

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

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

October 24, 2018

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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 (RTC)
Product Manufacturing Location:	Republic Technologies Canada 870 Boulevard Industriel, Bois-des-Filion Quebec, J6Z 4V7, Canada

2. Product information

New and Predicate Products

New Product Name	New Product STN	Predicate Product Name
Republic El Rey Blue King Size	SE0014701	Top Regular 100MM
Republic El Rey Blue 100MM	SE0014702	Top Gold 100MM
Republic El Rey Blue King Size	SE0014704	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	200 tubes per cardboard box

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco products substantially equivalent to the corresponding predicate products. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States.

The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) reports and any amendments submitted by the applicant, the new products are found substantially equivalent to the corresponding predicate products. The predicate products for SE0014701 and SE0014702 were previously found substantially equivalent and received marketing orders on September 26, 2013. The predicate product for SE0014704 is a grandfathered product.

The new products differ from the corresponding predicate products in ingredient levels and design features including ventilation, cigarette paper weight, tipping paper weight, tipping paper length, tube weight, filter weight, filter total denier, filter length, filter density, and filter pressure drop (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.

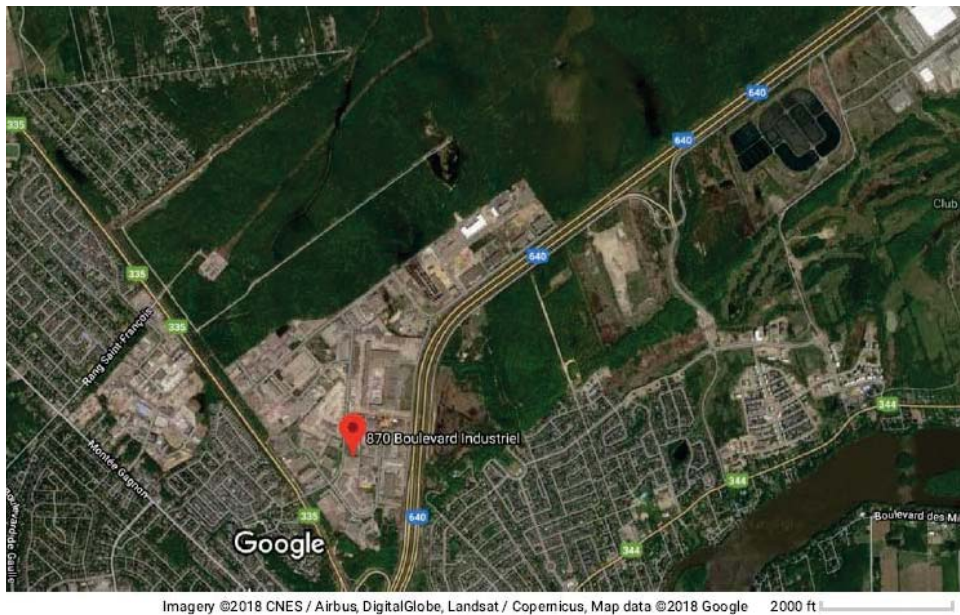
5. Potential Environmental Impacts of the Proposed Actions and the Alternatives – Manufacturing the New Products

The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts.

5.1 Affected Environment

The new and predicate products are manufactured at Republic Technologies Canada, 870 Boulevard Industriel, Bois-des-Filion, Quebec, J6Z 4V7, Canada. The manufacturing facility is in a mixed use commercial area consisting of office buildings, warehouses, small businesses, and light manufacturing facilities (Figure 1).

Figure 1. Location of the Manufacturing Facility¹



5.2 Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from manufacturing based on information gathered by the Agency and the submitted SE Reports, including market volume information for the new and predicate products (Confidential Appendix 2).

¹ Land use surrounding manufacturing facility via Google Map. Accessed June 8, 2018.

Environmental Resource	Analysis of Potential Impacts
Air quality	No air quality change surrounding the facility is anticipated because the ingredients in the new products are the same or similar to those already used in the facility. Additionally, based on the SE Reports, production of the new products will occupy less than 1% of the total production at the facility (Confidential Appendices 2 and 3).
Water resources	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 because production of the new products will occupy less than 1% of the total production at the facility (Confidential Appendices 2 and 3). 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 products.

5.4 Impacts from 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 will continue to be marketed and manufactured.

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

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

6.1. Affected Environment

The affected environment is the entire United States because the marketing orders will allow for the new tobacco products to be sold to consumers nationwide. The new products are RYO products that are intended to be filled with tobacco and smoked. Users may smoke RYO cigarettes indoors or outside, as the law permits.

6.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from use.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that no new compounds would be emitted from use of the new products. Therefore, the Agency does not anticipate that using the new products will lead to the release of new chemicals into the air, as compared to the predicate products or similar currently marketed products.
Environmental justice	The new products are expected to be used by the same consumers that use the predicate products. Therefore, no change in impacts to environmental justice populations are expected.

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 products.

6.4. Impacts from 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 has considered potential impacts to resources in the environment that may be affected by disposal of the new products and found no significant impacts.

7.1. Affected Environment

The affected environment is the entire United States because the marketing orders will allow for the new tobacco products to be sold to consumers nationwide who will dispose of the used products and packaging. The disposal will be via municipal solid waste (MSW) landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from disposal.

Environmental Resource	Analysis of Potential Impacts
Air quality	Introducing the new 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 products in MSW would not affect biological resources. Used product and packaging materials from the new 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 products into the U.S. market is not expected to increase the nationwide use of RYO tobacco products based on the Agency's assessment.
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.
Water resources and water quality	Proper disposal of used product and packaging materials from the new 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 products. Introducing the new 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 Appendices 2 and 3).
Regulatory compliance	It is assumed that the portion of product and packaging waste that is disposed of by users as litter, despite littering ordinances, will be no greater than the current tobacco product littering rates.

7.3. Cumulative Impacts

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

7.4. Impacts from 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 will 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:

Susana Addo Ntim, PhD, Center for Tobacco Products

Education: PhD in Environmental Science

Experience: Six years in various scientific activities

Expertise: Fate, transport and ecotoxicology of new and emerging contaminants, applications and environmental implications of nanotechnology

Reviewer:

Hoshing W. Chang, PhD, Center for Tobacco Products

Education: MS in Environmental Science and PhD in Biochemistry

Experience: Ten 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: Comparison of New and Predicate Products

The new and predicate products differ in certain additives and design features. There are differences in ventilation, ingredient levels, cigarette paper weight, tipping paper weight, tipping paper length, tube weight, filter weight, filter total denier, filter length, filter density, and filter pressure drop.

According to the SE Reports, the new products differ from the corresponding predicate products as listed in the following table:

STN	Ingredient Changes	Design Feature Changes
SE0014701	<p>Decreased – Adhesives (b) (4), and tipping glue), plasticizer (b) (4), plug wrap, and ink</p>	<p>Decreased – Cigarette paper weight per tube, tipping paper weight per tube, tube length, tube weight, tipping paper length, filter weight, filter length, filter pressure drop</p> <p>Increased – Filter density</p> <p>Added - Ventilation</p>
SE0014702	<p>Decreased – Adhesives (b) (4) and tipping glue) and ink</p> <p>Increased – plasticizer (b) (4)</p>	<p>Decreased – Cigarette paper weight per tube, tipping paper weight per tube, tube weight</p> <p>Increased – Tipping paper length, filter weight, and filter density</p>
SE0014704	<p>Decreased – Adhesives (b) (4) and tipping glue), (b) (4), and ink</p> <p>Increased – Plasticizer (b) (4)</p>	<p>Decreased – Tipping paper weight per tube, tipping paper length, filter weight, filter total denier, and filter density</p> <p>Increased – Cigarette paper weight per tube, Filter pressure drop</p> <p>Added - Ventilation</p>

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

STN	Unit	Current-Year (2017) Market Volume	First - Year Market Volume Projection		Fifth - Year Market Volume Projection	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0014701	Tubes	(b) (4)				
	Metric Tons					
SE0014702	Tubes					
	Metric Tons					
SE0014704	Tubes					
	Metric Tons					

Confidential Appendix 3: Percentage of the Facility’s Total Production Dedicated to the New Products

The projected first- and fifth-year market volumes (Confidential Appendix 2) for the new products were compared to the total 2016 cigarette tube production 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 (%)

$$= \frac{\text{Market Volume Projection (metric tons)}}{\text{Total Cigarette Tube Production at RTC (2016)}^2} \times 100\%$$

STN	Percentage of Facility’s Total Production Dedicated to New Products (%)	
	First - Year	Fifth - Year
SE0014701	(b) (4)	
SE0014702		
SE0014704		
Total		

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

² Total Cigarette Tube Production at RTC (2017) – (b) (4)