Programmatic Environmental Assessment for Marketing Orders for Republic Tobacco, LP "Altesse® Regular King Size, Gambler® Menthol King Size, and Gambler® Tubecut® Menthol King Size."

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

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Table of Contents

This programmatic environmental assessment (PEA) is for marketing orders for three roll-your-own (RYO) filtered cigarette 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 with 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 of Applicant

2301 Ravine Way
Glenview, Illinois 60025

3. Manufacturer

The manufacturer for the new RYO filtered cigarette tubes is located in a foreign country and that location is provided in Confidential Appendix 1.

4. Description of the Proposed Actions

The proposed actions are for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of three new RYO filtered cigarette tubes into interstate commerce. These authorizations are based on the finding that the new products are substantially equivalent to the corresponding predicate products that were either commercially marketed in the United States as of February 15, 2007, or previously authorized as substantially equivalent. The applicant intends to continue marketing one predicate product[1] and phase-out marketing the other predicate product[2] gradually after receiving marketing orders for the corresponding new products.

4.1. Requested Actions

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

4.2. Need for Actions

Republic Tobacco, LP wishes to introduce the new products as described into interstate commerce for commercial distribution in the United States. The applicant claims that the new products and the corresponding predicate products are substantially equivalent with only minor differences in the amount of some ingredients due to changes in supplier sources, but that the new products do not

[1] Top® Menthol King Size

[2] Altesse® Regular King Size

raise different questions of public health (sec. 910(a)(3)(A)(ii)). After considering the SE Reports, the Agency shall issue marketing orders under the provisions of sections 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 are Subjects of the Proposed Actions

4.3.1. Type of Tobacco Products

RYO filtered cigarette tubes

4.3.2. Product Names and the Submission Tracking Numbers (STN)

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
SE0012635	Altesse® Regular King Size	Altesse® Regular King Size
SE0012638	Gambler® Menthol King Size	Top® Menthol King Size
SE0012640	Gambler® Tubecut® Menthol King Size	Top® Menthol King Size

4.3.3. Description of the Product Package

The packaging materials of the finished new products are identical in composition and weight to those of the corresponding predicate products. See Appendix 1 for package size of the products.

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 marketed filtered cigarette tubes. The packaging materials would 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 product use.

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

The applicant claims that the ingredients in the new products are made to the same specifications as the corresponding predicate products. With one exception, the new products contain the same components and packaging materials. That exception is a slight modification in the tipping paper components. Additionally, although made to the same specifications, there is a slight change in the ingredients of the filter of the new products due to changes in supplier sources. See Confidential Appendix 2 for detailed information regarding the modifications in the new products.

5. Potential Environmental Impacts Due to the Proposed Actions

5.1. Potential Environmental Impacts Due to Manufacturing the New Products

The emission information for air, water and soil pollutants associated with the manufacturing of certain tobacco products from the country where the RYO filtered injector tube manufacturer is located is publicly available. When a search was performed for air, water and soil pollutants associated with the manufacturer of the new products using the publicly available database, no data were available.

The Agency anticipates the waste generated as a result of manufacturing the new products will be released to the environment, transferred to publicly owned treatment works (POTW), and disposed of in landfills in the same manner as any other products manufactured in the same facility and in a similar manner to other filtered cigarette tubes manufactured in the manufacturer's respective country. The new products are anticipated to compete with other filtered cigarette tubes on the market. In the SE Reports, the manufacturing facility has the necessary equipment to handle waste disposal from manufacturing the new products in a manner compliant with applicable laws and regulations.

The applicant stated that the manufacturer abides by all federal and regional emissions, solid waste, and liquid waste regulations and requirements of its respective country. In addition, the applicant stated that the suppliers for the manufacturing facility are certified by the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification (PEFC) and provided information on the certifications. By complying with the relevant environmental regulations and fulfilling sustainability measures, the manufacturing of the new products does 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).

After evaluating the projected market volume information of the new products and the corresponding predicate products in the first and fifth year of marketing the new products as well as the facility's current production of filtered cigarette tubes, the Agency found that the production of the new products occupies a fraction of the entire facility's production of filtered cigarette tubes

(Confidential Appendix 3). Therefore, the Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated by the facility from the production of all filtered cigarette tubes.

The applicant stated that the new products are intended to compete with the corresponding predicate products, as well as other RYO cigarette papers that are currently on the market. Therefore, there would be no anticipated expansion of the manufacturing facility, which was confirmed by the applicant, and no additional resources with new control measures for air emission, water discharge, or solid waste disposal are needed for manufacturing the new products. In addition, there would be no anticipated net increase in energy use or change in air emissions expected from manufacturing since the new products would compete with other currently marketed RYO products.

5.2. Potential Environmental Impacts Due to Use of the New Products

There is limited information on the extent of use of filtered cigarette tubes for RYO tobacco in the United States. However, statistical data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) shows a gradual linear increase in the use of RYO tobacco from 2000 to 2008 from 9.3 million pounds (4.7 billion cigarette-equivalents) to 21.8 million pounds (11 billion cigarette-equivalents), respectively (Figures 1 and 2).[3] This was followed by a sharp decline in RYO tobacco use to 6.5 million pounds (3.3 billion cigarette-equivalents) in 2010 and to 2.9 million pounds (1.5 billion cigarette-equivalents) in 2016.

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

Figure 1. Use of RYO (Million Pounds) in the United States, 1999 – 2016

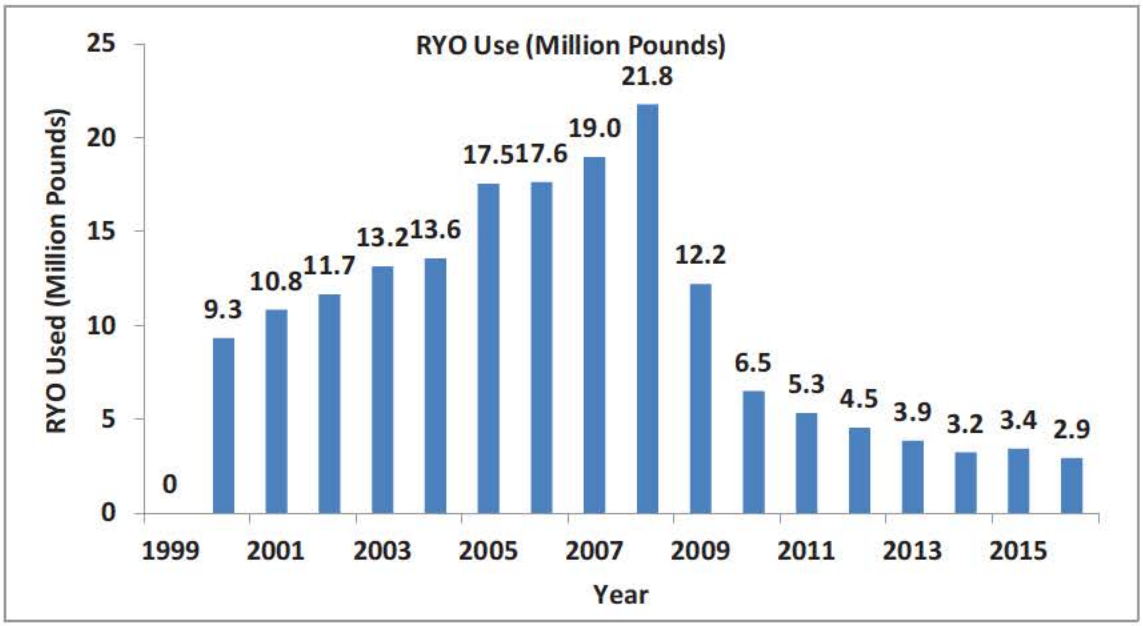
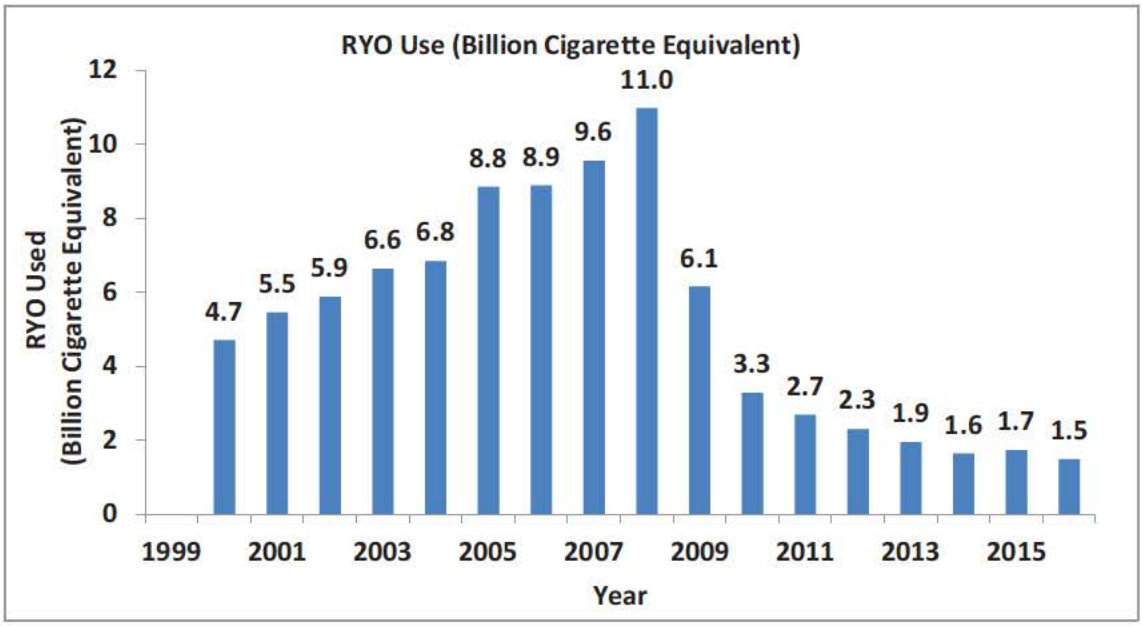


Figure 2. Use of RYO (Billion Cigarette-Equivalents) in the United States, 1999 – 2016



Overall, the use of RYO tobacco in the United States has decreased since 2008 and the Agency anticipates the same pattern will continue for at least the next few years. When burned, combusted tobacco products, such as RYO tobacco or cigarettes, release tobacco smoke to the environment, referred to as secondhand smoke (SHS). Ingredients in the SHS may dissipate on surfaces, interact with each other or interact with other environmental air pollutants leading to another source of

environmental exposure, referred to as thirdhand smoke (THS). There is no safe level of exposure to secondhand smoke [1, 2]. Even low levels of secondhand smoke can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% [3].
- 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 [1, 2].
- Secondhand smoke causes more than 40,000 deaths a year [3].

As noted, according to the SE Reports, the new products and the corresponding predicate products have minor differences in the tipping paper components and in the ingredients of the filter. Furthermore, the applicant claimed that the new products will compete with the other currently marketed RYO products. During use, the new products, like cigarettes, are usually burned to ash, carbon dioxide, water vapor, and products from incomplete combustion such as carbon monoxide. These combustion products are released in a similar manner from the new and predicate products, as well as from other filtered cigarettes. The released substances during use of the new products are negligible from the environmental viewpoint. Therefore, the Agency does not anticipate new substances to be released into the environment as a result of use of the new products, in comparison to the substances released by the predicate products or by other RYO or cigarettes currently on the market.

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

5.3.1 Disposal of Packaging Material

Disposal of the packaging materials 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 packing materials. Specifically, according to the U.S. Environmental Protection Agency (U.S. EPA), approximately 258.46 million tons of waste was generated in the United States in 2014, and approximately 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 3 and 4).[4] Paper and paperboard accounted 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%), of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery. On average, 4.4 pounds of waste was generated per person in the United States, of which 2.1 pounds was recycled, composted, or combusted for energy recovery [4].

[4] The ton unit in section 5.3.1 is U.S. short ton, unless specified otherwise

Figure 3. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960 – 2014

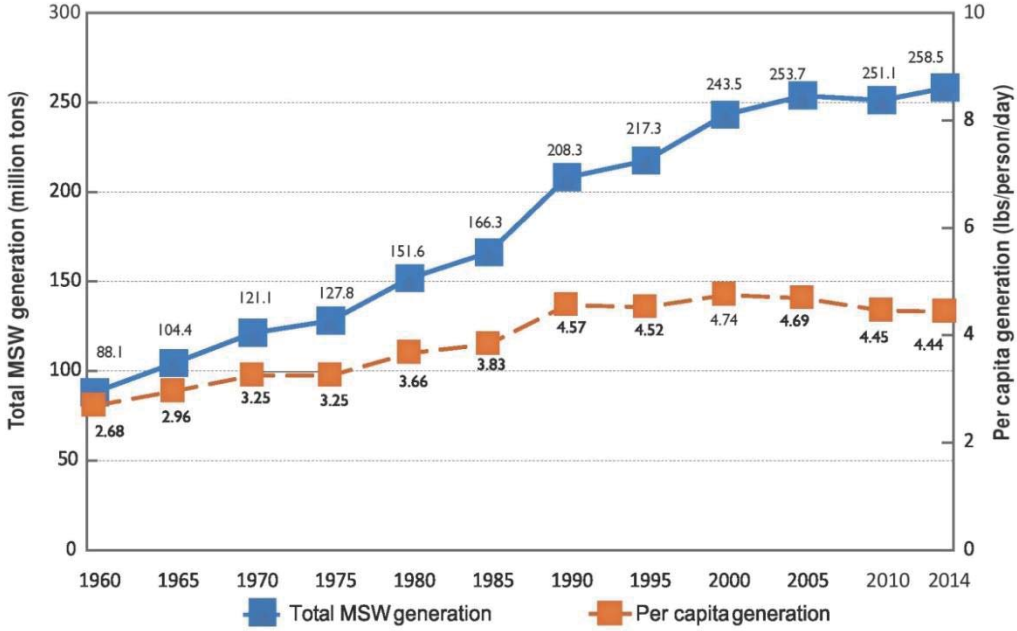


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

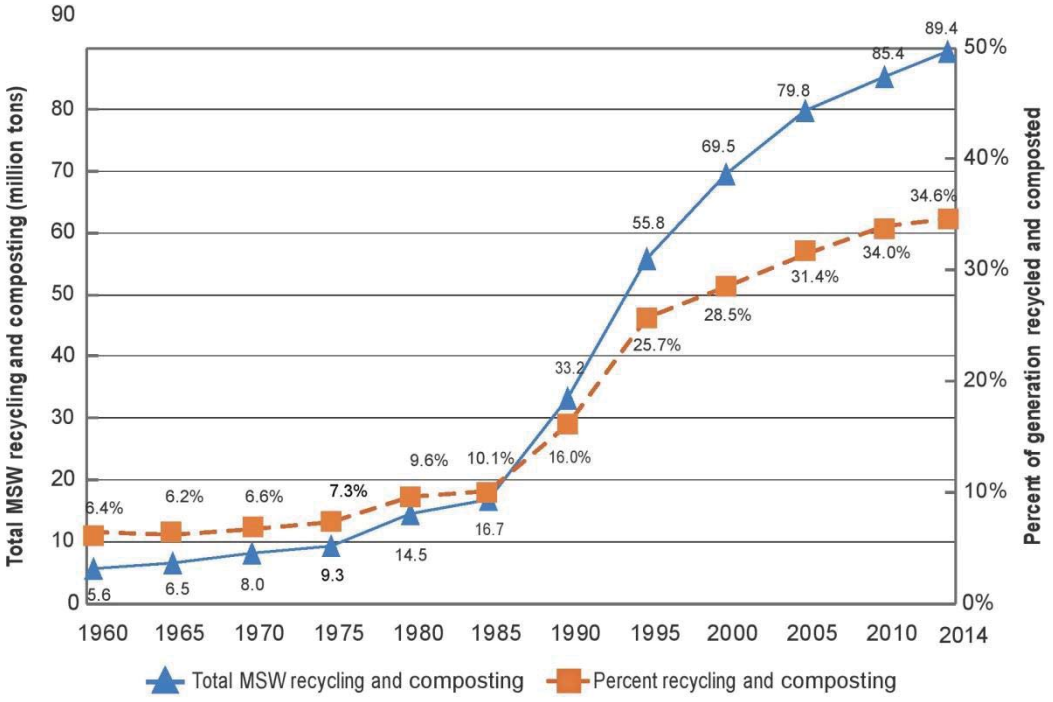


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the new products' packaging material will be similar to the disposal conditions of the packaging material used for other RYO cigarette tubes, and any other RYO tobacco products that are currently being marketed. After using the new products, the users may dispose of or recycle the packaging material.

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

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

5.3.2 Disposal of Used RYO Waste

A major existing environmental consequence of the use of combusted filtered cigarettes is the waste disposal of the cigarette butts. Evidence has shown that cigarette butts are the most prevalent items discarded into roads and streets in urban areas. Once dumped onto city streets, they move through the storm drains to streams, into the ocean, and back onto the beaches, while leaching toxicants, including arsenic, lead, nicotine and ethyl phenol, into the aquatic environment and soil along the way [5, 6]. Discarded filters are found to be the most collected item in beach clean-ups and litter surveys. An estimated 30% of the total waste (by count) on U.S. shorelines, waterways, and land is cigarette butt waste [6]. Researchers found that cigarette butts are a source for metal contamination, in which the butts gradually released multiple metals over a 34-day study period [7]. In addition, scientists stated that cigarette butts are a source for nicotine entering the aquatic ecosystem over a 24-hour simulated rainfall event [8].

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

5.3.3 Air Emissions

Landfill disposal or incineration of the used RYO tobacco products and packaging materials will produce greenhouse gas (GHG). According to the U.S. EPA, 64.7% of paper and paperboard waste generated in 2014 was recycled, leaving 28.4% disposed of in MSW landfills and 6.9% incinerated [4].

Methane (CH_4) is a potent GHG that has a global warming potential of 28-36 times greater than CO_2, and has an atmospheric life of about 12 years. Landfills are the third largest source of human-related CH_4 emissions in the United States, releasing an estimated 133.1 million metric tons (MMT) of CO_2-eq, accounting for approximately 18.2% of these emissions in 2015 [9]. The decomposition of landfill waste produces approximately 50% biogenic CO_2 and 50% CH_4, by volume, as well as trace amounts of non-CH_4 organic compounds and volatile organic compounds. According to a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines, only CH_4 generation and emissions are estimated and reported for landfills [10]. However, the Clean Air Act requires that all landfills constructed or modified after July 17, 2014 install landfill gas collection-and-control systems if they will have a waste capacity of 2.5 million metric tons or more. Additionally, all landfills must report GHG emissions to the U.S. EPA under 40 CFR 98.

The applicant estimated the amount of GHG emissions as a result of marketing the new products and the corresponding predicate products due to disposal. The Agency estimated the projected GHG emissions from the disposal of the used products and packaging waste in the first and fifth year of marketing the new products. The Agency found that the use and disposal of the new and predicate products would not result in a substantial or different impact on GHG emissions and the cumulative amount of GHG would be below the EPA threshold (Confidential Appendix 5). Because the projected wastes comprise a miniscule fraction of the total MSW in the United States, the GHG emitted from waste associated with the new products is negligible.

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. The applicant stated that the new products will compete with other similar tobacco products and according to the U.S. TTB data, the use of RYO tobacco products in the United States has decreased over the last ten years. Therefore, no increase of overall RYO products market volume and no net increase of energy use is expected from the proposed actions.

7. Mitigation

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

8. 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 United States. The environmental impact of this action would not change the existing condition of the manufacturing, use, and disposal of tobacco products as many other RYO cigarette paper products will continue to be marketed.

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

9. List of Preparers:

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

Preparer:

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Education: Ph.D. in Plant Molecular Biology and Virology
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Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

GHG emission estimation

Shannon Hanna, Ph.D., Center for Tobacco Products

Education: Ph.D. 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, soil/sediment and water quality

Reviewer:

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

Reviewer:

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

Education: Ph.D. in Biochemistry and M.S. in Environmental Science
Experience: About 10 years in NEPA practice
Expertise: Waste water treatment, environmental impact analysis

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 that are Covered Under this Programmatic Environmental Assessment (PEA)

12. Confidential Appendix

Confidential Appendix 1: Location of the Manufacturing Facility

Confidential Appendix 2: Modifications Between the New Products and the Corresponding Predicate Products

Confidential Appendix 3: Projected Market Volumes in the First and Fifth Year of Marketing the New Products

Confidential Appendix 4: Projected Waste of Packaging Material and Tube Filters in the First and Fifth Year of Marketing the New Products

Confidential Appendix 5: The Agency's Estimated GHG in the First and Fifth Year of Marketing the New Products

13. References

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

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

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

4) U.S. Environmental Protection Agency (EPA). Advancing Sustainable Materials Management: Facts and Figures Report 2014. Available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report. Accessed October 30, 2017.

5) Moriwaki, H, Kitajima, S, Katahira, K. Waste on the roadside, 'poi-sute' waste: its distribution and elution potential of pollutants into the environment. *Waste Management*. 2009; 29(3):1192-1197.

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

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

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

9) U.S. Environmental Protection Agency (EPA). Draft Report: Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2014. EPA 430-P-17-001. Issued February 15, 2017. Available at https://www.epa.gov/sites/production/files/2017-02/documents/2017_complete_report.pdf. Accessed April 26, 2017.

10) Intergovernmental Panel on Climate Change (IPCC). 2006 IPCC Guidelines for National Greenhouse Gas Inventories. Available at http://www.ipcc-nggip.iges.or.jp/public/2006gl/. Accessed April 7, 2017

11) O. Geiss, K. Dimitrios, Tobacco, Cigarettes and Cigarette Smoke: An Overview. *European Commission, Directorate-General Joint Research Centre, Institute for Health and Consumer Protection*, (2007).

12) U.S. Environmental Protection Agency (EPA). Waste Reduction Model (WARM). Available at https://www.epa.gov/warm. Accessed April 26, 2017.

APPENDIX 1

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

STN	New Product	Package Size	Predicate Product	Package Size	Amendments
SE0012635	Altesse® Regular King Size	100	Altesse® Regular King Size	200	SE0013469; SE0013716; SE0013822; SE0013842
SE0012638	Gambler® Menthol King Size	200	Top® Menthol King Size	200	
SE0012640	Gambler® Tubecut® Menthol King Size	200	Top® Menthol King Size	200	

CONFIDENTIAL APPENDIX 1
Location of the Manufacturing Facility

The location of the manufacturing facility for the new RYO filtered cigarette tubes is listed below and shown in Figure 5.

(b) (4) [redacted]

The facility is situated in a mixed-use commercial area consisting of office buildings, warehouses, small businesses, and light manufacturing facilities.

Figure 5. Location of the RYO Filtered Cigarette Tubes' Manufacturing Facility in Canada

CONFIDENTIAL APPENDIX 2

Modifications Between the New Products and the Corresponding Predicate Products

STN	Component	Ingredient	New Product	Predicate Product
SE0012635 SE0012638 SE0012640	Triacetin	(b) (4)		
SE0012635	Tipping Paper			
SE0012638 SE0012640	Tipping Paper			

CONFIDENTIAL APPENDIX 3

Projected Market Volumes in the First and Fifth Year of Marketing the New Products

STN	First-Year Projected Volume (metric tons)		Fifth-Year Projected Volume (metric tons)		First-Year Projected Volume (# of pieces)		Fifth-Year Projected Volume (# of pieces)	
	New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0012635	(b) (4) [redacted]							
SE0012638								
SE0012640*								
Total								
Cumulative Volumes[5]								
2016 Facility's Production of RYO Filtered Tubes			(b) (4) [redacted]			(b) (4) [redacted]		

* Note, the predicate product is the same as that in SE001238 and therefore, is counted only once.

The cumulative projected volumes of the news and predicate products in the first and fifth year of marketing the new products comprise (b) (4) [redacted] and (b) (4) [redacted] and of total facility's current production of RYO filtered tube products, respectively.

[5] Summation of market volumes of new and predicate products

CONFIDENTIAL APPENDIX 3

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 of the new products in 2018 and 2022. 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 products and the corresponding predicate products.

$\sum_{i=1}^{3} A_i = \sum_{i=1}^{3} (B_i + C_i + D_i + E_i)$	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)[6] of the new and predicate products (metric tons)
$B_i = \frac{F_i}{G_i} \times H \times O$	F_i: Total Projected market volume of the new and predicate product (total number of individual tubes) G_i: Number of tubes per retail box H_i: Weight of empty retail cardboard box (grams)
$C_i = \frac{F_i}{G_i \times I_i} \times J \times O$	I_i: Number of retail boxes per cardboard shipping case J_i: Weight of empty cardboard shipping case (grams)
$D_i = \frac{F_i}{G_i} \times K \times O$	K_i: Weight of plastic wrap per retail box (grams)
$E_i = \frac{F_i \, X \, L_i \, X \, M_i}{1000} \times O$	L_i: Weight of Tube (milligram) M_i: Cigarette butt ratio (%)[7]
$M_i = \frac{27}{N_i}$	N_i: Length of Tube (millimeter)= 84 mm O: 1.0 x 10^{-6} metric tons/gram

[6] Cigarette butt in this PEA is defined as the disposed of cigarette rolling paper containing remainder tobacco.

[7] ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed of as solid waste.

a) **Projected Waste of Packaging Material**

Projected Year	STN	*New Product*	*Predicate Product*	F_i	G_i	H_i	B_i	I_i	J_i	C_i	K_i	D_i
First-Year Projected Volume	SE0012635	(b) (4)	(b) (4)	(b) (4)	100	14.7	(b) (4)	100	600	(b) (4)	N/A[8]	(b) (4)
	SE0012638	(b) (4)	(b) (4)	(b) (4)	200	23.8	(b) (4)	50	600	(b) (4)	2.49	
	SE0012640*	(b) (4)		(b) (4)	200	23.8	(b) (4)	50	600	(b) (4)	2.49	
	Total	(b) (4)	(b) (4)	(b) (4)			(b) (4)			(b) (4)		
Fifth-Year Projected Volume	SE0012635	(b) (4)	(b) (4)	(b) (4)	100	14.7	(b) (4)	100	600	(b) (4)	N/A	
	SE0012638	(b) (4)	(b) (4)	(b) (4)	200	23.8	(b) (4)	50	600	(b) (4)	2.49	
	SE0012640*	(b) (4)		(b) (4)	200	23.8	(b) (4)	50	600	(b) (4)	2.49	
	Total	(b) (4)	(b) (4)	(b) (4)			(b) (4)			(b) (4)		

* Note, the predicate product is the same as that in SE001238 and therefore, is counted only once.

If the entire projected packaging waste generated from use of the products is disposed of in landfills, the projected cumulative cardboard waste (variables B and C above) generated in the first and fifth years of marketing the new products would be (b) (4) metric tons ((b) (4)) in 2018 and (b) (4) tons ((b) (4)) in 2022. This is a negligible fraction of the 258.5 million tons (equivalent to 234.5 metric tons) of total waste reported in the United States in 2014. Likewise, the projected plastic waste of (b) (4) metric tons in 2018 and (b) (4) metric tons in 2022 is a negligible fraction of the 234.5 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.[9] 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) tons ((b) (4) metric tons) in the first year and (b) (4) tons ((b) (4) metric tons) in the fifth year of marketing the new products.

[8] NA = Not applicable; this product does not have plastic wrap

[9] 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).

b) Projected Waste of the Tube Filters

Projected Year	STN	New Product	New Product L_i	N_i	New Product E_i	Predicate Product	Predicate Product L_i	N_i	Predicate Product E_i	Total Waste[10] E_i
First-Year Projected Volume	SE0012635	(b) (4)	192.949	84	(b) (4)	(b) (4)	194.522	84	(b) (4)	
	SE0012638	(b) (4)	198.866	84	(b) (4)	(b) (4)	198.689	84		
	SE0012640*	(b) (4)	198.866	84	(b) (4)					
	Total	(b) (4)			(b) (4)	(b) (4)				
Fifth-Year Projected Volume	SE0012635	(b) (4)	192.949	84	(b) (4)	(b) (4)	194.522	84		
	SE0012638	(b) (4)	198.866	84	(b) (4)	(b) (4)	198.689	84		
	SE0012640*	(b) (4)	198.866	84	(b) (4)					
	Total	(b) (4)			(b) (4)	(b) (4)				

* Note, the predicate product is the same as that in SE001238 and therefore, is counted only once.

If all the projected filter waste generated from use of the new and predicate products is disposed of in landfills, the projected waste of (b) (4) metric ton in 2018 and (b) (4) metric ton in 2022 will be a negligible fraction of the 234.5 million metric tons of total waste reported in the United States in 2014.

[10] This is the summation of projected tube filter waste from the new and predicate products

CONFIDENTIAL APPENDIX 4

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

GHG Emissions from Use of Products

The amount of CO_2-equivalent gases (CO_2-eq) emitted from the use of one cigarette is estimated at 45-65 mg [11]. As a conservative approach, the Agency used the upper limit of CO_2 emitted per cigarette to calculate the GHG emissions from use of the new and predicate products.

GHG Emissions from Use of Product (metric tons of CO_2-eq) =

$$Projected\ Market\ Volume\ of\ Product\ (cigarettes) \times 0.065 gCO2 \quad eq/cigarette \times 0.000001\ metric\ tons/g$$

Metric Tons of CO_2-eq				
STN	First-Year		Fifth-Year	
	New Product	Predicate Product	New Product	Predicate Product
SE0012635	(b) (4) [redacted]			
SE0012638				
SE0012640*				
Cumulative				

* Note, the predicate product is the same as that in SE001238 and therefore, is counted only once.

Estimated total GHG emissions associated with marketing the new and predicate products are (b) (4) [redacted] metric tons CO_2-eq in the first year and (b) (4) [redacted] ((b) (4) [redacted] metric tons CO_2-eq in the fifth year of marketing the new products. This is a negligible fraction of the 6.87 billion metric tons of CO_2-eq reported in the United States in 2014 [9].

GHG Emissions from Disposal of Products:

GHG emissions from the disposal of the new and predicate product packaging and used products were calculated using the Waste Reduction Model (WARM), version 14 [12]. 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 the packaging and used products is estimated at 2 metric tons of CO_2-eq for the first year and 2 metric tons of CO_2-eq for the fifth year of marketing the new products. This estimate is a negligible fraction ([redacted] of the 6.87 billion metric tons of CO_2-eq reported in the United States in 2014 [9]. 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.

Metric Tons of CO_2-eq				
STN	First-Year		Fifth-Year	
	New	Predicate	New	Predicate
SE0012635	(b)(4) [redacted]			
SE0012638				
SE0012640				
Cumulative				

* Note, the predicate product is the same as that in SE001238 and therefore, is counted only once.

The applicant estimated [redacted] metric tons of CO_2-eq in the first-year and [redacted] metric tons of CO_2-eq in the fifth-year for disposal of the new and predicate products combined using their own in-house methodology.