Programmatic Environmental Assessment for Market Authorizations for "Top Tobacco L.P. Real Menthol 3 oz Medium Bag, Real Silver 8 oz Large Bag, Top Turkish 0.6 oz Pouch, Top Turkish 6 oz Canister, Real Menthol 8 oz Large Bag, Real Full Flavor 8 oz Large Bag, Real Gold 3 oz Medium Bag, Real Full Flavor 3 oz Medium Bag, Real Gold 8 oz Large Bag, Real Silver 3 oz Medium Bag"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

September 5, 2017

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This programmatic environmental assessment (PEA) is for the market authorizations for 10 roll-your-own (RYO) tobacco filler and rolling paper products manufactured by Top Tobacco L.P. 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

Top Tobacco L.P.

2. Address

2301 Ravine Way
Glenview, IL 60025

3. Manufacturer

Top Tobacco L.P.
204 Top Tobacco Road
Lake Waccamaw, NC 28450

4. Description of Proposed Action

These proposed actions are for the Food & Drug Administration (FDA) to issue market authorizations under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of RYO tobacco products into interstate commercial distribution in the U.S.

The authorizations are based on the finding that these new products are substantially equivalent to the corresponding predicate products that were on the market as of February 15, 2007. The applicant claimed that the new products differ from the corresponding predicate products in changes to the tobacco blend and changes to the flavorings and filler ingredients. For some products, there are additional changes in package size, package type, or the inclusion of rolling papers (Confidential Appendix 1).

The applicant intends to market the new and predicate products simultaneously after receiving market authorizations for the new products, and provided marketing projections for the current year, first year, and fifth after marketing is authorized (Confidential Appendix 2).

4.1 Requested Action

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

4.2 Need for Action

Top Tobacco L.P. 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 but that the new products do not raise different questions of public health (sec 910(a)(3)(A)(ii) of the FD&C Act). After considering the substantial equivalence (SE) reports (SE0000169, 171, 187, 188, 197, 207, 230, 231, 244, and 252), the Agency shall issue orders 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 are the Subject of the Proposed Actions

4.3.1 Type of Tobacco Products

RYO tobacco filler and rolling paper

4.3.2 Product Names and Their Original Submission Tracking Numbers

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

STN	New Product	Predicate Product (Grandfathered Product)
SE0000169	Real Menthol 3 oz Medium Bag	TOP MENTHOL CANISTER
SE0000171	Real Silver 8 oz Large Bag	GAM/ULTLTE, 36 BAGS/CASE
SE0000187	Top Turkish 0.6 oz Pouch	TOP REG. POUCH
SE0000188	Top Turkish 6 oz Canister	TOP REG CAN
SE0000197	Real Menthol 8 oz Large Bag	TOP MENTHOL CANISTER
SE0000207	Real Full Flavor 8 oz Large Bag	TOP REG CAN
SE0000230	Real Gold 3 oz Medium Bag	TOP LITE CAN
SE0000231	Real Full Flavor 3 oz Medium Bag	TOP REG CAN
SE0000244	Real Gold 8 oz Large Bag	TOP LITE CAN
SE0000252	Real Silver 3 oz Medium Bag	GAM/ULTLTE, 36 BAGS/CASE

4.3.3 Description of the Product Packages

The packaging materials of six of the finished new products are different from those of their corresponding predicate products. In each case, the new product packaging components consist of changing from a canister to a bag and the exclusion of cigarette rolling papers. The other four finished new products do not have different packaging materials than their corresponding predicate products. The following table provides packaging information for the new and predicate products.

STN	New Product			Predicate Product		
	Name	Package Type	Rolling Papers Included	Name	Package Type	Rolling Papers Included
SE0000169	Real Menthol 3 oz Medium Bag	Bag	No	TOP MENTHOL CANISTER	Canister	Yes
SE0000171	Real Silver 8 oz Large Bag	Bag	No	GAM/ULTLTE, 36 BAGS/CASE	Bag	No
SE0000187	Top Turkish 0.6 oz Pouch	Pouch	Yes	TOP REG. POUCH	Pouch	Yes
SE0000188	Top Turkish 6 oz Canister	Canister	Yes	TOP REG CAN	Canister	Yes
SE0000197	Real Menthol 8 oz Large Bag	Bag	No	TOP MENTHOL CANISTER	Canister	Yes
SE0000207	Real Full Flavor 8 oz Large Bag	Bag	No	TOP REG CAN	Canister	Yes
SE0000230	Real Gold 3 oz Medium Bag	Bag	No	TOP LITE CAN	Canister	Yes
SE0000231	Real Full Flavor 3 oz Medium Bag	Bag	No	TOP REG CAN	Canister	Yes
SE0000244	Real Gold 8 oz Large Bag	Bag	No	TOP LITE CAN	Canister	Yes
SE0000252	Real Silver 3 oz Medium Bag	Bag	No	GAM/ULTLTE, 36 BAGS/CASE	Bag	No

Details of the package component materials and weights of each packaging component for the new and predicate products are described in Confidential Appendix 3.

4.3.4 Location of Manufacturing

The components are assembled into finished products for U.S. distribution at Top Tobacco L.P., located at 204 Top Tobacco Road, Lake Waccamaw, NC 28450 (Figure 1). The facility is bounded by US-76 (Andrew Jackson Highway) on the north, a storage facility and water tower on the east, an exhibition center across Top Tobacco Road to the south, and rural undeveloped land with scattered residences on the west (Google, 2017a).

Figure 1. Location of the RYO Tobacco Product Manufacturing Facility

4.3.5 Location of Use

Top Tobacco L.P. intends to distribute and sell the new tobacco products in the U.S.

4.3.6 Location of Disposal

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

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

The applicant claimed that the new products differ from the corresponding predicate products in changes to the tobacco blend and changes to the flavorings and filler ingredients. For some products included in this PEA, there are additional changes in package size, package type, or the inclusion of rolling papers (Confidential Appendix 1).

5. Environmental Introduction Due to the Proposed Actions

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

5.1.1. Tobacco Manufacturing in the Facility

According to Bloomberg (Bloomberg, 2017), Top Tobacco LP, doing business as Republic Tobacco, manufactures chewing and smoking tobacco. According to the SE Reports, they assemble RYO tobacco filler and rolling paper at this location. The applicant also stated that the manufacturing facility is state-of-the-art and has attained various certifications attesting to their commitment to sustainable sourcing and manufacturing practices.

5.1.2. Environmental Introduction from Manufacturing the New Tobacco Products

The Agency anticipates the environmental releases generated by manufacturing the new RYO tobacco products will be emitted to the air, discharged in wastewater to waterways directly or through publicly owned treatment works, and disposed of in the solid waste stream. These releases would occur in the same manner as the releases and waste generated from any other products manufactured in the same facility and in a similar manner to other RYO tobacco products manufactured in the U.S.

The applicant stated that manufacturing the new products would not require additional capacity for disposal of manufacturing waste, would not require an expansion of the manufacturing facility, would not emit any new compounds, would not require any additional environmental controls, and would not have any significant impact on greenhouse gas (GHG) emissions. These conclusions are consistent with applicant-provided information that forecasts

manufacturing of the new products to comprise, cumulatively, only a fraction of a percent of the total production at the product manufacturing facility (Confidential Appendix 4).

Based on information in the SE Reports, the product modifications include changes to the tobacco blend, and the flavorings and filler ingredients. While ingredient modification has the highest potential for changing the chemical compounds emitted during manufacturing, the applicant stated that no new compounds would be emitted. The new ingredients (Confidential Appendix 1) are found in consumer products, foods, or industrial processes. The new ingredients do not raise environmental concerns as inputs into manufacturing the new products due to these existing uses.

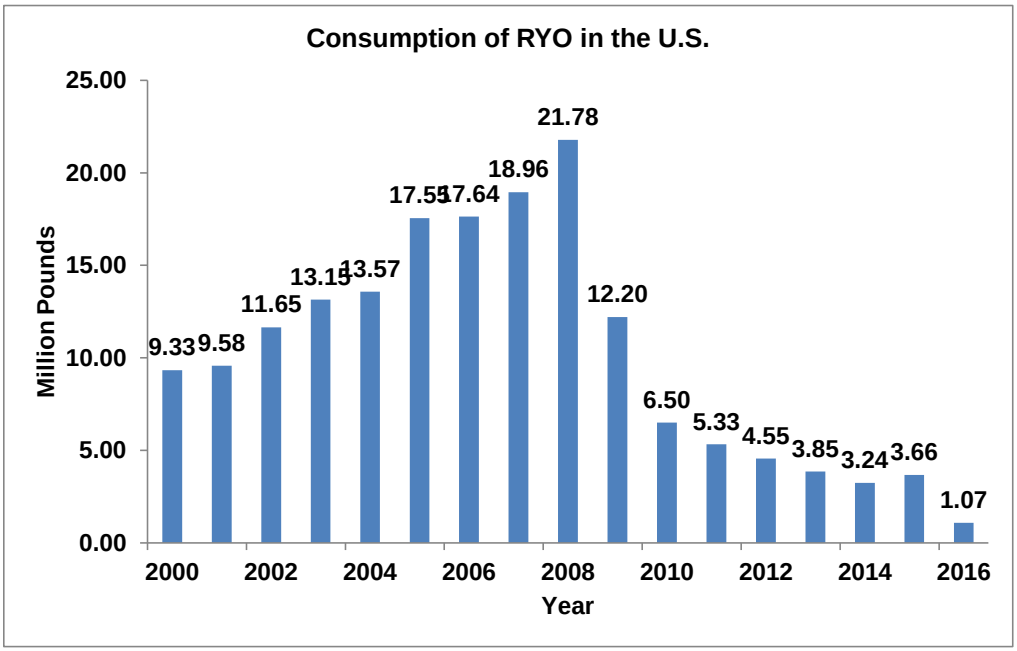
The applicant stated that the new products will compete with other currently marketed RYO products and the cumulative production volume of the new products is a small fraction of total production at the manufacturing facility. Therefore, no effects from increased GHG emissions are anticipated from the proposed actions.

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

5.2.1 Use of RYO Products in the U.S.

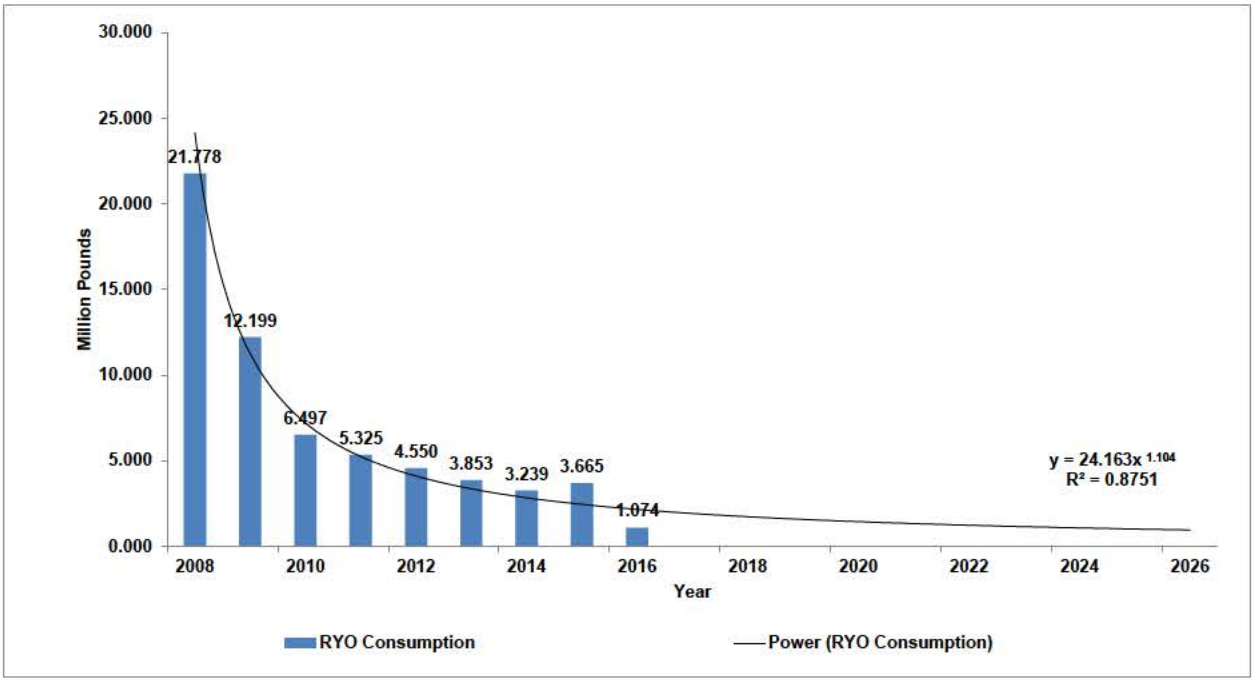
According to the U.S. Alcohol and Tobacco Tax and Trade Bureau's *Tobacco Statistical Release Reports*, the use of RYO tobacco products in the U.S. increased from 9.33 million pounds (4.23 million kilograms) in 2000 to 21.8 million pounds (9.89 million kilograms) in 2008. This was followed by a decrease from 12.2 million pounds (5.53 million kilograms) in 2009 to 1.07 million pounds (0.485 million kilograms) in 2016 (Figure 2) (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2017).

Figure 2. Use of RYO Tobacco Products in the U.S. in 2000–2016



To evaluate the environmental impact of the proposed actions due to use of the new products, the Agency analyzed the historical use data for 2008–2016 to forecast the future use of RYO tobacco products in the U.S. This was achieved by applying one best-fit power trend line with the R^2 value of 0.8751. Using this approach, the forecasted amount of RYO tobacco products to be used in the U.S. is estimated to be 1.902 million pounds (0.8627 million kilograms) in 2017 and 1.312 million pounds (0.5951 million kilograms) in 2021 (Figure 3). The Agency did not account for the historical data from 2000 to 2007 to forecast the future use of RYO tobacco products because there has been a clear overall downward trend in RYO consumption since 2008, whereas the data preceding 2008 showed a trend of annual increases in RYO consumption that is no longer evident.

Figure 3. Projected Use of RYO Tobacco Products in the U.S. in 2017–2021



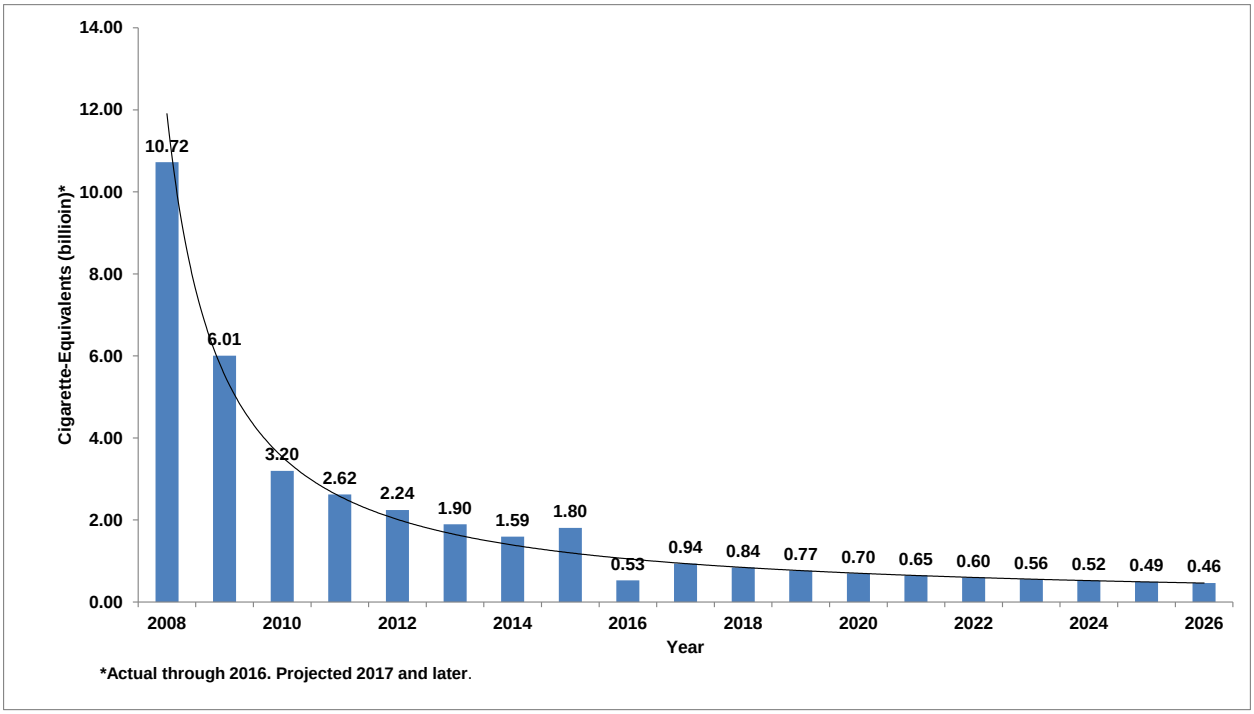
The results are also forecast in units of cigarette-equivalents, based on the assumption that 0.0325 ounces (0.921 grams) of tobacco is used per cigarette (National Association of Attorneys General, 1998) (Figure 4).

Year	RYO Tobacco Products (million pounds) [a]	RYO Tobacco Products (million cigarette-equivalents) [b]
2016	1.074	528.9
First year (2017)	1.902	936.2
Fifth year (2021)	1.312	645.7

[a] Projected first year and fifth year pounds RYO products: $24.163 (\text{year} - 2007)^{-1.104}$

[b] Cigarette-equivalents = RYO tobacco (pounds) x 16 ounces/pound x cigarette/0.0325 ounces RYO tobacco

Figure 4. Projected Use of RYO Cigarette-Equivalents in the U.S. in 2017−2021



When using cigarettes, the users inhale the mainstream smoke and release tobacco smoke to the environment, referred to as secondhand smoke. There is no safe level of exposure to secondhand smoke (U.S. Department of Health and Human Services, 2006a) (U.S. Department of Health and Human Services, 2006b). Even low levels of secondhand smoke can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30 percent (HHS 2006a, 2006b).
- 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 (HHS 2006a, 2006b).
- Secondhand smoke causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

5.2.2 Environmental Introduction from Use of the New Products

The applicant intends to market the new and predicate products after receiving market authorizations for the new products. Because the new products are expected to compete with other RYO products on the market, and represent a small fraction of the total RYO products market in the U.S (Confidential Appendix 5), the Agency anticipates minimal or no net increase in the use of all RYO products. Thus, the Agency also does not anticipate more substances to

be released into the environment from use of the new RYO products relative to the substances released by the predicate products and other RYO products already on the market.

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. The combustion products from the new products would be similar to and released in a similar manner as the combustion products of their predicate products and other RYO tobacco products. The amount of carbon dioxide generated during combustion that contributes to GHG emissions is miniscule (Confidential Appendix 6) and, because the new products will compete with other currently marketed RYO products, no net addition to GHG emissions is anticipated.

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

The environmental consequences from disposal following use of RYO tobacco products are associated with disposal of packaging and discarding the used RYO tobacco products. The Agency believes that the disposal of the new products will be similar to the disposal of other RYO tobacco products that are currently being marketed. After using the new products, the users may recycle the packaging material or dispose of it as MSW or litter. Used RYO tobacco products, consisting of cigarette butts,[1] are usually disposed of as MSW or litter.

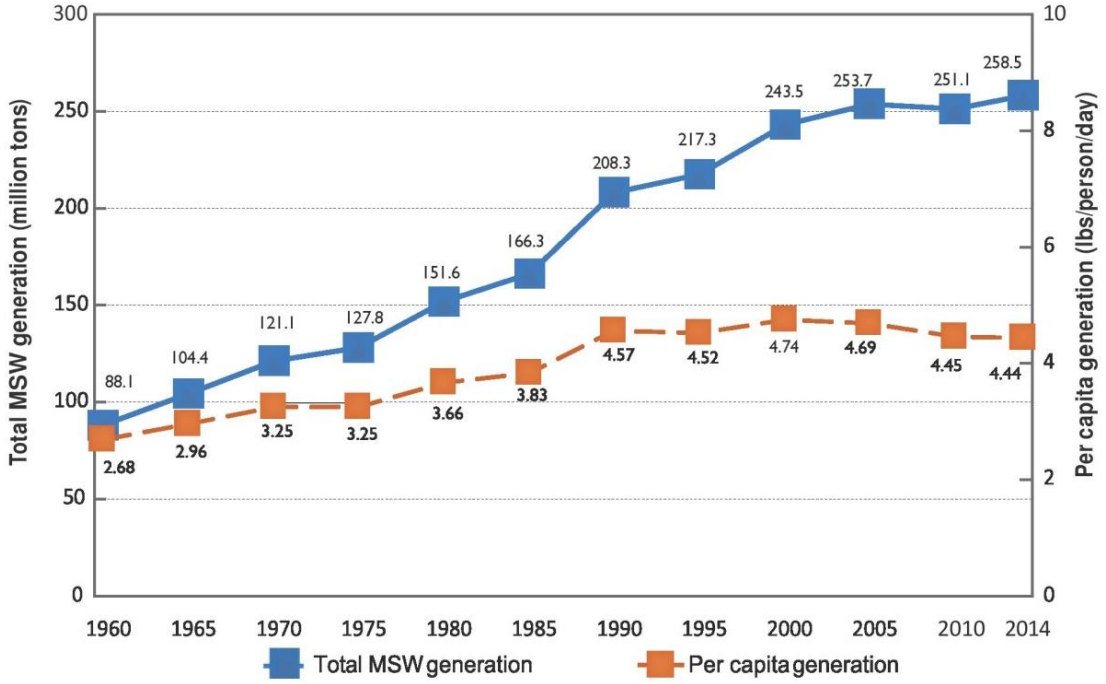
Packaging disposal and properly discarded used products contribute to using landfill capacity and air emissions from landfills. Improperly discarded used products generate litter.

5.3.1 Disposal Following Use of Roll-Your-Own Products

Following use, the packaging materials either would enter the recycling stream or be disposed of as MSW or litter. In 2014, approximately 258.46 million tons (234.47 metric tons) of trash was generated in the U.S., and approximately 89.4 million tons 81.1 million metric tons) of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 5 and 6). Paper and paperboard account for 68.61 million tons (62.24 million metric tons) (26.5%) of the total MSW generated in 2014. Plastics account for 33.25 million tons (30.16 metric tons) (12.9%) of total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (69.55 million metric tons) (29.7%), of which 39.13 million tons (35.50 million metric tons) was made of paper and paperboard. Of the total paper and paperboard MSW, 44.4 million tons (40.3 million metric tons) (64.7%) was recycled, 19.47 million tons (17.66 million metric tons) (28.4%) was disposed of in landfills, and 4.74 million tons (4.30 million metric tons) (6.9%) was combusted with energy recovery. On average, 4.4 pounds (2.0 kilograms) of waste was generated per person per day in the U.S., of which 2.1 pounds (0.95 kilograms) was recycled, composted, or combusted for energy recovery (U.S. Environmental Protection Agency, 2016a).

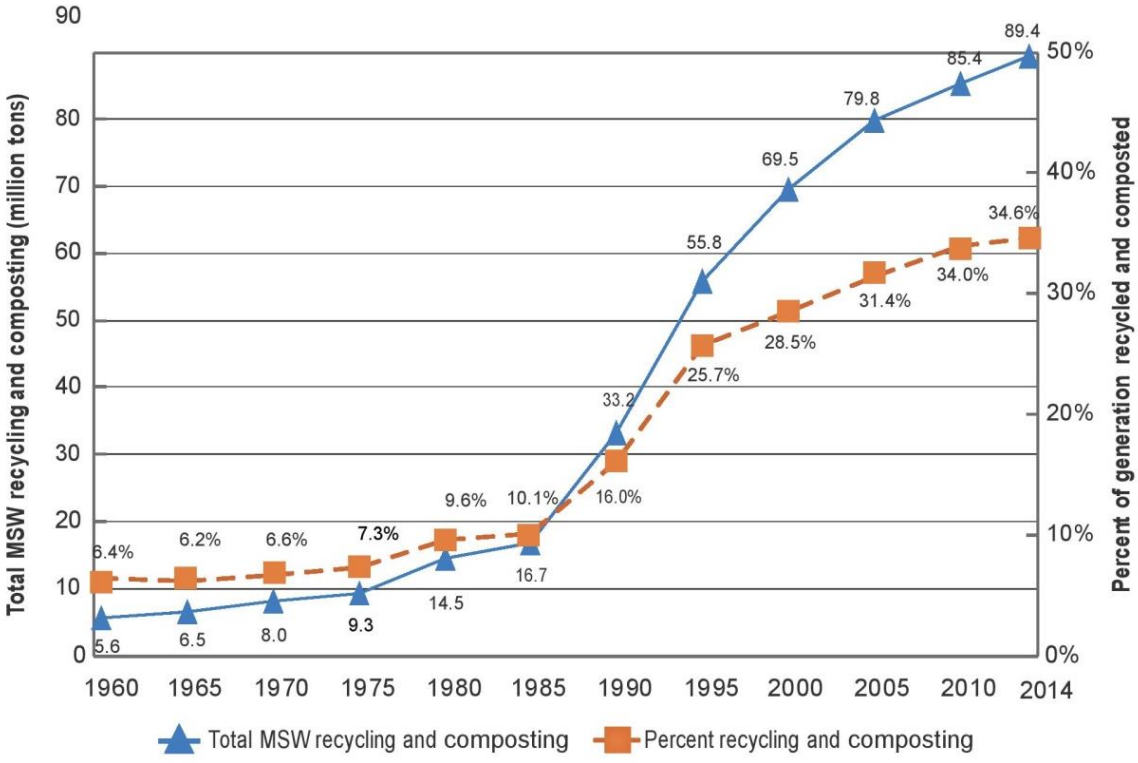
[1] "Cigarette butt" is defined in this PEA as cigarette rolling paper containing remainder tobacco that is disposed of following use. The cigarette butt may or may not also include a filter, depending if the RYO cigarette had one.

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



Source: (U.S. Environmental Protection Agency, 2016b)

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



Source: (U.S. Environmental Protection Agency, 2016b)

The Agency used the projected market volumes for the first and fifth years of marketing to estimate the waste from disposal of packaging and used product material (cigarette butts), accounting for recycling of product waste and overall U.S. recycling of MSW. The estimated waste from packaging and product disposal after use would be miniscule compared to the total MSW forecasted to be discarded in the U.S. (Confidential Appendix 7).

Because the new RYO tobacco products will compete with other similar RYO tobacco products on the market and the estimates described above and detailed in Confidential Appendix 7 indicate a negligible contribution to U.S. MSW, construction of new solid waste landfills or incinerators are not anticipated due to the proposed action.

5.3.2 Environmental Introduction from Disposal Following use of the New Products

Air Emissions from Landfill Disposal of Packaging Waste and Used Products

Landfill disposal or incineration of the used RYO tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs.

Methane is a potent GHG that has a global warming potential 28–36 times greater than carbon dioxide and persists in the atmosphere for about 12 years. Landfills are the third largest source of human-related methane emissions in the U.S., accounting for approximately 15.4% of these emissions in 2015 (U.S. Environmental Protection Agency, 2017). Estimated GHG emissions from disposal of the used products and packaging associated with the new and predicate products are miniscule (Confidential Appendix 6).

Litter from Improperly Discarded Use Products

Cigarette butt waste may have an end-of-life-cycle scenario as either managed or unmanaged waste. Managed waste is handled by an organized solid waste collection and management system. Managed waste is treated as MSW and either incinerated with energy recovery or landfilled. Unmanaged waste consists of littered cigarette butts. For the managed waste, 80.4% by weight enters landfills, and the remaining 19.6% by weight is incinerated for energy recovery (U.S. Environmental Protection Agency, 2016a).

The environmental effects of cigarette butt litter were summarized as follows (Novotny, et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide… The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste... Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Introducing the new products into the U.S. market is not expected to increase the nationwide use of RYO tobacco; instead, they would compete for market share with existing products. Thus, authorizing the new products is not expected to affect the overall level of cigarette butt litter in the U.S., but may displace the level of litter from other RYO products.

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 would be manufactured, used, and disposed of in the same way as other RYO tobacco products. Therefore, the fate of any materials released is anticipated to be the same as any materials from other RYO tobacco products manufactured in the same or similar facilities that are used and discarded in the same manner.

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

The applicant stated that the RYO product manufacturing facility is in compliance with all federal, state, and local environmental regulations; they intend to continue complying with all relevant federal, state, and local environmental regulations; and they are unaware of any violations of any relevant federal, state, and local environmental regulations.

As discussed in sections 5.1 through 5.3, the amount of materials anticipated to enter the environment due to the manufacturing, use, and disposal of the new products are small fractions when compared to that of all RYO tobacco products projected to be manufactured and used in the U.S. No new substances or new types 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 changes in ingredients do not raise concerns related to Endangered Species Act-listed species or critical habitat, or species protected under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (Confidential Appendix 8).

The applicant stated that manufacturing the new products would result in no more than a negligible net increase in energy use. This conclusion is consistent with applicant-provided information that forecasts manufacturing of the new products to comprise, cumulatively, only a fraction of a percent of the total production at the product manufacturing facility (Confidential Appendix 4).

9. Mitigation

The Agency did not identify significant adverse environmental effects for the new products. Therefore, no mitigation measures were developed.

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

RYO tobacco products, as the predicate products and many other similar RYO tobacco products will continue to be marketed.

Alternative B (Proposed actions). There is no significant environmental effect due to the proposed actions of authorizing the new products and the associated manufacturing, use, and disposal following use of the products.

11. List of Preparers

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

Preparers:

Christine M. Modovsky, M.S., Center for Tobacco Products (product-specific analyses)
- Education: M.S. in Environmental Science
- Experience: 29 years in environmental compliance and analysis
- Expertise: NEPA analysis, regulatory compliance, evaluation of environmental health and ecological effects

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- Education: Ph.D. in Plant Molecular Biology and Virology
- Experience: 23 years in various scientific activities
- Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA implementation

Catherine W. McCollum, Ph.D., Center for Tobacco Products (impact analysis framework)
- Education: Ph.D. in Biochemistry and Cell Biology
- Experience: 10 years in various scientific activities
- Expertise: NEPA analysis, environmental impact analysis, ecotoxicity, developmental toxicology

Reviewers:

Hoshing W. Chang, Ph.D., Center for Tobacco Products
- Education: M.S. in Environmental Science and PhD in Biochemistry
- Experience: 8 years in FDA-related NEPA review
- Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

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 Related Amendments Covered Under this Programmatic Environmental Assessment

14. Confidential Appendix List

Confidential Appendix 1: Comparison of the New and Corresponding Predicate Products

Confidential Appendix 2: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products

Confidential Appendix 3: Package Materials and Mass for New and Predicate Products

Confidential Appendix 4: Fraction of Manufacturing for Production of New and Predicate Products

Confidential Appendix 5: Comparison of the U.S. Market Volumes for the New and Predicate Products with Total RYO Tobacco Products

Confidential Appendix 6: Greenhouse Gas Emissions from Use and Disposal of the Products

Confidential Appendix 7: Projected Product and Packaging Waste from Disposal after Use

Confidential Appendix 8: Evaluation of Potential Effects of the Proposed Actions to Protected Species

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APPENDIX 1: Submission Tracking Numbers for the SE Reports and Related Amendments Covered Under this Programmatic Environmental Assessment

Top Tobacco L.P. submitted the 10 SE Reports listed below on March 16, 2011, seeking FDA's market authorization under section 905(j) of the FD&C Act. FDA sent the applicant three Advice/Information letters in November and December 2012. In response, the applicant submitted amendments (listed below) to each original SE Report in December 2012 and January 2013 that included EAs. Subsequent amendments submitted by the applicant in 2014, 2015, and 2016 provided additional product information, including clarifying the names of the new and corresponding predicate products, the size of the rolling papers, and the future marketing status of the predicate products.

SE Report	Product	Amendments				
SE0000169	Real Menthol 3 oz Medium Bag	SE0005264	SE0010213	SE0010147		
SE0000171	Real Silver 8 oz Large Bag	SE0005284	SE0010211			
SE0000187	Top Turkish 0.6 oz Pouch plus one 32-count booklet of rolling papers	SE0005261	SE0010212	SE0010147		
SE0000188	Top Turkish 6 oz Canister plus two 100-count booklets of rolling papers	SE0005279	SE0010214			
SE0000197	Real Menthol 8 oz Large Bag	SE0005254	SE0010213		SE0010255	SE0010202 SE0012047 SE0013704 SE0013735
SE0000207	Real Full Flavor 8 oz Large Bag	SE0005519	SE0010214	SE0010147		
SE0000230	Real Gold 3 oz Medium Bag	SE0005529	SE0010215			
SE0000231	Real Full Flavor 3 oz Medium Bag	SE0005528	SE0010214			
SE0000244	Real Gold 8 oz Large Bag	SE0005868	SE0010215		SE0013724	
SE0000252	Real Silver 3 oz Medium Bag	SE0005876	SE0010211			

CONFIDENTIAL APPENDIX 1: Comparison of the New and Corresponding Predicate Products

The applicant claims that the new products differ from the corresponding predicate products in the following ways: changes to the tobacco blend and changes to the flavorings and filler ingredients. For some products, there are additional changes in package size, package type, or the inclusion of rolling papers.

The applicant provided the product material details for the new and predicate products as listed in the following table. The information listed here is taken directly from the SE Reports and amendments.

New Product				Predicate Product		
STN	**Name**	**Components**	**Materials**	**Name**	**Components**	**Materials**
SE0000169	Real Menthol 3 oz Medium Bag	Tobacco filler	(b) (4)	TOP MENTHOL CANISTER	Tobacco filler	(b) (4)
		Bag			Canister	
		No rolling papers			Rolling papers (2 100-count booklets)	
					Rolling paper booklet covers (2)	
SE0000171	Real Silver 8 oz Large Bag	Tobacco filler		GAM/ ULTLTE, 36 BAGS/ CASE	Tobacco filler	
		Bag			Bag	
SE0000187	Top Turkish 0.6 oz Pouch	Tobacco filler		TOP REG. POUCH	Tobacco filler	
		Pouch			Pouch	
		Rolling papers (1 32-count booklet)			Rolling papers (1 32-count booklet)	
		Rolling paper booklet cover			Rolling paper booklet cover	

New Product				Predicate Product		
STN	**Name**	**Components**	**Materials**	**Name**	**Components**	**Materials**
SE0000188	Top Turkish 6 oz Canister	Tobacco filler	(b) (4)	TOP REG CAN	Tobacco filler	(b) (4)
		Canister			Canister	
		Rolling papers (2 100-count booklets)			Rolling papers (2 100-count booklets)	
		Rolling paper booklet covers (2)			Rolling paper booklet covers (2)	
SE0000197	Real Menthol 8 oz Large Bag	Tobacco filler		TOP MENTHOL CANISTER	Tobacco filler	
		Bag			Canister	
		No rolling papers	NA		Rolling papers (2 100-count booklets)	
			NA		Rolling paper booklet covers (2)	

New Product				Predicate Product		
STN	**Name**	**Components**	**Materials**	**Name**	**Components**	**Materials**
SE0000207	Real Full Flavor 8 oz Large Bag	Tobacco filler	(b) (4)	TOP REG CAN	Tobacco filler	(b) (4)
		Bag			Canister	
		No rolling papers	NA		Rolling papers (2 100-count booklets)	
			NA		Rolling paper booklet covers (2)	
SE0000230	Real Gold 3 oz Medium Bag	Tobacco filler	(b) (4)	TOP LITE CAN	Tobacco filler	(b) (4)
		Bag			Canister	
		No rolling papers	NA		Rolling papers (2 100-count booklets)	
			NA		Rolling paper booklet covers (2)	

New Product				Predicate Product		
STN	Name	Components	Materials	Name	Components	Materials
SE0000231	Real Full Flavor 3 oz Medium Bag	Tobacco filler	(b) (4)	TOP REG CAN	Tobacco filler	(b) (4)
		Bag			Canister	
		No rolling papers	NA		Rolling papers (2 100-count booklets)	
			NA		Rolling paper booklet covers (2)	
SE0000244	Real Gold 8 oz Large Bag	Tobacco filler	(b) (4)	TOP LITE CAN	Tobacco filler	(b) (4)
		Bag			Canister	
		No rolling papers	NA		Rolling papers (2 100-count booklets)	
			NA		Rolling paper booklet covers (2)	
SE0000252	Real Silver 3 oz Medium Bag	Tobacco filler	(b) (4)	GAM/ ULTLTE, 36 BAGS/ CASE	Tobacco filler	
		Bag			Bag	

CONFIDENTIAL APPENDIX 2: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products

STN	Name	Unit	Market Volume (number of units)	
			First Year	Fifth Year
SE0000169	Real Menthol 3 oz Medium Bag	Bag	(b) (4)	
SE0000171	Real Silver 8 oz Large Bag	Bag		
SE0000187	Top Turkish 0.6 oz Pouch	Pouch		
SE0000188	Top Turkish 6 oz Canister	Canister		
SE0000197	Real Menthol 8 oz Large Bag	Bag		
SE0000207	Real Full Flavor 8 oz Large Bag	Bag		
SE0000230	Real Gold 3 oz Medium Bag	Bag		
SE0000231	Real Full Flavor 3 oz Medium Bag	Bag		
SE0000244	Real Gold 8 oz Large Bag	Bag		
SE0000252	Real Silver 3 oz Medium Bag	Bag		

Predicate Products	Name	Unit	Current Year	First Year	Fifth Year
Predicate for SE0000169 and 197	TOP MENTHOL CANISTER	Canister	(b) (4)		
Predicate for SE0000171 and 252	GAM/ULTLTE, 36 BAGS/ CASE	Bag			
Predicate for SE0000187	TOP REG. POUCH	Pouch			
Predicate for SE0000188, 207, and 231	TOP REG CAN	Can			
Predicate for SE0000230 and 244	TOP LITE CAN	Can			

CONFIDENTIAL APPENDIX 3: Package Materials and Mass for New and Predicate Products

Mass of Materials Used in New and Predicate Products				
STN	**Name**	**Packaging**	**Material(s)**	**Mass (g)**
SE0000169	Real Menthol 3 oz Medium Bag	Bag	(b) (4)	
		Paper Insert		
SE0000171	Real Silver 8 oz Large Bag	Bag		
		Paper Insert		
SE0000187	Top Turkish 0.6 oz Pouch	Pouch		
		Overwrap		
		Rolling paper booklet cover		
SE0000188	Top Turkish 6 oz Canister	Canister		
		Insert		
		Rolling paper booklet covers (2 per canister – combined mass)		
SE0000197	Real Menthol 8 oz Large Bag	Bag		
		Paper Insert		
SE0000207	Real Full Flavor 8 oz Large Bag	Bag		
		Paper Insert		
SE0000230	Real Gold 3 oz Medium Bag	Bag		
		Paper Insert		
SE0000231	Real Full Flavor 3 oz Medium Bag	Bag		
		Paper Insert		
SE0000244	Real Gold 8 oz Large Bag	Bag		
		Paper Insert		
SE0000252	Real Silver 3 oz Medium Bag	Bag		
		Paper Insert		
Predicate for SE0000169 and 197	TOP MENTHOL CANISTER	Canister		
		Insert		
		Rolling paper booklet covers (2 per canister – combined mass)		
Predicate for SE0000171 and 252	GAM/ULTLTE, 36 BAGS/ CASE	Bag		
		Paper Insert		
Predicate for SE0000187	TOP REG. POUCH	Pouch		
		Overwrap		
		Rolling paper booklet cover		

Mass of Materials Used in New and Predicate Products				
STN	**Name**	**Packaging**	**Material(s)**	**Mass (g)**
Predicate for SE0000188, 207, and 231	TOP REG CAN	Canister	(b) (4)	
		Insert		
		Rolling paper booklet covers (2 per canister – combined mass)		
Predicate for SE0000230 and 244	TOP LITE CAN	Canister		
		Insert		
		Rolling paper booklet covers (2 per canister – combined mass)		

CONFIDENTIAL APPENDIX 4: Fraction of Manufacturing for Production of New and Predicate Products

STN	Name	Percent of Factory Capacity			
		First Year		Fifth Year	
		Pounds of tobacco	% Capacity [a]	Pounds of tobacco	% Capacity [a]
Smokeless tobacco: Top Tobacco L.P., 204 Top Tobacco Road, Lake Waccamaw, NC 28450					
SE0000169	Real Menthol 3 oz Medium Bag	(b) (4)			
SE0000171	Real Silver 8 oz Large Bag				
SE0000187	Top Turkish 0.6 oz Pouch				
SE0000188	Top Turkish 6 oz Canister				
SE0000197	Real Menthol 8 oz Large Bag				
SE0000207	Real Full Flavor 8 oz Large Bag				
SE0000230	Real Gold 3 oz Medium Bag				
SE0000231	Real Full Flavor 3 oz Medium Bag				
SE0000244	Real Gold 8 oz Large Bag				
SE0000252	Real Silver 3 oz Medium Bag				
	All new products				

[a] Total production capacity of RYO tobacco factory (pounds per year): 6,841,235

CONFIDENTIAL APPENDIX 5: Comparison of the U.S. Market Volumes for the New and Predicate Products with Total RYO Tobacco Products

The current-year, first-year, and fifth-year market volumes (Confidential Appendix 2) of the new and predicate products occupying the U.S. market were compared to the total current and projected RYO tobacco market volumes (Figures 3 and 4 in section 5.2) in the U.S.

STN	Name	Market Volume					
		Current Year		First Year		Fifth Year	
		Pounds of RYO tobacco	% RYO Market [a]	Pounds of RYO tobacco	% RYO Market [a]	Pounds of RYO tobacco	% RYO Market [a]
SE0000169	Real Menthol 3 oz Medium Bag	NA	0%	(b) (4)			
SE0000171	Real Silver 8 oz Large Bag	NA	0%				
SE0000187	Top Turkish 0.6 oz Pouch	NA	0%				
SE0000188	Top Turkish 6 oz Canister	NA	0%				
SE0000197	Real Menthol 8 oz Large Bag	NA	0%				
SE0000207	Real Full Flavor 8 oz Large Bag	NA	0%				
SE0000230	Real Gold 3 oz Medium Bag	NA	0%				
SE0000231	Real Full Flavor 3 oz Medium Bag	NA	0%				
SE0000244	Real Gold 8 oz Large Bag	NA	0%				
SE0000252	Real Silver 3 oz Medium Bag	NA	0%				
Predicate for SE0000169 and 197	TOP MENTHOL CANISTER	(b) (4)					
Predicate for SE0000171 and 252	GAM/ ULTLTE, 36 BAGS/ CASE						
Predicate for SE0000187	TOP REG. POUCH						
Predicate for SE0000188, 207, and 231	TOP REG CAN						
Predicate for SE0000230 and 244	TOP LITE CAN						

[a] Current year RYO tobacco market in U.S.: (b) (4)

Projected first year (2017) RYO tobacco market in U.S.:

Projected fifth year (2021) RYO tobacco market in U.S.:

CONFIDENTIAL APPENDIX 6: Greenhouse Gas Emissions from Use and Disposal of the Products

GHG Emissions from Use of Products

The amount of CO_2-equivalent gases (CO_2-eq) emitted from the use of cigarettes has been estimated to be 45–65 mg per cigarette (Geiss & Dimitrios, 2007). As a conservative approach, the high end of this range was used to calculate the GHG emissions from use of each cigarette-equivalent containing (b) (4) ounces (b) (4) of RYO tobacco (National Association of Attorneys General, 1998) from the new and predicate products. The total GHG emissions were estimated to be (b) (4) metric tons of CO_2-eq for the first year and fifth years, respectively. In each case, this is a negligible fraction (b) (4) of the 6.87 billion metric tons of CO_2-eq estimated to have been generated in the U.S. in 2014.

STN	Name	Metric Tons of CO_2-eq		
		Current Year	First Year	Fifth Year
SE0000169	Real Menthol 3 oz Medium Bag	(b) (4)		
SE0000171	Real Silver 8 oz Large Bag			
SE0000187	Top Turkish 0.6 oz Pouch			
SE0000188	Top Turkish 6 oz Canister			
SE0000197	Real Menthol 8 oz Large Bag			
SE0000207	Real Full Flavor 8 oz Large Bag			
SE0000230	Real Gold 3 oz Medium Bag			
SE0000231	Real Full Flavor 3 oz Medium Bag			
SE0000244	Real Gold 8 oz Large Bag			
SE0000252	Real Silver 3 oz Medium Bag			
Subtotal, new products:				
Predicate for SE0000169 and 197	TOP MENTHOL CANISTER			
Predicate for SE0000171 and 252	GAM/ ULTLTE, 36 BAGS/ CASE			
Predicate for SE0000187	TOP REG. POUCH			
Predicate for SE0000188, 207, and 231	TOP REG CAN			
Predicate for SE0000230 and 244	TOP LITE CAN			
Total, new and predicate products:				
Total U.S. generation of CO_2-eq (2014):				
New and predicate products as a % of total U.S. generation of CO_2-eq:				

GHG Emissions from Disposal of Products

GHG emissions from the product waste and packaging were calculated using the GHG emission rates from the Waste Reduction Model (WARM), v. 14 (U.S. Environmental Protection Agency, 2016c). WARM estimates GHG emissions across different material types commonly found in MSW. Taking into account the rates for recycling, landfill disposal, and combustion with energy recovery of the various material types in the new and predicate products, the total amount of GHG emissions from product waste and packaging disposal was estimated to be (b) (4) metric tons of CO_2-eq for the first year and fifth years, respectively. In each case, this is a negligible fraction (b) (4) or less) of the 6.87 billion metric tons of CO_2-eq estimated to have been generated in the U.S. in 2014.

STN	Name	Metric Tons of CO_2-eq		
		Current Year	First Year	Fifth Year
SE0000169	Real Menthol 3 oz Medium Bag	(b) (4)		
SE0000171	Real Silver 8 oz Large Bag			
SE0000187	Top Turkish 0.6 oz Pouch			
SE0000188	Top Turkish 6 oz Canister			
SE0000197	Real Menthol 8 oz Large Bag			
SE0000207	Real Full Flavor 8 oz Large Bag			
SE0000230	Real Gold 3 oz Medium Bag			
SE0000231	Real Full Flavor 3 oz Medium Bag			
SE0000244	Real Gold 8 oz Large Bag			
SE0000252	Real Silver 3 oz Medium Bag			
	Subtotal, new products:			
Predicate for SE0000169 and 197	TOP MENTHOL CANISTER			
Predicate for SE0000171 and 252	GAM/ ULTLTE, 36 BAGS/ CASE			
Predicate for SE0000187	TOP REG. POUCH			
Predicate for SE0000188, 207, and 231	TOP REG CAN			
Predicate for SE0000230 and 244	TOP LITE CAN			
	Total, new and predicate products:			
	Total U.S. generation of CO_2-eq (2014):			
	New and predicate products as a % of total U.S. generation of CO_2-eq:			

CONFIDENTIAL APPENDIX 7: Projected Product and Packaging Waste from Disposal after Use

To analyze the environmental effects from used product (cigarette butts) and packaging waste due to the proposed action, the Agency estimated the weights of the waste that would be generated from disposal after use of the products in the first and fifth years of marketing. Projected used product and packaging waste is the sum of the cigarette butt and the paper, cardboard, plastic, and mixed materials specific to the packaging for each product (Confidential Appendix 3), as follows:

$$\sum_{i=1}^{15} A_i \text{ (tons)} = \sum_{i=1}^{15} (B_i + C_i + D_i + E_i)$$

$$B_i\text{(tons)} = F \times G_i \times H_i \ (ounces) \times \frac{pound}{16\ ounces} \times \frac{ton}{2{,}000\ pounds}$$

$$C_i\text{(tons)} = I_i \ (pounds) \times \frac{16\ ounces}{pound} \times \frac{package}{M_i \ (ounces)} \times N_i \ (grams) \times O \times \frac{ton}{907{,}184.74\ grams}$$

$$D_i\text{(tons)} = I_i \ (pounds) \times \frac{16\ ounces}{pound} \times \frac{package}{M_i \ (ounces)} \times (P_i \ (grams) + \ Q_i \ (grams) \times R) \times \frac{ton}{907{,}184.74\ grams}$$

$$E_i\text{(tons)} = I_i \ (pounds) \times \frac{16\ ounces}{pound} \times \frac{package}{M_i \ (ounces)} \times S_i \ (grams) \times \frac{ton}{907{,}184.74\ grams}$$

$$G_i = I_i \ (pounds) \times \frac{16\ ounces}{pound} \times \frac{cigarette\text{-}equivalent}{0.0325\ ounces\ RYO\ tobacco}$$

$$H_i \ (ounces) = \frac{J \ (millimeters)}{K_i \ (millimeters)} \times \left(\frac{0.0325\ ounces\ RYO\ tobacco}{cigarette\text{-}equivalent} + \frac{L_i \ (ounces)}{cigarette\text{-}equivalent} \right)$$

A_i = total cigarette butt and packaging waste generated by the new and predicate products (tons)

B_i = cigarette butts generated by the used products (tons)

C_i = cardboard and paper waste generated by the packaging for the new and predicate predicates (tons)

D_i = plastic waste generated by the packaging for the new and predicate predicates (tons)

E_i = mixed and other materials waste generated by the packaging for the new and predicate predicates (tons)

F = fraction of cigarette butts disposed of in MSW = 0.66 (34% are littered)

G_i = cigarette-equivalents for market projection of product

H_i = weight per cigarette butt (ounces)

I_i = market volume projection (pounds)

J = cigarette butt length (millimeters). For filtered cigarettes: the greatest of 23 mm, length of filter + 8 mm, or length of overwrap + 3 mm, from draft 2015 revisions to ISO 3308 intense smoking regimen (Section 7.2.1). For unfiltered cigarettes: 27 mm, from ISO 15592-3:2008(E).

K_i = cigarette rolling paper length (millimeters)

L_i = cigarette rolling paper weight (ounces)

M_i = RYO tobacco per package unit (ounces)

N_i = cardboard/paper insert per package unit (grams)

O = fraction of cardboard paper waste not recycled = 1 - 0.647 = 0.353 (U.S. EPA 2016a)

P_i = plastic film overwrap per package unit (grams)

Q_i = other plastic packaging per unit (grams)

R = fraction of other plastic packaging waste not recycled = 1 - 0.058 = 0.942 (U.S. EPA 2016a)

S_i = mixed and other material packaging per unit (grams)

The product packaging elements are disposed of as MSW or recycled, and the cigarette butts are disposed of as MSW or litter. The Agency estimated the amount of MSW that would be disposed of in landfills or incinerated, after accounting for portions of the paper and plastic packaging being recycled at rates of 64.7% for paper and cardboard products and 5.8% for LLDPE plastic products (U.S. Environmental Protection Agency, 2016a). The total estimated MSW generated from the new and predicate products is [redacted] and [redacted] metric tons) in the first and fifth years of marketing, respectively. This is a negligible fraction (less than [redacted] of the 192,080,000 tons (174,250,000 metric tons) of total MSW generated and not recycled (258,460,000 million tons [234,470,000 metric tons] generated – 66,380,000 million tons [60,220,000 metric tons] recycled) in the U.S. in 2014.

The following tables detail the parameters used in the calculations for MSW generation from the predicate products in the current year, and the new and predicate products in the first and fifth years of marketing the new products.

	STN	Name	S	R	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
Current Year	Predicate for SE0000169 and 197	TOP MENTHOL CANISTER	[redacted]																		
	Predicate for SE0000171 and 252	GAM/ ULTLTE, 36 BAGS/ CASE																			
	Predicate for SE0000187	TOP REG. POUCH																			
	Predicate for SE0000188, 207, and 231	TOP REG CAN																			
	Predicate for SE0000230 and 244	TOP LITE CAN																			
	MSW from disposal of predicate products after use (tons)																				[redacted]
	Total MSW disposed of (not recycled) in U.S. (2014) (tons)																				
	MSW from product disposal as a % of total MSW disposed of in U.S.																				

	STN	Name	S	R	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
First Year	SE0000169	Real Menthol 3 oz Medium Bag	(b) (4)																		
	SE0000171	Real Silver 8 oz Large Bag																			
	SE0000187	Top Turkish 0.6 oz Pouch																			
	SE0000188	Top Turkish 6 oz Canister																			
	SE0000197	Real Menthol 8 oz Large Bag																			
	SE0000207	Real Full Flavor 8 oz Large Bag																			
	SE0000230	Real Gold 3 oz Medium Bag																			
	SE0000231	Real Full Flavor 3 oz Medium Bag																			
	SE0000244	Real Gold 8 oz Large Bag																			
	SE0000252	Real Silver 3 oz Medium Bag																			
																					Subtotal, MSW from disposal of new products after use (tons) (b) (4)
	Predicate for SE0000169	TOP MENTHOL CANISTER	(b) (4)																		
	Predicate for SE0000171	GAM/ ULTLTE, 36 BAGS/ CASE																			
	Predicate for SE0000187	TOP REG. POUCH																			
	Predicate for SE0000188,	TOP REG CAN																			
	Predicate for SE0000230	TOP LITE CAN																			
																					MSW from disposal of new and predicate products after use (tons) (b) (4)
																					Total MSW disposed of (not recycled) in U.S. (2014) (tons)
																					MSW from product disposal as a % of total MSW disposed of in U.S.

	STN	Name	S	R	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
Fifth Year	SE0000169	Real Menthol 3 oz Medium Bag	(b) (4)																		
	SE0000171	Real Silver 8 oz Large Bag																			
	SE0000187	Top Turkish 0.6 oz Pouch																			
	SE0000188	Top Turkish 6 oz Canister																			
	SE0000197	Real Menthol 8 oz Large Bag																			
	SE0000207	Real Full Flavor 8 oz Large Bag																			
	SE0000230	Real Gold 3 oz Medium Bag																			
	SE0000231	Real Full Flavor 3 oz Medium Bag																			
	SE0000244	Real Gold 8 oz Large Bag																			
	SE0000252	Real Silver 3 oz Medium Bag																			
																					Subtotal, MSW from disposal of new products after use (tons) (b) (4)
	Predicate for SE0000169 and 197	TOP MENTHOL CANISTER	(b) (4)																		
	Predicate for SE0000171 and 252	GAM/ ULTLTE, 36 BAGS/ CASE																			
	Predicate for SE0000187	TOP REG. POUCH																			
	Predicate for SE0000188, 207, and 231	TOP REG CAN																			
	Predicate for SE0000230 and 244	TOP LITE CAN																			
																					MSW from disposal of new and predicate products after use (tons) (b) (4)
																					Total MSW disposed of (not recycled) in U.S. (2014) (tons)
																					MSW from product disposal as a % of total MSW disposed of in U.S.

CONFIDENTIAL APPENDIX 8: Evaluation of Potential Effects of the Proposed Actions to Protected Species

The applicant claims that the new products differ from the corresponding predicate products in the following ways: changes to the tobacco blend and changes to the flavorings and filler ingredients. For some products, there are additional changes in package size, package type, or the inclusion of rolling papers. For changes to the tobacco blend and changes to the flavorings and filler ingredients, (b) (4) (components for this flavor are listed in Amendment SE0013704, Exhibit 19) are filler ingredients present in new products but not in the corresponding predicate products. None of these ingredients raise concerns related to Endangered Species Act (ESA)-listed species or critical habitat, or species protected under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). All other product ingredients and packaging components in the new products are present in one or more of the predicate products.

Regarding materials sourcing impacts from the addition of rolling papers to six of the new products for which the corresponding predicates did not include rolling papers, the applicant stated that

> [T]he rolling paper suppliers for the manufacturing facility located in (b) (4) are certified by the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification (PEFC). The FSC certification demonstrates that the products come from responsibly managed sources. The PEFC certification confirms the commitment to curbing deforestation, maintaining biodiversity, and protecting ecologically important forest areas... Accordingly, the manufacture of the Current Products is carried out under controls and standards that protect the environment, including those species and habitats addressed under the ESA and CITES… [W]e have confirmed that no plants used for the manufacture of the Current and Predicate Products are listed as an endangered plant on the CITES list. The FSC Standard for Chain of Custody Certification (FSC-STD-40-004 V2-1 EN) that applies to cigarette paper (and with which [the French facility] complies) also prohibits the use of components made from species listed in CITES Appendices I, II, or III.7.

Therefore, no impacts to ESA- or CITES-listed resource values are anticipated from the proposed actions.