Environmental Assessment for Marketing Order for Republic Tobacco, LP "Top Silver King Size"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

January 11, 2018

Contents

This environmental assessment (EA) is for the marketing order for a roll-your-own (RYO) filtered cigarette tube manufactured by Republic Tobacco, LP. Information presented in the EA is based on the submission referenced in Appendix 1, unless noted or referenced otherwise. This EA 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)

4. Description of Proposed Action

This 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 RYO filtered cigarette tube into interstate commerce for commercial distribution in the United States. 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 intends to market the new and predicate products simultaneously after receiving a marketing order for the new product.

4.1 Requested Action

An order finding the listed tobacco product is substantially equivalent to the predicate product.

4.2 Need for Action

Republic Tobacco, LP wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the United States. The applicant claims that the new and predicate products differ only in the quantity of the filtered tubes in the retail box (sec 910(a)(3)(A)(ii) of the FD&C Act). In addition, the applicant claims that the new and predicate products have identical packaging composition. After considering the substantial equivalence (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 the Subject of the Proposed Action

4.3.1 Type of Tobacco Product

RYO filtered cigarette tube

4.3.2 Product Name and Submission Tracking Number

The name of the new product is listed below, along with the submission tracking number (STN) and the name of the predicate product. See Appendix 1 for an additional STN associated with the new and predicate products.

STN	New Product	Predicate Product
SE0012177	Top Silver King Size	Top Silver King Size

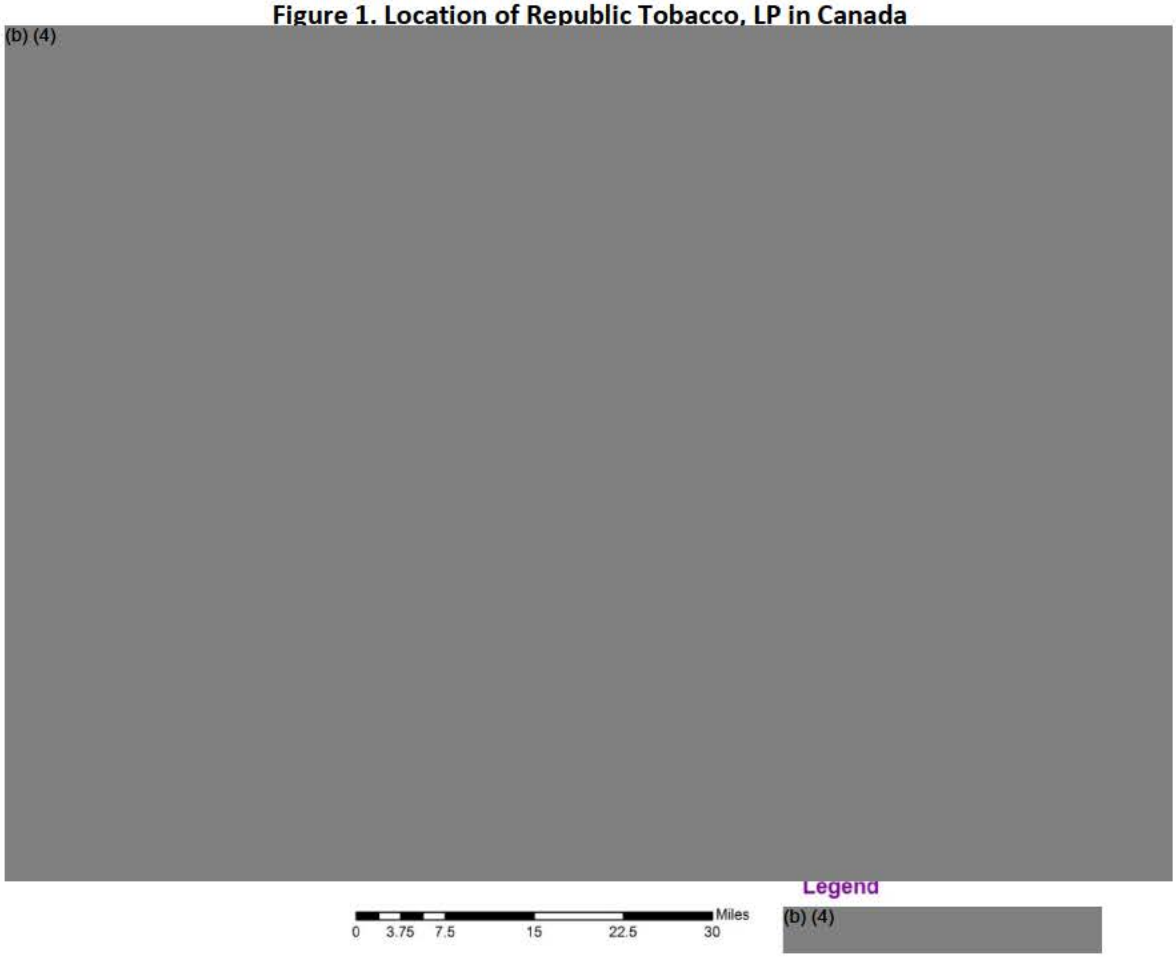
4.3.3 Description of the Product Package

The new product weighs 0.1 g and is a filtered cigarette tube; a retail unit is a single retail box that contains 250 filtered cigarette tubes. 40 of these retail boxes come in each shipping case. Details of the package components and weights of each packaging component for the new product are described in Appendix 1.

4.3.4 Location of Manufacturing

(b) (4)

Figure 1. Location of Republic Tobacco, LP in Canada



The facility is located in the (b) (4) This basin covers approximately (b) (4) The facility is based in the suburban area of (b) (4) with population of 9,485) (Statistics Canada, 2011).

4.3.5 Location of Use

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

4.3.6 Location of Disposal

Once used, the new tobacco product will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as the predicate product 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 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 Product

The applicant claims that the new product differs from the predicate product in the quantity of the filtered tubes in the retail box and the number of retail boxes per shipping case. The new product has 250 filtered tubes per box compared to 200 filtered tubes per box in the predicate product. There are 40 retail boxes per shipping case for the new product and 50 retail boxes per shipping case for the predicate product.

5 Potential Environmental Impacts Due to the Proposed Action

5.1 Potential Environmental Impacts Due to Manufacturing the New Product

The emission information associated with all tobacco products as reported in the Environment and Climate Change Canada's (ECC) National Pollutant Release Inventory (NPRI) database is publicly available (NPRI, 2017). In 2015, Canadian tobacco facilities released 2.56 tones of PM_{10} (particulate matter <=10 microns) and 1.26 tones of $PM_{2.5}$ (particulate matter <=2.5 microns) to the air[1]. A search in the NPRI database indicates that the (b) (4) facility is not listed in the database, therefore the facility is likely not required to report according the criteria listed in the NPRI's guideline[2]. The NPRI is Canada's legislated, publicly accessible inventory of pollutant releases (to air, water and land), disposals and transfers for recycling.

The applicant stated that they are in compliance with all Canadian federal, provincial and local environmental regulations and they provided information on the manufacturer's permits. The applicant also claimed that their paper and acetate tow ingredients are produced from renewable and sustainable resources in accordance with the Forest Stewardship Council, the program for the endorsement of forest certification scheme, and Canadian Sustainable Forest Management. Complying with the relevant environmental regulations and fulfilling sustainability measures do not appear to threaten any endangered species or critical habitat.

The applicant predicted that the manufacturing of the new product will encompass a slight fraction of the total production at the manufacturing facility (Confidential Appendix 2). Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new product.

The applicant stated that the production processes for the new product is identical to those of all other productions at the manufacturing facility. 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 product and no additional environmental control practices are needed.

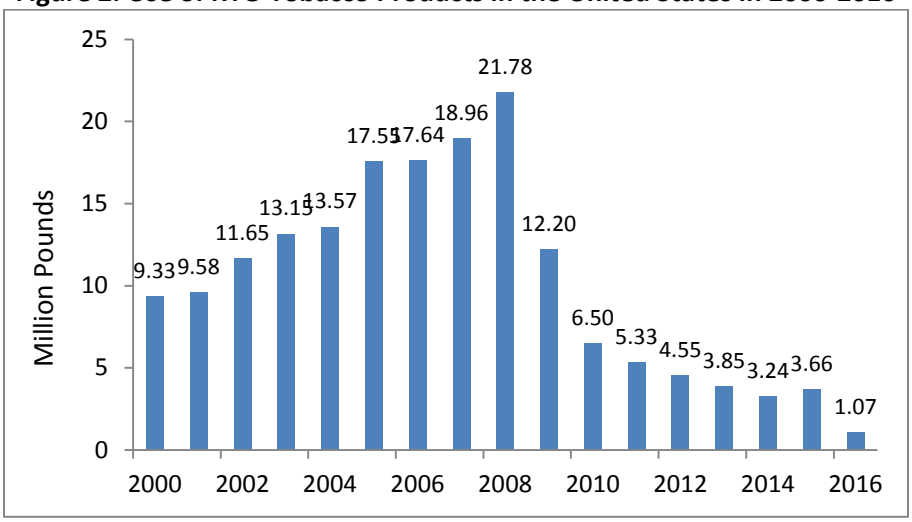
[1] The data extraction is conducted from NPRI database (https://www.ec.gc.ca/inrp-npri/). Under the Canadian Environmental Protection Act, 1999, owners or operators of facilities that meet the NPRI reporting requirements are required to report to the NPRI. This database is managed by the Environment and Climate Change Canada and as of the 2015 year, it tracks 343 listed substances and groups of substances. Data associated with the tobacco facilities is extracted by using North American Industry Classification System (NAICS) codes of 3122. Not all pollutants release data of tobacco facilities are listed in the database.

[2] https://www.ec.gc.ca/inrp-npri/28C24172-53CB-4307-8720-CB91EE2A6069/2016-17%20Guide%20for%20Reporting%20-%20EN.pdf

5.2 Potential Environmental Impacts Due to Use of the New Product

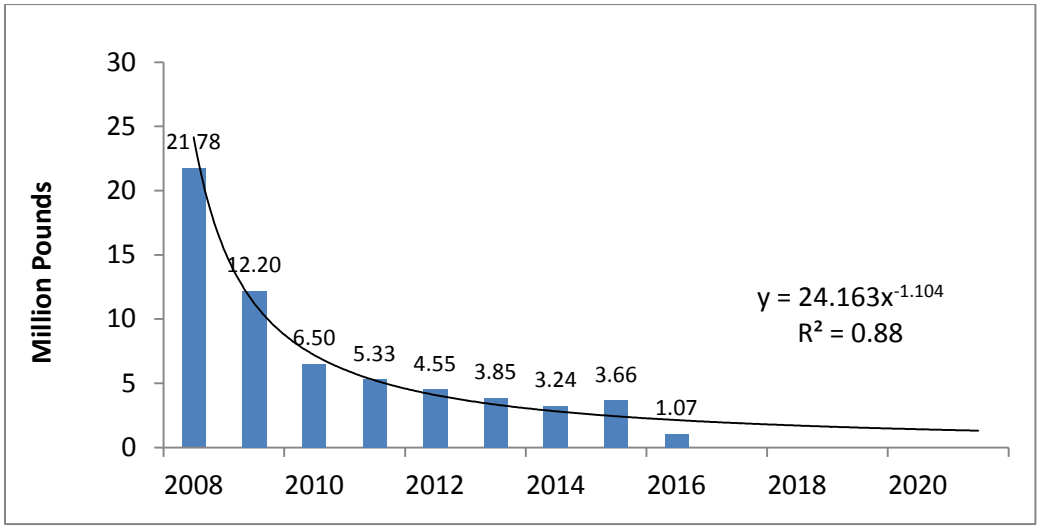
According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of RYO tobacco products in the United States increased from 9.33 million pounds in 2000 to 21.78 million pounds in 2008. This was followed by a decrease in use from 12.20 million pounds in 2009 to 1.07 million pounds in 2016 (Figure 2) (US TTB, 2017).

Figure 2. Use of RYO Tobacco Products in the United States in 2000-2016



To evaluate the environmental impact of the proposed action due to the use of the new product, the Agency analyzed historical use data for 2008-2016 to forecast the future use of RYO tobacco products in the United States. This was achieved by using one best-fit power trend line with the R^2 value of 0.88. Using this approach, the amount of RYO tobacco products forecasted to be used is estimated to be 1.90 million pounds in 2017 and 1.31 million pounds in 2021 (Figure 3).

Figure 3. Forecasted Use of RYO Tobacco in the United States



The applicant intends to market the predicate product simultaneously with the new product after receiving a marketing order for the new product. The projected market volumes for the new product in the first and fifth year of marketing the new product occupy a small portion of the total projected estimate of use of RYO products in the United States (Confidential Appendix 3). Furthermore, because the new product is expected to compete with the predicate product and other RYO products on the market, the Agency anticipates minimal increase in the use of all RYO products. Therefore, the Agency does not anticipate that the chemicals released into the environment from use of RYO products, including the predicate product, will be increased due to the addition of the new RYO product to the commercial market.

When burned, a RYO cigarette produces environmental tobacco smoke (ETS) or secondhand smoke. The ETS composed of sidestream smoke (SS), emitted from the smoldering tobacco between puffs, and exhaled mainstream smoke (MS) from the smoker (DHHS, 1991).

ETS contains many of the toxic agents and carcinogens that are present in MS, but in diluted form. The major source of ETS is SS, which contains higher amounts of some toxic and carcinogenic agents than MS when in its undiluted form. The primary reason that undiluted SS and MS have different concentrations of toxic and carcinogenic agents is that peak temperatures in the burning cone of a cigarette reach 800° to 900°C during puffing, but only 600°C between puffs, resulting in less complete combustion of tobacco during generation of SS. In addition, most of the burning cone is oxygen deficient during smoldering and produces a strongly reducing environment (DHHS, 1991).

There is no safe level of exposure to secondhand smoke. Even low levels of secondhand smoke can harm children and adults in many ways as described below.

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (DHHS, Surgeon General Report, 2010).
- 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 (DHHS, Surgeon General Report, 2010).
- Secondhand smoke causes more than 40,000 deaths a year (DHHS, Surgeon General Report, 2010).

As noted, the applicant claimed that the new product differs from the predicate product in the quantity of the filtered tubes in the retail box. Therefore, the Agency does not anticipate any new chemicals to be emitted into the environment from the use of the new product, compared to the chemicals released by the predicate product that is currently on the market.

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

To better understand the potential environmental impacts due to disposal of the new tobacco product, the Agency uses the environmental pathways of disposed packaging materials and the environmental pathways of discarded cigarette waste.

5.3.1 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 4 and 5) (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 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 very small portion of the total MSW forecasted to be disposed of in the United States. (Confidential Appendix 4).

Figure 4. Municipal Solid Waste Generation Rates in the United States, 1960-2014

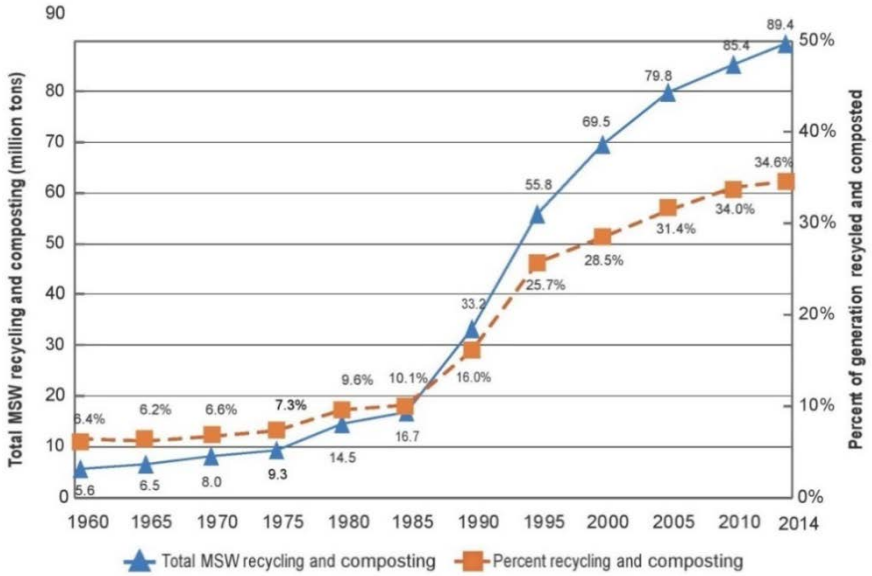


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 5. Municipal Solid Waste Recycling Rates in the United States, 1960-2014

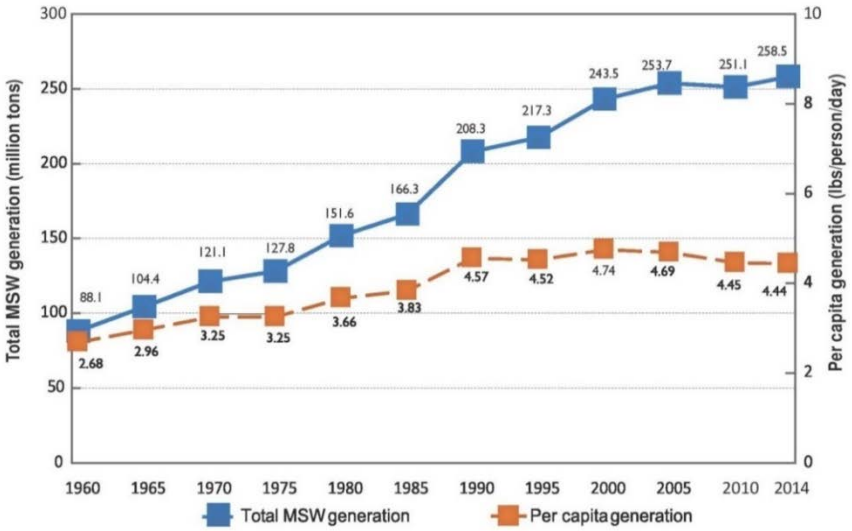


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

As previously discussed, because the applicant stated that the new product will compete with other similar products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfills is not anticipated 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 due to disposal of the new product. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other RYO cigarette tubes that were used in the United States.

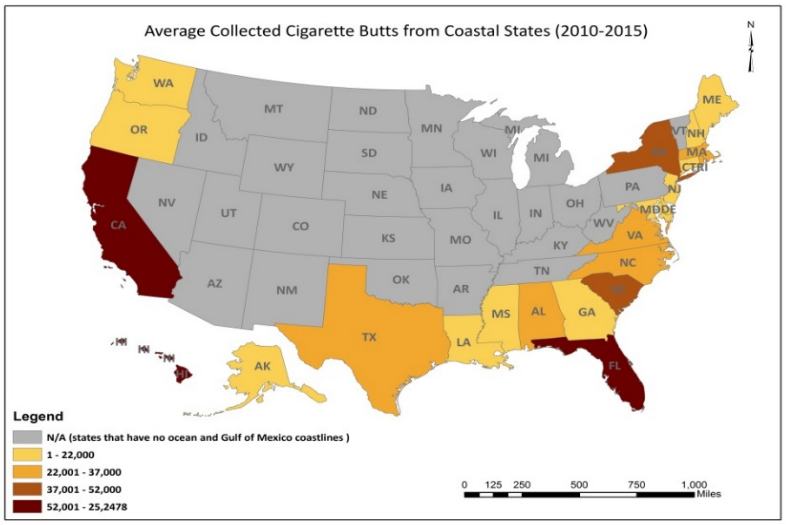
5.3.2 Disposal of RYO Waste

The Agency uses information from the U.S. EPA and "Keep America Beautiful" to estimate the rates of managed and unmanaged RYO tobacco products entering the environment from disposal of RYO tobacco products. The managed waste is treated as MSW and either incinerated with energy recovery or landfilled. As discussed previously, based on the 2014 information by the U.S. EPA (U.S. EPA, 2014) of the trash generated in the United States, 34.6% is recycled and composted. This leaves 65.4% of the trash that was moved to landfills and possibly combusted with energy recovery. This is how the managed waste of the used cigarettes would be handled. For 100% of all the managed waste, landfilled and combusted, based on this information, 80.4% by-weight enters landfills, and the remaining 19.6% by-weight is incinerated for energy recovery (US EPA, 2014).

The majority of unmanaged cigarette waste ends up in oceans and 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 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 6).

Figure 6. 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. As such, introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO. Thus, authorizing the new product is not expected to affect the overall level of cigarette butt litter in the United States. Based on this, and the above-mentioned information regarding waste, construction of new POTWs or landfills are not anticipated due to the proposed action.

6 Use of Resources and Energy

The applicant stated that there will be no change in how the new product is manufactured compared to the predicate product. The same raw materials and energy will be used to manufacture the new product

as are used to manufacture the predicate product. Although the applicant anticipates a small increase in overall production volume at the manufacturing facility, the applicant stated that the proposed action will not require an expansion of the manufacturing facility. Additionally, the applicant stated that the new product will compete with other similar cigarettes, therefore no increase of overall cigarette market volume and no net increase of energy use due to manufacturing the new product will be expected from the proposed action. The applicant stated that no adverse effects to endangered or threatened species or critical habitat are expected from manufacturing the new product.

7 Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for manufacturing, use, and disposal following use of the new product. 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 product 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 tobacco products as many other similar RYO tobacco 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 associated manufacture, use, and disposal following use of the new tobacco product.

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.

Preparers:

Mehran Niazi, Ph.D., Center for Tobacco Products
Education: Ph.D. in Environmental Sciences
Experience: 12 years in environmental fate and transport and environmental modeling
Expertise: Water quality modeling, environmental fate and transport

Reviewers:

Hoshing W. Chang, Ph.D., 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 Report and Related Amendment, Package Sizes, and Weights of Packaging Materials of the New and Predicate Products Covered Under this Environmental Assessment (EA)

12 Confidential Appendix List

Confidential Appendix 1:	The First-, and Fifth-Year Market Volume Projections for the New and Predicate Products
Confidential Appendix 2:	Percentage of the Facility's Total Production Dedicated to the New Product
Confidential Appendix 3:	Percentage of the Projected Total RYO Market in the United States Occupied by the New and Predicate Products in 2017 and 2021
Confidential Appendix 4:	The First- and Fifth-Year Projections of Paper Waste of Packaging Materials Associated with Marketing the New and Predicate Products

13 References

DHHS. (1991). Environmental Tobacco Smoke in the Workplace: Lung Cancer and Other Health Effects. *Current Intelligence Bulletin*, pp. 91-108.

DHHS. (2010). *Surgeon General Report.* Atlanta: 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,.

Heikkila, T. (2007). (b) (4)

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

Novotny, T., Lum, K., & Smith, E. (2009). Cigarettes Butts and the Case for an Environmental Policy on Hazardous Cigarette Waste. *Int J Environ Res Public Health*, 1695-1705.

NPRI. (2017). Retrieved 10 20, 2017, from Environment and Climate Change Canada: https://www.ec.gc.ca/inrp-npri/

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 Report and Related Amendment, Package Sizes, and Weights of Packaging Materials of the New and Predicate Products Covered Under this Environmental Assessment (EA)

STN	Product Name	Weight of Empty Retail Box (g)	Tubes per Retail Box	Weight of empty shipping case (g)	Retail Boxes per Shipping Case	Amendment
SE0012177	Top Silver King Size	30.2	250	484	40	SE0014378
Predicate	Top Silver King Size	26.4	200	484	50	

CONFIDENTIAL APPENDIX 1

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

STN	First-Year Market Volume (Metric Tons)		Fifth-Year Market Volume (Metric Tons)	
	New Product	Predicate Product	New Product	Predicate Product
SE0012177	(b) (4)			

CONFIDENTIAL APPENDIX 2

Percentage of the Facility's Total Production Dedicated to the New Product

STN	Percentage of the New Product to Facility's Total Production, 1st Year	Percentage of the New Product to Facility's Total Production, 5st Year
SE0012177	(b) (4)	

The applicant claimed that the new RYO tobacco product is intended to increase the facility's total production by (b) (4) in the first year and (b) (4) in the fifth year after the new product receives a marketing order.

CONFIDENTIAL APPENDIX 3

Percentage of the Projected Total RYO Market in the United States Occupied by the New and Predicate Products in 2017 and 2021

STN	Year	Forecasted Use of Total RYO Tobacco in the United States (lb)[3]	Projected Market Volume (lb)[4]	Projected Market Occupation of New Product in the U.S. (%)
SE0012177	First	1,902,000	(b) (4)	
	Fifth	1,312,000		
Predicate	First	1,902,000		
	Fifth	1,312,000		

First Year Market Occupation of New Product (%)

$$= \frac{\text{First-Year Market Volume Projection}}{\text{Forecasted Use of RYO in the U.S. for 2017}} \times 100\%$$

Fifth Year Market Occupation of New Product (%)

$$= \frac{\text{Fifth-Year Market Volume Projection}}{\text{Forecasted Use of RYO in the U.S. for 2021}} \times 100\%$$

The projected market volume for the new product is (b) (4) and (b) (4) pounds in 2017 and 2021, respectively. Compared to the amount of RYO projected to be used in the United States, the new product would occupy (b) (4) and (b) (4) of the total market of RYO in 2017 and 2021, respectively (see section 5.2).

[3] See Figure 5.
[4] See Confidential Appendix 1.

CONFIDENTIAL APPENDIX 4

The First- and Fifth-Year Projections of Paper Waste of Packaging Materials Associated with Marketing the New and Predicate Products

To analyze the environmental effects from total waste due to the proposed action, 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 summation of the projected cardboard retail boxes and cartons.

$$\sum_{i=1}^{1} A_i = \sum_{i=1}^{1} (B_i + C_i)$$

$$B_i = \frac{D_i}{E_i} \times F \times I$$

$$C_i = \frac{D_i}{E_i \times G_i} \times H \times I$$

A_i: Projected paper waste generation of the product (metric tons)
B_i: Projected retail cardboard box waste generation of the product (metric tons)
C_i: Projected shipping case waste generation of the product (metric tons)
D_i: Projected market volume of the product (# individual cigarette injector tubes)
E_i: Number of cigarette injector tubes per retail box
F: Weight of empty retail box (grams)
G_i: Number of retail boxes per shipping case
H: Weight of empty shipping case (grams)
I: 1.0 x 10^{-6} metric tons/gram

	STN	H	G	F	E	D	C	B	A
First Year	SE0012177	(b) (4)	40	(b) (4)	250	(b) (4)			
	Predicate Product		50		200				
Fifth Year	SE0012177		40		250				
	Predicate Product		50		200				

If all the projected packaging waste generated from use of the new product is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new product 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 cardboard boxes is 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 (b) (4) in the first year and (b) (4) metric tons (b) (4) in the fifth year of marketing the new product.