Programmatic Environmental Assessment for Marketing Orders for Six New Roll-Your-Own Filtered Cigarette Tubes 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 (RTC)
Product Manufacturing Address:	Republic Technologies Canada 870 Boulevard Industriel Quebec, J6Z 4V7, Canada

2. Product information

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

STN	New Product Name	Predicate Product Name
SE0014618	Top Premier Blue King Size	Top Regular 100MM
SE0014619	Top Premier Blue 100MM	Top Gold 100MM
SE0014620	Top Premier Blue King Size	200CT Gambler Reg Tube
SE0014621	Top Premier Regular 100MM	Top Regular 100MM
SE0014622	Top Premier Menthol King Size	Top Menthol King Size
SE0014623	Top Premier 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	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 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 applicant submitted to the Agency six substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue marketing orders, after considering the SE Reports, if the new products are found substantially equivalent to the corresponding predicate products. The predicate products for SE0014620 and SE0014623 are grandfathered products commercially marketed in the United States as of February 15, 2007. The predicate products for SE0014618, SE0014619, SE0014621, and SE0014622 were previously found to be substantially equivalent by FDA.

The new products differ from the corresponding predicate products in ingredient levels and design features (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 corresponding predicate products are manufactured at 870 Boulevard Industriel, Bois-des-Filion, Quebec J6Z 4V7, Canada (Figure 1). The manufacturing facility is located 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.

Figure 1. Location of the Manufacturing Facility

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the new products based on information gathered by the Agency and the information in the SE Reports, 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 increase in facility production due to the new and predicate products (Confidential Appendix 2). The applicant stated that (1) the facility has a dust control system to control the emissions, (2) manufacturing the new products would not require new or revised permit for air emissions, and (3) the manufacturing process for the new products is identical to the manufacturing process for other production at the RTC factory.
Water resources and water quality	No impacts on water resources are expected 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. The applicant stated that the new products are intended to compete with similar tobacco products currently manufactured at the facility and therefore, would not require any additional environmental controls for water discharges.
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 or new construction is anticipated. Therefore, no changes in zoning or land use would be expected and no adverse effects on soils would occur from manufacturing the new products.
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 also stated that the manufacturing process would be 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). Therefore, no adverse effects on listed species or their habitat and biological resources would be expected.
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, revenue, taxes, or community resources, such as police force and fire department resources, are expected because no facility expansion is anticipated. The applicant stated that the new products are intended to compete with and eventually replace similar tobacco products currently manufactured at the facility.
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 the new products would cumulatively occupy a small percentage of the

	facility's total production of RYO tobacco products (Confidential Appendices 2 and 3). The applicant also stated that 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	There would be no facility expansion and the applicant did not propose any land disturbance. Therefore, there would be no effects on floodplains, wetlands, or coastal zones.
Regulatory compliance	The applicant stated that the manufacturing facility would comply with all applicable Canadian federal and regional emissions, solid waste and liquid waste regulations and requirements.

5.3 Cumulative Impacts

The Agency did not identify any actions from manufacturing the new products that would lead to cumulative impacts when considered with the proposed actions.

5.4 Impacts from No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing RYO tobacco products, as many other similar RYO tobacco products will continue to be marketed and thereof manufactured in the United States.

6. Potential Environmental Impact 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 would allow for the new tobacco products to be sold to consumers nationwide. The new RYO tobacco products are intended to be filled with tobacco and users may smoke them indoors or outdoors, as the law permits.

6.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from use of the new 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 chemicals would be emitted from use of the new products because the ingredients in the new products are used in other similar tobacco products currently on the market. 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 changes in impact to environmental justice are expected.

6.3. Cumulative Impacts

The Agency did not identify any actions due to use of the new products that would lead to cumulative impacts when considered with the proposed actions.

6.4. Impacts from No-Action Alternative

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

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

The Agency 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. The disposal will be via municipal solid waste (MSW) landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential impacts from disposal of the new products based on information submitted in the SE Reports, 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).

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; therefore, 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 new product and packaging materials in the MSW 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 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 littering of the new products and packaging waste, despite state and local ordinances, will be no greater than the littering rate of the currently marketed RYO tobacco products.

7.3. Cumulative Impacts

The Agency did not identify any actions due to disposal of the new products that would lead to cumulative impacts when considered with the proposed actions.

7.4. Impacts from No-Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of disposal of RYO tobacco products, as many other similar tobacco products would continue to be marketed and thereof disposed of in the United States.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment (PEA):

Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Twenty five years in various scientific activities including seven years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. 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

Comparison of the New Products to the Corresponding Predicate Products

STN	Ingredient Changes from Predicate Product	Design Features from Predicate Product
SE0014618	**Decreased** – Cigarette paper, tipping paper, plug wrap, filter (b) (4) , rod print ink (b) (4) , and tipping glue **Increased** – Tipping paper (b) (4) **Added** – Tipping paper (b) (4) and tipping glue (b) (4))	**Decreased** – Filtered tube length, tipping paper length, filtered tube mass, filter denier per filament, filter pressure drop, and filter length **Increased** – Cigarette paper base porosity and filter density **Added** – Filter ventilation
SE0014619	**Decreased** – **Cigarette paper**, Tipping paper, plug wrap, filter (b) (4) , rod print ink ((b) (4) , and tipping glue **Increased –** Filter ((b) (4)) **Added** – Cigarette paper (b) (4) and tipping glue (b) (4)	**No changes**
SE0014620	**Decreased** – Tipping paper, filter (b) (4) , rod print ink (b) (4) and tipping glue **Increased – Cigarette paper** (b) (4) tipping paper (b) (4) , and plug wrap (b) (4) and filter plasticizer (b) (4) **Added** – Tipping glue (b) (4)	**Decreased** – Filtered tube mass, filter total denier, and filter density **Increased** – Cigarette base paper porosity, filter denier per filament, and filter pressure drop **Added** – Filter ventilation
SE0014621	**Decreased** – Tipping paper, plug wrap, filter (b) (4) rod print ink (b) (4)), and tipping glue	**Increased** – Filter density and filter pressure drop

STN	Ingredient Changes from Predicate Product	Design Features from Predicate Product
	Increased – Tipping paper ([redacted] (b) (4) [redacted] tipping glue [redacted] (b) (4) [redacted])	
SE0014622	**Decreased** – Tipping paper [redacted] (b) (4) [redacted], filter [redacted] (b) (4) [redacted] rod print ink [redacted] (b) (4) [redacted] tipping glue (tipping glue and [redacted] (b) (4) [redacted]), and menthol **Increased –** Tipping paper [redacted] (b) (4) [redacted]) and plug wrap [redacted] (b) (4) [redacted]	**Decreased** – Filtered tube mass, filter total denier, filter denier per filament, and filter density
SE0014623	**Decreased** – Tipping paper, filter [redacted] (b) (4) [redacted] rod print ink ([redacted] (b) (4) [redacted] and tipping glue **Increased** – Plug wrap [redacted] (b) (4) [redacted] and filter [redacted] (b) (4) [redacted] **Added** – Plug wrap [redacted] (b) (4) [redacted]) and tipping glue [redacted] (b) (4) [redacted])	**Decreased** – Filtered tube mass, filter total denier, and filter density **Increased** – Filter denier per filament and filter pressure drop

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections for the New 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
SE0014618	Cigarette Tubes	[redacted] (b) (4)				
	Metric Tons					
SE0014619	Cigarette Tubes					
	Metric Tons					
SE0014620	Cigarette Tubes					
	Metric Tons					
SE0014621	Cigarette Tubes					
	Metric Tons					
SE0014622	Cigarette Tubes					
	Metric Tons					
SE0014623	Cigarette Tubes					
	Metric Tons					
Cumulative Production[1]	**Cigarette Tubes**					
	Metric Tons					

[1] Cumulative Production is the summation of new products or predicate products.

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 2017 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 (%)

$$= \frac{\text{Market Volume Projection (Number of Cigarette Tubes)}}{\text{Total Filtered Cigarette Tube Production at RTC (2017)}^{2}} \times 100\%$$

STN	Percentage of the Facility's Total Production Dedicated to the New Products (%)	
	First-Year	Fifth-Year
SE0014618	(b) (4)	
SE0014619		
SE0014620		
SE0014621		
SE0014622		
SE0014623		
Total		

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

[2] Total cigarette tube production at RTC facility in 2017 was (b) (4)