Programmatic Environmental Assessment for Marketing Orders for Republic Tobacco, LP "Job® Double Wide Gold, Job® 1.25 Silver, Job® 1.0 Gold, Job® 1.5 Slim Gold, OCB® Organic Hemp 1-1/4, OCB® Organic Hemp Single Wide, OCB® Organic Hemp Single Wide, OCB® Organic Hemp King Size Slim, Top® Silver King Size, Top® Menthol King Size, Top® Menthol King Size, Altesse® Regular King Size, and Altesse® Regular King Size"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

December 12, 2017

Contents

This programmatic environmental assessment (PEA) is for marketing orders for thirteen roll-your-own (RYO) paper, filter tips and filtered injector tubes manufactured by Republic Tobacco, LP. Information presented in the PEA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This PEA has been prepared in accordance to 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

Republic Tobacco, LP

2. Address

2301 Ravine Way
Glenview, IL 60025

3. Manufacturers

The RYO paper supplier for SE0011107, SE0011111, SE0011112, SE0011115, SE0011117, SE0011118, SE0011119, and SE0011120 is located in a foreign country and that location is provided in Confidential Appendix 1.

The RYO filtered injector tube supplier for SE0011135, SE0011184, SE0011185, SE0011186, SE0011187 is also located in a foreign country and that location is provided in Confidential Appendix 1.

4. Description of Proposed Action

The proposed actions are for FDA to issue market orders under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of multiple RYO paper and filtered injector tubes into interstate commercial distribution in the United States. The authorization is based on the finding that the new products are substantially equivalent to the corresponding predicate products that were on the market as of February 15, 2007. The applicant intends to market the new and predicate products simultaneously after receiving marketing orders for the new products.

4.1 Requested Action

Orders finding the listed tobacco products are substantially equivalent to the corresponding predicate products.

4.2 Need for Action

Republic Tobacco, LP wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the United States. The applicant claims that the new and corresponding predicate products are identical in every characteristic, but differ in packaged quantities (sec 910(a)(3)(A)(ii) of the FD&C Act). In addition, the applicant claims that the new and corresponding predicate products have identical packaging composition. After considering the substantial equivalence (SE) reports, the Agency shall issue an order pursuant to section 910(a)(2) of the FD&C Act when finding the new products to be substantially equivalent to the predicate product.

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

4.3.1 Types of Tobacco Product

RYO paper (SE0011107, SE0011111, SE0011112, SE0011115, SE0011117, SE0011118, SE0011119, and SE0011120)
Filtered injector tubes (SE0011135, SE0011184, SE0011185, SE0011186, SE0011187)

4.3.2 Product Names and STNs

The names of the new products are listed below, along with the submission tracking numbers (STN) and the names of the corresponding predicate products. See Appendix 1 for additional STNs associated with the new and predicate products.

STN	New Product	Predicate Product
SE0011107	Job® Double Wide Gold	Job® Double Wide Gold
SE0011111	Job® 1.25 Silver	Job® 1.25 Silver
SE0011112	Job® 1.0 Gold	Job® 1.0 Gold 24's
SE0011115	Job® 1.5 Slim Gold	Job® 1.5 Slim Gold
SE0011117	OCB® Organic Hemp 1-1/4	OCB® Organic Hemp 1-1/4
SE0011118	OCB® Organic Hemp Single Wide	OCB® Organic Hemp Single Wide
SE0011119	OCB® Organic Hemp Single Wide	OCB® Organic Hemp Single Wide
SE0011120	OCB® Organic Hemp King Size Slim	OCB® Organic Hemp King Size Slim
SE0011135	Top® Silver King Size	Top® Silver King Size
SE0011184	Top® Menthol King Size	Top® Menthol King Size
SE0011185	Top® Menthol King Size	Top® Menthol King Size
SE0011186	Altesse® Regular King Size	Altesse® Regular King Size
SE0011187	Altesse® Regular King Size	Altesse® Regular King Size

4.3.3 Description of the Product Package

The packaging materials for the new and corresponding predicate products are identical in composition packaging material and packaging weights for(SE0011107, SE0011111, SE0011112, SE0011115, SE0011117, SE0011118, SE0011119, and SE0011120. For SE0011135, SE0011184, SE0011185, SE0011186, and SE0011187 the packaging materials for the new and corresponding predicate products are identical in composition packaging material, but differ in packaging weights.

4.3.4 Location of Use

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

4.3.5 Location of Disposal

Once used, the new tobacco products will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as the corresponding predicate products and any other RYO products. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates that the geographic distribution of waste from disposal after use will correspond to the geographic pattern of the product use.

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

The applicant claims that the new products differ from the corresponding predicate products in quantity and packaging weight.

5 Potential Environmental Impacts Due to the Proposed Action

5.1 Potential Environmental Impacts Due to Manufacturing the New Products

Potential Chemical Emissions from RYO Paper Supplier

When a search was performed for air, water and soil pollutant information associated with the RYO paper supplier using a publicly available database European Pollutant Release and Transfer Register (E-PRTR), no data were available. Similarly, when a search was performed for air, water and soil pollutant information for all tobacco products in the suppliers' country using E-PRTR, no data were available (E-PRTR, 2017).

The applicant stated that the RYO paper supplier abides by all federal and regional emissions, solid waste, and liquid waste regulations and requirements of the its respective country. In addition, the applicant stated that the facility is certified by the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification (PEFC) and provided information on the certifications. Complying with the relevant environmental regulations and fulfilling sustainability measures do not appear to threaten any endangered species or critical habitat. Furthermore, the applicant stated that the facility has in place controls and standards that protect the environment, specifically species and habitats addressed under the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

The applicant stated that the facility holds ISO 9001 and ISO 14001 certifications, showing effective quality management and environmental management systems. Also, the applicant stated that the manufacturing of the new products will not require additional or new environmental controls, resources for manufacturing waste disposal or result in the emission of any different greenhouse gases (GHGs). The applicant also stated that the new products are intended to compete with the predicate products, as well as other RYO cigarette papers that are currently on the market, so the net increase of energy would be negligible, if there is any net increase at all. Lastly, the applicant stated that the manufacturing of the new products will not require an expansion or construction of a new facility.

Potential Chemical Emissions from RYO Filtered Injector Tube Supplier

The emission information associated with the manufacturing of certain tobacco products from the country where the RYO filtered injector tube supplier is located is publicly available. In 2015, the database reports 2.56 tones of PM_{10} (particulate matter $\leq$ 10 microns) and 1.26 tones of $PM_{2.5}$ (particulate matter $\leq$ 2.5 microns) to the air by tobacco facilities. The RYO filtered injector tube supplier is not listed in this database.

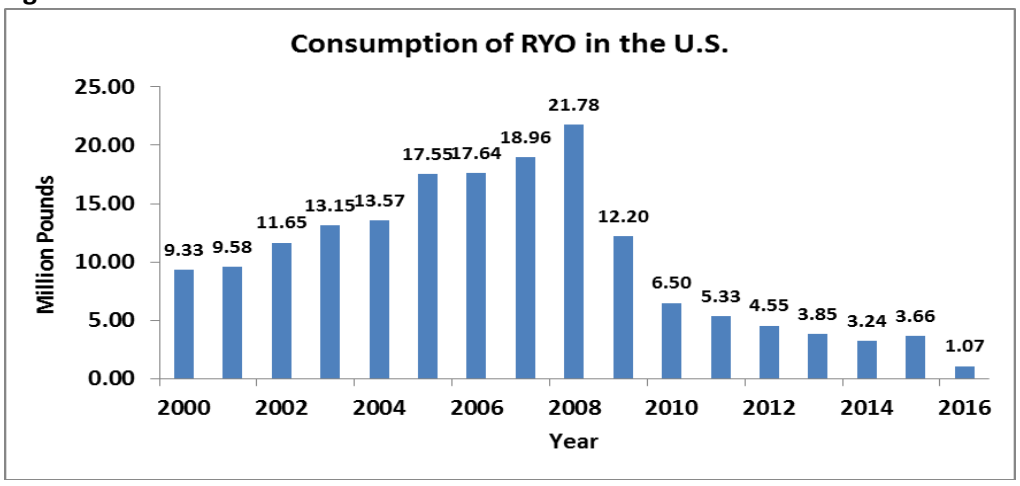
The applicant stated that the RYO filtered injector tube supplier abides by all applicable federal and regional emissions, solid waste, and liquid waste regulations and requirements for the respective country. In addition, the applicant stated that the facility has in place controls and standards that protect the environment, specifically species and habitats addressed under the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). Moreover, the applicant stated that the suppliers for the facility are certified by the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification (PEFC). Complying with the relevant environmental regulations and fulfilling sustainability measures do not appear to threaten any endangered species or critical habitat.

Also, the applicant stated that manufacturing the new products will not require additional or new environmental controls, additional resources for manufacturing waste disposal or result in the emission of any different GHGs. The applicant also stated that the new products are intended to compete with the predicate products, as well as other RYO cigarette papers that are currently on the market, so the net increase of energy would be negligible, if there is any increase at all. The applicant stated that the production processes for the new products are identical to other productions at the manufacturing facility. Lastly, the applicant stated that manufacturing the new products will not require an expansion or construction of a new facility.

5.2 Potential Environmental Impacts Due to Use of the New Products

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of RYO tobacco in the United States increased from 9.33 million pounds in 2000 to 21.78 million pounds in 2008. This was followed by a decrease in use from 12.20 million pounds in 2009 to 1.07 million pounds in 2016 (Figure 1) (US TTB, 2017).

Figure 1. Use of RYO Tobacco in the United States in 2000-2016



Overall, the use of RYO tobacco in the United States have decreased since 2008 and the Agency anticipates the same pattern will continue for at least the next few years. Furthermore, the applicant claimed that the new products will compete and replace with other currently marketed RYO products. Therefore, quantitatively the Agency does not anticipate more chemicals to be emitted into the environment from the use of the new products, compared to the chemicals released from the use of the predicate products that are currently on the market.

As noted, the applicant claimed that the new products differ from the predicate products in quantity and packaging weight. Therefore, the Agency does not anticipate new chemicals to be emitted into the environment from the use of the new products, compared to the chemicals released by use of the predicate products that are currently on the market.

5.3 Potential Environmental Impacts Due to Disposal of the New Tobacco Products

5.3.1 Environmental Impacts Due to Disposal of Packaging Materials

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the United States, including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packaging materials. Specifically, in 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the United States, and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 1 and 2) (US EPA, 2014). Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), out of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW generated, 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 (US EPA, 2014).

To estimate the waste from the disposal of packaging material, the Agency utilized the projected market volumes for the first and fifth years of marketing of the new and predicate products, assuming all used product material is disposed of in MSW. The estimated waste from packaging disposal and product material following product use would be a miniscule portion of the total MSW forecasted to be disposed of in the United States. (Confidential Appendix 3 and 4).

Figure 2. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014

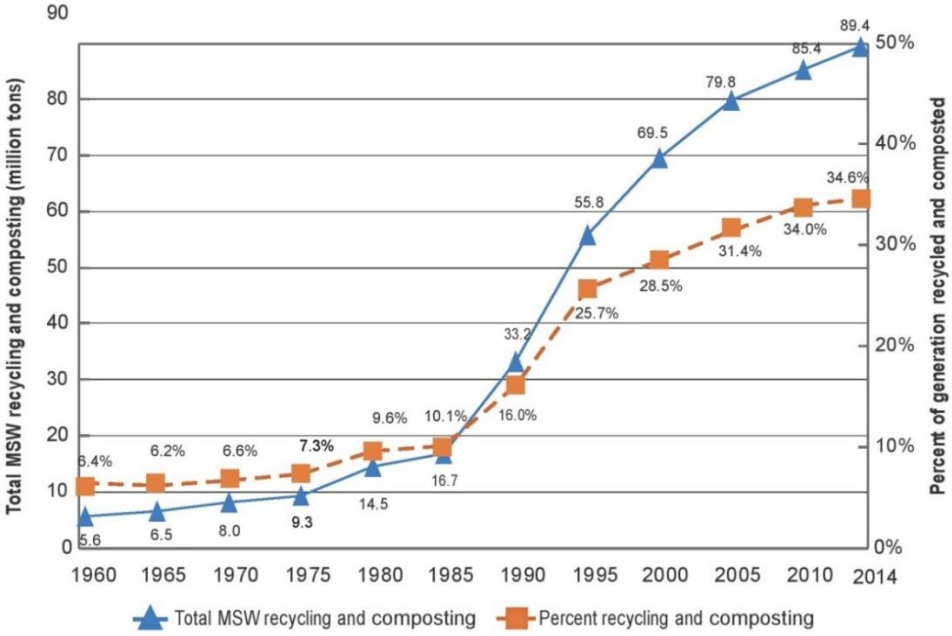


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 3. MSW Recycling Rates in the United States, 1960-2014

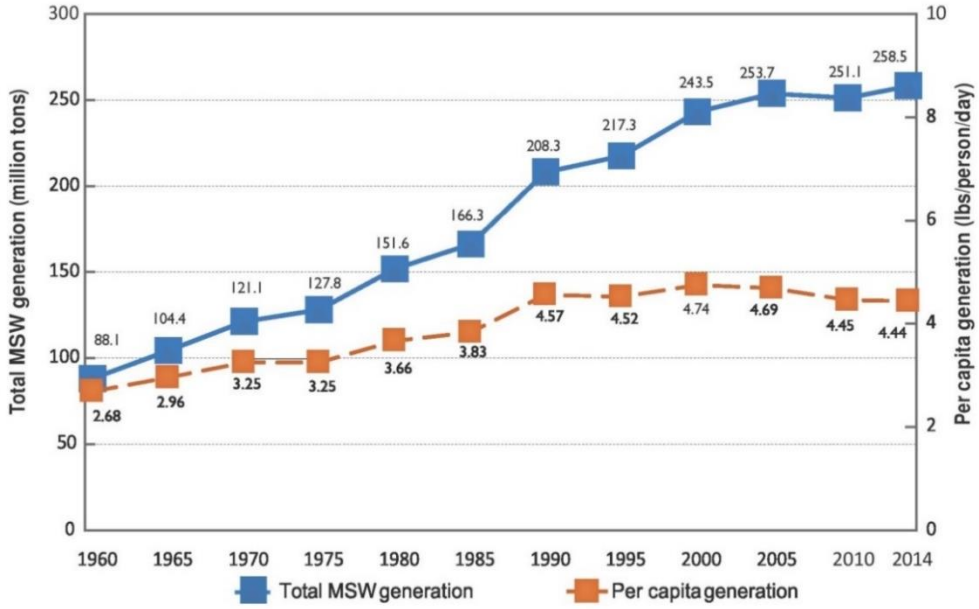


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

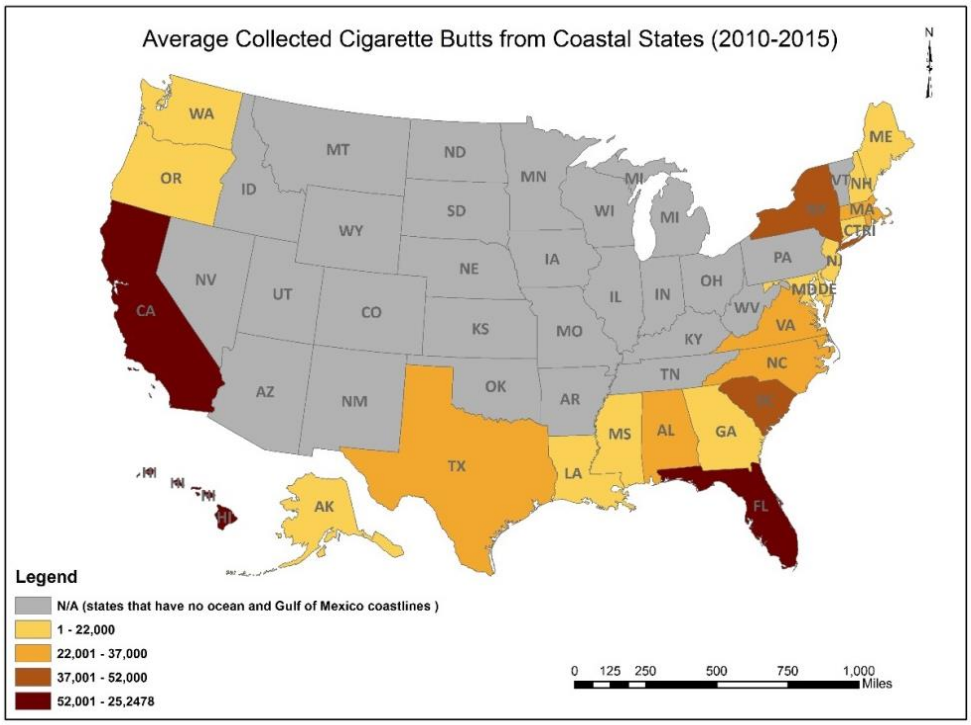
5.3.2 Environmental Impacts due to Disposal of RYO Waste

Once the consumer is done using the product, like combusted cigarettes, RYO cigarette tubes usually undergo a series of scenarios for both managed and unmanaged waste. The managed waste is the waste that is handled by an organized solid waste collection. The unmanaged waste is the result of users littering cigarettes.

According to a report published by "Keep America Beautiful", an observational study of 767 smokers conducted in 44 locations, showed 35% of used cigarettes were disposed of properly (with MSW) with a resulting 65% littering rate for cigarette butts (Schultz, 2009).

The majority of unmanaged cigarette waste ends up in oceans and on beaches across the United States and worldwide. The annual Ocean Conservancy's International Coastal Cleanup (ICC) reports that cigarette waste has been the single most collected item since coastal clean-ups began (Novotny, Lum, & Smith, 2009). Using the data from the ICC, the Agency produced a map displaying the average collected cigarette waste (2010-2015) from coastal states (excluding Great Lakes coast) on the international coastal cleanup day (Niazi & Forche, 2016) (Figure 4).

Figure 4. Collected Cigarette Waste from Coastal States (2010-2015)



A threat assessment study focusing on the most common types of litter that are found along the world's coastlines, based on data gathered during three decades of international coastal clean-up efforts, was conducted by Wilcox et al., 2016. The study was conducted based on elicited information from experts on the ecological threat of entanglement, ingestion and chemical contamination for three major marine taxa: seabirds, sea turtles and marine mammals (Wilcox & Mallos, 2016). The result of this study shows that cigarette butts are ranked seventh out of 20 marine debris items of interest for which information was elicited.

As previously discussed, the new RYO cigarette tubes will compete with other similar RYO tobacco products on the market and based on the above-mentioned information regarding waste, construction of new publicly owned treatment works (POTWs) or landfills are not anticipated due to the proposed actions.

6 Use of Resources and Energy

The applicant stated that there will be no change in how the new products are manufactured compared to the corresponding predicate products. The same raw materials and energy will be used to manufacture the new products compared to the predicate products and the applicant does not anticipate any increased energy or resource needs in order to manufacture the new products. The applicant stated that the proposed actions will not require an expansion of the manufacturing facility. Because the applicant stated that the new products will compete with other similar RYO and with the predicate products, no increase of overall RYO products market volume and no net increase of energy use will be expected from the proposed actions.

7 Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects due to manufacturing, use, and disposal following use of the new products. Therefore, no mitigation measures are discussed.

8 Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco products in the United States. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of new tobacco products as many other similar RYO tobacco products will continue to be marketed.

Alternative B (Proposed actions): There is no substantial environmental effect due to the proposed actions of authorizing the new products (Confidential Appendix 1) and associated manufacture, use, and disposal following use of the new tobacco products.

9 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.

<u>Preparers:</u>

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

Education:	M.S. in Biology
Experience:	22 years in environmental regulation and laboratory toxicology
Expertise:	Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

<u>Reviewers:</u>

Hoshing W. Chang, PhD, Center for Tobacco Products

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

Experience: 9 years in FDA-related NEPA review
Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

10 List of Agencies and Persons Consulted

Not applicable.

11 Appendix List

Appendix 1: Submission Tracking Numbers for the SE Reports and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

12 Confidential Appendix List

Confidential Appendix 1:	Location of Suppliers
Confidential Appendix 2:	The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products
Confidential Appendix 3:	Percentage of the Manufacturing Facility's Total Production Dedicated to the New Products
Confidential Appendix 4:	The First- and Fifth-Year Projection of Cardboard Waste from the Packaging Materials Associated with Marketing the New and Predicate Products (SE0011107, SE0011111, SE0011112, SE0011115, SE0011117, SE0011118, SE0011119, and SE0011120)
Confidential Appendix 5:	The First- and Fifth-Year Projection of Cardboard Waste from the Packaging Materials Associated with Marketing the New and Predicate Products (SE0011135, SE0011184, SE0011185, SE0011186, and SE0011187)
Confidential Appendix 6:	The First- and Fifth-Year Projection of Filter Waste from the Injector Tube Materials Associated with Marketing the New and Predicate Products (SE0011135, SE0011184, SE0011185, SE0011186, and SE0011187)

13 References

Agency, E. E. (2017, November 1). *NPRI. (2017). Retrieved 10 20, 2017, from Environment and Climate Change Canada: https://www.ec.gc.ca/inrp-npri/*. Retrieved from E-PRTR : http://prtr.ec.europa.eu/#/facilitylevels

E-PRTR. (2017, November 1). Retrieved from European Environment Agency: http://prtr.ec.europa.eu/#/facilitylevels

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Niazi, M., & Forche, R. (2016). Using GIS to Enrich Our Understanding of Tobacco Life Cycle. *SETAC North America 37th Annual Meeting.* Orlando.

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Schultz, W. (2009). *Littering Behavior in America Results of a National Study.* Keep America Beautiful.

Statistics Canada. (2011). Retrieved 10 20, 2017, from http://www12.statcan.gc.ca/census-recensement/2011/dp-pd/index-eng.cfm

US EPA. (2014). Retrieved 10 20, 2017, from Materials and Waste Management in the United States Key Facts and Figures: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures

US TTB. (2017). Retrieved 10 20, 2017, from https://ttb.gov/tobacco/index.shtml

Wilcox, C., & Mallos, N. (2016). Using Expert Elicitation to Estimate the Impacts of Plastic Pollutionon on Marine Wildlife. *Marine Policy*, 107-114.

APPENDIX 1

Submission Tracking Numbers for the SE Reports and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

Submission Tracking Numbers for the SE Reports and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

Table 1a. New and Predicate Products That Are RYO paper

STN	Package Size Leaves		New	Predicate	Amendments
	New	Predicate			
SE0011107	24	32	Job® Double Wide Gold	Job® Double Wide Gold	SE0011758 SE0011919
SE0011111	24	32	Job® 1.25 Silver	Job® 1.25 Silver	SE0011758 SE0011919
SE0011112	32	48	Job® 1.0 Gold	Job® 1.0 Gold 24's	SE0011758 SE0011919
SE0011115	24	32	Job® 1.5 Slim Gold	Job® 1.5 Slim Gold	SE0011758 SE0011919
SE0011117	24	50	OCB® Organic Hemp 1-1/4	OCB® Organic Hemp 1-1/4	SE0011758
SE0011118	50	100	OCB® Organic Hemp Single Wide	OCB® Organic Hemp Single Wide	SE0011758
SE0011119	24	100	OCB® Organic Hemp Single Wide	OCB® Organic Hemp Single Wide	SE0011758
SE0011120	24	32	OCB® Organic Hemp King Size Slim	OCB® Organic Hemp King Size Slim	SE0011758

Table 1b. New and Predicate Products That Are Filtered Injector Tubes

STN	Package Size Injector Tubes		New	Predicate	Amendments
	New	Predicate			
SE0011135	250	200	Top® Silver King Size	Top® Silver King Size	SE0011758
SE0011184	250	200	Top® Menthol King Size	Top® Menthol King Size	SE0011758 SE0011919
SE0011185	250	200	Top® Menthol King Size	Top® Menthol King Size	SE0011758 SE0011919
SE0011186	200	100	Altesse® Regular King Size	Altesse® Regular King Size	SE0011758 SE0011919
SE0011187	250	100	Altesse® Regular King Size	Altesse® Regular King Size	SE0011758 SE0011919

CONFIDENTIAL APPENDIX 1
Location of Suppliers

The RYO paper manufacturing location for SE0011107, SE0011111, SE0011112, SE0011115, SE0011117, SE0011118, SE0011119, and SE0011120 is listed below and shown in Figure 5. The RYO paper manufacturing facility is in an industrial park.

(b) (4)

RYO filtered injector tube manufacturing location for SE0011135, SE0011184, SE0011185, SE0011186, an SE0011187 is listed below and show in Figure 6. The RYO filtered injector tube manufacturing facility is in an industrial park.

(b) (4)

CONFIDENTIAL APPENDIX 2

The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products

STN	Measure	Current-Year Market Volume (# RYO)	First-Year Market Volume (# RYO)		Fifth-Year Market Volume (#RYO)	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0011107	Booklets	(b) (4)				
SE0011111	Booklets					
SE0011112	Booklets					
SE0011115	Booklets					
SE0011117	Booklets					
SE0011118	Booklets					
SE0011119	Booklets					
SE0011120	Booklets					
SE0011135	Retail Boxes					
SE0011184	Retail Boxes					
SE0011185	Retail Boxes					
SE0011186	Retail Boxes					
SE0011187	Retail Boxes					

CONFIDENTIAL APPENDIX 3

Percentage of the Manufacturing Facility's Total Production Dedicated to the New Products

STN	Percentage of the New Product to Facility's Total Production, 1st Year Booklets	Percentage of the New Product to Facility's Total Production, 5st Year Booklets
SE0011107	(b) (4)	
SE0011111		
SE0011112		
SE0011115		
SE0011117		
SE0011118		
SE0011119		
SE0011120		

The applicant claimed that the new RYO tobacco paper products are intended to account for approximately (b) (4) to (b) (4) of the facility's total production (b) (4) RYO booklets).

STN	Percentage of the New Product to Facility's Total Production, 1st Year Retail Boxes	Percentage of the New Product to Facility's Total Production, 5st Year Retail Boxes
SE0011135	(b) (4)	
SE0011184		
SE0011185		
SE0011186		
SE0011187		

The applicant claimed that the new RYO tobacco paper products are intended to account for approximately (b) (4) to (b) (4) of the facility's total production (b) (4) RYO retail boxes).

CONFIDENTIAL APPENDIX 4

The First- and Fifth-Year Projection of Cardboard Waste from the Packaging Materials Associated with Marketing the New and Predicate Products (SE0011107, SE0011111, SE0011112, SE0011115, SE0011117, SE0011118, SE0011119, and SE0011120)

To analyze the environmental effects from the total waste due to the proposed actions, the Agency estimated the first- and fifth-year projected weight of the packaging materials waste (in metric tons) that would be generated from disposal after use of the new and predicate products in 2017 and 2021. Projected waste generation is the total of the projected cardboard booklets of the new and predicate products.

$$\sum_{i=1}^{15} A_i = \sum_{i=1}^{15} B_i \times C_i \times D_i$$

A: Projected cardboard waste generation of the products (metric tons)
B: Projected market volume of booklets
C: Weight of booklet (grams)
D: 1.0 x 10^{-6} metric tons/gram

	STN NEW	C	B	A
First Year	SE0011107	(b) (4)		
	SE0011111			
	SE0011112			
	SE0011115			
	SE0011117			
	SE0011118			
	SE0011119			
	SE0011120			
	Total New Products		(b) (4)	
	STN Predicate	**C**	**B**	**A**
	SE0011107	(b) (4)		
	SE0011111			
	SE0011112			
	SE0011115			
	SE0011117			
	SE0011118			
	SE0011119*			
	SE0011120			
	Total Predicate Products		(b) (4)	

* Predicate product for SE0011119 information is already accounted for as it is the same product that is the predicate product for SE0011118

	STN New	C	B	A
Fifth Year	SE0011107	(b) (4)		
	SE0011111			
	SE0011112			
	SE0011115			
	SE0011117			
	SE0011118			
	SE0011119			
	SE0011120			
	Total New Products		(b) (4)	

	STN Predicate	C	B	A
Fifth Year	SE0011107	(b) (4)		
	SE0011111			
	SE0011112			
	SE0011115			
	SE0011117			
	SE0011118			
	SE0011119*			
	SE0011120			
	Total Predicate Products		(b) (4)	

* Predicate product for SE0011119 information is already accounted for as it is the same product that is the predicate product for SE0011118

If all of the projected packaging waste generated from use of the new products is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new products would be (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021. This is a negligible fraction of the 234.47 million 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. If 64.7% of the booklets are recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed of in landfills would be decreased to (b) (4) metric tons (0.353 × (b) (4) metric tons) in the first year and (b) (4) metric tons (0.353 × (b) (4) metric tons) in the fifth year of marketing the new products.

CONFIDENTIAL APPENDIX 5

The First- and Fifth-Year Projection of Cardboard Waste from the Packaging Materials Associated with Marketing the New and Predicate Products (SE0011135, SE0011184, SE0011185, SE0011186, and SE0011187)

To analyze the environmental effects from total waste due to the proposed actions, the Agency estimated the first- and fifth-year projected weight of the packaging materials waste (in metric tons) that would be generated from disposal after use of the new and predicate products in 2017 and 2021. Projected waste generation is the total of the projected cardboard retail box of the new and predicate products.

$$\sum_{i=1}^{10} A_i = \sum_{i=1}^{10} B_i \times C_i \times D_i$$

A: Projected cardboard waste generation of the products (metric tons)
B: Projected market volume of retail boxes
C: Weight of retail box (grams)
D: 1.0 x 10^{-6} metric tons/gram

	STN NEW	C	B	A
First Year	SE0011135	(b) (4)		
	SE0011184			
	SE0011185			
	SE0011186			
	SE0011187			
	Total New Products		(b) (4)	
	STN Predicate	C	B	A
	SE0011135	(b) (4)		
	SE0011184			
	SE0011185			
	SE0011186			
	SE0011187			
	Total Predicate Products		(b) (4)	

	STN New	C	B	A
Fifth Year	SE0011135	(b) (4)		
	SE0011184			
	SE0011185			
	SE0011186			
	SE0011187			
	Total New Products		(b) (4)	

STN Predicate	C	B	A
SE0011135	(b) (4)		
SE0011184			
SE0011185			
SE0011186			
SE0011187			
Total Predicate Products		(b) (4)	

If all the projected packaging waste generated from use of the new products is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new products would be (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the United State 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. If 64.7% of the cardboard retail boxes are recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed of in landfills would be decreased to (b) (4) metric tons (0.353 × (b) (4) metric tons) in the first year and (b) (4) metric tons (0.353 × (b) (4) metric tons) in the fifth year of marketing the new products.

CONFIDENTIAL APPENDIX 6

The First- and Fifth-Year Projection of Filter Waste from the Injector Tube Materials Associated with Marketing the New and Predicate Products (SE0011135, SE0011184, SE0011185, SE0011186, and SE0011187)

To analyze the environmental effects from total filter waste due to the proposed actions, the Agency estimated the first- and fifth-year projected weight of the filter materials waste (in metric tons) that would be generated from disposal after use of the new and predicate products in 2017 and 2021. Projected waste generation is the total of the projected filter of the new and predicate products.

$$\sum_{i=1}^{10} A_i = \sum_{i=1}^{10} B_i \times C_i \times D_i$$

A: Projected filter waste generation of the products (metric tons)
B: Projected market volume of filtered tubes
C: Weight of filter (grams)
D: 1.0×10^{-6} metric tons/gram

	STN NEW Products	C	B	A
First Year	SE0011135	(b) (4)		
	SE0011184			
	SE0011185			
	SE0011186			
	SE0011187			
	Total New Products		(b) (4)	
	STN Predicate	C	B	A
	SE0011135	(b) (4)		
	SE0011184			
	SE0011185			
	SE0011186			
	SE0011187			
	Total Predicate Products		(b) (4)	

	STN New Products	C	B	A
Fifth Year	SE0011135	(b) (4)		
	SE0011184			
	SE0011185			
	SE0011186			
	SE0011187			

Total New Products		(b) (4)	
STN Predicate	C	B	A
SE0011135	(b) (4)		
SE0011184			
SE0011185			
SE0011186			
SE0011187			
Total Predicate Products		(b) (4)	

Typically, a cigarette butt is disposed of as waste or litter. If all the projected filters were disposed of in landfills, the projected cumulative filter waste generated in the first and fifth years of marketing the new products would be (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.