controls for water discharges.

5.4 Soil, Land Use, and Zoning

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

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 search of the U.S. Fish and Wildlife Services' (U.S. FWS) critical habitat and endangered species maps shows two threatened species (one bog turtle and one northern long-eared bat), one endangered plant, and one at-risk fresh water mussel

[1] 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.

[2] USGS. National Water Information System: Mapper. Available at: https://maps.waterdata.usgs.gov/mapper/index.html. Accessed May 23, 2018.

are listed in Forsyth County.[3,4] The applicant also reviewed the U.S. FWS maps and stated that the manufacturing facility is not within or near a critical habitat, or endangered animal and plant species.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant provided detailed information for the following air emission, storm water, and wastewater permits:

(1) Air permit number 00745-TV-35 issued by the Forsyth County Office of Environmental Assistance Protection. The permit expired November 27, 2012; the applicant submitted permit renewal on February 9, 2012 and provided a copy of the permit renewal submission. The applicant stated that according to the Forsyth County environmental permitting regulations, the facility can continue to operate until the new permit is issued. The applicant also stated that the facility complies with the requirements of this permit, which include submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
(2) Storm water permit number NCG060079 issued by the North Carolina Department of Environmental Quality; expires October 31, 2018. The applicant stated that the facility complies with the requirements of this permit, which include maintaining storm water pollution prevention plans, quantitative and qualitative discharge monitoring, and site inspections.
(3) Waste water permit number IUP 3001 issued by the North Carolina Department of Environmental Quality; expires June 30, 2022. The applicant stated that the facility complies with the requirements of this permit, which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

The applicant also stated that the facility performs the following additional activities to comply with the applicable environmental regulations:

- maintaining and complying with five separate Spill Prevention Control and Countermeasure plans, as required by the U.S. Environmental Protection Agency (EPA) Oil Pollution Prevention Regulations;
- reporting greenhouse gas emissions to EPA on an annual basis;
- submitting EPA Tier 2 to EPA TRI, permit # 27050RJRYN7855A expiring on July 1, 2018, and North Carolina Right-to-Know reports; and
- complying with Department of Homeland Security Chemical Antiterrorism Standards and with applicable solid and hazardous waste regulations.

The Agency's search of EPA's Enforcement and Compliance History Online (ECHO) did not reveal any violations of the federal environmental laws and regulations.[5]

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[3] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/raleigh/species/cntylist/forsyth.html. Accessed May 24, 2018.

[4] Critical habitat map available at: https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449. Accessed May 24, 2018.

[5] U.S. EPA ECHO Detailed Facility Report: R.J. Reynolds Tobacco Company, Richmond, VA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000345225. Accessed May 24, 2018.

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.

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.

Manufacturing the new products would not disproportionately impact minority populations, because only eight percent of the population within a three-mile radius of the manufacturing facility is minority per 2010 U.S. Census and American Community Survey data.[6] In addition, the facility is not located in an Indian reservation.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the facility's production of all combusted, filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment, transferred to a publicly owned treatment works (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 manufacturing the new products would not require any additional environmental controls for solid waste disposal. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

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 environment from the facility's tobacco manufacturing. A search in EPA's Toxic Release Inventory (TRI) database showed that in 2016, R.J. Reynold's manufacturing facility in Tobaccoville, North Carolina released 10,030 pounds of ammonia and 18,909 pounds of nicotine and nicotine salts to air (a total of 28,939 pounds), and 1 pound of ammonia and 3 pounds of nicotine and nicotine salts to land, but no TRI-reportable chemicals were released to water (Table 1).[7] No other hazardous air pollutants were reported. Ammonia's adverse health effects are ocular and respiratory; nicotine and

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[6] U.S. EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: https://echo.epa.gov/detailed-facility-report?fid=110000345225. Accessed May 24, 2018.

[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 Jun 14, 2018.

nicotine salts have known adverse developmental effects.[8] The TRI database search did not show that the R.J. Reynolds manufacturing facility disposed of, treated, or released into the environment any other 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 R.J. Reynolds Facility

Production-Related Waste Managed or Released			Chemical Mass (pounds)
Recycled			0
Energy Recovery			0
Treated*			2,871
Subtotal Waste Managed			*2,871*
On-site Release	Air	Ammonia	10,030
		Nicotine and Salts	18,909
	Water	Ammonia	0
		Nicotine and Salts	0
	Land	Ammonia	1
		Nicotine and Salts	3
Off-site Release		Ammonia	493
		Nicotine and Salts	4,409
Subtotal Waste Released			*33,845*
Total Production-Related Waste			**36,716**
* Ammonia only			

According to the North Carolina Department of Environmental Quality, water quality in Headwaters Muddy Creek watershed where the facility is located, is relatively good compared to other sub basins in the greater Yadkin-Pee Dee River basin.[9]

The applicant stated that manufacturing the new products would not require revised or new air, waste water, or storm water permits.

5.11 No Action Alternative

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

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[8] U.S. 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's address and clicking on the facility's location on the map. Accessed Jun 14, 2018.

[9] North Carolina Department of Environmental Quality. *Yadkin River Headwaters*. Available at: https://files.nc.gov/ncdeq/Water%20Quality/Planning/BPU/BPU/Yadkin/Yadkin%20Plans/2010%20Plan/2_03040101%20Yadkin%20River%20Headwaters-2010.pdf. Accessed Jun 14, 2018.

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 could 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 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 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 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 the original products and any 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 (Confidential Appendix 2); 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

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).

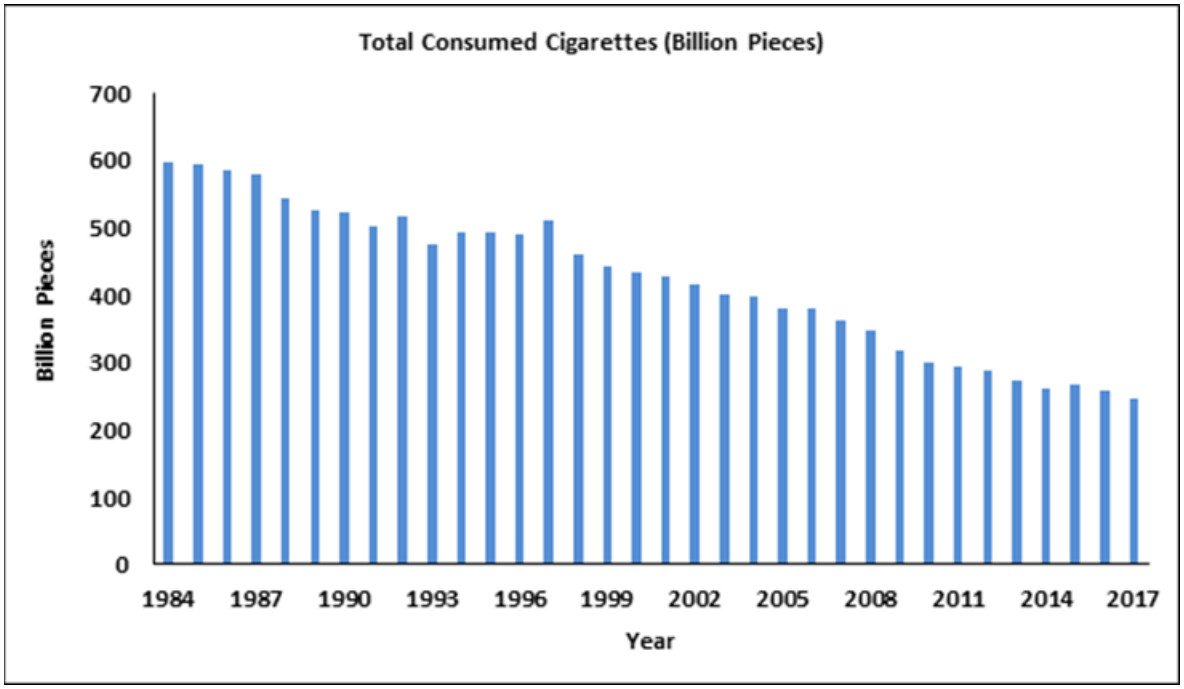
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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. It 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, the use of cigarettes in the United States is declining, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, (Figure 2).[10] 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; other studies). 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. 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. Cigarette Consumption in the United States, 1984 – 2017



[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.

As of December 2015, 26 states and the District of Columbia have implemented comprehensive smoke-free laws (Tynan, Holmes, Promoff, Hallett, Hopkins, & Frick, 2016). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

6.5. 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 Products

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on publicly available information such as the documented continuous decline of cigarette use in the United States and the applicant's submitted information, including market volume projections for the new products, the Agency found no significant impacts.

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 nationwide.

7.2. Air Quality

The Agency does not anticipate disposal of the 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 new products' 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 (Confidential Appendix 3). Therefore, the fate and effects of any materials emitted into the air from disposal of the new products is 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 new products' package materials 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 new products' packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

7.3. 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,[11,12] the new products are not expected to change the fire frequency as the disposal of the new products would be the same as the disposal of cigarettes that are currently marketed in the United States.

7.4. Water Resources

No changes in any impacts on water resources are expected due to disposal of the cigarette butts from the new products because the chemicals in the new products are the same as in currently marketed cigarettes and the new products are anticipated to compete with or replace other currently marketed cigarettes.

7.5. 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 disposal of 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.

7.6. 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, which can persist in the environment for more than 10 years (Novotny and Zhao, 1999). Cigarette butts are among the most common forms of litter found on beaches (Claereboudt, 2004; Smith, Livingston and Doolittle, 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson, Oliver, and Thomson, 2014), roads, and streets (Healton, Cummings, O'Connor and Novotny, 2011; Patel, Thomson and Wilson, 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 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 buffs, and the mass transfer behavior of combustion products along the cigarette.[13]

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[11] 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 May 22, 2018.

[12] UC Davis Health News. Available at: https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763. Accessed May 22, 2018.

[13] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed April 24, 2018.

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

7.7. 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.

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: Sixteen years in various scientific activities
Expertise: NEPA analysis, environmental impact analysis and risk assessment, applied ecology, geo-statistics

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

9. A Listing of Agencies and Persons Consulted

Not applicable.

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Patel, V., G. W., Thomson, and N., Wilson. (2013). Cigarette butt littering in city streets: A new methodology for studying and results. *Tobacco Control*. 22(1): 59-62.

Seco Pon, J. P., and M. E., Becherucci. (2012). Spatial and temporal variations of urban litter in Mar del Plata, the major coastal city of Argentina. *Waste Management*. 32(2): 343-348.

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CONFIDENTIAL APPENDIX 1

Modifications: New Products as Compared with the Corresponding Original Products

STN	Component	Modification
EX0000251	Cigarette paper	Deletion of non-fire standards compliant (non-FSC) cigarette paper
		Addition of FSC cigarette paper
	Tipping paper	Deletion of cork tipping paper
		Addition of cork-on-white tipping paper
	Monogram ink	Deletion of monogram ink on the barrel
	Additives in the tobacco blend	Deletion of (b) (4)
		Decrease in (b) (4)
		Increase in (b) (4) and (b) (4)
EX0000252	Cigarette paper	Deletion of non-FSC cigarette paper
		Addition of FSC cigarette paper
	Tipping paper	Deletion of cork tipping paper
		Addition of cork-on-white tipping paper
	Monogram ink	Deletion of monogram ink on the barrel
	Chemical constituents	Deletion of (b) (4)
		Decrease in (b) (4)
		Increase in (b) (4) and (b) (4)
EX0000253	Cigarette paper	Deletion of non-FSC cigarette paper
		Addition of FSC cigarette paper
	Tipping paper	Deletion of cork tipping paper
		Addition of cork-on-white tipping paper
	Monogram ink	Deletion of monogram ink on the barrel
	Chemical constituents	Deletion of (b) (4)
		Decrease in (b) (4)
		Increase in (b) (4) and (b) (4)
EX0000254	Cigarette paper	Deletion of non-FSC cigarette paper
		Addition of FSC cigarette paper
	Tipping paper	Deletion of cork tipping paper
		Addition of cork-on-white tipping paper
	Monogram ink	Deletion of monogram ink on the barrel
	Chemical constituents	Deletion of (b) (4)
		Decrease in (b) (4)
		Increase in (b) (4) and (b) (4)

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.[14] The new products account for a fraction of a percent of the forecasted cigarette use in the United States. In addition, the applicant stated that they intend to discontinue marketing the original products if marketing orders are granted for the new products and that the new products would replace the currently marketed original products.

STN	Projected Market Volume			
	First-Year		Fifth-Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used [15]	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used [16]
EX0000251	(b) (4)			
EX0000252				
EX0000253				
EX0000254				
Total				

[14] The Agency used historical data regarding total use of cigarettes from 2002 to 2017 to mathematically estimate the total amount of cigarettes used in the United States. Using the best-fit trend line with an R^2 value of 0.9786, the forecasted number of cigarettes that would be used in the United States is estimated at 236.26 billion cigarettes in the first year and 210.92 billion cigarettes in the fifth year of marketing the new products.

[15] Projected Market Occupation of the New Product in the United States (%)=

$$\frac{\text{Projected Market Volume of the New Products (cigarette } \textit{pieces})}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \; x \; 100$$

[16] See footnote # 15.

CONFIDENTIAL APPENDIX 3

Projected Waste of Cigarette Butts in the First and Fifth Years of Marketing the New Products

$\sum_{i=1}^{3} A_i = \sum_{i=1}^{3} (B_i \times C_i \times D_i \, X \, G)$ $D_i = \frac{E}{F_i}$	A_i: Projected waste generation of cigarette butts of the new product (metric tons) B_i: Projected market volume of the new product (number of individual cigarettes C_i: Weight of cigarette (gram) D_i: Cigarette butt ratio E: Cigarette butt length [1] F_i: Length of cigarette (millimeter) G: 1.0×10^{-6} metric tons/gram

Projected Year	STN	*Market Volume (# of cigarettes)*	*Cigarette Weight (grams)*	*Cigarette Length (mm)*	*Cigarette Butt Waste (tons)*
		B_i	C_i	F_i	A_i
First-Year	EX0000251	(b) (4)	0.9	80	(b) (4)
	EX0000252		1.1195	99	
	EX0000253		0.9	80	
	EX0000254		1.1205	99	
	Total				
Fifth-Year	EX0000251		0.9	80	
	EX0000252		1.1195	99	
	EX0000253		0.9	80	
	EX0000254		1.1205	99	
	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 would be negligible fractions of the 234.47 million metric tons of total waste reported in the United States in 2014 (U.S. EPA, 2016).

[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.