Environmental Assessment for a Marketing Order for a New Combusted Filtered Cigarette

Manufactured by

R.J. Reynolds Tobacco Company

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

January 24, 2020

1. Applicant and Manufacturer Information

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

2. Product Information

New Product Name, Submission Tracking Number (STN), and Predicate Product Name

New Product Name	STN	Predicate Product Name
Pall Mall Orange Filter Box	SE0015581	Pall Mall Ultra Light Box

Product Identification

Product Category	Cigarettes
Product Sub-Category	Combusted Filtered
Number of Products per Retail Unit	20 cigarettes per pack, 10 packs per carton.
Product Package	The packaging materials consist of a foil inner liner, solid bleached sulphate board inner frame, polypropylene pack overwrap, solid bleached sulphate board pack and solid bleached sulphate paperboard carton.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce a new tobacco product into interstate commerce for commercial distribution in the United States and submitted to the Agency a substantial equivalence (SE) report to obtain a marketing order. The Agency shall issue a marketing order if the new product is found substantially equivalent to the predicate product. The predicate product is a grandfathered product (GF1200551) commercially marketed in the United States as of February 15, 2007.

The new product differs from the predicate product due to changes in the cigarette paper, adhesives, filter tow, tobacco blend, and quantities of ingredients added to the tobacco (Confidential Appendix 1).

4. Alternatives to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for the new tobacco product in the United States.

5. Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product

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

- Components of the cigarette are commonly used in other products manufactured at the facility
- The predicate product would not be marketed simultaneously if a marketing order was issued for the new product.
- No facility expansion is expected due to manufacturing the new product.

5.1 Affected Environment

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

Figure 1. Location of the Manufacturing Facility[1]

The manufacturing facility is located in Forsyth County, NC in Headwaters Muddy Creek watershed, hydrologic unit code 03040101, which is the largest of the Yadkin River tributaries.[2,3] The facility is

[1] Google. 2019. Map of 7855 King Tobaccoville Road, Tobaccoville, NC 27050. Retrieved from Google Maps: www.google.com/maps. November 18, 2019.

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

surrounded by woodlands; 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.

5.2 Air Quality

The Agency does not anticipate that manufacturing the new product would lead to release of any new chemicals into the air. The applicant stated that manufacturing the new product is not expected to result in changes in air emissions. The applicant also stated that manufacturing the new product would not require any additional environmental controls for air emissions.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new product would cause any new chemicals to be discharged into the water. The applicant stated that manufacturing the new product is not expected to result in changes in wastewater discharge and, would not require any additional environmental controls for wastewater discharges.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new product would lead to changes in soil, land use, or zoning. The applicant stated that there would be no expected facility expansion or new construction due to manufacturing the new product. 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 that manufacturing the new product 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 Service's (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 are listed in Forsyth County.[4,5] 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 manufacturing facility has the following permits:

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[3] USGS. National Water Information System: Mapper. Available at: https://maps.waterdata.usgs.gov/mapper/index.html. Accessed November 18, 2019.

[4] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/raleigh/species/cntylist/forsyth.html. Accessed November 19, 2019.

[5] Critical habitat map available at: https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449. Accessed November 19, 2019.

(1) Air permit number 00745-TV-39 issued by the Forsyth County Office of Environmental Assistance Protection.[6]
(2) Storm water permit number NCG060079 issued by the North Carolina Department of Environmental Quality.[7]

Additionally, the facility submits release data to the EPA under the provisions of the Toxic Release Inventory (TRI) program (permit # 27050RJRYN7855A).

The Agency's search of the Environmental Protection Agency (EPA)'s Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the federal environmental laws and regulations.[8]

5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics are anticipated due to manufacturing the new product. The Agency does not anticipate any impacts on employment, revenue, or taxes because no facility expansion is expected.

Manufacturing the new product would not disproportionately impact minority populations, because only 9% of the population within a three-mile radius of the manufacturing facility is minority per 2010 U.S. Census and American Community Survey data.[9] In addition, the facility is not located in or near Native American lands.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new product 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 product would be released to the environment and disposed of in landfills 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 product 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 product and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.

5.10 Cumulative Impacts

The Agency does not anticipate the proposed action would incrementally increase or change the chemicals released to the environment from the tobacco manufacturing facility. A search in EPA's TRI

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[6] Air permit available at: https://www.co.forsyth.nc.us/EAP/assets/doc/00745_TV_permit.pdf Accessed November 19, 2019.

[7] U.S. EPA ECHO Detailed Facility Report: R.J. Reynolds Tobacco Company, Tobaccoville, NC. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000345225. Accessed November 19, 2019.

[8] Ibid.

[9] Ibid.

database showed that in 2018, R.J. Reynold's manufacturing facility in Tobaccoville, North Carolina released 8,399 pounds of ammonia and 19,639 pounds of nicotine and nicotine salts to air (a total of 28,038 pounds), and 885 pounds of ammonia and 4,884 pounds of nicotine and nicotine salts (a total of 5,769 pounds) offsite (Table 1).[10] Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts have known adverse developmental effects.[11] The TRI database search did not show that the R.J. Reynolds manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at R.J. Reynolds Facility in 2018

Production-Related Waste Managed or Released		Chemical Mass (pounds)
Recycled		0
Energy Recovery		0
Treated*		5,815
Subtotal Waste Managed		*5,815*
On-Site Release	Ammonia	8,399
	Nicotine and Nicotine Salts	19,639
Off-Site Release	Ammonia	885
	Nicotine and Nicotine Salts	4,884
Subtotal Waste Released		*33,807*
Total Production-Related Waste		**39,622**
* Ammonia plus nicotine and nicotine salts		

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.[12]

5.11 Impacts of the No-Action Alternative

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

[10] U.S. Environmental Protection Agency (EPA). *TRI Data* https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Facility/27050RJRYN7855A. Accessed November 18, 2019.

[11] 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 address and clicking on the facility location on the map. Accessed November 18 , 2019.

[12] 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 November 18, 2019.

6. Potential Environmental Impacts of the Proposed Action and Alternatives – Use of the New Product

The Agency considered potential impacts to resources in the environment that could be affected by use of the new product 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 product (Confidential Appendix 2) and the documented decline in cigarette use in the United States.

6.1 Affected Environment

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

6.2 Air Quality

The Agency does not anticipate that new chemicals would be released into the environment as a result of use of the new product, 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 product would be released in the same manner as the combustion products of the original product and any other marketed cigarettes; (2) the new product is expected to compete with, or replace, other currently marketed cigarettes; and (3) the ingredients in the new product are used in other currently marketed tobacco products.

6.3 Environmental Justice

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

6.4 Cumulative Impacts

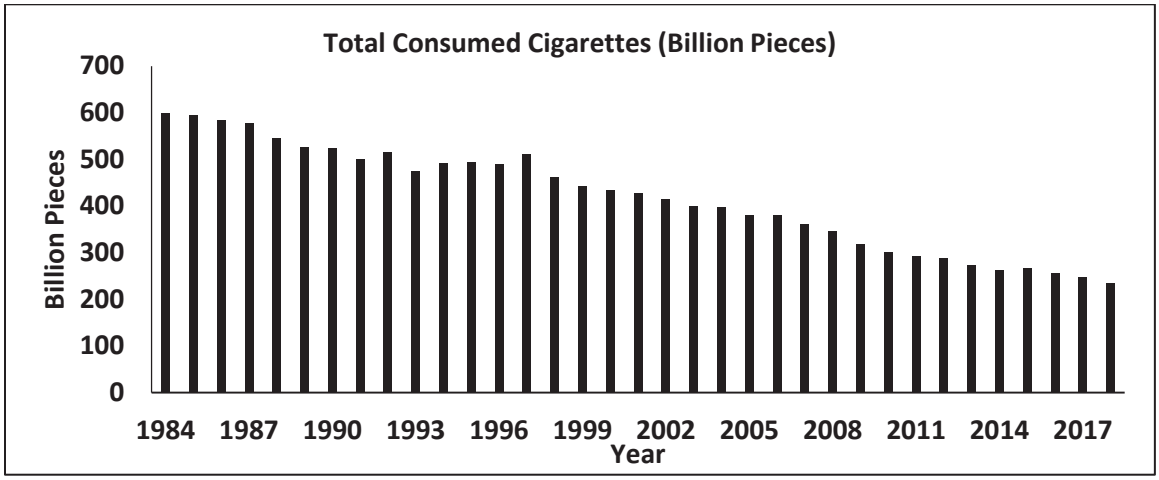
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigarettes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants,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

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

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. Such exposure can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).
- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

However, use of cigarettes in the United States is declining according to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).[13] This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. Exposure to SHS declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010 as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

Figure 2. Use of Cigarettes in the United States, 1984 – 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 of the No-Action Alternative

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

7. Potential Environmental Impacts of the Proposed Action and Alternatives – Disposal of the New Product

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new product. Based on publicly available information such as the documented

[13] U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: https://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed November 18, 2019.

continuous decline of cigarette use in the United States, and the applicant's submitted information, including market volume projections for the new product (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 order would allow for the new tobacco product to be sold to consumers in the United States.

7.2 Air Quality

The Agency does not anticipate disposal of the new product 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 product. The chemicals in the new product's cigarette butts are commonly used in other currently marketed cigarettes. Because the new product is anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new product would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new product 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 product's 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 product's 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 action is 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,[14,15] the new product is not expected to change the fire frequency as (1) the disposal of the new product and packaging materials would be the same as the disposal of other similar tobacco products 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 product is anticipated to replace similar marketed cigarettes.

7.4 Water Resources

No changes in any impacts on water resources are expected due to disposal of the cigarette butts and packaging from the new product because the chemicals in the new product would be used in currently marketed cigarettes. Furthermore, the new product would compete with or replace other cigarettes currently on the market.

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[14] 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 November 18, 2019.

[15] UC Davis Health News. Available at: https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763. Accessed November 18, 2019.

7.5 Solid Waste

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

7.6 Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new product. The waste generated due to disposal of the new product would 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 product; therefore, there would be no disproportionate impacts on minority or low-income populations.

7.7 Cumulative Impacts

A major existing environmental consequence of the use of the new product, 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).

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 filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.[16]

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

7.8 Impacts of the No-Action Alternative

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

[16] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed November 18, 2019.

8. List of Preparers

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

Preparer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
Education: Ph.D. in Environmental Science and Management
Experience: Four 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

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, NEPA analysis, regulatory compliance

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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Confidential Appendix 1. Changes in the New Product as Compared with the Predicate Product

STN	Component	Change from the Predicate Product
SE0015581	Cigarette paper	• Change from FSC paper to alternate FSC paper • Increase in cigarette paper weight
	Cigarette paper seam adhesive	• Change from cigarette paper seam adhesive to alternate cigarette seam adhesive
	Filter centerline adhesive	• Change from cigarette filter centerline adhesive to alternate filter centerline adhesive
	Filter tow	• Change from filter tow to alternate filter tow • Decrease in filter tow weight
	Tipping paper adhesive	• Change from tipping paper adhesive to alternate tipping paper adhesive • Decrease in tipping paper adhesive weight
	Tobacco blend	• Slight modifications in tobacco blend ratio
	Ingredients	• Slight increases in several ingredients added to tobacco

Confidential Appendix 2. Market Volume Projections for the New Product and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Product

First- and fifth-year market volume projections of the new product were compared to the total forecasted use of cigarettes in the United States.[17] The projected use of the new product in the first and fifth year of marketing after a marketing order is issued accounts for about (b) (4) respectively, of the forecasted cigarette use in the United States. In addition, the applicant stated that the new product would compete with similar tobacco products currently on the market. Lastly, the applicant stated they do not intend to simultaneously market the predicate product and new product if a marketing order is issued.

STN	Current Market Volume	Projected Market Volume			
		First Year		Fifth Year	
		New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[18]	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used[19]
SE0015581	(b) (4)				

[17] The Agency used historical data regarding total use of cigarettes from 2002 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R^2 value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 228.657 billion cigarettes in the first year and 205.021 billion cigarettes in the fifth year of marketing the new product.

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

[19] Ibid.