

Programmatic Environmental Assessment for Market Authorizations for Republic Tobacco, LP “High Card Regular 100 mm, High Card Gold King Size, High Card Menthol King Size, High Card Regular King Size, Top Gold 100 mm, Top Gold 100 mm, Top Regular 100 mm, Top Regular 100 mm, Top Silver 100 mm, Top Silver 100 mm”

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

August 15, 2017

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This programmatic environmental assessment (PEA) is for the marketing authorizations of multiple roll-your-own (RYO) cigarette injector tubes manufactured by "Republic Tobacco, LP". Information presented in the PEA is based on the submission 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. Manufacturer

(b) (4)

A large rectangular area of the document is redacted with a solid black box. The redaction covers the manufacturer's name and any other identifying information that might have been present.

4. Description of Proposed Actions

These proposed actions are for FDA to issue marketing authorizations under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of multiple roll-your-own (RYO) cigarette injector tubes into interstate commercial distribution in the U.S. The authorization is based on the finding that these new products are substantially equivalent to their corresponding predicate products that were previously found substantially equivalent and received market authorization on September 26, 2013 (corresponding predicate products for SE0013920-SE0013923), November 7, 2014 (corresponding predicate products for SE0013916-SE0013919) and March 27, 2015 (corresponding predicate products for SE0013924 and SE0013925). The applicant intends to market both the new and corresponding predicate products concurrently after receiving market authorizations 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 U.S. The applicant claims that the new products and corresponding predicate products have different characteristics (sec 910(a)(3)(A)(ii) of the FD&C Act), but they differ only in product quantity. In addition, the applicant claimed that the new and corresponding predicate products have identical product and packaging composition. After considering the substantial equivalence (SE) reports

(SE0013916 -SE0013925), the Agency shall issue an order under the provisions of section 910 and 905(j) of the FD&C Act when finding the new products to be substantially equivalent to the corresponding predicate products.

4.3 Identification of the New Tobacco Products that is the Subject of the Proposed Actions

4.3.1 Type of Tobacco Products

Roll-your-own (RYO) cigarette tubes with filters

4.3.2 Product Names and Their Original STNs

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

New Product		Predicate Product	
STN	Product Name	STN	Product Name
SE0013916	High Card Regular 100 mm	SE0004369	High Card Regular 100 mm
SE0013917	High Card Gold King Size	SE0004358	High Card Gold King Size
SE0013918	High Card Menthol King Size	SE0004374	High Card Menthol King Size
SE0013919	High Card Regular King Size	SE0004370	High Card Regular King Size
SE0013920	Top Gold 100 mm	SE0003199	Top Gold 100 mm
SE0013921	Top Gold 100 mm	SE0003199	Top Gold 100 mm
SE0013922	Top Regular 100 mm	SE0003200	Top Regular 100 mm
SE0013923	Top Regular 100 mm	SE0003200	Top Regular 100 mm
SE0013924	Top Silver 100 mm	SE0010368	Top Silver 100 mm
SE0013925	Top Silver 100 mm	SE0010368	Top Silver 100 mm

4.3.3 Description of the Product Package

The packaging materials of the finished new products are identical in materials and composition to those of their corresponding predicate products. However, the new products contain more cigarette tubes per box, therefore the boxes are larger for the new products compared to their corresponding predicate products. The new products' packaging consists of a cardboard retail box containing the cigarette tubes. Details of the package components and weights of each packaging component for the new products are described in Confidential Appendix 1.

4.3.4 Location of Manufacturing



(Figure 1)

(b) (4)



The manufacturing facility of the RYO cigarette tube is located outside of the U.S.

4.3.5 Location of Use

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

4.3.6 Location of Disposal

Once used, the new tobacco products will be disposed of in landfills as municipal solid waste (MSW) or as litter in the same manner as the 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 the distribution of waste from disposal after use will correspond to the pattern of the product use.

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

The applicant claims that a difference in product quantity is the only difference between the new and corresponding predicate products.

5. Environmental Introduction Due to the Proposed Actions

5.1. Introduction as a Result of Manufacturing the New Tobacco Products

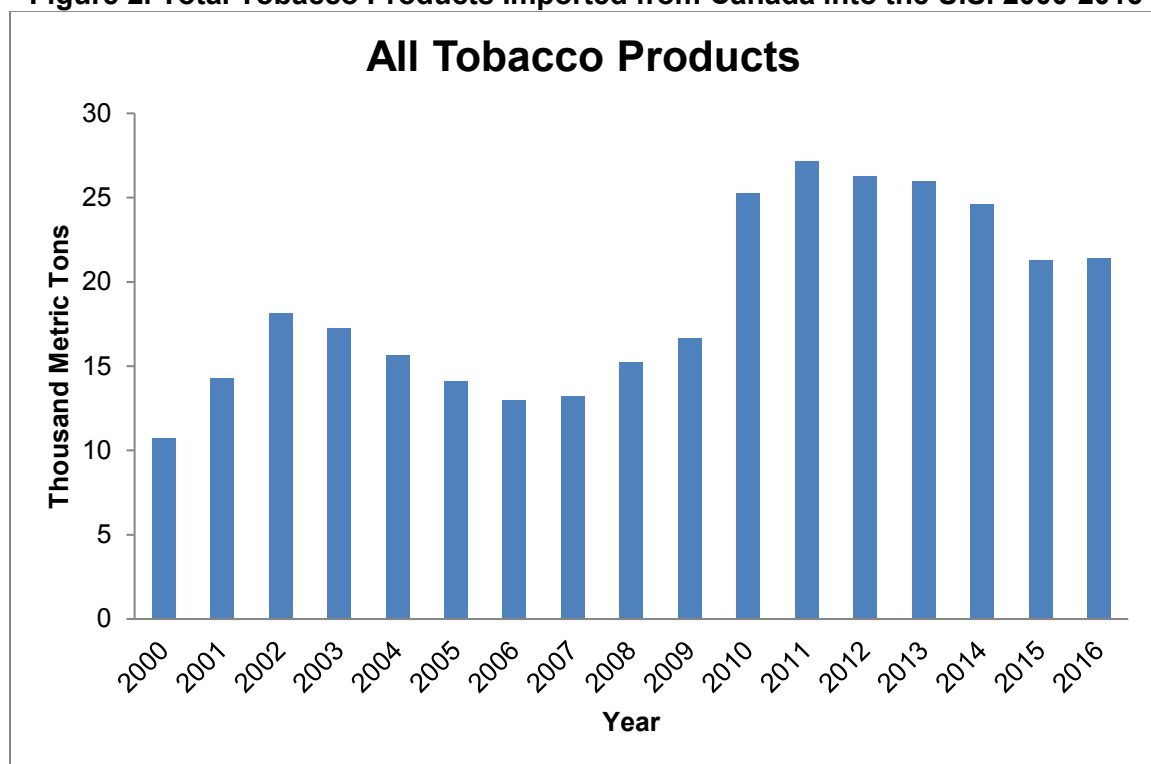
¹ Manufacturer address via Google Map. Accessed June 2, 2017.

5.1.1. Tobacco Products Imported from Canada

Tobacco Import and Tobacco Market Volumes. According to the U.S. International Trade Commission (USITC), the import of tobacco products to the U.S. from Canada has increased from 10,725 metric tons in 2000 to 21,392 metric tons in 2016 (Figure 2).² When examining the change in import of cigarette paper in the form of booklets and tubes to the U.S. from Canada over the same period of time, there was a significant increase from 25 metric tons in 2000 to 2,983 metric tons in 2016 (Figure 3).

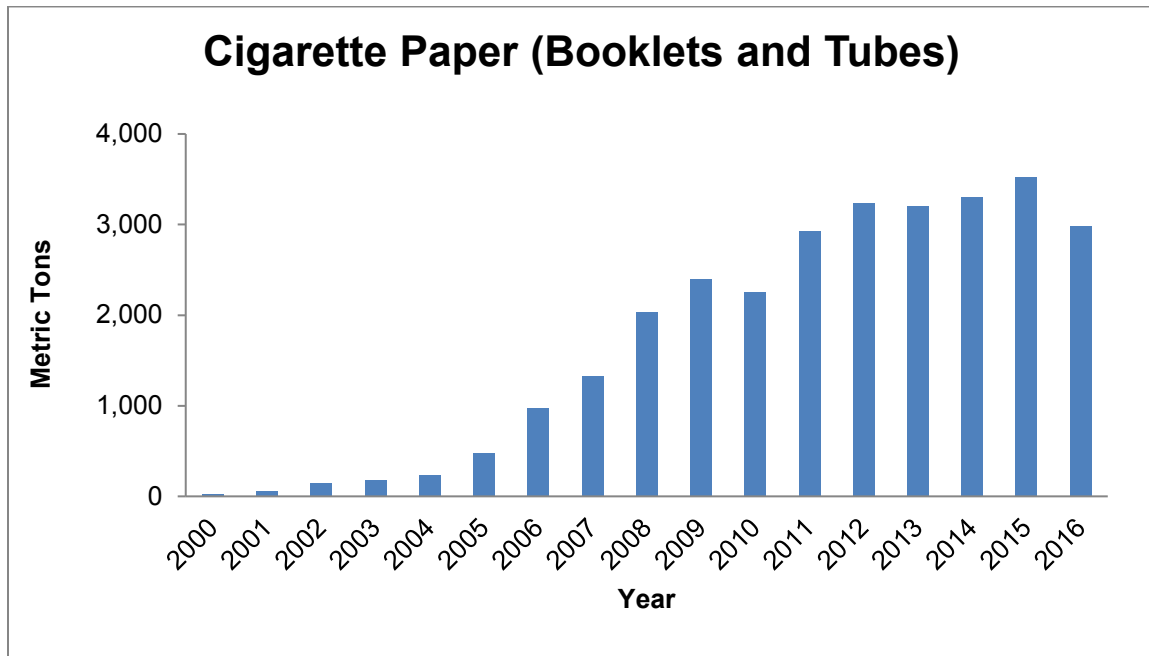
Cigarette rolling papers in the form of booklets and tubes that were imported to the U.S. from Canada in 2016 represented 13.9% of the total amount of tobacco products imported from Canada in 2016.

Figure 2. Total Tobacco Products Imported from Canada into the U.S. 2000-2016



² Data from the United States International Trade Commission, available at: <http://dataweb.usitc.gov/>. Accessed on February 17, 2017.

Figure 3. U.S. Import of Cigarette Papers in the Form of Booklets and Tubes from Canada in 2000-2016



5.1.2. Environmental Introduction from Manufacturing the New Tobacco Products

Introduction from Manufacturing the New Products in the Proposed Actions. The Agency anticipates the waste generated as a result of manufacturing the new RYO tobacco products will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other RYO tobacco products manufactured in Canada. The applicant stated that the new products are intended to compete with and replace other currently marketed RYO cigarette paper products. Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new products. Additionally, the Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the production of all cigarette tubes.

Based on information in the SE Reports, the only difference between the new and corresponding predicate products is the quantity of cigarette tubes per box. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products.

The applicant provided the first- and fifth-year market volumes for the new products (Confidential Appendix 2). Comparing the projected market volume of the new products with the forecasted market volume of all tobacco products imported into the U.S. from Canada in 2017 and 2021, the cumulative projected market volumes of the new products are a small fraction of the total forecasted market volumes in 2017 and 2021 (Appendices 2 and 3, Confidential Appendix 2). Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed.

The manufacturing facility is located in Canada and the applicant stated that the facility is in compliance with applicable Canadian environmental laws and regulations. The applicant also stated that the RYO tubes are produced from renewable and sustainable resources and their manufacture does not appear to threaten any endangered species or critical habitat.

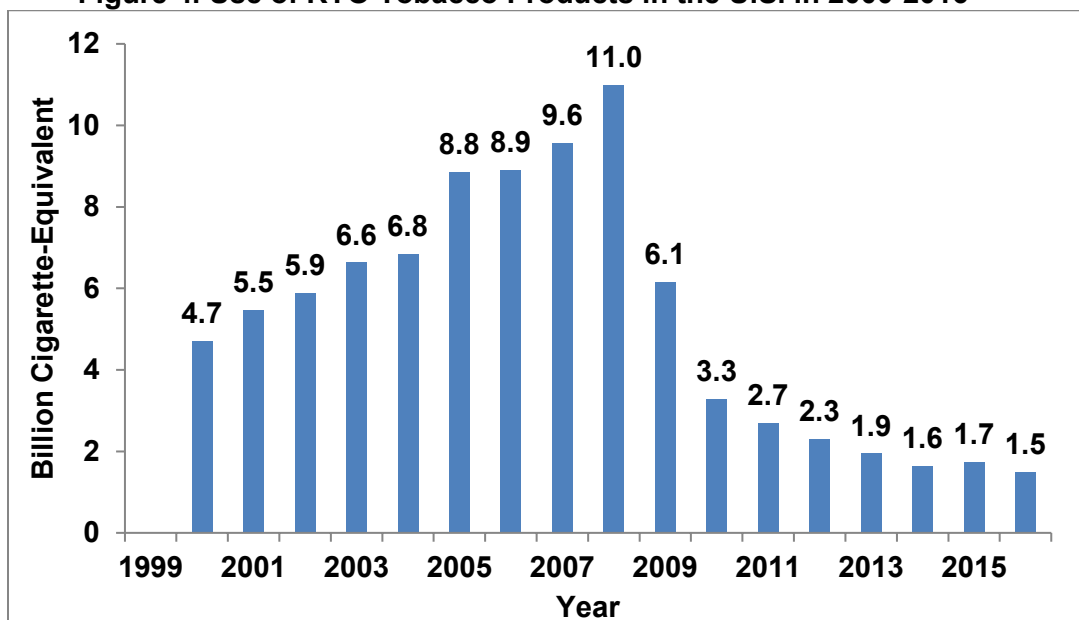
Because the new products are intended to compete with and replace other currently marketed RYO products, no addition of greenhouse gas (GHG) emissions is anticipated. In addition, the applicant stated that they are unaware of any provincial or federal Canadian emissions, solid waste or liquid waste regulations or requirements that are applicable to the manufacturing facility but that they would comply with such regulations if there were.

5.2. Environmental Introduction as a Result of Use of the New Tobacco Products

5.2.1. Use of the RYO Tobacco Products in the U.S.

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of RYO tobacco products in the U.S. increased from 4.7 billion cigarette-equivalents in 2000 to 11.0 billion cigarette-equivalents in 2008. This was followed by a decrease in use from 6.1 billion cigarette-equivalents [1] in 2009 to 1.5 billion cigarette-equivalents in 2016 (Figure 4) [2, 3].

Figure 4. Use of RYO Tobacco Products in the U.S. in 2000-2016⁴



5.2.2. Environmental Introduction from Use of the New Products

Because the new products are expected to compete with other RYO products on the market, the Agency anticipates minimal or no net increase in the use of all RYO

products. Subsequently, the Agency does not anticipate new substances to be released into the environment as a result of use of the new RYO products, relative to the substances released by the predicate products, and other RYO products, already on the market. As noted, the only difference between the new products and corresponding predicate products is the quantity of cigarette tubes per box. During use, the new products are burned to ash, carbon dioxide, and water vapor, as well as products of incomplete combustion such as carbon monoxide. These combustion products from the new products are released in a similar manner to their predicate products and other RYO cigarette tube products.

5.3. Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Products

The environmental consequences resulting from disposal following use of RYO cigarette tubes are due to a) disposal of packaging material, b) discarding of the used RYO tobacco products, and c) air emissions.

5.3.1. *Disposal Following Use of RYO Cigarette Tubes and Filters*

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 (234.47 million metric tons) of trash was generated in the U.S., and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 5 and 6) [4]. 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 [4].

Figure 5. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960-2014

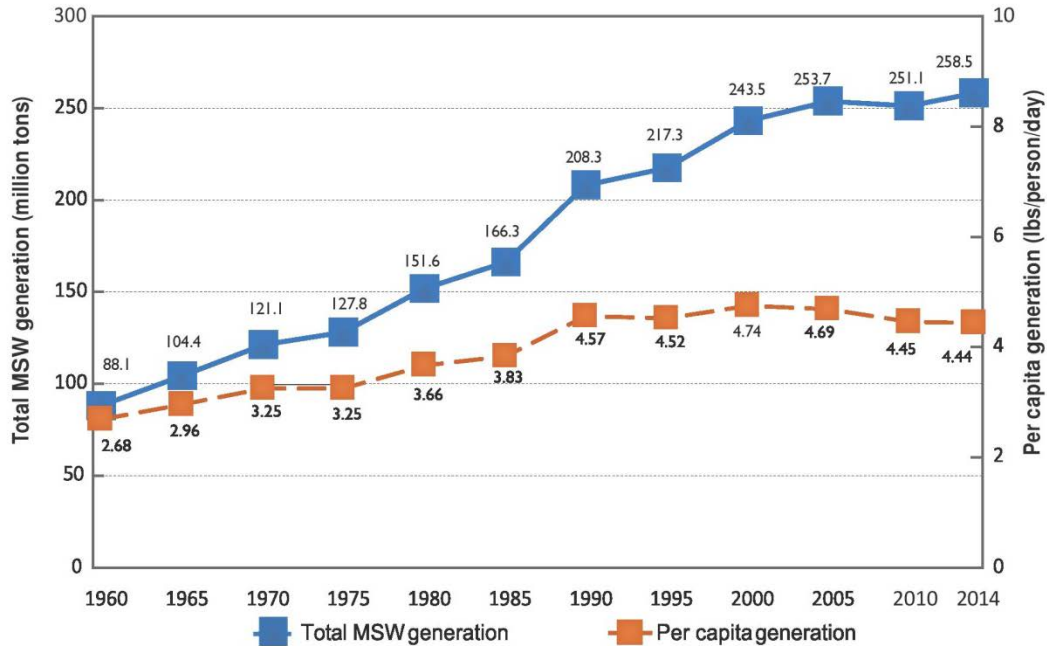


Figure Excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 6. MSW Recycling Rates in the U.S., 1960-2014

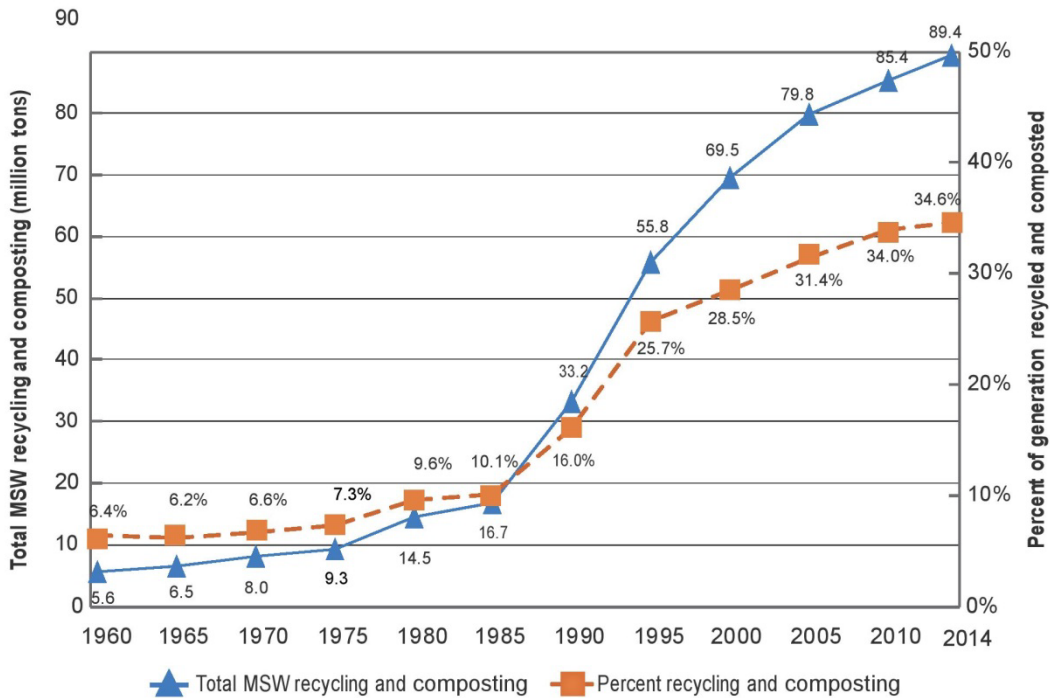


Figure Excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

b) Disposal of Used RYO Tobacco Products Following Use

Used RYO tobacco products are usually disposed of in MSW landfills or as litter. When discarded as litter, the spent products are likely to move by run-off to the ocean. When discarded as MSW, the products would enter landfills. The Agency utilized the historical data for use of RYO tobacco products in the U.S. to forecast the future use of RYO tobacco products (Appendix 3) and calculate the projected tobacco waste accordingly. Assuming that all used RYO tobacco products will be disposed of as MSW, the estimated waste of used RYO tobacco products is a fraction of a percent of the total 258.46 million tons (234.47 million metric tons) of projected MSW to be generated in the U.S. Comparing the projected market volume of the new products with the forecasted total U.S. MSW, the projected waste generated from use of the new products is negligible.

Forecast of Waste of Used RYO Tobacco Products as Compared to Total MSW Forecast in the U.S.		
Year	Projected Use (Equivalent to Projected Waste) of RYO Tobacco Products in the U.S. (Billion Cigarette-Equivalent) ^a	Percent of Projected Waste of RYO Tobacco Products to Total MSW Forecasted in the U.S. (%) ³
1 st Year	(b) (4)	
5 th Year		

^a See Appendix 3

c) Air Emissions

The used RYO tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs. However, the Clean Air Act requires that all landfills constructed or modified after July 17, 2014 that have a waste capacity of 2.5 million metric tons or more to have landfill gas collection-and-control systems installed. Additionally, all landfills must report GHG emissions to the EPA under 40 CFR 98.

Global methane emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related methane emissions in the U.S., releasing an estimated 115.7 million metric tons of CO₂-equivalents. This accounted for approximately 15.4% of total methane generation and emissions in the U.S. in 2015⁴. Because the new products are intended to compete with and replace similar RYO tobacco products and the waste generated from the new products comprises a negligible fraction of the total MSW, the GHG emitted from waste associated with the new products is negligible according to quantified GHG emissions from disposal of the new products (Confidential Appendix 5) in this PEA.

³ RYO Tobacco Products in percentage: 1st Year
5th Year

(b) (4)

⁴ Data from EPA's Landfill Methane Outreach Program about-landfill-gas

nformation-

5.3.2 *Environmental Introduction from Disposal Following Use of the New Products*

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other RYO cigarette tubes and other RYO tobacco products that are currently being marketed. After using the new products, the users may dispose of or recycle the packaging material. Users may also discard the combusted cigarette tubes and other ingredients (filters), as discussed above, as MSW or litter.

To determine the amount of waste due to disposal of packaging material and product material, the Agency used the projected market volumes in the first and fifth years after issuance of an authorization order for the new products. The calculated waste of the packaging materials and product materials of the new products were determined to be miniscule compared to the forecasted MSW to be generated in the U.S. (Confidential Appendix 1). In addition, paper components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

As previously discussed, because 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 POTWs or landfill is not anticipated due to the proposed actions.

The waste generated from using the new products is expected to make up a negligible fraction of the total MSW; no additional control of air emissions is anticipated in the landfills.

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

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment because the new products are anticipated to be manufactured, used, and disposed of in the same way as other RYO tobacco products, including cigarette tubes and filters. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other RYO tobacco products, including cigarette tubes and filters, manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use.

7. Environmental Effects of New Materials Released into the Environment due to the Proposed Actions

The applicant stated that they are unaware of any provincial or federal Canadian emissions, solid waste or liquid waste regulations or requirements that are applicable to the manufacturing facility but that they would comply with such regulations if there were. Therefore, cumulative introduction of materials released into the environment is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

As discussed above, the amount of materials anticipated to enter the environment due to the manufacturing and use of the new products are small fractions when compared to that of the projected RYO tobacco products imported from Canada and used in the U.S. The Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all RYO tobacco products. In

addition, the amount of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction of the total forecasted MSWs in the U.S. Consequently, no new substances or new type of emissions are expected to be released, and therefore no new environmental controls are needed. No new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The new products will compete with other currently marketed RYO tobacco products. The applicant also stated that the proposed actions will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total RYO market volumes in the U.S., the Agency found that the projected market volumes of the new products are a small fraction of the total forecasted market volume in 2017 and 2021. Because the new products will compete with other similar RYO products, no increase of overall RYO tobacco product market volume and no net increase of energy use will be expected from the proposed actions. The applicant stated that all ingredients used to manufacture the new products, as well as the corresponding predicate products, are from renewable and sustainable resources. Accordingly, no additional use of resources and energy is anticipated.

9. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for the new products and the use as RYO. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Actions

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco products in the U.S. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products as the predicate products (Confidential Appendices 1 and 4) and many similar RYO tobacco products would continue to be marketed.

Alternative B (Proposed actions): There is no substantial environmental effect due to the proposed actions of authorizing the new products and associated manufacture, use, and disposal following use of the new tobacco products (Confidential Appendices 1, 3, and 4).

Therefore, the difference between the environmental impacts of these two alternatives is negligible, or non-existent.

11. 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.

Preparers:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
Education: PhD in Environmental Science and Management
Experience: Four years in environmental science, three years in toxicology
Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, and soil, sediment, and water quality

Gregory G. Gagliano, M.S., Center for Tobacco Products
Education: M.S. in environmental science
Experience: 34 years in environmental toxicology and Risk Assessment
Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

12. List of Agencies and Persons Consulted

Not applicable.

13. 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)
- Appendix 2: Forecast of All Tobacco Products Imported into the U.S. from Canada
- Appendix 3: Projected Use of Cigarettes and RYO in the U.S. in the First and Fifth Year of Marketing the New Products

14. Confidential Appendix List

- Confidential Appendix 1: The First- and Fifth-Year Projection of Paper and Cardboard Waste of Packaging Materials and Product Materials Associated with Marketing the Products
- Confidential Appendix 2: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products
- Confidential Appendix 3: Comparison of the Current-Year Market Volume for the Predicate Products with Total RYO Tobacco Products Used in the U.S.
- Confidential Appendix 4: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total RYO Tobacco Products Used in the U.S.
- Confidential Appendix 5: The Agency's Estimated GHG Emissions in the First and Fifth Year of Marketing the New and Predicate Products

15. References

1. National Association of Attorneys General, *Master Settlement Agreement*. 1998.
2. 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 March 15, 2017.
3. Centers for Disease Control and Prevention (CDC). Economic Facts about Tobacco Production and Use. Available at

- http://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/. Accessed January 16, 2015.
4. Environmental Protection Agency (EPA). Materials and Waste Management in the United States Key Facts and Figures. Available at <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures>. Accessed May 17, 2016.
 5. Environmental Protection Agency (EPA). *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015*. 2017(EPA 430-P-17-001).
 6. Geiss, O. and K. Dimitrios, *Tobacco, Cigarettes and Cigarette Smoke: An Overview*. European Commission, Directorate-General Joint Research Centre, Institute for Health and Consumer Protection, 2007(EUR 22783 EN).
 7. Environmental Protection Agency (EPA). *Waste Reduction Model (WARM)*. Available at: <https://www.epa.gov/warm>. Accessed July 20, 2017.

APPENDIX 1

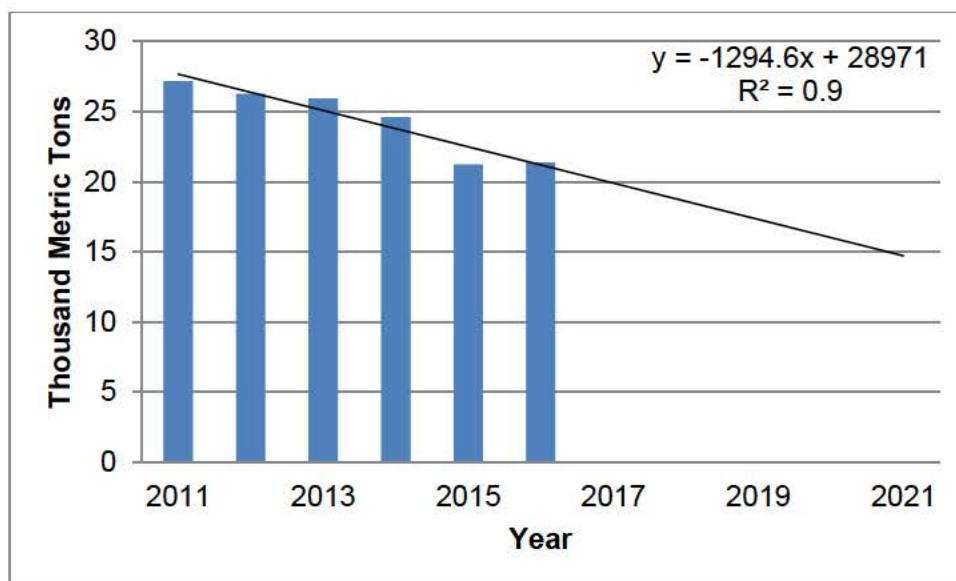
Submission Tracking Numbers (STNs) for the SE Reports and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

STN	Product Name	Product	Tubes per box	Boxes per Shipping Case	Amendments
SE0013916	High Card Regular 100 mm	New	250	40	SE0014098
		Predicate	200	50	
SE0013917	High Card Gold King Size	New	250	40	SE0014098
		Predicate	200	50	
SE0013918	High Card Menthol King Size	New	250	40	SE0014098
		Predicate	200	50	
SE0013919	High Card Regular King Size	New	250	40	SE0014098
		Predicate	200	50	
SE0013920	Top Gold 100 mm	New	250	40	SE0014098
		Predicate	200	50	
SE0013921	Top Gold 100 mm	New	250	40	SE0014098
		Predicate	200	50	
SE0013922	Top Regular 100 mm	New	250	40	SE0014098
		Predicate	200	50	
SE0013923	Top Regular 100 mm	New	250	40	SE0014098
		Predicate	200	50	
SE0013924	Top Silver 100 mm	New	250	40	SE0014098
		Predicate	200	50	
SE0013925	Top Silver 100 mm	New	250	40	SE0014098
		Predicate	200	50	

APPENDIX 2

Forecast of All Tobacco Products Imported into the U.S. from Canada

To evaluate the environmental impact of the proposed actions due to import of the new products, historical data regarding the import of all tobacco products from Canada into the U.S. from 2011 to 2016 was used to forecast the manufacture of RYO tobacco products in Canada then imported into the U.S.⁵ This was achieved by using one best-fit linear trend line with the R^2 value of 0.9. Accordingly, the forecasted amount of all tobacco products to be imported from Canada into the U.S. is estimated to be 19,909 metric tons in 2017 and 14,730 metric tons in 2021. The amount of all tobacco products imported from Canada into the U.S. was 21,392 metric tons in 2016.



Year ⁶	All Tobacco Products Imported from Canada (Metric Tons)
2016	21,392
2017 (Forecasted)	19,909
2021 (Forecasted)	14,730

⁵ Forecast trend lines extrapolated from USITC data. USITC data is available from <http://dataweb.usitc.gov/>. Accessed February 17, 2017.

⁶ $2017 = -1294.6 * 7 + 28971 = 19908.8$
 $2021 = -1294.6 * 11 + 28971 = 14730.4$

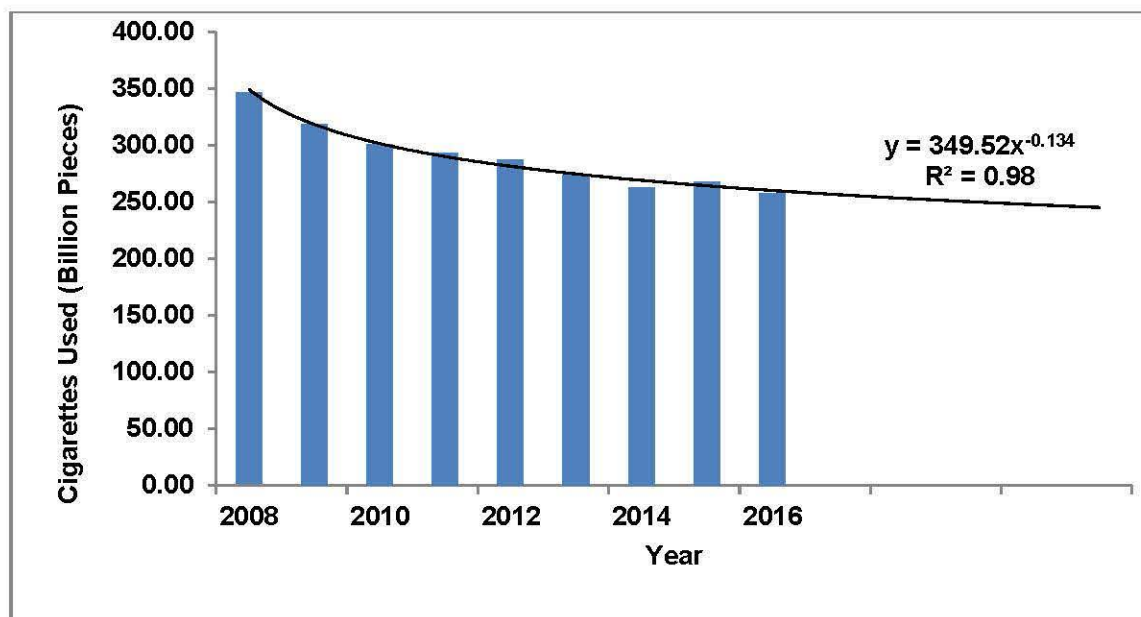
APPENDIX 3

Projected Use of Cigarettes and RYO in the U.S. in the First and Fifth Year of Marketing the New Products

To evaluate the environmental impact of the proposed actions due to use of the new products, historical data regarding total use of cigarettes and RYO from 2008 to 2016 was employed to mathematically estimate the forecast of the total amount of cigarettes used in the U.S.⁷ This was achieved by using the one best-fit trend line with R^2 value above 0.9.

Projected Use of Cigarettes in the U.S.:

Using the best-fit power trend line with the R^2 value of 0.98, the forecasted number of cigarettes that will be used in the U.S. is estimated to be 256.73 billion (230,575 metric tons) in 2017 and 245.41 billion (220,410 metric tons) in 2021.⁸

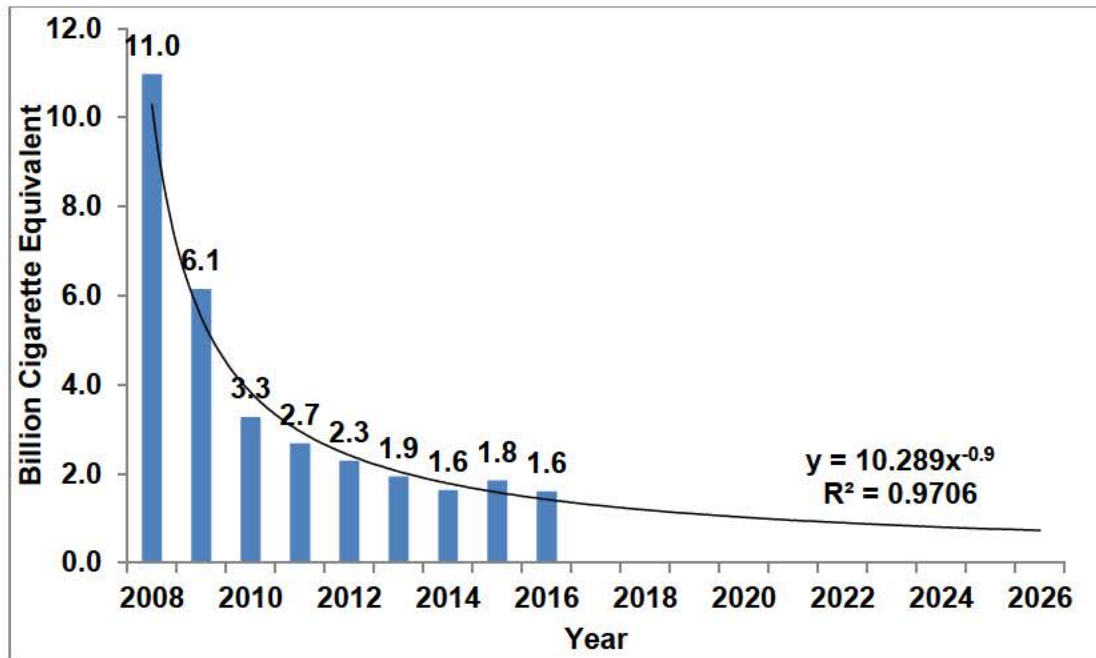


⁷ Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 15, 2017.

⁸ Billion cigarette equivalent value is calculated based on the assumption that approximately 0.9 grams of tobacco is used per cigarette [1]. Billion cigarette equivalent = $\frac{(x \text{ million pounds tobacco} \times 10^6) \times (\frac{453.59 \text{ g}}{0.9 \text{ g}})}{10^9}$

Projected Use of RYO Tobacco in the U.S.:

Using the best-fit power trend line with the R^2 value of 0.981, the forecasted number of RYO tobacco that will be used in the U.S. is estimated to be 1.24 billion cigarette-equivalents (1,120 metric tons) in 2017 and 0.91 billion cigarette-equivalents (820 metric tons) in 2021.⁸



Year	RYO		Cigarettes		Total Combusted Products	
	Billion Cigarette-Equivalents	Metric Tons	Billion Pieces	Metric Tons	Billion Pieces	Metric Tons
1 st Year (2017)	(b) (4)					
5 th Year (2021)						

CONFIDENTIAL APPENDIX 1

Projected Waste of Packaging Material and Tube Filters in the First and Fifth Year of Marketing the New Products

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 and product 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 summation of the projected cardboard retail boxes, plastic wrap of retail boxes, tip filters, and shipping cases of the new and predicate products:

$\sum_{i=1}^{10} A_i = \sum_{i=1}^{10} (B_i + C_i + D_i + E_i)$ $F_i = F1_i + F2_i$ $B_i = \frac{F_i}{G_i} \times H \times P$ $C_i = \frac{F_i}{G_i \times I_i} \times J \times P$ $D_i = \frac{F_i}{G_i} \times K \times P$ $E_i = \frac{F_i \times L_i \times N_i}{100} \times P$ $N_i = \frac{M_i}{O_i} \times 100$	A_i: Projected total waste generation of the product (metric tons) B_i: Projected waste generation of retail cardboard boxes of the new and predicate products (metric tons) C_i: Projected waste generation of cardboard shipping cases of the new and predicate products (metric tons) D_i: Projected waste generation of retail box plastic of the new and predicate products (metric tons) E_i: Projected waste generation of tube filter tips (cigarette butts) of the new and predicate products (metric tons) F_i: Total Projected market volume of the new and predicate product (total number of individual tubes) $F1_i$: Projected market volume of the new product (total number of individual tubes) $F2_i$: Projected market volume of the predicate product (total number of individual tubes) G_i: Number of tubes per retail box H_i: Weight of empty retail cardboard box (grams) I_i: Number of retail boxes per cardboard shipping case J_i: Weight of empty cardboard shipping case (grams) K_i: Weight of plastic wrap per retail box (grams) L_i: Weight of Tube (gram) M_i: Cigarette butt length⁹ N_i: Cigarette butt ratio (%) O_i: Length of Tube (millimeter) P: 1.0×10^{-6} metric tons/gram
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a) Projected Waste of Packaging Material

Projected waste of packaging generation is calculated below:

⁹ Based on draft 2015 revisions to ISO 3308 intense smoking regimen (see Section 7.2.1): butt length is the greatest of 23 mm, length of filter + 8 mm, or length of overwrap + 3 mm.

Projected Year	STN	Projected market volume of new	Projected market volume of predicate	Projected market volume of new + predicate	# of tubes per box G_i	Weight of retail box H_i	Retail box waste B_i	# of boxes per shipping case I_i	Weight of cardboard shipping case J_i	Cardboard shipping case waste C_i	Weight of plastic wrap K_i	Retail box plastic waste D_i
First-Year Projected Volume	SE0013916	(b) (4)			250	32.0	0.054	40	532	0.022	0	0
	SE0013917	(b) (4)			250	30.2	0.039	40	484	0.016	0	0
	SE0013918	(b) (4)			250	29.6	0.027	40	484	0.011	2.49	(b) (4)
	SE0013919	(b) (4)			250	30.2	0.11	40	484	0.044	0	0
	SE0013920	(b) (4)			250	32.0	4.58	40	532	1.90	0	0
	SE0013921	(b) (4)			250	32.0	0.96	40	532	0.40	0	0
	SE0013922	(b) (4)			250	32.0	18.81	40	532	7.82	0	0
	SE0013923	(b) (4)			250	32.0	2.88	40	532	1.20	0	0
	SE0013924	(b) (4)			250	32.0	0.59	40	532	0.25	0	0
	SE0013925	(b) (4)			250	32.0	0.19	40	532	0.080	0	0
	Total	(b) (4)					(b) (4)					
Fifth-Year Projected Volume	SE0013916	(b) (4)			250	32.0	0.068	40	532	0.028	0	0
	SE0013917	(b) (4)			250	30.2	0.041	40	484	0.017	0	0
	SE0013918	(b) (4)			250	29.6	0.028	40	484	0.012	2.49	(b) (4)
	SE0013919	(b) (4)			250	30.2	0.12	40	484	0.046	0	0
	SE0013920	(b) (4)			250	32.0	4.48	40	532	1.86	0	0
	SE0013921	(b) (4)			250	32.0	0.94	40	532	0.39	0	0
	SE0013922	(b) (4)			250	32.0	18.43	40	532	7.66	0	0
	SE0013923	(b) (4)			250	32.0	2.82	40	532	1.17	0	0
	SE0013924	(b) (4)			250	32.0	0.59	40	532	0.24	0	0
	SE0013925	(b) (4)			250	32.0	0.19	40	532	0.078	0	0
	Total	(b) (4)					(b) (4)					

Note: SE0013920 and SE0013921, SE0013922 and SE0013923, and SE0013924 and SE0013925 have the same predicate product, therefore market volumes for the predicate products were grayed out to avoid duplication of data.

If all the projected packaging waste generated from use of the 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 (b) (4) in 2017 and (b) (4) metric tons (b) (4) in 2021. This is a negligible fraction of the 258.5 million tons of total waste reported in the U.S. in 2014. Likewise, the projected plastic waste of (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021 is a negligible fraction of the 258.5 million tons of total waste reported in the U.S. 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 U.S.¹⁰ If 64.7% of the cardboard boxes is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed in landfills (Variable B and C above) would be decreased to (b) (4) metric tons (b) (4) metric tons in the first year and (b) (4) metric tons (b) (4) metric tons in the fifth year of marketing the new product.

b) Projected Waste of the Tube Filters in the First and Fifth Year of Marketing the New Products

Projected filter waste generated is calculated below:

		New Product				Predicted Product				Total Waste E_i
Projected Year	STN	Projected market volume O_i	Length of tube O_i	Weight of tube L_i	Cigarette butt waste E_i	Projected market volume O_i	Length of tube O_i	Weight of tube L_i	Cigarette butt waste E_i	
First-Year Projected Volume	SE0013916	(b) (4)	100	0.3006	0.016	(b) (4)	100	0.3006	0.026	(b) (4)
	SE0013917	(b) (4)	84	0.1929	0.0068	(b) (4)	84	0.1929	0.011	(b) (4)
	SE0013918	(b) (4)	84	0.1929	0.0046	(b) (4)	84	0.1929	0.0074	(b) (4)
	SE0013919	(b) (4)	84	0.1929	0.019	(b) (4)	84	0.1929	0.030	(b) (4)
	SE0013920	(b) (4)	100	0.3006	1.36	(b) (4)	100	0.3006	2.18	(b) (4)
	SE0013921	(b) (4)	100	0.3006	0.74	(b) (4)	100	0.3006		(b) (4)
	SE0013922	(b) (4)	100	0.3006	5.61	(b) (4)	100	0.3006	8.97	(b) (4)
	SE0013923	(b) (4)	100	0.3006	2.23	(b) (4)	100	0.3006		(b) (4)
	SE0013924	(b) (4)	100	0.3006	0.18	(b) (4)	100	0.3006	0.28	(b) (4)
	SE0013925	(b) (4)	100	0.3006	0.15	(b) (4)	100	0.3006		(b) (4)
	Total	(b) (4)				(b) (4)				(b) (4)
Fifth-Year Projected Volume	SE0013916	(b) (4)	100	0.3006	0.026	(b) (4)	100	0.3006	0.027	(b) (4)
	SE0013917	(b) (4)	84	0.1929	0.0071	(b) (4)	84	0.1929	0.011	(b) (4)
	SE0013918	(b) (4)	84	0.1929	0.0049	(b) (4)	84	0.1929	0.0078	(b) (4)
	SE0013919	(b) (4)	84	0.1929	0.020	(b) (4)	84	0.1929	0.032	(b) (4)
	SE0013920	(b) (4)	100	0.3006	1.34	(b) (4)	100	0.3006	2.14	(b) (4)
	SE0013921	(b) (4)	100	0.3006	0.73	(b) (4)	100	0.3006		(b) (4)
	SE0013922	(b) (4)	100	0.3006	5.49	(b) (4)	100	0.3006	8.79	(b) (4)
	SE0013923	(b) (4)	100	0.3006	2.19	(b) (4)	100	0.3006		(b) (4)
	SE0013924	(b) (4)	100	0.3006	0.17	(b) (4)	100	0.3006	0.28	(b) (4)
	SE0013925	(b) (4)	100	0.3006	0.15	(b) (4)	100	0.3006		(b) (4)
	Total	(b) (4)				(b) (4)				(b) (4)

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 April 4, 2017).

Note: SE0013920 and SE0013921, SE0013922 and SE0013923, and SE0013924 and SE0013925 have the same predicate product, therefore market volumes for the predicate products were grayed out to avoid duplication of data.

If all the projected filter waste generated from use of the products is disposed in landfills, the projected waste of (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021 will be a negligible fraction of the 258.5 million tons of total waste reported in the U.S. in 2014.

CONFIDENTIAL APPENDIX 2

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

STN	Unit	Current-Year Market Volume	First-Year Market Volume		Fifth-Year Market Volume	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0013916	Individual Injector Tubes	(b) (4)				
	Metric Tons					
SE0013917	Individual Injector Tubes					
	Metric Tons					
SE0013918	Individual Injector Tubes					
	Metric Tons					
SE0013919	Individual Injector Tubes					
	Metric Tons					
SE0013920	Individual Injector Tubes					
	Metric Tons					
SE0013921	Individual Injector Tubes					
	Metric Tons					
SE0013922	Individual Injector Tubes					
	Metric Tons					
SE0013923	Individual Injector Tubes					
	Metric Tons					
SE0013924	Individual Injector Tubes					
	Metric Tons					
SE0013925	Individual Injector Tubes					
	Metric Tons					

Note: SE0013920 and SE0013921, SE0013922 and SE0013923, and SE0013924 and SE0013925 have the same predicate product, therefore market volumes for the predicate products were grayed out to avoid duplication of data.

CONFIDENTIAL APPENDIX 3

Comparison of the Current-Year Market Volume for the Predicate Products with Total RYO Tobacco Products Used in the U.S.

The current-year market volume of the predicate products occupying the U.S. market was compared to the use of total RYO tobacco in the U.S. (Appendices 2 and 3, and Confidential Appendix 3). The percent of the total RYO market occupied in the current year of marketing of the predicate products was calculated using the equation below:

$$\text{2016 Market Occupation of Predicate Products (\%)} = \frac{\text{2016 Market Volume (metric tons)}}{\text{Use of RYO in the U.S. for 2016 (metric tons)}} \times 100\%$$

STN	Year	Use of Total RYO Tobacco in the U.S. (Metric Tons) ¹¹	Current Market Volume of Predicate Product (Metric Tons) ¹²	RYO Market Occupation of Predicate Product in the U.S. (%)	Cigarette Market Occupation of Predicate Product in the U.S. (%)
SE0013916	2016	(b) (4)			
SE0013917	2016				
SE0013918	2016				
SE0013919	2016				
SE0013920	2016				
SE0013921	2016				
SE0013922	2016				
SE0013923	2016				
SE0013924	2016				
SE0013925	2016				
Total					

Note: SE0013920 and SE0013921, SE0013922 and SE0013923, and SE0013924 and SE0013925 have the same predicate product, therefore market volumes for the predicate products were grayed out to avoid duplication of data.

¹¹ See Appendix 3.

¹² See Confidential Appendix 2.

CONFIDENTIAL APPENDIX 4

Comparison of the First- and Fifth-Year Market Volume Projections for the New and Predicate Products with Total RYO Tobacco Products Used in the U.S.

The first- and fifth-year market volumes of the new products projected to occupy the U.S. market were determined by comparing the projected market volume of the new products to the forecasted use of tobacco in the U.S. (Appendices 2 and 3, and Confidential Appendix 3). The percent of the U.S. tobacco market occupied in the projected first and fifth year of marketing of the new products was calculated using the equations below:

$$\text{First Year Market Occupation of New Products (\%)} = \frac{\text{First-Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of tobacco in the U.S. for 2017 (metric tons)}} \times 100\%$$

$$\text{Fifth Year Market Occupation of New Products (\%)} = \frac{\text{Fifth-Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of tobacco in the U.S. for 2021 (metric tons)}} \times 100\%$$

STN	Year	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons) ¹³	Projected Market Volume of New Product (Metric Tons) ¹⁴	Projected Market Volume of Predicate Product (Metric Tons) ¹⁴	Projected RYO Market Occupation of New and Predicate Products in the U.S. (%)	Projected Cigarette Market Occupation of New and Predicate Products in the U.S. (%)
SE0013916	2017	(b) (4)				
	2021					
SE0013917	2017					
	2021					
SE0013918	2017					
	2021					
SE0013919	2017					
	2021					
SE0013920	2017					
	2021					
SE0013921	2017					
	2021					
SE0013922	2017					
	2021					
SE0013923	2017					

¹³ See Appendix 3.

¹⁴ See Confidential Appendix 2.

STN	Year	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons) ¹³	Projected Market Volume of New Product (Metric Tons) ¹⁴	Projected Market Volume of Predicate Product (Metric Tons) ¹⁴	Projected RYO Market Occupation of New and Predicate Products in the U.S. (%)	Projected Cigarette Market Occupation of New and Predicate Products in the U.S. (%)
	2021	(b) (4)				
SE0013924	2017					
	2021					
SE0013925	2017					
	2021					
Total	2017					
	2021					

Note: SE0013920 and SE0013921, SE0013922 and SE0013923, and SE0013924 and SE0013925 have the same predicate product, therefore market volumes for the predicate products were grayed out to avoid duplication of data.

The combined projected market volume of the new and predicate products is (b) (4)) metric tons in 2017 and (b) (4)) metric tons in 2021. This is an increase from the current market volume of the predicate product, (b) (4) metric tons¹⁵.

¹⁵ See Confidential Appendix 3

CONFIDENTIAL APPENDIX 5

The Agency's Estimated GHG Emissions in the First and Fifth Year of Marketing the New and Predicate Products

a) GHG Emissions from Use of Products:

The amount of CO₂-equivalent gases (CO₂-eq) emitted from the use of one cigarette is estimated at 45-65 mg [6]. As a conservative approach, the Agency used the upper limit of CO₂ emitted-per-cigarette to calculate the GHG emissions from use of the new and predicate products. Although this method overestimates GHGs because this product is only for RYO cigarette tubes with filters that are not packaged with tobacco, this is the best available estimate for GHGs associated with use. Additionally, the Agency anticipates that the new and predicate products will be filled with tobacco and used similarly to a conventional cigarette.

GHG Emissions from Use of Product (metric tons of CO₂-eq) =

$$\text{Projected Market Volume of Product (cigarette tubes)} \times 0.065 \text{ gCO}_2 \\ - \text{eq/cigarette} \times 0.000001 \text{ metric tons/g}$$

Metric Tons of CO ₂ -eq				
STN	First-Year		Fifth-Year	
	New	Predicate	New	Predicate
SE0013916	(b) (4)			
SE0013917				
SE0013918				
SE0013919				
SE0013920				
SE0013921				
SE0013922				
SE0013923				
SE0013924				
SE0013925				
Total				
Projected from Cigarettes & RYO ¹⁶				

Note: SE0013920 and SE0013921, SE0013922 and SE0013923, and SE0013924 and SE0013925 have the same predicate product, therefore market volumes for the predicate products were grayed out to avoid duplication of data.

Estimated total GHG emissions associated with marketing the products are (b) (4) metric tons CO₂-eq in the first year and (b) (4) metric tons CO₂-eq in the fifth year. This is a negligible fraction of the 6.87 billion metric tons of CO₂-eq reported in the U.S. in 2014 [7].

¹⁶ See Appendix 3

b) GHG Emissions from Disposal of Products Following Use:

GHG emissions from the disposal of packaging and products following use of the new and predicate products were calculated using the Waste Reduction Model (WARM), version 14 [8]. WARM is a calculation tool that estimates GHG emissions across different material types commonly found in MSW. Taking into account the rates for recycling and landfill disposal of various material types, the total amount of GHG emissions from the disposal of packaging and products following use is estimated at 4.7 metric tons of CO₂-eq for the first year and 4.6 metric tons of CO₂-eq for the fifth year of marketing after authorization of the new products. This estimate is a negligible fraction (0.00000067%) of the 6.87 billion metric tons of CO₂-eq reported in the U.S. in 2014 [7]. Recycling rate of paper was considered for entries into the WARM model to reduce the landfill input, however, the metric tons recycled was not entered into the model because the intent is to determine the GHG emissions associated with MSW generation.

STN	Metric Tons of CO ₂ -eq			
	First-Year		Fifth-Year	
	New	Predicate	New	Predicate
SE0013916	<1	<1	<1	<1
SE0013917	<1	<1	<1	<1
SE0013918	<1	<1	<1	<1
SE0013919	<1	<1	<1	<1
SE0013920	<1	<1	<1	<1
SE0013921	<1		<1	
SE0013922	1	2	1	2
SE0013923	<1		<1	
SE0013924	<1	<1	<1	<1
SE0013925	<1		<1	
Total	2.3	2.4	2.2	2.4
Projected from Cigarettes & RYO¹⁷	(b) (4)			

*Note, the applicant estimated 192 metric tons of CO₂-eq in the first-year and 188 metric tons of CO₂-eq in the fifth-year for disposal of the new and predicate products combined using their own in house methodology. SE0013920 and SE0013921, SE0013922 and SE0013923, and SE0013924 and SE0013925 have the same predicate product, therefore market volumes for the predicate products were grayed out to avoid duplication of data.

¹⁷ See Appendix 3