

**Programmatic Environmental Assessment for Marketing
Orders for New Roll-Your-Own Filtered Cigarette Tubes
Manufactured by Republic Tobacco, LP**

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

February 6, 2020

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1. Applicant and Manufacturer Information

Applicant Name:	Republic Tobacco, LP
Applicant Address:	2301 Ravine Way Glenview, IL 60025
Manufacturer Name:	Republic Technologies Canada (the RTC factory)
Product Manufacturing Location:	Republic Technologies Canada 870 Boulevard Industriel Bois-des-Filion Quebec, J6Z 4V7, Canada

2. Product information

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

New Product STN	New Product Name	Predicate Product Name
SE0015610	Top Premier Menthol 100MM	Top Premier Menthol 100MM
SE0015611	Top Menthol 100MM	Top Premier Menthol 100MM
SE0015631	Top Menthol King Size	Top McClintock Menthol King Size

Product Identification

Product Category	Roll-Your-Own
Product Sub-Category	Filtered Cigarette Tube
Number of Products per Retail Unit and Product Package	200 tubes per cardboard retail box with 50 boxes per cardboard shipping case.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency, substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue marketing orders, after considering the SE Reports, if the new tobacco products are found substantially equivalent to the corresponding predicate tobacco products. The predicate tobacco products have all previously been found to be substantially equivalent.

The new tobacco products differ from the predicate tobacco products due to changes in ingredients and colors in the tipping paper (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

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

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

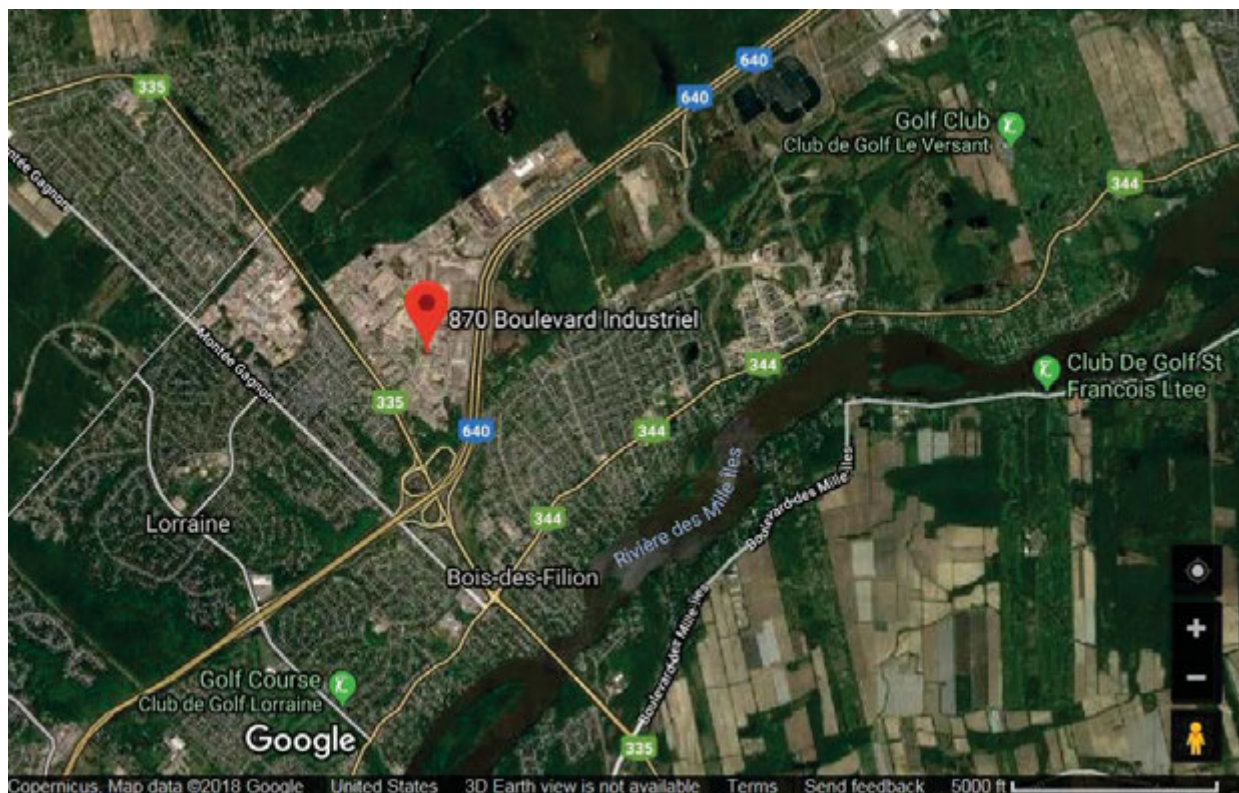
The Agency evaluated potential environmental impacts that may be caused by manufacturing the new tobacco products and found no significant impacts.

5.1 Affected Environment

The new and predicate products are manufactured at 870 Boulevard Industriel, Bois-des-Filion, Quebec J6Z 4V7, Canada (Figure 1). The manufacturing facility is in an industrial area consisting of office buildings, warehouses, small businesses, and light manufacturing facilities. The facility area is separated from des Mille Iles River to the south and southeast by a multifamily housing residential area across a two-lane highway.

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

Figure 1. Location of the Manufacturing Facility¹



5.2 Analysis of Potential Environmental Impacts

The Agency evaluated potential environmental impacts from manufacturing the new tobacco products based on information gathered by the Agency and the applicant's submitted information, including projected market volumes for the new and predicate tobacco products (Confidential Appendix 2).

¹ Land use surrounding manufacturing facility via Google Map. Accessed October 26, 2018.

Environmental Resource	Analysis of Potential Impacts
Air quality	No air quality change surrounding the facility would be expected although, there might be increased production due to the new and predicate tobacco products (Confidential Appendix 2). The applicant stated that (1) the new tobacco products are expected to compete and potentially replace other cigarette tubes manufactured at the facility; therefore, the production of the new tobacco products would occupy a small portion of the total production at the facility (Confidential Appendix 3), (2) the facility has a dust control system to control the emissions, (3) manufacturing the new tobacco products would not require a new or revised permit for air emissions, and (4) the manufacturing process for the new tobacco products are similar to the manufacturing process for other production at the RTC Factory.
Water resources and water quality	No impacts on water quality is anticipated because the liquid waste discharge is not anticipated to change at the manufacturing facility; little change in the ingredients being used in the facility is expected. No impacts on water resources are anticipated; the applicant stated that no expansion of the manufacturing facility is anticipated.
Land use and zoning	No conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use is expected because no facility expansion is anticipated. No zoning changes are anticipated because no construction that would require land use is projected.
Biological resources	The applicant stated that the suppliers for the RTC factory are certified by the Canadian Sustainable Forest Management, the Forest Stewardship Council (the FSC) and the Programme of Forest Certifications (the PEFC). The applicant stated that the manufacturing process is carried out under controls and standards that protect the environment, including species and habitats addressed under the Endangered Species Act (ESA) and Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). No effects on listed species or their habitat and biological resources are anticipated because no facility expansion is anticipated.
Geological features and soils	No effects on geological features or soils are expected because no facility expansion is anticipated.
Socioeconomic conditions	No facility expansion is anticipated; therefore, no impacts are expected on employment, state or municipal revenue and taxes, or on police force and fire department resources.
Solid waste and hazardous materials	The applicant stated that no additional capacity for disposal of manufacturing waste or any additional environmental controls would be required. Additionally, proper disposal of any waste related to manufacturing the new products would be handled in compliance with applicable laws and regulations.
Floodplains, wetlands, and coastal zones	No effects to floodplains, wetlands, or coastal zones are expected because no facility expansion is anticipated.
Regulatory compliance	The applicant stated that the manufacturing facility would comply with all applicable Canadian federal, regional and local regulations and requirements; this includes those related to emissions, solid waste and liquid waste.

5.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the proposed actions from manufacturing the new tobacco products.

5.4 Impacts of the No-Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of manufacturing roll-your-own (RYO) tobacco products at the listed facility, as many similar RYO tobacco products will continue to be manufactured.

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

The Agency evaluated potential impacts to resources in the environment that may be affected by use of the new tobacco products and found no significant impacts.

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. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from use of the new tobacco products based on information gathered by the Agency and the submitted SE Reports.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that no new compounds would be emitted from use of the new tobacco products. The ingredients in the new tobacco products are commonly used in other currently marketed RYO products. Therefore, the Agency does not anticipate that using the new tobacco products would lead to the release of new chemicals into the air, as compared to the predicate tobacco products or similar currently marketed products.
Environmental justice	No new emissions are expected due to use of the new tobacco products. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.3. Cumulative Impacts

No actions were identified that, when considered with the proposed actions, would lead to cumulative impacts from use of the new tobacco products.

6.4. Impacts of the No-Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of the use of RYO tobacco products, as many other similar RYO tobacco products will continue to be marketed and therefore used.

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

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new tobacco products and 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 applicant to distribute and sell the new tobacco products to consumers in the United States.

7.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from disposal of the new tobacco products based on information in the SE Reports, including market volume information for the new and predicate tobacco products (Confidential Appendix 2)

Environmental Resource	Analysis of Potential Impacts
Air quality	Introducing the new tobacco products into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, thus, disposal of the used products and packaging would not significantly affect air quality.
Biological resources	Proper disposal of the used products and packaging materials from the new tobacco products in municipal solid waste stream would not affect biological resources. Used product and packaging materials from the new tobacco products may be littered in undeveloped areas and wildlife habitat. However, littering levels are not expected to change from the current levels due to existing tobacco products. Introducing the new tobacco products into the U.S. market is not expected to increase the nationwide use of RYO tobacco products based on the Agency's assessment and projected market volumes reported by the applicant (Confidential Appendix 2).
Water resources and water quality	Proper disposal of used product and packaging materials from the new tobacco products in the municipal solid waste stream will not affect water resources. Improper disposal could occur in or near surface water. However, littering levels are not expected to change from the current levels due to existing tobacco products. Introducing the new tobacco products into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, based on the projected market volumes reported by the applicant (Confidential Appendix 2).

Environmental justice	No significant environmental impacts associated with the disposal of the used products and packaging were identified, therefore no disproportionate impacts to environmental justice populations are anticipated.
Regulatory compliance	It is assumed that the portion of product and packaging waste that is disposed of by users as litter, despite littering ordinances, would be no greater than the current tobacco product littering rates.

7.3. Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the proposed actions from disposal of the new tobacco products.

7.4. Impacts of the No-Action Alternative

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

8. List of Preparers

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this programmatic environmental assessment.

Preparer:

Dilip Venugopal, Ph.D., Center for Tobacco Products

Education: M.S. in Ecology and Ph.D. in Entomology

Experience: Seventeen 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: Eleven years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1. Modifications: The New Tobacco Products Compared to the Predicate Tobacco Products

STN	Component	Change from the predicate product
SE0015610 SE0015611 SE0015631	Tipping Paper	Changes in additives levels.

Confidential Appendix 2. Market Volume Projections for the New and Predicate Tobacco Products

STN	Unit	First - Year Market Volume Projection		Fifth - Year Market Volume Projection	
		New Product	Predicate Product	New Product	Predicate Product
SE0015610	(b) (4)				
SE0015611					
SE0015631					

Confidential Appendix 3. Percentage of the Facility's Total Production Dedicated to the New Tobacco Products

The projected first- and fifth-year market volumes (Confidential Appendix 2) for the new products were compared to the total 2018 tube production² at the RTC manufacturing facility to evaluate the percentage of overall production that would be used to manufacture the new products. The percentage of the total production at the manufacturing facility dedicated to the new products was estimated by the following equation:

Production Fraction of New Product (%)

$$= \frac{\text{Market Volume Projection (Tubes)}}{\text{Total Tube Production at RTF (2018)}} \times 100\%$$

STN	Percentage of Facility's Total Production Dedicated to New Products (%)	
	First - Year	Fifth - Year
SE0015610	(b) (4)	
SE0015611		
SE0015631		
Total		

The new RYO tobacco products cumulatively would account for (b) (4) of the facility's total production in the first- and fifth-year, respectively.

² Total tube production at RTF (2018) – (b)(4) Tubes