

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

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

April 17, 2019

**Table of Contents**

1. Applicant and Manufacturer Information..... 3

2. Product information ..... 3

3. The Need for the Proposed Action ..... 3

4. Alternatives to the Proposed Action..... 3

5. Potential Environmental Impacts of the Proposed Action and the Alternatives – Manufacturing the New Product..... 4

    5.1 Affected Environment ..... 4

    5.2 Analysis of Potential Environmental Impacts ..... 5

    5.3 Cumulative Impacts..... 6

    5.4 Impacts of the No-Action Alternative ..... 6

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

    6.1. Affected Environment ..... 6

    6.2. Analysis of Potential Environmental Impacts ..... 6

    6.3. Cumulative Impacts..... 7

    6.4. Impacts of the No-Action Alternative ..... 7

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

    7.1. Affected Environment ..... 7

    7.2. Analysis of Potential Environmental Impacts ..... 7

    7.3. Cumulative Impacts..... 8

    7.4. Impacts of the No-Action Alternative ..... 8

8. List of Preparers..... 8

9. List of Agencies and Persons Consulted ..... 8

CONFIDENTIAL APPENDIX 1..... 9

Modifications: The New Products Compared to the Original Products ..... 9

CONFIDENTIAL APPENDIX 2..... 10

Market Volume Projections for the New and Predicate Products..... 10

CONFIDENTIAL APPENDIX 3..... 11

Percentage of the Facility’s Total Production Dedicated to the New Product ..... 11

### 1. Applicant and Manufacturer Information

<b>Applicant Name:</b>	Republic Tobacco, LP
<b>Applicant Address:</b>	2301 Ravine Way Glenview, IL 60025
<b>Manufacturer Name:</b>	Republic Technologies Canada (the RTC factory)
<b>Product Manufacturing Address:</b>	Republic Technologies Canada 870 Boulevard Industriel Quebec, J6Z 4V7, Canada

### 2. Product information

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

STN	New Product Name	Predicate Product Name
SE0014881	Top Premier Menthol 100MM	Premier Menthol 100MM

#### Product Identification

<b>Product Category</b>	Roll-Your-Own
<b>Product Subcategory</b>	Filtered Cigarette Tube
<b>Number of Products per Retail Unit and Product Package</b>	200 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 FDA to issue a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco product substantially equivalent to the predicate product. 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 a marketing order. The Agency shall issue a marketing order, after considering the SE Report, if the new product is found substantially equivalent to the predicate product. The predicate product is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new product differs from the predicate product due to changes in ingredient levels and design features (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.

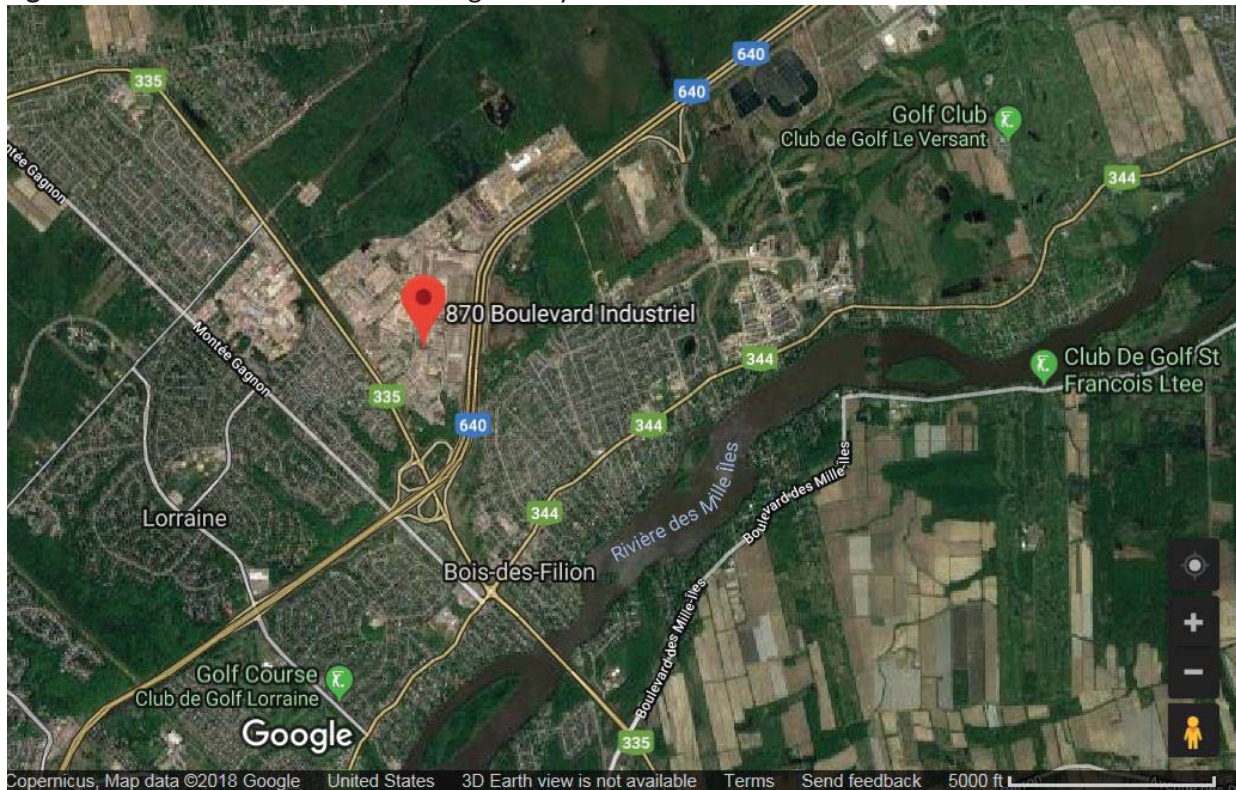
## 5. Potential Environmental Impacts of the Proposed Action and the Alternatives – Manufacturing the New Product

The Agency evaluated potential environmental impacts that may be caused from manufacturing the new 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).

**Figure 1.** Location of the Manufacturing Facility<sup>1</sup>



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 Îles 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.

<sup>1</sup> Land use surrounding manufacturing facility via Google Map. Accessed October 26, 2018.

## 5.2 Analysis of Potential Environmental Impacts

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

Environmental Resource	Analysis of Potential Impacts
Air quality	No air quality change surrounding the facility would be expected although, there might be an increased production of the new and predicate products (Confidential Appendix 2). The applicant stated that (1) the new product is expected to compete and potentially replace other cigarette tubes currently on the market; the production of the new product 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 product would not require a new or revised permit for air emissions, and (4) the manufacturing process for the new 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 (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,	No effects on floodplains, wetlands, or coastal zones are expected because no

wetlands, and coastal zones	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 action from manufacturing the new 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, as many similar RYO tobacco products would continue to be manufactured at the listed manufacturing facility.

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

The Agency considered potential impacts to resources in the environment that may be affected by use of the new 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 product based on information gathered by the Agency and the submitted SE Report.

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

**6.4. Impacts of the No-Action Alternative**

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

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

The Agency has considered potential impacts to resources in the environment that maybe affected by disposal of the new 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 order 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 product based on information submitted in the SE Report, including market volume information for the new and predicate products (Confidential Appendix 2) and the percentage of the facility's total production dedicated to the new products (Confidential Appendix 3).

<b>Environmental Resource</b>	<b>Analysis of Potential Impacts</b>
Air quality	Introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, thus, disposal of the used product and packaging would not significantly affect air quality.
Water resources and water quality	Proper disposal of used product and packaging materials from the new product in the municipal solid waste stream would 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 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).
Biological resources	Proper disposal of the used product and packaging materials from the new product in MSW would not affect biological resources. Used product and packaging materials from the new 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 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 Appendices 2)
Environmental justice	No significant environmental impacts associated with the disposal of the used product 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 action from disposal of the new 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 products, as many other similar tobacco products would continue to be marketed.

## 8. List of Preparers

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

#### **Preparer:**

Ronald L. Edwards Jr., MS, Center for Tobacco Products

Education: MS in Biology

Experience: Twenty-four years in environmental regulation and laboratory toxicology

Expertise: Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

#### **Reviewer:**

Hoshing W. Chang, PhD, Center for Tobacco Products

Education: MS in Environmental Science and PhD in Biochemistry

Experience: Ten years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

## 9. List of Agencies and Persons Consulted

Not applicable.



CONFIDENTIAL APPENDIX 1

Modifications: The New Products Compared to the Original Products

STN	Ingredient Changes	Design Feature Changes
SE0014881	Decreased (b) (4) [Redacted] [Redacted] Increased (b) (4) [Redacted]	Decreased (b) (4) [Redacted] [Redacted] Increased (b) (4) [Redacted] [Redacted]

CONFIDENTIAL APPENDIX 2

Market Volume Projections for the New and Predicate Products

STN	Unit	Current-Year (2017) Market Volume	First-Year Market Volume		Fifth-Year Market Volume	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0014881	Tubes	(b) (4)	(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) of the new product were compared to the total 2017 cigarette tube production 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 (%)

$$\frac{\text{Market Volume Projection (Number of Cigarette Tubes)}}{\text{Total Filtered Cigarette Tube Production at RTC (2017)}} \times 100\%$$

STN	Percentage of the Facility's Total Production Dedicated to the New Products (%)	
	First-Year	Fifth-Year
SE0014881	(b) (4)	

The new RYO tobacco product would account for (b) (4)% and (b) (4)% of the facility's total production in the first- and fifth-year, respectively, if a marketing order for the new product is issued.

---

<sup>2</sup> Total cigarette tube production at RTC facility in 2017 was (b) (4) tubes