

**Programmatic Environmental Assessment for Marketing  
Orders for Six Filtered Cigarette Tube Products  
Manufactured by Republic Tobacco LP**

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

**August 29, 2018**

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**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 (RTC)                                    |
| <b>Address Where the Product is Manufactured:</b> | 870 Boulevard Industriel<br>Bois-des-Filion<br>Quebec, J6Z 4V7 CANADA |

**2. Product information**

**New and Predicate Products**

| <b>New Product Name</b>          | <b>New Product STN</b> | <b>Predicate Product Name</b> |
|----------------------------------|------------------------|-------------------------------|
| Top McClintock Blue King Size    | SE0014665              | 200 CT GAMBLER REG TUBE       |
| Top McClintock Regular 100 MM    | SE0014666              | Top Regular 100 MM            |
| Top McClintock Menthol King Size | SE0014667              | Top Menthol King Size         |
| Top McClintock Regular King Size | SE0014668              | 200 CT GAMBLER REG TUBE       |
| Top McClintock Blue 100 MM       | SE0014674              | Top Gold 100MM                |
| Top McClintock Blue King Size    | SE0014675              | Top Regular 100 MM            |

**New Product Identification**

|   |                   |
|---|-------------------|
| <b>Product Type</b>                         | Roll-Your-Own     |
| <b>Product Sub-Category</b>                 | Injector Tube     |
| <b>Number of Tubes per Retail Sale Unit</b> | 200 tubes per box |

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

The proposed action, requested by the applicant, is for FDA to issue marketing orders finding the new tobacco products substantially equivalent to the predicate products 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. The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) report and the amendments submitted by the applicant, the new products are found substantially equivalent to the predicate products.

The predicate product for SE0014665 and SE0014668 is a grandfathered product; a grandfathered product is a tobacco product that was commercially marketed as of February 15, 2007. The agency found the predicate products for SE0014666, SE0014674, and SE0014675 to be substantially equivalent on September 26, 2013; the predicate product for SE0014667 was found substantially equivalent on December 18, 2017. The new products differ from the corresponding predicate products in the following product characteristics: tube weight, tipping paper, amount of seam adhesives, amount of acetate tow and triacetin levels. (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.

**5. Potential Environmental Impact of the Proposed Action and the Alternatives – Manufacturing the New Products**

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

**5.1 Affected Environment**

Republic Technologies of Canada (RTC) is located north of Greater Montreal in Quebec, Canada (Figure 1).

The facility is flanked by; a gymnastics school to the west, a motorcycle dealership to the east, a scanning machine distributor to the north and a recycling center to the south.

**Figure 1.** Location of the Republic Technologies Canada



The proposed action was evaluated for potential environmental impacts from manufacturing based on Agency-gathered information and the applicant’s submitted information, including projected market volumes for the new and predicate products (Confidential Appendix 2 and 3).

| Environmental Resource | Analysis of Potential Impacts   |
|------------------------|---|
| Air quality            | No air quality change surrounding the facility is anticipated because the ingredients in the new product are essentially the same as those used in the facility. Additionally, based on the SE Reports, the new product manufacturing will occupy less than 0.03637 % of the total production at the facility (Confidential Appendix 2, Confidential Appendix 3). |

| Environmental Resource                   | Analysis of Potential Impacts   |
|--|---|
| Water resources                          | No impacts on water quality is anticipated because the liquid waste discharge is not anticipated to change at the manufacturing facility. This is because essentially the same ingredients are already being used in the facility as would be used to manufacture the new tobacco products. No impacts on water resources are anticipated because 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 would occur that would require land use.  |
| Biological resources                     | The applicant stated that the cigarette paper suppliers for the new products 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 manufacturing of the new and predicate products 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 impacts on employment, state or municipal revenue, or police and fire department resources are expected. Expansion of the manufacturing facility will not be necessary.  |
| 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 manufacturing the new products will occupy less than 0.03637 % of the total production at the facility (Confidential Appendix 2, Confidential Appendix 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 action.

**5.4 Impacts from No Action Alternative**

The environmental impact of the no-action alternative would not change the existing condition of manufacturing filtered cigarette tubes, as many similar products will continue to be marketed.

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

The Agency considered the potential impact to environmental resources caused by use of the new products and found no significant impact.

**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 filtered cigarette tubes that are intended to be filled with tobacco and smoked. Users may smoke filtered cigarette tubes indoors or outside, as the law permits.

**6.2. Analysis of Potential Environmental Impacts**

The proposed action was evaluated for potential environmental impacts from use.

| <b>Environmental Resource</b> | <b>Analysis of Potential Impacts</b>   |
|-------------------------------|--|
| 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. |
| 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 action, would lead to cumulative impacts.

**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 filtered cigarette tubes as many similar filtered cigarette tubes will continue to be marketed and therefore used.

## 7. Potential Environmental Impact of the Proposed Action and the Alternatives – Disposal of the New products

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

### 7.1. Affected Environment

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

### 7.2. Analysis of Potential Environmental Impacts

The proposed action was 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 affect air quality.  |
| Biological resources   | Proper disposal of 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 because 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        | Proper disposal of used products and packaging materials from the new products disposed of in the municipal solid waste would not affect water resources. Used products and packaging materials from the new products may be littered 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 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 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 action was identified that will lead to a cumulative impact due to the proposed action.

#### **7.4. Impacts from No Action Alternative**

The environmental impact of the no-action alternative would not change the existing condition of the disposal of RYO tobacco products, as many similar filtered cigarette tubes 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 environmental assessment.

##### Preparer:

Thomas Creaven, PhD, Center for Tobacco products

Education: BS in Chemistry/Biology and PhD in Neuroscience

Experience: Three years in NEPA review, ten years in science education

Expertise: NEPA review, science education,

##### Reviewer:

Hoshing W. Chang, PhD, Center for Tobacco products

Education: MS in Environmental Science and PhD in Biochemistry

Experience: Nine 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 products differ from the corresponding predicate products in certain design features and composition. The product differences are in the tube weight and amounts of adhesive, acetate tow and triacetin. The applicant provided the product material details for the new and predicate products as listed in the following table. The information listed here is taken directly from the SE Report and amendments.

| Product STN | Injector Tube Weight (mg) | Glue Seam/Filter weight (mg) | Acetate Tow mg/tube | (b) (4) mg/tube | Tipping Glue mg/tube |
|-------------|---------------------------|------------------------------|---------------------|-----------------|----------------------|
| SE0014665   | Decrease                  | Decrease                     | Decrease            | Decrease        | Decrease             |
| SE0014666   | Decrease                  | Decrease                     | Increase            | Decrease        | Decrease             |
| SE0014667   | Decrease                  | Decrease                     | Decrease            | Decrease        | Decrease             |
| SE0014668   | Decrease                  | Decrease                     | Decrease            | Increase        | Decrease             |
| SE0014674   | Decrease                  | No Change                    | No change           | Increase        | Decrease             |
| SE0014675   | Decrease                  | Decrease                     | Decrease            | Decrease        | Decrease             |

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

| STN       | Unit        | 2017 Market Volume | First-Year Market Volume |                    | Fifth-Year Market Volume |                    |
|-----------|-------------|--------------------|--------------------------|--------------------|--------------------------|--------------------|
|           |             | Predicate Products | New Products             | Predicate Products | New Products             | Predicate Products |
| SE0014665 | Tubes       | <b>(b)</b>         | <b>(4)</b>               |                    |                          |                    |
|           | Metric Tons |                    |                          |                    |                          |                    |
| SE0014666 | Tubes       |                    |                          |                    |                          |                    |
|           | Metric Tons |                    |                          |                    |                          |                    |
| SE0014667 | Tubes       |                    |                          |                    |                          |                    |
|           | Metric Tons |                    |                          |                    |                          |                    |
| SE0014668 | Tubes       |                    |                          |                    |                          |                    |
|           | Metric Tons |                    |                          |                    |                          |                    |
| SE0014674 | Tubes       |                    |                          |                    |                          |                    |
|           | Metric Tons |                    |                          |                    |                          |                    |
| SE0014675 | 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) of the new products were compared to the total number (b) (4) of injector tubes manufactured at the RTC facility in 2017. The percentage of the facility’s overall production that would be used to manufacture the new products is minuscule in both the first and fifth years after receiving marketing orders for the new products.<sup>1</sup>

| STN          | Percentage of the New Products to Facility’s Total Production (%) |              |
|--------------|---|--------------|
|              | First - Year  | Fifth – Year |
| SOE014665    | (b)   | (4)          |
| SOE014666    |   |              |
| SE0014667    |   |              |
| SE0014668    |   |              |
| SE0014674    |   |              |
| SE0014675    |   |              |
| <b>Total</b> |   |              |

Manufacturing the new products would account for (b) (4) % and (b) (4) % of the facility’s total production in the first- and fifth-year of marketing the new product, respectively.

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<sup>1</sup> Production Fraction of New Product (%) =  $\frac{\text{Market Volume Projections (metric tons)}}{\text{Total Injector Tube Production at RTC}}$