

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

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

February 27, 2020

Table of Contents

1.	Applicant and Manufacturer Information	3
2.	Product Information	3
3.	The Need for the Proposed Actions.....	3
4.	Alternatives to the Proposed Actions.....	4
5.	Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Tobacco Products	4
5.1	Affected Environment.....	4
5.2	Air Quality	5
5.3	Water Resources.....	6
5.4	Soil, Land Use, and Zoning	6
5.5	Biological Resources.....	6
5.6	Regulatory Compliance	6
5.7	Socioeconomics and Environmental Justice	7
5.8	Solid Waste and Hazardous Materials	7
5.9	Floodplains, Wetlands, and Coastal Zones.....	7
5.10	Cumulative Impacts.....	7
5.11	Impacts of the No-Action Alternative	8
6.	Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Tobacco Products	9
6.1.	Affected Environment.....	9
6.2.	Air Quality	9
6.3.	Environmental Justice	9
6.4.	Cumulative Impacts.....	9
6.5.	Impacts of the No-Action Alternative	11
7.	Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Tobacco Products	11
7.1.	Affected Environment.....	11
7.2.	Air Quality	11
7.3.	Biological Resources.....	11
7.4.	Water Resources	12
7.5.	Solid Waste.....	12
7.6.	Socioeconomics and Environmental Justice	12
7.7.	Cumulative Impacts.....	12
7.8.	Impacts of the No-Action Alternative	13
8.	List of Preparers.....	13
9.	A Listing of Agencies and Persons Consulted	13
10.	References.....	13
	CONFIDENTIAL APPENDIX 1. Modifications: New Tobacco Products as Compared with the Corresponding Original Tobacco Products.....	16
	CONFIDENTIAL APPENDIX 2. Market Volumes for the Original Tobacco Products and Market Volume Projections for New and Corresponding Original Tobacco Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Tobacco Products	17

1. Applicant and Manufacturer Information

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

2. Product Information

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

New Product Name	STN	Original Product Name
True Blue 100 Box	EX0000975	True Blue 100 Soft Pack
True Blue 100 Soft Pack	EX0000976	
Pall Mall Red Filter 100 Box	EX0000977	Pall Mall Red Filter 100

Product Identification

Product Category:	Cigarette
Product Subcategory:	Combusted filtered
Product Number per Retail Unit:	Twenty cigarettes per pack with ten packs per carton.
Product Package:	EX0000975 and EX0000977: The packaging materials consist of a machine glazed paper laminated to aluminum foil inner liner, inner frame solid bleached sulphate paperboard box, polypropylene film overwrap, and solid bleached sulphate paperboard carton. EX0000976: The packaging materials consist of a machine glazed paper laminated to aluminum foil inner liner, paper label and closure, polypropylene film overwrap, and solid bleached sulphate paperboard carton.

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 combusted, 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 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 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 original products were previously found exempt from the requirements of substantial equivalence by FDA and received marketing orders. The new products are made by modifying the corresponding original products. These modifications are to the ingredients in the tipping paper and filter tow (Confidential Appendix 1). The product package changed from soft pack in the original product to box in the new product in EX0000975.

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 Tobacco 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 tobacco products are expected to replace portions of 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 affected environment includes human and natural environments surrounding the facility. The new products would be manufactured at the address listed in section 1 of this document (Figure 1).

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Tobacco 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 (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 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 that 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, 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 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 mixtures 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).

the new products are not expected to change the fire frequency as (1) the disposal of the new products 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 products are 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 products because the chemicals in the new products would be used in currently marketed cigarettes. Furthermore, the new products would compete with or replace other cigarettes currently on the market.

7.5. Solid Waste

The Agency does not foresee the introduction of the new products 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 products would be handled 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 products. The waste generated due to disposal of the new products 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 products; 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 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).

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 are declining because the use of cigarettes in the United States is declining.

7.8. Impacts of the No-Action Alternative

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

8. List of Preparers

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

Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-two years in various scientific activities including eight years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

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.

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¹⁶ NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed February 13, 2020.

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CONFIDENTIAL APPENDIX 1. Modifications: New Tobacco Products as Compared with the Corresponding Original Tobacco Products

STN	Modification
EX0000975 EX0000976	<ul style="list-style-type: none">• Deletion of filter tow and addition of an alternate filter tow.
EX0000977	<ul style="list-style-type: none">• Deletion of tipping adhesive and addition of an alternate tipping adhesive.

