Programmatic Environmental Assessment for Marketing Orders for New Combusted, Filtered Cigarettes Manufactured by R.J. Reynolds Tobacco Company

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

July 9, 2021

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1. Applicant and Manufacturer Information

Applicant Name:	RAI Services Company
Applicant Address:	401 N. Main Street Winston-Salem, NC 27101
Manufacturer Name:	R.J. Reynolds Tobacco Company
Product Manufacturing Location:	7855 King Tobaccoville Road Tobaccoville, NC 27050

2. Products Information

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

New Product Names	STNs	Original Product Names	STNs
Tareyton Classic 100 Soft Pack	EX0001387/PD1	Tareyton 100's Soft Pack	GF1501104
Tareyton Classic Soft Pack	EX0001388/PD1	Tareyton Soft Pack	GF1501105
Tareyton Classic 100 Soft Pack	EX0001390/PD1	Tareyton 100's Soft Pack	GF1702758

Product Identification

Product Category:	Cigarette
Product Subcategory:	Combusted, Filtered
Product Number per Retail Unit:	20 cigarettes per pack and 10 packs per carton.
Product Package:	The packaging materials consist of inner liner made of paper laminated to aluminum foil, inner frame box and carton made of cardboard or soft pack and soft pack closure made of coated paper, and film overwrap made of polypropylene film.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (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 three filtered cigarettes. 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 will 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 products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products exemptions 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 exemptions from demonstrating substantial equivalence.

The applicant stated that the new and original products will not be simultaneously marketed. The new products differ from the corresponding original products by eliminating and adding an adhesive or paper and a change in the amount o (b) (4) in the filter tow (Confidential Appendix 1).

4. Alternative to the Proposed Actions

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

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

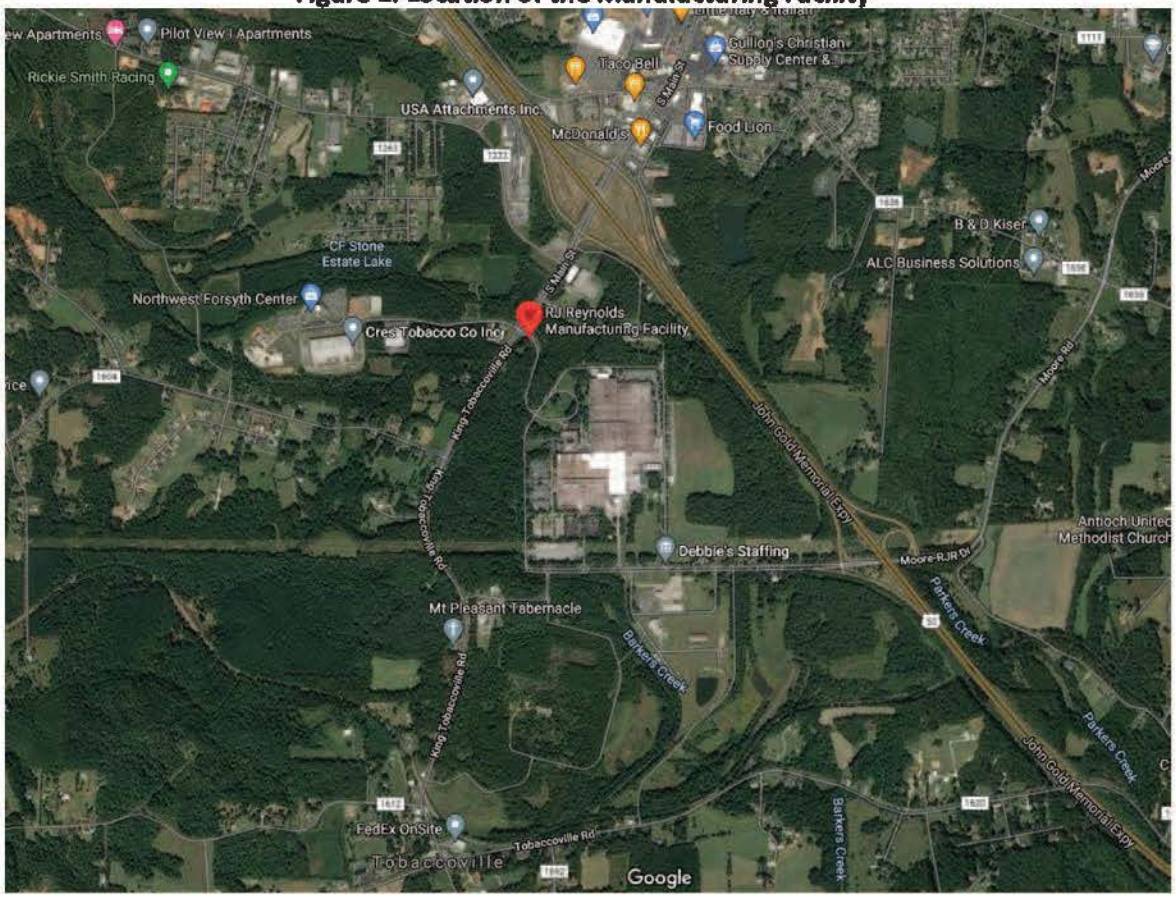
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- The new products will compete with similar tobacco products currently on the market.
- No facility expansion or new construction is expected due to manufacturing the new products.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturing Facility[1]



The manufacturing facility is in the Forsyth County within the Headwaters Muddy Creek watershed and it is surrounded to the north by highway 52 (a four-lane, divided highway) and mixed use residential and commercial lands, to the east and south by agricultural and forest lands, and to the east by residential land.

5.2 Air Quality

The Agency does not anticipate that manufacturing the new products will cause the 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 result in changes in air emissions or require any additional environmental controls for air emissions.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products will cause the discharge of any new chemicals into water. The applicant stated that manufacturing the new products will not require any additional environmental controls for water discharges and, therefore, will not require a revised or new wastewater discharge permit.

[1] Map of 7855 King Tobaccoville Road, Tobaccoville, NC 27050. Retrieved from Google maps. Accessed June 11, 2021.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products will lead to changes in soil, land use, or zoning. The applicant stated that there will be no expected facility expansion due to manufacturing the new products. Therefore, there will 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 that manufacturing the new products will 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 Agency review of the storm water permit shows the outfall from the facility is Barkers Creek in the Yadkin-Pee Dee River Basin that in the 2014 assessment was classified as impaired for aquatic life harvesting.[2,3] U.S. Fish and Wildlife Service (FWS) map shows that the facility is not within or near a critical habitat, or endangered plant species, and revealed one bat (Northern Long-eared bat) as threatened and three birds (Praire Warbler, Red-headed Woodpecker, and Wood Thrush) of conservation concern listed in the Forsyth county or the surrounding area.[4, 5]

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The agency verified the applicant statement, including review of the following permits.

(1) Permit for the operation of emission sources and associated air pollution control devices in the manufacturing facility issued by the County of Forsyth Office of Environmental Assistance and Protection in Winston-Salem with number 00745-TV-40.[6]
(2) Permit for discharge of stormwater at the manufacturing site in a regulated outfall issued by the State of North Carolina Department of Environmental Quality Division of Energy, Mineral, and Land Resources with number NCG60079.[7]

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[2] U.S. Environmental Protection Agency. Clean Water Act Permit NCG60079 Available at: https://enviro.epa.gov/enviro/pcs_det_reports_v2.pcs_tst?npdesid=NCG060079&npvalue=1&npvalue=2&npvalue=3&npvalue=4&npvalue=5&npvalue=6&rvalue=13&npvalue=7&npvalue=8&npvalue=10&npvalue=11&npvalue=12

[3] U.S. Environmental Protection Agency. Barkers Creek water body ID NC12-94-1. Available at: https://ofmpub.epa.gov/waters10/attains_waterbody.control?p_au_id=NC12-94-1&p_cycle=2014&p_state=NC&p_report_type=

[4] U.S. Fish and Wildlife Services (U.S. FWS). Critical habitat map available at: https://fws.maps.arcgis.com/home/webmap/viewer.html?useExisting=1&layers=794de45b9d774d21aed3bf9b5313ee24. Accessed February 18, 2021, 2021.

[5] Environmental Conservation Online System. U.S. Fish and Wildlife Services (U.S. FWS). Site information available at: https://ecos.fws.gov/ipac/location/QSN62MDJUJBLXLR2EGMP556SOY/resources#endangered-species. Accessed February 18, 2021.

[6] Forsyth County North Carolina Air Quality Regulation. Available at: https://www.co.forsyth.nc.us/eap/assets/doc/00745_1V_permit.pdf. Accessed June 30, 2021.

[7] EPA ECHO Detailed Facility Report: Dosal Tobacco Corporation. Available at: https://echo.epa.gov/detailed-facilityreport?fid=110000345225 Accessed June 11, 2021.

(3) Permit for management of hazardous waste generated in the manufacturing facility issued by the North Carolina Department of Environmental and Natural Resources with number NCD982076739.[7]

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]

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 compete with, or 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 will not require facility expansion. Also, as discussed, the emissions and discharges from the facility are not expected to change due to manufacturing the new products. The agency review found that the facility is not located within Native American lands.[8] Thus, no disproportionate impacts to environmental justice populations will occur as a result of manufacturing the new products.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products will 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 will be released to the environment and disposed of in landfills or recycle in the same manner as any other waste generated from any other products manufactured in the same facility. The applicant stated that manufacturing the new products will not change the types of waste or increase the amount of waste disposal. Therefore, as discussed, no new or revised waste permit or construction of new waste management facility is expected.

A search in EPA's Toxic Release Inventory (TRI) database showed that in 2019, the R.J. Reynolds Tobacco Company manufacturing facility released to the environment 18,279 pounds of nicotine or nicotine salts and 7,832 pounds of ammonia (Table 1). The TRI database search did not show that the R.J. Reynolds Tobacco Company manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products.[9]

[8] U.S. Forest Service, Federal and Indian Lands and Land Cessions Viewer. Available at: https://usfs.maps.arcgis.com/apps/webappviewer/index.html?id=fe311f69cb1d43558227d73bc34f3a32 Accessed June 11, 2021.

[9] U.S. Environmental Protection Agency (EPA). TRI data search of TRI ID 27050RJRYN7855A. Available at: https://enviro.epa.gov/facts/tri/ef-facilities/#/Facility/27050RJRYN7855A/R%20J%20REYNOLDS%20TOBACCO%20CO%20TVILL Accessed June 9, 2021.

Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at R.J. Reynolds Tobacco Company in 2019

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			0
Energy Recovery			0
Ammonia	Off-Site Treated	Transfer to POTW[10]	5,422
		Other	871
Nicotine and Nicotine Salts	Off-Site Treated	Transfer to POTW[13]	1,259
		Other	5,399
Subtotal Waste Managed			*12,951*
Ammonia	On-Site Disposal/ Release	Air fugitive	0
		Water	0
		Air stack	7,832
Nicotine and Nicotine Salts	On-Site Disposal/ Release	Air fugitive	0
		Water	0
		Air stack	18,279
Subtotal Waste Released			*26,111*
Total Production-Related Waste			***39,062***

5.9 Floodplains, Wetlands, and Coastal Zones

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

5.10 Impacts from No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of manufacturing cigarettes at the listed facility, as many similar products will continue to be manufactured.

6. Potential Environmental Impacts of the Proposed Actions and Alternative – 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 (Confidential Appendix 2) for the new products and the documented cigarette use in the United States.

[10] POTW = Publicly owned treatment works

6.1. Affected Environment

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

6.2. Air Quality

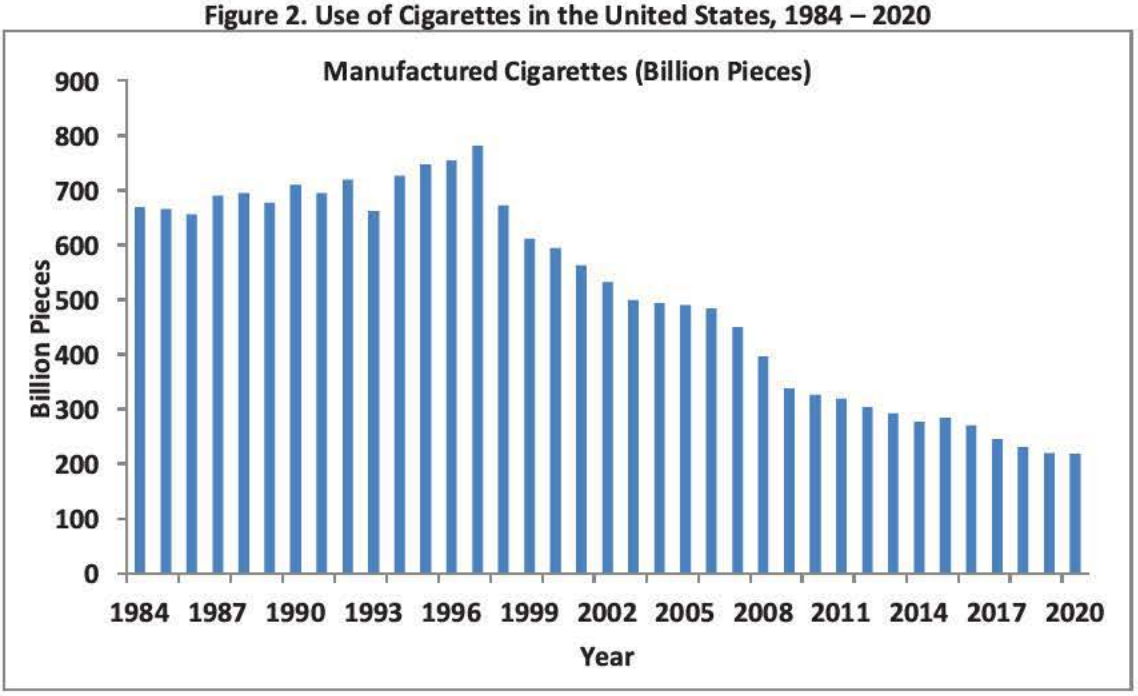
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos and pipes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment 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) (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2021). 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. 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 – 2020



As of December 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.

The Agency does not anticipate that new chemicals will 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 will 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, 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 will be no disproportionate impacts on minority or low-income populations.

6.4. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of use of cigarettes, as many similar products will continue to be used in the United States.

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 (Confidential Appendix 2), 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 will allow for the applicant to distribute and sell the new products to consumers in the United States.

7.2. Air Quality

The Agency does not anticipate disposal of the new products or the packaging materials will 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. 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.

The applicant stated that no changes in air quality from disposal of the new products' package materials will be expected because 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 and the waste generated due to disposal of the new products' packaging is a minuscule portion of the municipal solid waste in the United States (U.S. Environmental Protection Agency, 2019) 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 products like cigarettes has been implicated in many fire incidents,[11] the disposal of the new products is not expected to change the fire frequency because (1) the disposal of the new products will be similar to the disposal of cigarettes that are currently marketed in the United States, and (2) there will be no anticipated increase in number of cigarettes being disposed of as the new products are anticipated to compete with, or replace, similar marketed cigarettes.

7.4. Water Resources

The Agency does not anticipate any new impacts on water resources due to disposal of the cigarette butts and packaging from the new products because the chemicals in the new products are used in

[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 February 17, 2021.

currently marketed cigarettes. Furthermore, the new products will compete with other cigarettes currently on the market.

7.5. Solid Waste

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 (Seco Pon and Becherucci, 2012).

Toxic compounds in cigarette butts leech out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015; Venugopal et ai., 2021). 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 filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.[12]

The Agency does not foresee the introduction of the new products will notably affect the current cigarette butt waste generated form all cigarettes. The waste generated due to disposal of the new products will be handled in the same manner as any other waste generated from any other cigarettes disposed of in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 2) and a portion of those will 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 products. The waste generated due to disposal of the new products will 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 will be no disproportionate impacts on minority or low-income populations.

7.7. Impacts of the No-Action Alternative

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

8. List of Preparers

[12] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed February 26, 2021.

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

Preparer:

Chad Baisden, MS, Center for Tobacco Products
Education: MS in Natural Resources
Experience: Five years in various scientific activities
Expertise: Environmental risk assessment, regulatory compliance

Reviewer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
Education: Ph.D. in Environmental Science and Management
Experience: Five years in environmental science, three years in toxicology
Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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

U.S. Alcohol and Tobacco Tax and Trade Bureau. (2021). Tobacco Statistics. *U.S. Department of the Treasury*. Available at https://www.ttb.gov/tobacco/tobacco-stats.shtml (updated June 3, 2021). Accessed June 9, 2021.

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.

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Venugopal PD, Hanna SK, Gagliano GG, Chang HW. (2021). No Butts on the Beach: Aquatic Toxicity of Cigarette Butt Leachate Chemicals. *Tobacco Regulatory Science*. 2021;*1*:17-30.

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

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. Modifications: New Products as Compared with the Corresponding Original Products

STN	Modification
EX0001387	• Deletion of a tobacco additive [Fire Standards Compliant ("FSC") 2 cigarette paper] • Addition of a tobacco additive (alternate FSC cigarette paper) • An increase in the quantity of two existing tobacco additives (tipping adhesive and cork tipping paper)
EX0001388	• Deletion of a tobacco additive [Fire Standards Compliant ("FSC") 2 cigarette paper] • Addition of a tobacco additive (alternate FSC cigarette paper) • An increase in the quantity of two existing tobacco additives (tipping adhesive and cork tipping paper)
EX0001390	• Deletion of a tobacco additive [Fire Standards Compliant ("FSC") 2 cigarette paper] • Addition of a tobacco additive (alternate FSC cigarette paper) • An increase in the quantity of two existing tobacco additives (tipping adhesive and cork tipping paper)

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 of the new products were compared to the total forecasted use of cigarettes in the United States.[13] The projected use of the new products in the first and fifth year of marketing after marketing orders are issued account for abo (b) (4) a (b) (4) respectively, of the forecasted cigarette use in the United States. The applicant stated that they will not market the original product and the new products simultaneously. In addition, the applicant stated that the new tobacco products currently on the market.

STN	Market Volume				
	Current Year	Projected Volume			
		First-Year		Fifth-Year	
	(Cigarettes)	Product (Cigarettes) [14]	Product as a Percent of Total Cigarettes Used [15]	Product (Cigarettes) [14]	Product as a Percent of Total Cigarettes Used [15]
EX0001387	(b) (4)				
Original to EX0001387 (GF1501104)	(b) (4)	(b) (4)			
EX0001388	(b) (4)				
Original to EX0001388 (GF1501105)	(b) (4)	(b) (4)			
EX0001390	(b) (4)				
Original to EX0001390 (GF1702758)	(b) (4)	(b) (4)			
Total	(b) (4)				(b) (4)

[13] The Agency used historical data regarding total use of cigarettes from 1997 to 2020 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 0.9844, the forecasted number of cigarettes that will be used in the United States is estimated at 228.441 billion cigarettes in the first year and 161.201 billion cigarettes in the fifth year of marketing the new products.

[14] Market volume for the new products only. Applicant stated that the new products will replace the total portion of the marketed original products.

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