Environmental Assessment for Marketing Order for New Roll-Your-Own Filtered Cigarette Tube Manufactured by Republic Tobacco, LP

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

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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 Number (STN), Name, and Predicate Product Name

New Product STN	New Product Name	Predicate Product Name
SE0015680	Altesse Regular King Size	200CT GAMBLER REG TUBE

Product Identification

Product Category	Roll-Your-Own
Product Sub-Category	Filtered Cigarette Tube
Number of Products per Retail Unit and Product Package	250 tubes per cardboard retail box with 50 boxes per cardboard shipping case.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for Food and Drug Administration (FDA) to issue marketing order 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 product into interstate commerce for commercial distribution in the United States and submitted to the Agency, a substantial equivalence (SE) report to obtain marketing order. The Agency shall issue a marketing order, after considering the SE Report, if the new tobacco product is found substantially equivalent to the predicate tobacco product. The predicate tobacco product was previously found to be substantially equivalent.

The new tobacco product differs from the predicate tobacco product due to changes in product quantity, and injector tube components (Confidential Appendix 1).

4. Alternatives to the Proposed Action

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

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

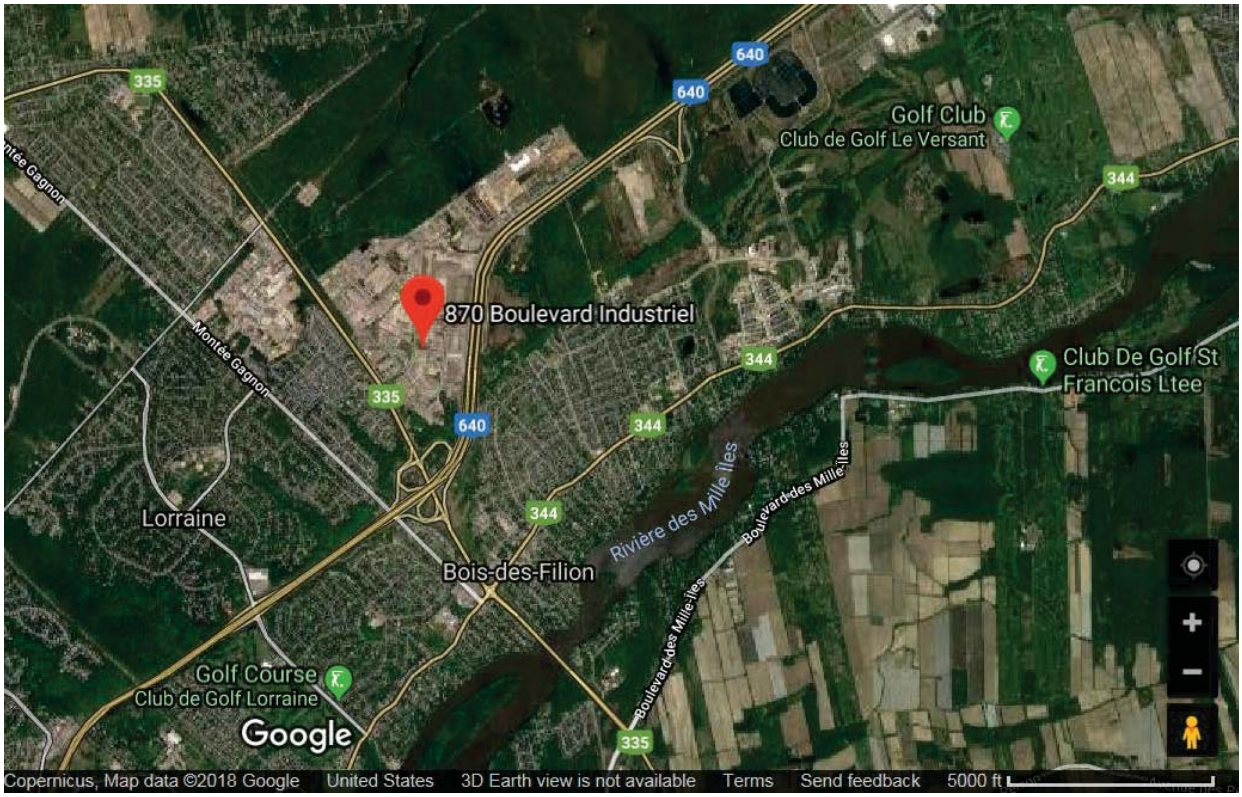
The Agency evaluated potential environmental impacts that may be caused by manufacturing the new tobacco product and found no significant impacts.

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 Facility[1]



5.2 Analysis of Potential Environmental Impacts

The Agency evaluated potential environmental impacts from manufacturing the new tobacco product 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 product is expected to compete and potentially replace other cigarette tubes manufactured at the facility; therefore, the production of the new tobacco product would occupy a small portion of the total production at the facility (Confidential Appendix 3), (2) manufacturing the new tobacco product would not require a new or revised permit for air emissions, and (3) the manufacturing process for the new tobacco product is 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 and the Programme of Forest Certifications. 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 and Convention on International Trade in Endangered Species of Wild Fauna and Flora. 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 product 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 action was identified that would lead to cumulative impacts due to the proposed action from manufacturing the new tobacco product.

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 Action and the Alternatives – Use of the New Product

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

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. Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from use of the new tobacco product 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 product. The ingredients in the new tobacco product is commonly used in other currently marketed RYO products. Therefore, the Agency does not anticipate that using the new tobacco product would lead to the release of new chemicals into the air, as compared to the predicate tobacco product or similar currently marketed products.
Environmental justice	No new emissions are expected due to use of the new tobacco product. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.3. Cumulative Impacts

No action was identified that, when considered with the proposed action, would lead to cumulative impacts from use of the new tobacco product.

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 Action and the Alternative – Disposal of the New Product

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new tobacco product 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 product to consumers in the United States.

7.2. Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from disposal of the new tobacco product 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 product 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 product in municipal solid waste stream would not affect biological resources. Used product and packaging materials from the new tobacco product 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 product 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 product 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 product 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 action was identified that would lead to cumulative impacts due to the proposed action from disposal of the new tobacco product.

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 product, 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 Product Compared to the Predicate Product

STN	Component	Change from the predicate product
SE0015680	Product quantity	Increase in the number of injector tubes in retail box to 250 from 200 in the predicate product
	Injector tube	Decrease in tube weight
	Filter	Decrease in filter weight and density, and the associated decrease in ingredients
	Tipping paper	Decrease in tipping paper weight

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

STN	Unit	First - Year Market Volume Projection		Fifth - Year Market Volume Projection	
		New Product	Predicate Product	New Product	Predicate Product
SE0015680	Tubes	(b) (4)			
	Metric Tons				

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

The projected first- and fifth-year market volumes (Confidential Appendix 2) for the new product was compared to the total 2019 tube production[2] at the RTC manufacturing facility to evaluate the percentage of overall production that would be used to manufacture the new product. The percentage of the total production at the manufacturing facility dedicated to the new product 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) [redacted]	

The new RYO tobacco product would account for less than (b) (4) [redacted] of the facility's total production in the first- and fifth-year, respectively.

[2] Total tube production at RTF (2019) – (b) (4) Tubes