

**Environmental Assessment for Marketing Order for Republic
Tobacco, LP, “TOP Menthol King Size”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

October 31, 2017

Table of Contents

- 1. Name of Applicant 4
- 2. Address4
- 3. Manufacturer 4
- 4. Description of the Proposed Action..... 4
 - 4.1 Requested Action.....4
 - 4.2 Need for Action.....4
 - 4.3 Identification of the New Tobacco Product that is Subject of the Proposed Action5
 - 4.3.1 Type of Tobacco Product.....5
 - 4.3.2 Product Name and Submission Tracking Number (STN).....5
 - 4.3.3 Description of the Product Package5
 - 4.3.4 Location of Manufacturing.....5
 - 4.3.5 Location of Use.....6
 - 4.3.6 Location of Disposal6
 - 4.4 Modification(s) Identified as Compared to the Predicate Product6
- 5. Environmental Introduction Due to the Proposed Action..... 6
 - 5.1 Environmental Introduction as a Result of Manufacturing the New Product.....6
 - 5.1.1. Tobacco Products Imported from Canada6
 - 5.1.2 Environmental Introduction from Manufacturing the New Product.....7
 - 5.2 Environmental Introduction as a Result of Use of the New Product.....8
 - 5.2.1. Use of Filtered Cigarette Tubes8
 - 5.2.2 Environmental Introduction from Use of the New Product.....9
 - 5.3 Environmental Introduction as a Result of Disposal Following Use9
 - 5.3.1 Disposal Following Use of Filtered Cigarette Tubes 10
 - 5.3.2 Environmental Introduction from Disposal Following Use of the New Product..... 12
- 6. Fate of Materials Released into the Environment Due to the Proposed Action 12
- 7. Environmental Effects of New Materials Released into the Environment Due to the Proposed Action 13
- 8. Use of Resources and Energy 13
- 9. Mitigation..... 13
- 10. Alternatives to the Proposed Action..... 13
- 11. List of Preparers 14

12.	List of Agencies and Persons Consulted.....	14
13.	Appendix List.....	14
APPENDIX 1 16		
	Submission Tracking Number for the SE Report with Names and Package Size of the New and Predicate Products, and Related Amendment Covered Under this Environmental Assessment.....	16
APPENDIX 2 17		
	Forecast of Total Tobacco Imported from Canada to the United States.....	17
APPENDIX 3 18		
	Projected Use of Cigarettes in the United States	18
CONFIDENTIAL APPENDIX 1		
	The First- and Fifth-Year Market Volume Projections of the New Product.....	19
CONFIDENTIAL APPENDIX 2		
	Percentage of the Projected Total Tobacco Importation from Canada Occupied by the New Product in the First and Fifth Years of Marketing the New Product	20
CONFIDENTIAL APPENDIX 3		
	Percentage of the Projected Total Cigarette Market in the United States Occupied by the New Product in the First and Fifth Years of Marketing the New Product	21
CONFIDENTIAL APPENDIX 4		
	First- and Fifth-Year Projections of Waste Associated with Use of the New Product	22

This environmental assessment (EA) is for the marketing order of a roll-your-own (RYO) tobacco filtered cigarette tube manufactured by Republic Tobacco, LP. Information presented in the EA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This EA has been prepared in accordance with 21 CFR 25.40 as part of a submission under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

1. Name of Applicant

Republic Tobacco, LP

2. Address

2301 Ravine Way
Glenview, Illinois 60025

3. Manufacturer

(b) (4) [Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

4. Description of the Proposed Action

The proposed action is for FDA to issue a marketing order under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of a new roll-your-own (RYO) tobacco filtered cigarette tube into interstate commerce. The authorization is based on the finding that the new product is substantially equivalent to the predicate product that was on the market as of February 15, 2007. The applicant stated that the predicate product will be discontinued after the new product is authorized.

4.1 Requested Action

Order finding the listed tobacco product is substantially equivalent to the predicate product.

4.2 Need for Action

Republic Tobacco, LP submitted SE Report SE0012366 seeking a marketing order for the introduction of their new product (as described in Section 4.3) into interstate commerce for commercial distribution in the United States. The applicant claims that the new and predicate products are substantially equivalent, differing only in an increase in the weight of the tipping paper and changes in the residual processing chemicals in one filter ingredient due to a change in supplier, but the new product does not raise different questions of public health (sec. 910(a)(3)(A)(ii)). After considering the SE Report, the Agency shall issue an order under the provisions of sections 910 and 905(j) of the FD&C Act when finding the new product to be substantially equivalent to the predicate product.

4.3 Identification of the New Tobacco Product that is Subject of the Proposed Action

4.3.1 Type of Tobacco Product

RYO filtered cigarette tubes

4.3.2 Product Name and Submission Tracking Number (STN)

STN	New Product	Predicate Product
SE0012366	TOP Menthol King Size	TOP Menthol King Size

See Appendix 1 for additional STNs associated with the new product.

4.3.3 Description of the Product Package

The new product are RYO filtered cigarette tubes. A cardboard retail carton contains 200 tubes. The retail carton has a cellophane wrap.

4.3.4 Location of Manufacturing

The manufacturer, ^{(b) (4)} [REDACTED], is located at ^{(b) (4)} [REDACTED] (Figure 1). The facility is located in a mixed use commercial area consisting of office buildings, warehouses, small businesses, and light manufacturing facilities.¹



¹ Land use reconnaissance via aerial photo, Google Earth. Accessed 5/11/2016.

4.3.5 Location of Use

Republic Tobacco, LP intends to distribute and sell the new tobacco product to U.S. consumers in the United States.

4.3.6 Location of Disposal

The used and unused filtered cigarette tubes will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as any other marketed filtered cigarette tubes. Following use, the packaging materials either would enter the recycling stream or be disposed of in MSW landfills or as litter. The geographic distribution of waste from disposal after use should correspond to the pattern of product use.

4.4 Modification(s) Identified as Compared to the Predicate Product

The applicant claims that the new product contains the same design, components, packaging materials, and ingredients and is made to the same specifications as the predicate product, with the exception of an increase in the weight of the tipping paper and changes in the residual processing chemicals in one filter ingredient due to a change in supplier.

5. Environmental Introduction Due to the Proposed Action

5.1 Environmental Introduction as a Result of Manufacturing the New Product

5.1.1 Tobacco Products Imported from Canada

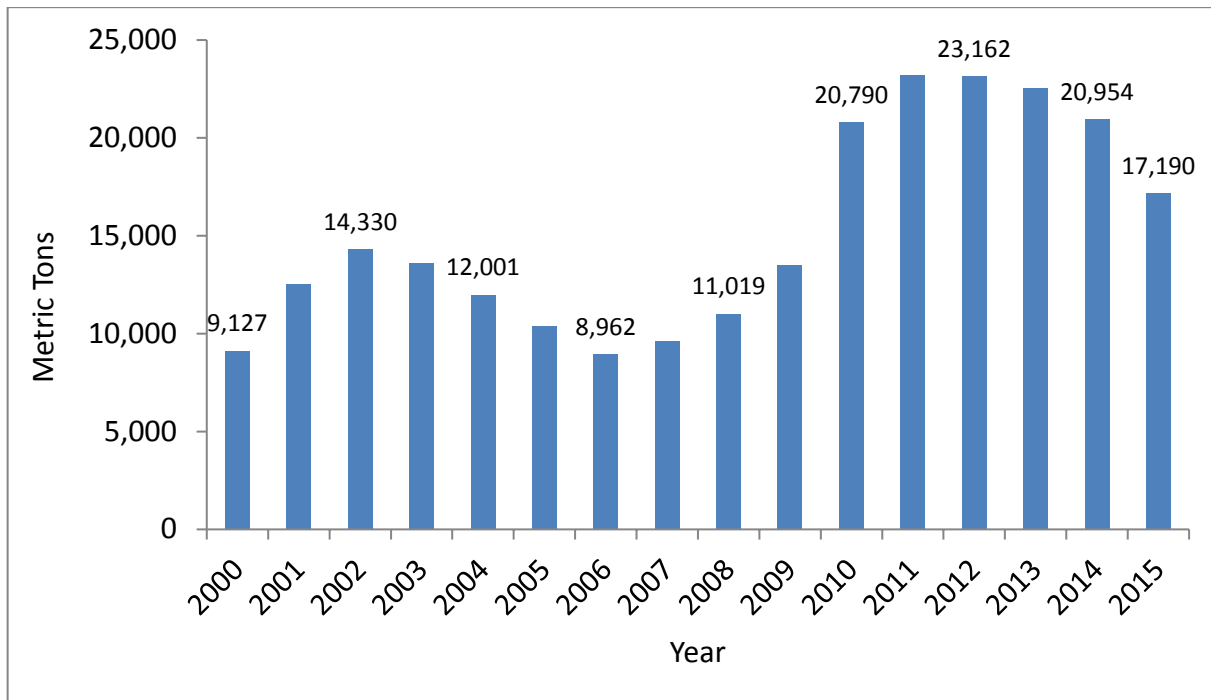
Based on information collected by the U.S. International Trade Commission, the worldwide U.S. import of cigarettes decreased from 51,930 metric tons in 2014 to 50,026 metric tons in 2015. Likewise, all tobacco products imported from Canada (Table 1 and Figure 2)² decreased from 20,954 metric tons in 2014 to 17,190 metric tons in 2015.

Table 1. U.S. Tobacco Imports – All Tobacco Products from Canada and All Cigarettes from All Countries in 2014 and 2015

Year	Total Weight of Cigarette Imported from All Countries to the U.S. (metric tons)	Total Weight of All Tobacco Products Imported from Canada to the U.S. (metric tons)
2014	51,930	20,954
2015	50,026	17,190

² U.S. International Trade Commission. https://dataweb.usitc.gov/scripts/tariff_current.asp?Phase=List_items&lookfor=481310. Accessed on March 23, 2016.

Figure 2. Total Tobacco Products Imported from Canada into the U.S., 2000 – 2015



5.1.2 Environmental Introduction from Manufacturing the New Product

The Agency anticipates the waste generated as a result of manufacturing the new product will be released to the environment, transferred to publicly owned treatment works, and disposed of in landfills in the same manner as any other product manufactured in the same facility and in a similar manner to other filtered cigarette tubes manufactured in Canada. The new product is expected to compete with other filtered cigarette tubes. Therefore, the Agency does not expect the introduction of the new product to notably affect the current manufacturing waste generated from the production of all filtered cigarette tubes in Canada.

According to information in the SE Report, the only difference between the new and predicate products is an increase in the weight of the tipping paper and changes in the residual processing chemicals in one filter ingredient due to a change in supplier. The applicant claims the manufacturing facility will be in compliance with federal and provincial Canadian regulations for air emissions, solid waste, and liquid waste. Therefore, the Agency anticipates no new substances or new type of emissions to be released into the environment as a result of manufacturing the new product. In addition, (b) (4), the Agency anticipates no new construction of manufacturing facilities by the applicant as a result of manufacturing the new product and no need for new control practices for air emission, water discharge, or solid waste disposal.

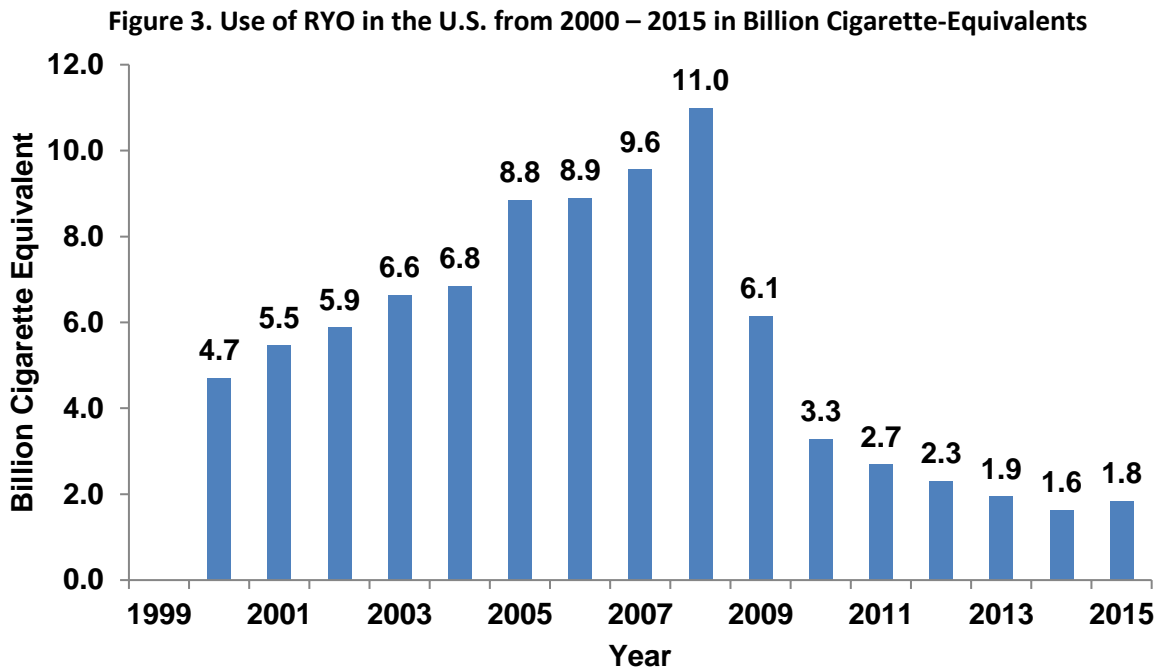
The applicant provided the first- and fifth-year market volume projections for the new product (Confidential Appendix 1). Comparing the projected market volumes of the new product with the forecasted market volumes of the total imported tobacco products from Canada to the United States., the individual and cumulative projected market volumes of the new products are a small share of the total forecasted market volumes in both years (Appendix 2 and Confidential Appendix 2).

(b) (4) and compete with other currently marketed RYO products, no net increase in greenhouse gas emissions from manufacturing is anticipated.³

5.2 Environmental Introduction as a Result of Use of the New Product

5.2.1 Use of Filtered Cigarette Tubes

Statistics reports from the U.S. Alcohol and Tobacco Tax and Trade Bureau show a gradual linear increase from 2000 to 2008 in the use of RYO tobacco in the United States from 4.7 billion cigarette-equivalents to 11 billion cigarette-equivalents (Figure 3).⁴ This was followed by a sharp decline in RYO tobacco use to 3.3 billion cigarette-equivalents in 2010 and to 1.6 billion cigarette-equivalents in 2015.



³The Council on Environmental Quality's recommends a qualitative analysis when agencies lack tools, methodologies, or data inputs to quantify greenhouse gas emissions from a proposed action. Guidance available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf. Accessed December 2, 2016.

⁴ U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed September 27, 2016.

Appendix 3 provides information on historical and projected future use in the United States of manufactured cigarettes.

When using cigarettes, the users inhale the mainstream smoke and release tobacco smoke to the environment, referred to as secondhand smoke. There is no safe level of exposure to secondhand smoke.^{5,6} Even low levels of secondhand smoke can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30 percent.⁸
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness.⁷
- Secondhand smoke causes more than 40,000 deaths a year.⁸

5.2.2 Environmental Introduction from Use of the New Product

As noted, according to the SE Report, the new and predicate tobacco products differ only in the weight of tipping paper and the residual processing chemicals in one filter ingredient due to a change in supplier. During use, the new product, like other cigarettes, is usually burned to ash, carbon dioxide, water vapor, and products from incomplete combustion such as carbon monoxide. These combustion products are released in a similar manner from the new and predicate products, as well as from other filtered cigarettes. The released substances during use of the new product are negligible from the environmental viewpoint. Essentially, the Agency does not anticipate new substances to be released into the environment as a result of use of the new product, in comparison to the substances released by the predicate product.

5.3 Environmental Introduction as a Result of Disposal Following Use

The waste that is generated following use of the new and predicate products consists of the disposed packaging materials and the discarded cigarette tube filters. Although the cardboard

⁵ U.S. Department of Health and Human Services (HHS). 2006. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

⁶ HHS. 2006. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

⁷ See previous two footnotes.

⁸ HHS. 2014. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta, GA.

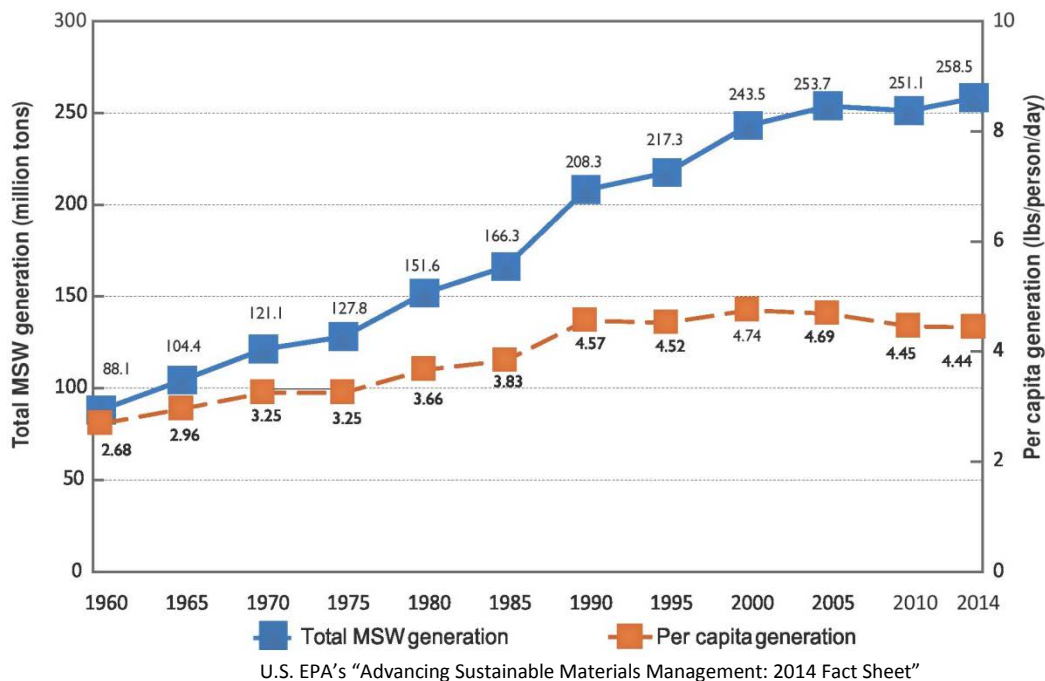
and paper board material is biodegradable, the filters can persist in the environment for an extended time (see below).⁹

5.3.1 Disposal Following Use of Filtered Cigarette Tubes

a) Disposal of packaging material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2014, approximately 258.46 million tons of trash was generated in the United States, and approximately 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 3 and 4). Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Plastics account for 33.25 million tons (12.9%) of total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery. On average, 4.4 pounds of waste was generated per person in the United States, of which 2.1 pounds was recycled, composted, or combusted for energy recovery.¹⁰

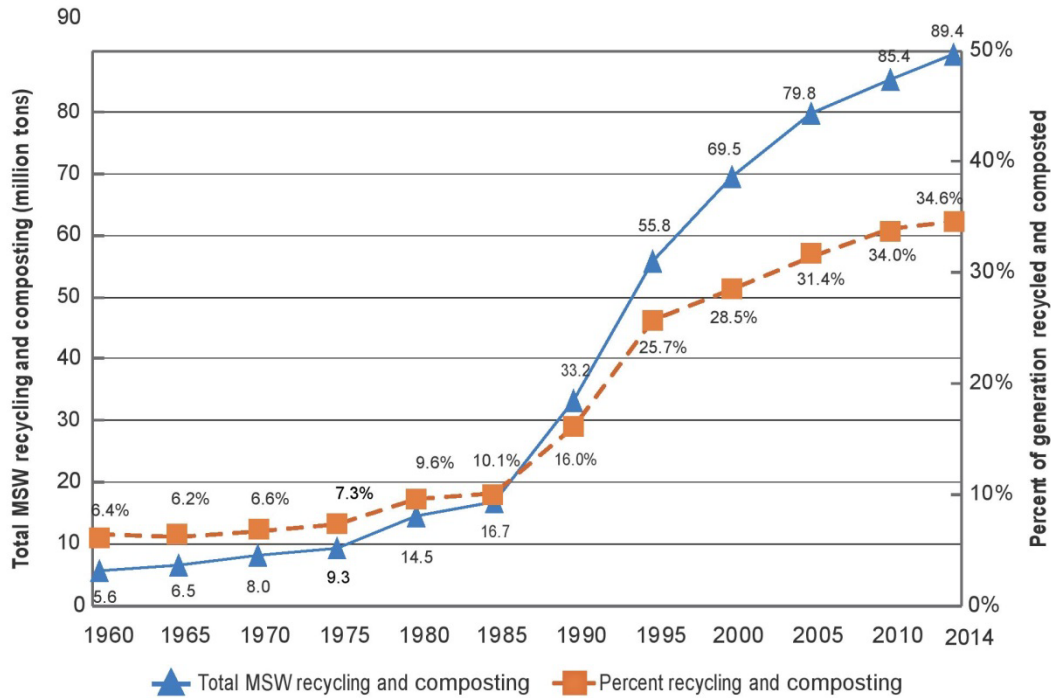
Figure 4. MSW Generation Rates in the U.S., 1960 – 2014



⁹ Novotny TE and Zhao F. Consumption and production waste: Another externality of tobacco use. *Tobacco Control* 1999; 8:75-80.

¹⁰ EPA. *Advancing Sustainable Materials Management: Facts and Figures Report*. Available at: <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report> (accessed December 7, 2016).

Figure 5. MSW Recycling Rates in the U.S., 1960 – 2014



U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

b) Disposal of cigarette tube filters following use

A major existing environmental consequence of the use of filtered cigarette tubes is the waste disposal of the filters (cigarette butts). Evidence has shown that cigarette butts are the most prevalent items discarded into roads and streets in urban areas. Once dumped onto city streets, they move through the storm drains to streams, into the ocean, and back onto the beaches, while leaching toxicants into the environment along the way. Discarded filters are found to be the most collected item in beach clean-ups and litter surveys. An estimated 30 percent of the total waste (by count) on U.S. shorelines, waterways, and land is cigarette filter waste.¹¹

Cigarette tube filters most commonly contain cellulose diacetate, which may persist under normal environmental conditions for 18 months to 10 years.^{12,13} Researchers found that cigarette filters are a source for metal contamination, in which the filters gradually released

¹¹ Tobacco Control Legal Consortium. Policy Tools for Minimizing Public Health and Environmental Effects of Cigarette Waste. March 2014. Available at: <http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-cigarette-waste-2014.pdf>. March 27, 2015.

¹² U.S. Department of Health and Human Services. Reducing the health consequences of smoking: 25 years of progress. A report of the Surgeon General, 1989. Rockville, Maryland: Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1989. (DHHS Publication No (CDC) 89-8411.).

¹³ Ach A. Biodegradable plastics based on cellulose acetate. *Journal of Macromolecular Science: Pure and Applied Chemistry* 1993; A30:733–40.

multiple metals over a 34-day study period.¹⁴ In addition, scientists stated that cigarette filters are a source for nicotine entering the aquatic ecosystem over a 24-hour simulated rainfall event.¹²

5.3.2 Environmental Introduction from Disposal Following Use of the New Product

The Agency believes that the disposal of the new product will be similar to the disposal conditions of other filtered cigarette products that are currently being marketed. After using the new product, the users may dispose of or recycle the packaging paper material and cellophane wrap. Users may also discard the cigarette filters and ashes as MSW or as litter.

a) Disposal of packaging material

To estimate the amount of waste from disposal of paper and cellophane packaging material, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products after issuance of the marketing order for the new product (Confidential Appendix 4). The calculated cumulative waste of the paper and cellophane packaging material is determined to be miniscule compared to the forecasted MSW to be generated in the United States. In addition, because paper components are more likely to be recycled, at least a portion of the waste is likely to be recycled.

b) Disposal of cigarette tube filters

To estimate the amount of waste from disposal of cigarette filters, the Agency used the first- and fifth-year projected volumes of marketing the new products (Confidential Appendix 4). Although the waste generated from cigarette filters remains as an environmental concern, the calculated cumulative waste of the filters due to the proposed action is determined to be miniscule compared to the forecasted MSW to be generated in the United States.

Because the new product will compete with other filtered tobacco products on the market and based on the above-mentioned information regarding waste, construction of new landfills is not anticipated due to the proposed action.

6. Fate of Materials Released into the Environment Due to the Proposed Action

The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment because the predicate product (filtered cigarette tubes with substantially equivalent attributes and characteristics as the new product) has been sold and the new product is anticipated to be manufactured the same way as other products in the same facility and be used and disposed of the same way as other filtered cigarettes in the United States.

Therefore, the fate of any materials released to the environment is anticipated to be the same as other products manufactured in the facility. No new types of materials are anticipated to be released to the

¹⁴ Moerman, JW; Potts, GE. Analysis of metals leached from smoked cigarette litter. *Tobacco Control*. 2011; 20(Suppl. 1):I30-I35.

¹² Roder Green, AL; Putschew, A; Nehls, T. Littered cigarette butts as a source of nicotine in urban waters. *Journal of Hydrology*. 2014; 519:3466-3474.

environment because the new product is substantially equivalent to the predicate product and will be made using the same materials and processes as the predicate product.

7. Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

The applicant stated that the manufacturing operation will comply with all provincial and federal environmental laws in Canada. Therefore, cumulative introduction is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

Furthermore, as discussed above, the amount of materials anticipated to enter the environment due to manufacturing and use of the new product are small fractions when compared to that of the cigarettes imported in the United States. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new product occupies a small fraction of the total forecasted MSW in the United States. Consequently, no new environmental effects are anticipated due to the new product.

8. Use of Resources and Energy

In the SE Report, the applicant stated that the paper and acetate tow ingredients are produced from renewable and sustainable resources in accordance with the Forestry Stewardship Council, Pan European Forest Certification, and the Canadian Sustainable Forest Management. These standards require raw materials to be obtained from sustainable and renewable resources that do not impact critical habitats or endangered species. As to both resource and energy use, the new product will compete with other currently marketed tobacco products.

Furthermore, comparing the projected market volumes of the new product with the forecasted market volumes of the total imported tobacco products from Canada to the United States, the projected market volumes of the new product are small fractions of the total forecasted market volumes. Accordingly, no additional use of resources and energy is anticipated.

9. Mitigation

During review of the available data and information, the Agency did not identify adverse environmental effects for the new product and the proposed use as filtered cigarette tubes. Therefore, no mitigation measures were developed.

10. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco product in the United States. The environmental impact of this action would not change

the existing condition of the manufacturing, use, and disposal following use of tobacco products as many other RYO cigarette paper products will continue to be marketed.

Alternative B (Proposed action): There is no substantial environmental effect due to the proposed action of authorizing the new product and the associated manufacture, use, and disposal from use of the new tobacco product.

11. List of Preparers

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

Preparer:

Gregory G. Gagliano, MS, Center for Tobacco Products

Education: MS in Environmental Science

Experience: 34 years in environmental toxicology and risk assessment

Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

Reviewer:

Hoshing Chang, PhD, Center for Tobacco Products

Education: PhD in Biochemistry and MS in Environmental Science

Experience: 9 years in NEPA practice

Expertise: Waste water treatment, environmental impact analysis

12. List of Agencies and Persons Consulted

Not applicable.

13. Appendix List

Appendix 1: Submission Tracking Number for the SE Report with Names and Package Size of the New and Predicate Products, and Related Amendment Covered Under this Environmental Assessment

Appendix 2: Forecast of Total Tobacco Imported from Canada to the United States

Appendix 3: Projected Use of Cigarettes in the United States

Confidential Appendix 1: The First- and Fifth-Year Market Volume Projections of the New Product

Confidential Appendix 2: Percentage of the Projected Total Tobacco Importation from Canada Occupied by the New Product in the First and Fifth Year of Marketing the New Product

Confidential Appendix 3: Percentage of the Projected Total Cigarette Market in the United States Occupied by the New Product in the First and Fifth Years of Marketing the New Product

Confidential Appendix 4: First- and Fifth-Year Projections of Waste Associated with Use of the New Product

APPENDIX 1

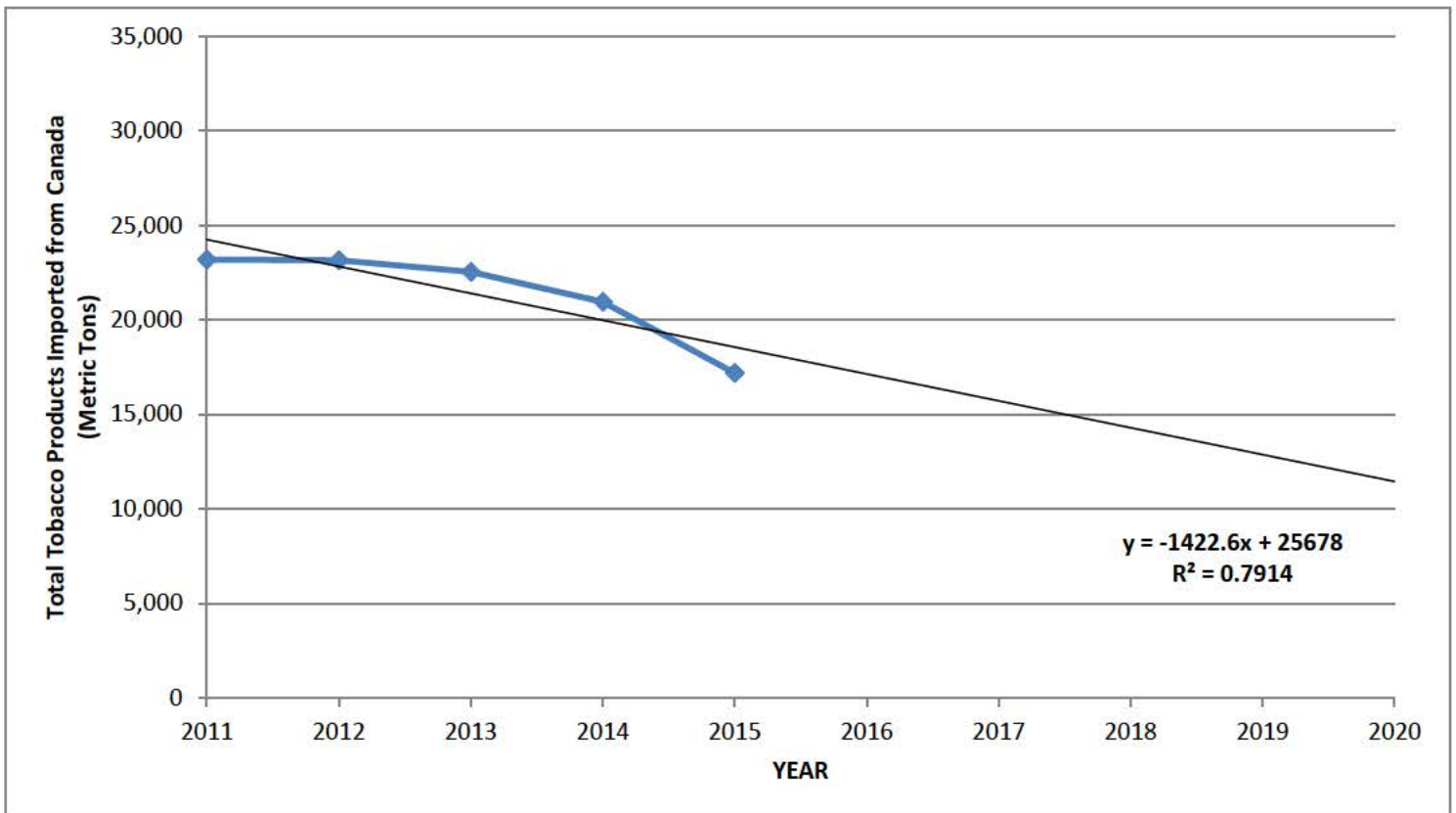
Submission Tracking Number for the SE Report with Names and Package Size of the New and Predicate Products, and Related Amendment Covered Under this Environmental Assessment

STN	New Product	Package Size	Predicate Product	Package Size	Amendment
SE0012366	TOP Menthol King Size	200 per box	TOP Menthol King Size	200 per box	SE0013042

APPENDIX 2

Forecast of Total Tobacco Imported from Canada to the United States

To evaluate the environmental impact of the proposed action due to manufacturing the new product, historical data regarding total tobacco products imported from Canada to the United States from 2011 to 2015 were used to forecast the manufacturing of total tobacco products. This was achieved by using a best-fit linear trend line with the R^2 value of 0.79. Accordingly, the forecasted amount of the total tobacco products to be imported from Canada to the United States are estimated to be 17,142 and 11,452 metric tons in the first and fifth years of marketing the new product, respectively.

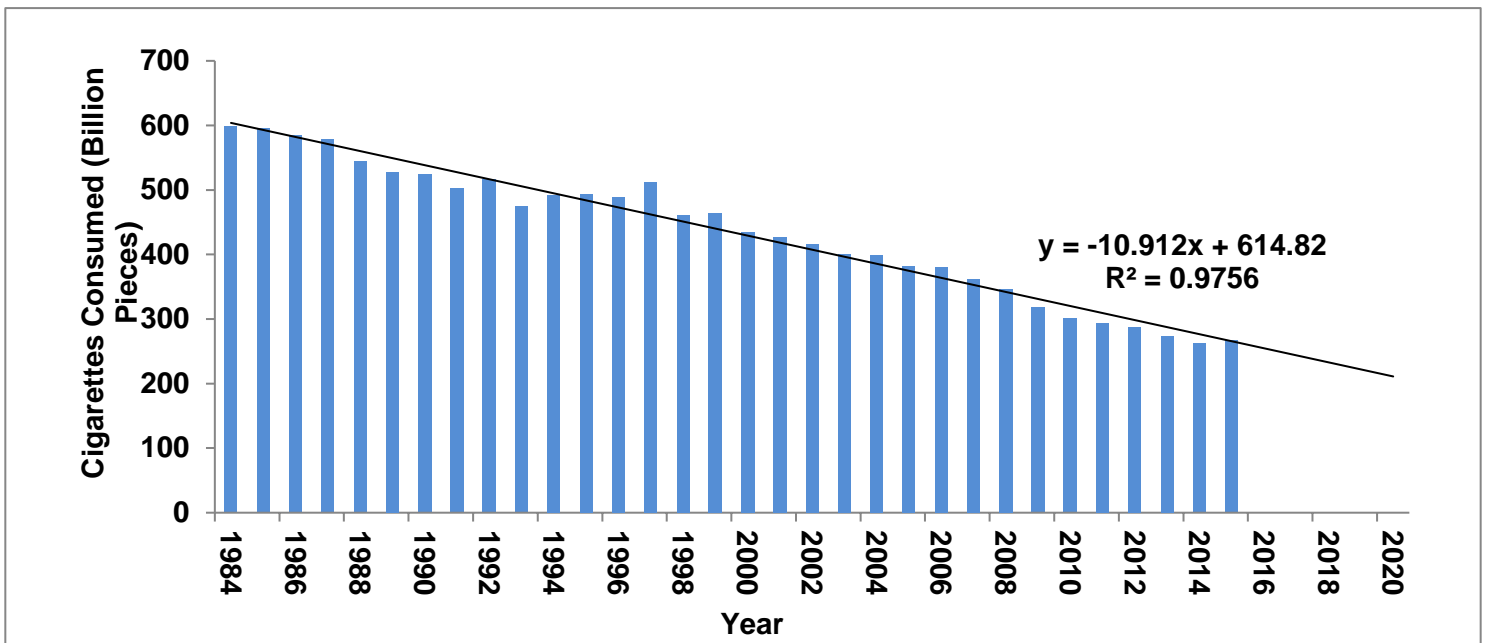


APPENDIX 3

Projected Use of Cigarettes in the United States

To evaluate the environmental impact of the proposed action due to use of the new product, historical data regarding use of total cigarettes from 1984 to 2015 was used to mathematically estimate the forecast of the total number of cigarettes used in the United States. This was achieved by using one best-fit power trend line with the R^2 value of 0.98.

Accordingly, the forecasted total number of cigarettes that will be used in the United States is estimated to be 254.72 billion and 211.08 billion in the first and fifth years of marketing the new product, respectively.



CONFIDENTIAL APPENDIX 1

The First- and Fifth-Year Market Volume Projections of the New Product

STN	Product Name	1st-Year Projected Market Volume (tubes)	1st-Year Projected Market Volume (metric tons)	5th-Year Projected Market Volume (tubes)	5th-Year Projected Market Volume (metric tons)
SE0012366	TOP Menthol King Size	(b) (4)			
Total Projected Market Volume of New Product		(b) (4)			

CONFIDENTIAL APPENDIX 2

Percentage of the Projected Total Tobacco Importation from Canada Occupied by the New Product in the First and Fifth Years of Marketing the New Product

Year	Weight of Total Tobacco Forecasted to be Imported from Canada (metric tons)	New Product	
		Weight (metric tons)	Percent of Total Tobacco Imported from Canada
First year of marketing new product	(b) (4)		
Fifth year of marketing new product			

The projected market volumes in weights for the new product are (b) (4) and (b) (4) metric tons in the first and fifth years of marketing the new product, respectively. Compared to the forecasted volume for the total amount of tobacco products imported from Canada, the first- and fifth-year market volume of the new product may occupy (b) (4) and (b) (4) of the total market of all tobacco products imported from Canada, respectively (see section 5.1.1).

CONFIDENTIAL APPENDIX 3

**Percentage of the Projected Total Cigarette Market in the United States Occupied by the New Product
in the First and Fifth Years of Marketing the New Product**

Year	Projected Cigarette Use in the U.S. (millions of cigarettes)	New Product	
		Projected Use (millions of RYO tubes)	Percent of Total Cigarette Use
First year of marketing the new product	(b) (4)		
Fifth year of marketing the new product			

The projected market volume for the new product is (b) (4) million and (b) (4) million cigarettes in the first and fifth years of marketing the new product, respectively. Compared to the number of cigarettes projected to be used in the United States, the new product would occupy (b) (4) and (b) (4) of the total market of cigarettes in the first and fifth years, respectively (see section 5.1.1).

CONFIDENTIAL APPENDIX 4

First- and Fifth-Year Projections of Waste Associated with Use of the New Product

To analyze the environmental effects from waste due to the proposed action, the Agency estimated the mass of the projected packaging and product materials waste (in tons) that would be generated from disposal after use of the new products in the first and fifth years of marketing the new product. Projected waste generation is the sum of the plastic overwrap, cardboard box, and used filter tip waste generation of the new product:

$$A = B + C + D$$

where:

$$B = \frac{E}{F} \times G \times J$$

$$C = \frac{E}{F} \times H \times J$$

$$D = E \times I \times J$$

- A: Projected total waste generation from use of the new product (metric tons)
- B: Projected plastic overwrap waste generation of the new product (metric tons)
- C: Projected retail cardboard box waste generation of the new product (metric tons)
- D: Projected tip waste generation of the new product (tons)
- E: Projected market volume of the new product (filtered tubes)
- F: Number of filtered tubes per retail cardboard box
- G: Mass of plastic overwrap on retail cardboard box (grams)
- H: Mass of empty retail cardboard box (grams)
- I: Mass of tip (grams)
- J: 1×10^{-6} metric tons/gram (unit conversion factor)

	STN	I	H	G	F	E	D	C	B	A
First Year	SE0012366	(b) (4)								
Fifth Year	SE0012366									

If all the waste (plastic overwrap, cardboard box, and used filter tip) generated from use of the new product is disposed of in landfills, the projected cumulative waste disposed of in the first and fifth years of marketing the new product would be (b) (4) and (b) (4) metric tons, respectively. This is a negligible fraction (b) (4) of the 258.5 million tons (234.5 metric tons) of total waste reported in the United States in 2014.

A portion of the generated cardboard waste is likely to be recycled, with an overall recycling rate for paper and paperboard products of 64.7% in the United States.¹⁵ If 64.7% of the cardboard boxes is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed of in landfills (Variable C above) would be decreased to $0.353 \times (b) (4)$ metric tons = $(b) (4)$ metric tons in the first year and $0.353 \times (b) (4)$ metric tons = $(b) (4)$ metric tons in the fifth year of marketing the new product. In this case, accounting for potential recycling, the total waste (cardboard, plastic, and tip) disposed of would be decreased to $(b) (4)$ and $(b) (4)$ tons in the first and fifth years, respectively. This represents a decrease in the negligible fraction $(b) (4)$ of the 258.5 million tons (234.5 million metric tons) of solid waste disposed of in the United States in 2014.

The used cigarette filter tips can be disposed of in landfills, but they can also be discarded on streets and roadsides where they may move through storm drains into surface waters. When the used filter tips enter the environment, they can move into the ocean and ultimately back onto land, on beaches. Littered filter tips may leach potentially toxic materials into stormwater, which can reach surface water systems through runoff or contaminate soil and groundwater through infiltration.

¹⁵ EPA. Advancing Sustainable Materials Management: Facts and Figures Report. Available at: <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report> (accessed December 7, 2016).