

**Programmatic Environmental Assessment for Market  
Authorizations of Top Tobacco, LP “Top GoldOP GOLD 0.6  
oz Pouch, Top Regular Plain-Vu 0.65 oz Pouch, Top Regular  
0.6 oz Pouch, Top Menthol 0.6 oz Pouch, Top Menthol Plain-  
Vu 0.65 oz Pouch, Gambler Full Flavor 0.6 oz Pouch, Gambler  
Menthol 0.6 oz Pouch, Drum Halfzware Shag 5 oz Canister,  
and Drum Halzware Shag 1.14 oz Pouch”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

September 29, 2017

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This programmatic environmental assessment (PEA) is for the market authorization of roll-your-own (RYO) tobacco bundled with cigarette paper manufactured by Top 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 a submission under section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

**1. Name of Applicant**

Top Tobacco, LP

**2. Address**

2301 Ravine Way  
Glenview, Illinois 60025

**3. Manufacturer**

Top Tobacco, LP  
204 Top Tobacco Road  
Lake Waccamaw, NC 28450

**4. Description of the Proposed Action**

This proposed action is for FDA to issue a market authorization under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of multiple roll-your-own (RYO) tobacco bundled with cigarette papers into interstate commercial distribution in the U.S. The authorization is based on the finding that the new products are substantially equivalent to the corresponding predicate products that were on the market as of February 15, 2007. The applicant intends to market the new and corresponding predicate products simultaneously after receiving market authorization for the new products.

**4.1. Requested Action**

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

**4.2. Need for Action**

Top Tobacco, LP wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the U.S. The applicant claims that the new and corresponding predicate products differ only in product quantity (sec 910(a)(3)(A)(ii) of the FD&C Act). In addition, the applicant claimed that the new and corresponding predicate products are the same in product composition. After considering the SE Report, the Agency shall issue an order pursuant to section 910(a)(2) of the FD&C Act when finding the new products to be substantially equivalent to the corresponding predicate products.

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

##### **4.3.1. Type of Tobacco Products**

Roll-your-own (RYO) tobacco bundled with cigarette papers

##### **4.3.2. Product Names and Original STNs**

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

<b>STN</b>	<b>New Product</b>	<b>Predicate Product</b>
SE0011172	Top® Gold 0.6 oz Pouch	TOP LITE POUCH
SE0011173	Top® Regular Plain-Vu 0.65 oz Pouch	REG-PLAIN VIEW
SE0011174	Top® Regular 0.6 oz Pouch	TOP REG. POUCH
SE0011175	Top® Menthol 0.6 oz Pouch	TOP MENTHOL POUCH 12
SE0011176	Top® Menthol Plain-Vu 0.65 oz Pouch	MENTHOL-PLAIN VIEW
SE0011177	Gambler® Full Flavor 0.6 oz Pouch	GAMBLER. POUCH REG.
SE0011179	Gambler® Menthol 0.6 oz Pouch	GAMBLER. POUCH MEN.
SE0011180	Drum® Halfzware Shag 5 oz Canister	DRUM CAN
SE0011181	Drum® Halfzware Shag 1.14 oz Pouch	DRUM POUCH

##### **4.3.3. Description of the Product Package**

The packaging materials of the new and corresponding predicate products are identical in materials and composition. The new products' packaging consists of either a plastic pouch or steel canister containing the loose tobacco and a booklet of rolling papers. The pouches are wrapped with an overwrap and include a peelable tape. Details of the packaging components for the new products are described in Confidential Appendix 1.

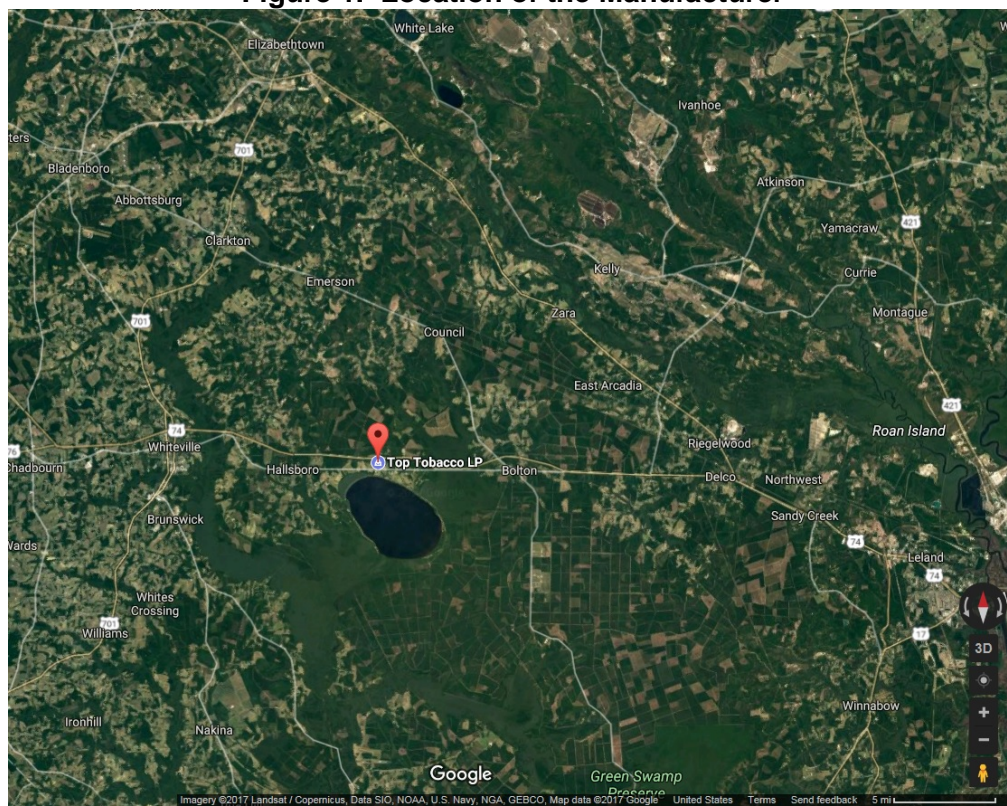
##### **4.3.4. Location of Manufacturing**

Top Tobacco, LP  
204 Top Tobacco Road  
Lake Waccamaw, NC 28450  
(see Figure 1).<sup>1</sup>

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<sup>1</sup> Manufacturer address via aerial photo, Google Earth. Accessed 04/04/2016.

**Figure 1. Location of the Manufacturer**



Manufacturer address via Google Maps. Accessed August 16, 2017.

The cigarette rolling papers are manufactured overseas (Confidential Appendix 2). The cigarette rolling papers are shipped to the Top Factory for final product packaging.

#### **4.3.5. Location of Use**

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

#### **4.3.6. Location of Disposal**

Once used, the new tobacco products will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as the corresponding predicate products and any other RYO products. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates the distribution of waste from disposal after use will correspond to the pattern of the product use (further detail on pathway of disposal is provided in section 5.3.2).

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

The applicant claims that a difference in product quantity is the only difference between the new and corresponding predicate products (Appendix 1).

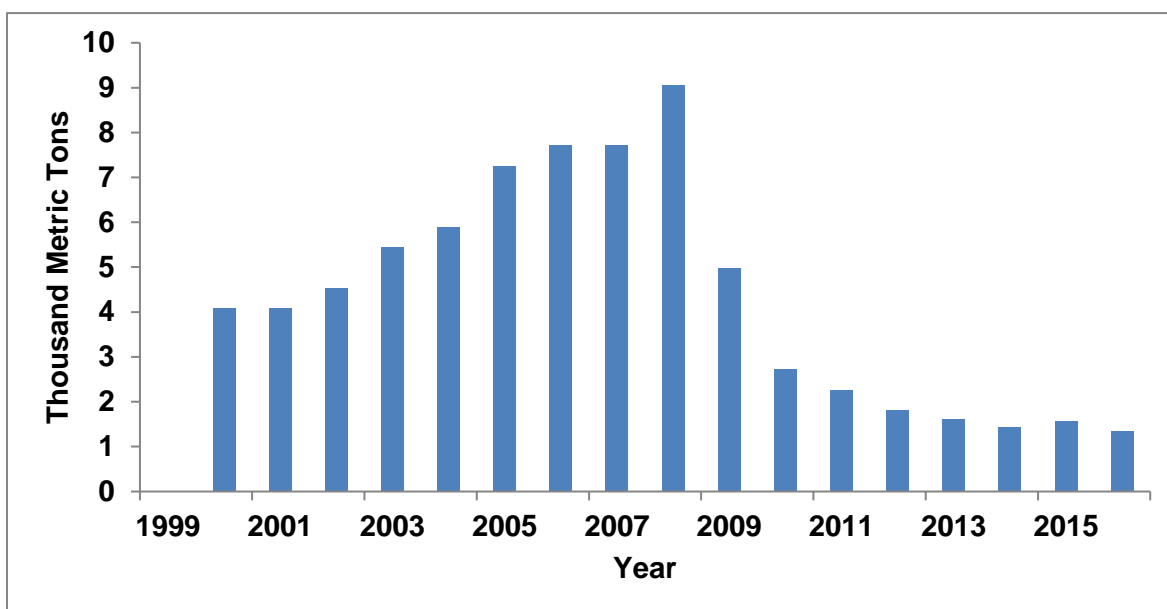
## 5. Environmental Introduction Due to the Proposed Action

### 5.1. Introduction as a Result of Manufacturing the New Tobacco Product

#### 5.1.1. Tobacco Manufacture in the U.S. and Pollution Emission by Top Tobacco's Waccamaw Facility

Tobacco Manufacturing in the U.S. As of June 2017, a total of 1242 tobacco production establishments are registered under 915(c) of the FD&C Act. These manufacturers produced 1349 metric tons of RYO tobacco in 2016 with a decline starting in 2009 (Figure 2) [1]. As of June 2017, 29 different tobacco manufacturers were registered as a "non-participating manufacturer" under the Master Settlement Agreement and 128 were registered as a "participating manufacturer" in the State of North Carolina, including Top Tobacco, LP [2].

**Figure 2. Total RYO Tobacco Manufactured in the U.S. 1999-2016**



#### Ammonia and Nicotine, Including Nicotine Salts from Tobacco Manufacturing Facilities.

The emission information associated with all tobacco products as reported in the EPA's Toxic Release Inventory (TRI) database is publicly available.<sup>2</sup> In 2015, U.S. tobacco

<sup>2</sup> The estimation is done by using the Toxics Release Inventory (TRI), a dataset (<http://www.epa.gov/tri/>) compiled by the U.S. Environmental Protection Agency (EPA). This database allows users to retrieve information on toxic chemicals handled by many facilities across the U.S., including details on quantities of chemicals managed through disposal or other release, recycling, energy recovery or treatment. Data associated with the tobacco manufacturing industry is retrieved by using North American Industry Classification System (NAICS) codes beginning with 3122. Not all toxic release data of tobacco manufacturers are included in the database. The database includes information from any facility that (1) falls within a TRI-reportable industry sector or is federally-owned or operated; (2) has 10 or more full-time (or equivalent) employees; and (3) manufactures, processes or otherwise uses (MPOU) a TRI-listed chemical

manufacturers released 475,000 pounds of ammonia and 280,000 pounds of nicotine and nicotine salts to the air<sup>3</sup>; no ammonia and 72,900 pounds of nicotine and nicotine salts to the land<sup>4</sup>; 220 pounds of ammonia and 279 pounds of nicotine and nicotine salts to the water<sup>5</sup>; and 19,550 pounds of ammonia and 83,384 pounds of nicotine and nicotine salts transferred to publicly owned treatment works (POTWs) or an off-site location.<sup>6</sup> This database does not include all tobacco manufacturers as all are not TRI-reportable facilities. A search in the TRI database indicates that the Top Tobacco Lake Waccamaw facility is not TRI-reportable in 2015<sup>7</sup>. Therefore, no waste information for this facility specifically is available.

### 5.1.2. Environmental Introduction from Manufacturing the New Tobacco Product

*Introduction from Manufacturing the New Products in the Proposed Action.* The Agency anticipates the waste generated as a result of manufacturing the new RYO tobacco products will be released to the environment, transferred to POTWs, and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other RYO tobacco products manufactured in the U.S..

Based on information in the SE Reports, the only difference between the new and corresponding predicate products is a decrease in the quantity of tobacco (Appendix 1). Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products.

The applicant stated that the new products comprise a very small fraction of the total volume of production at these facilities (Confidential Appendix 3). In addition, the applicant claimed that the new products are intended to compete with and (b) (4). The applicant claimed that no expansion of the manufacturing facility is anticipated for manufacturing the new products, (b) (4). Therefore, the Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the production of all RYO tobacco products.

Because the applicant claimed that the new products are intended to compete with and (b) (4), no addition of air emissions (e.g., greenhouse gases (GHG), and sulfur and nitrogen containing compounds) is anticipated. In addition, the applicant claimed that the facility is in compliance with all

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<https://www.epa.gov/sites/production/files/documents/TRIListChangesUpdate11282011.pdf>) in an amount above the TRI reporting threshold during a calendar year.

<sup>3</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=air\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=air_total_release)

<sup>4</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=land\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=land_total_release)

<sup>5</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=water\\_total\\_release](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=water_total_release)

<sup>6</sup> [http://oaspub.epa.gov/enviro/ef\\_metadata.html.tri\\_page?p\\_column\\_name=off\\_site\\_total\\_transfers](http://oaspub.epa.gov/enviro/ef_metadata.html.tri_page?p_column_name=off_site_total_transfers)

<sup>7</sup> Information accessed from the "Find TRI Facilities" function (located at <https://www.epa.gov/toxics-release-inventory-tri-program>) using the reported manufacturer address (above) and choosing the R.J. Reynold Tobaccoville facility from the resulting map. Search performed August 9, 2017.

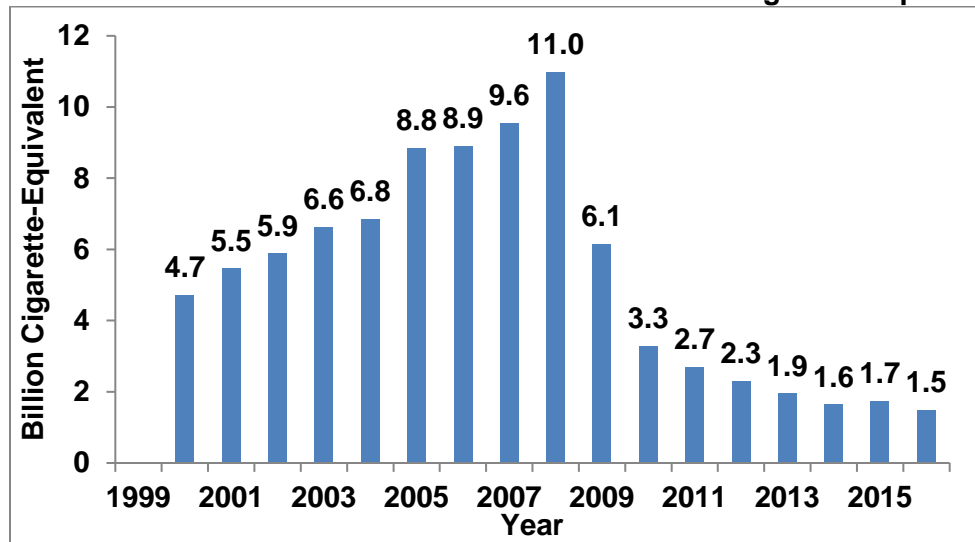
applicable laws and regulations including local and regional emissions, solid waste, liquid waste, and GHG emissions regulations.

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

### 5.2.1 Use of RYO Tobacco Products

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

**Figure 3. Use of RYO in the U.S. in 2000 – 2016 in Billion Cigarette-Equivalents**



The new products are intended to be constructed into cigarettes by the consumer. 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 [4, 5]. 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 [6].
- 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; it can cause coughing, wheezing, phlegm, and breathlessness [4, 5].
- Secondhand smoke causes more than 40,000 deaths a year [6].

### 5.2.2 Environmental Introduction from the Use of the New Products

The applicant intends to (b) (4)

(b) (4). Because the new products are expected to compete with and (b) (4), the Agency

anticipates minimal or no net increase in the use of all RYO products. Additionally, the new products make up a small fraction of the total RYO products used in the U.S. (Confidential Appendix 4). Subsequently, the Agency does not anticipate new substances to be released into the environment as a result of use of the new RYO products, relative to the substances released by the corresponding predicate products already on the market because the only change in the new products compared to the corresponding predicate products is in product quantity. There are no physical property changes between the new and corresponding predicate products; no new substances would be released into the environment.

Subsequently, the Agency does not anticipate new substances to be released into the environment as a result of use of the new RYO products, relative to the substances released by the corresponding predicate products and other RYO products already on the market.

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

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

#### **5.3.1 Disposal Following Use of RYO Tobacco and Rolling Paper**

##### **(a) Disposal of Packaging Material**

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the U.S., and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 4 and 5). 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[7].

**Figure 4. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960-2014**

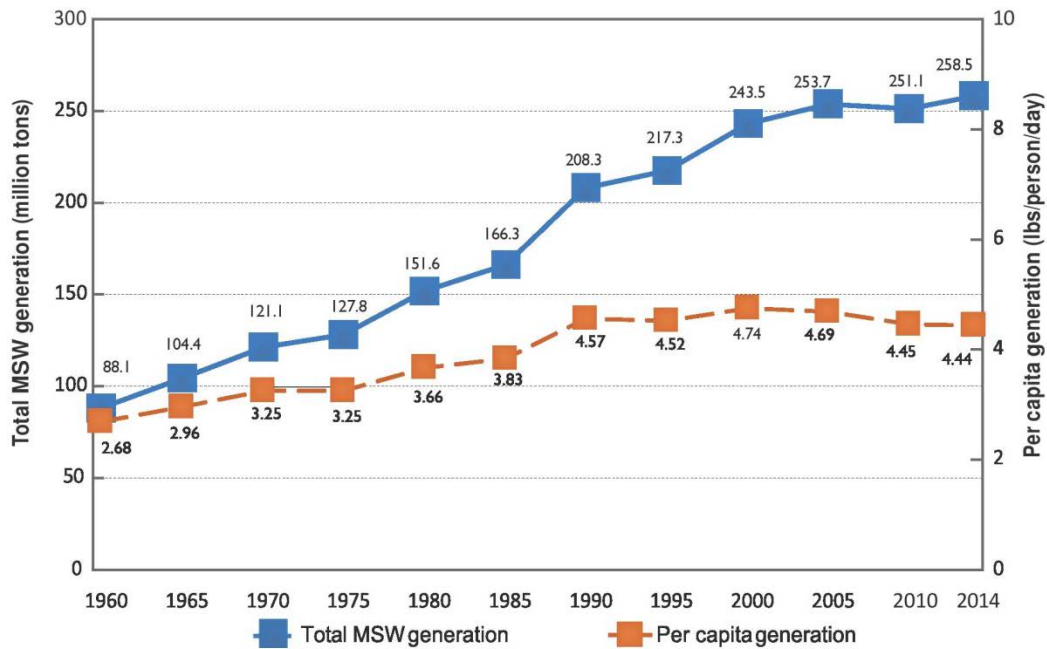


Figure from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

**Figure 5. MSW Recycling Rates in the U.S., 1960-2014**

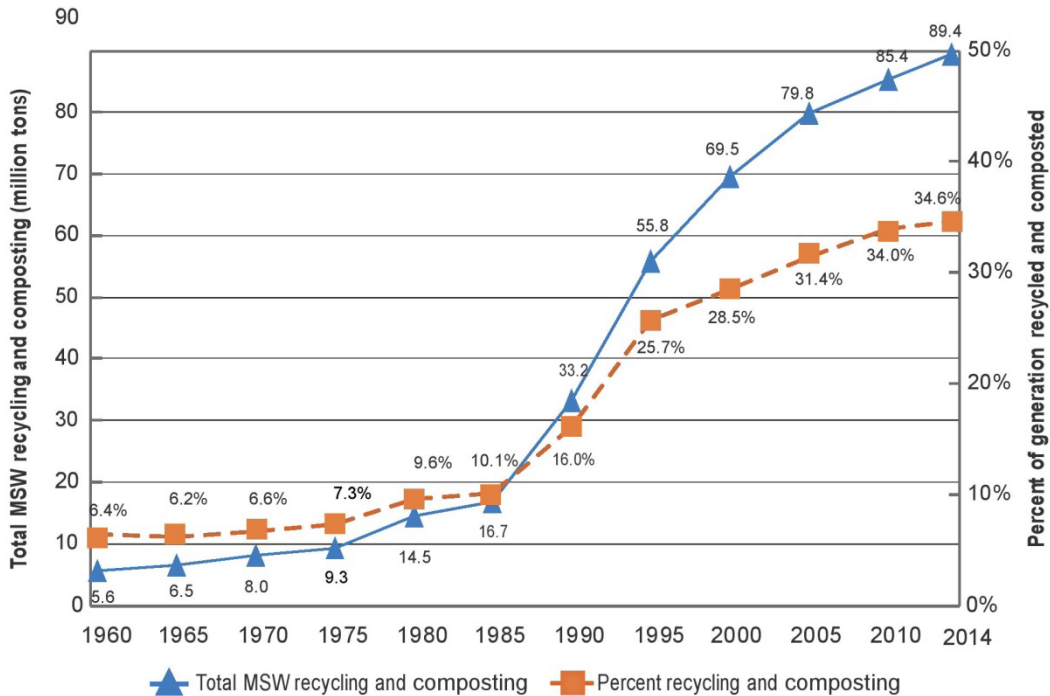


Figure from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

(b) Disposal of Used RYO Tobacco Paper Following Use

Because RYO papers can be consumed with or without filters, like cigarettes, the end of life pathway of RYO tobacco products is assumed to have the same pathway as filtered or unfiltered cigarette waste (cigarette butts).

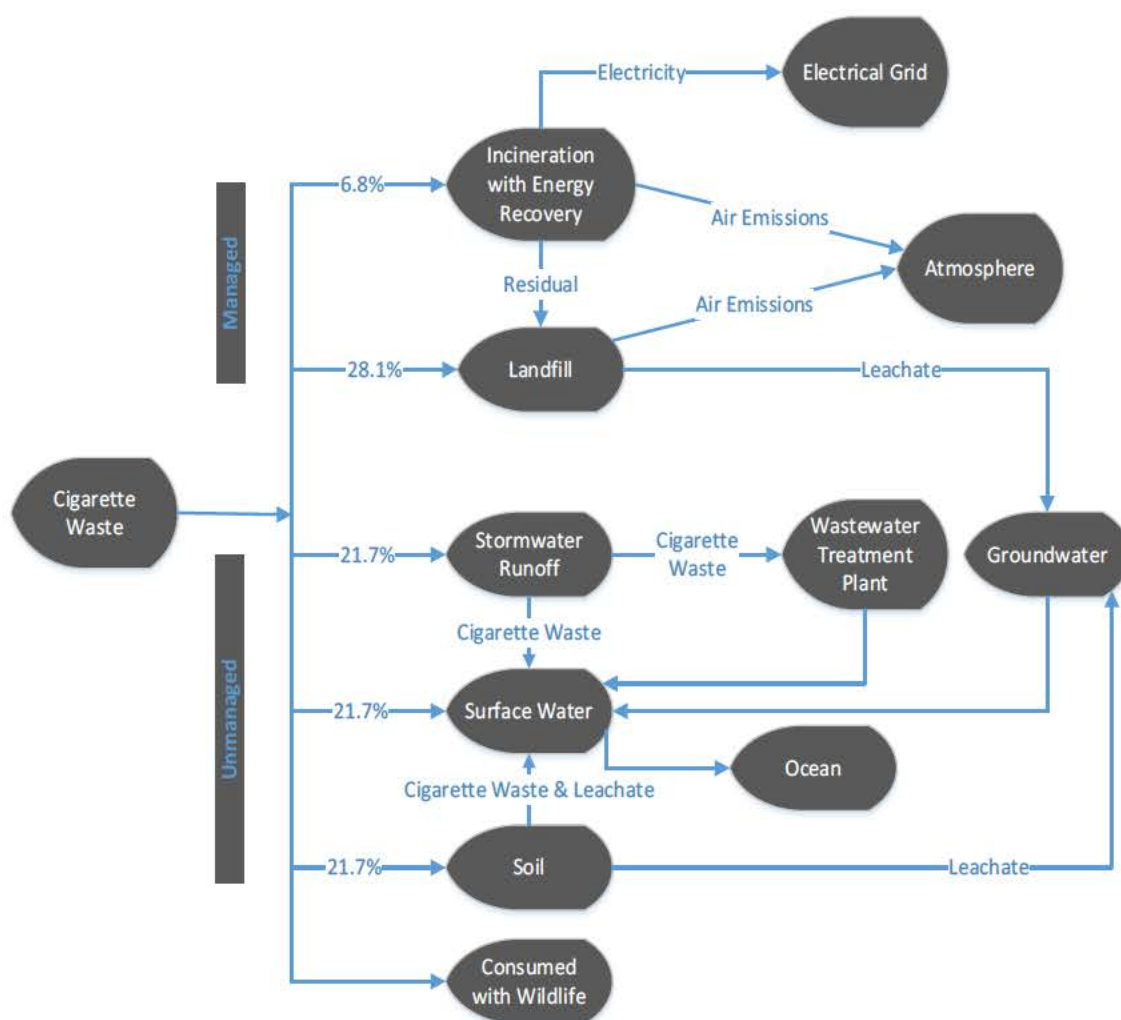
At the end of life, cigarette butt waste usually undergoes a series of scenarios for both managed and unmanaged waste (Figure 6). The managed waste is the waste that is handled by an organized solid waste collection and management system. The managed waste is treated as municipal solid waste (MSW) and either incinerated with energy recovery or landfilled. The unmanaged waste is the result of users littering cigarettes. According to a report published by “Keep America Beautiful”, a study of 767 smokers showed 35% of used cigarettes were disposed of properly (with MSW) with a resulting 65% littering rate for cigarette butts[5]. This study was done by observing the cigarettes users’ behavior in 44 locations.<sup>8</sup>

For the managed waste, 80.4% by-weight of the managed waste enters landfills, and the remaining 19.6% by-weight is incinerated for energy recovery [6]; that is, approximately 28.1% by-weight ( $80.4\% \times 35\%$ ) of the total cigarette waste enters the landfills and 6.8% by-weight ( $19.6\% \times 35\%$ ) of the total cigarette waste enters the incinerators. For the unmanaged waste, the Agency assumes that cigarette butt waste enters the storm water runoff, surface water, and soil in equal amounts; that is, 21.7% each by-count of total cigarette butt waste (8).

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<sup>8</sup> Including city center, retail, medical/hospital, gas station, bar/restaurant, recreational, and rest area settings.

**Figure 6. End of life pathways for cigarette waste**



Note that the percentages indicate the likelihood of a cigarette butt following each end of life pathway.

### (c) Air Emissions

The used tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs. Methane ( $\text{CH}_4$ ) is a potent GHG that has a global warming potential of 28-36 times greater than  $\text{CO}_2$ , and has an atmospheric life of about 12 years. Global  $\text{CH}_4$  emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related  $\text{CH}_4$  emissions in the U.S., releasing an estimated 115.7 million metric tons of  $\text{CO}_2$ -equivalents, accounting for approximately 15.4% of total  $\text{CH}_4$  emissions in 2015 [8]. The decomposition of landfill waste produces approximately 50% biogenic  $\text{CO}_2$  and 50%  $\text{CH}_4$ , by volume, as well as trace amounts of non- $\text{CH}_4$  organic compounds and volatile organic compounds. However, only  $\text{CH}_4$  generation and emissions are estimated and reported for landfills, a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines [9].

### **5.3.2 Environmental Introduction from Disposal Following Use of the New Product**

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other RYO tobacco products that are currently being marketed and will be transported under the similar pathways discussed above.

To determine the amount of waste due to disposal of packaging material and product material, the Agency used the projected market volumes in the first and fifth years after issuance of marketing orders for the new products (Confidential Appendix 5). The calculated waste of the packaging materials of the new products were determined to be miniscule compared to the forecasted MSW to be generated in the U.S. (Confidential Appendix 1). In addition, paper components are more likely to be recycled; at least a portion of the new products' waste is likely to be recycled.

As previously discussed, because the applicant states that the (b) (4) and based on the above-mentioned information regarding waste, construction of new POTWs or landfills is not anticipated due to the proposed action.

The waste generated from using the new products is expected to make up a negligible fraction of the total MSW. The Clean Air Act requires that all landfills constructed or modified after July 17, 2014 that have a waste capacity of 2.5 million metric tons or more have landfill gas collection-and-control systems installed. Additionally, all landfills must report GHG emissions to the EPA under 40 CFR 98. No additional control of any emissions is anticipated in the landfills.

Comparing the projected market volume of the new products with the forecasted total U.S. MSW, the projected waste generated from use of the new products is a negligible fraction of the total MSW. Therefore, the GHG emitted from the waste associated with the new products is negligible and no additional control of air emissions is anticipated in the landfills.

## **6. Fate of Materials Released into the Environment Due to the Proposed Action**

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment because the new products are anticipated to be manufactured, used, and disposed of in the same way as other RYO tobacco products. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other RYO tobacco products manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use because the new products have identical properties to the corresponding predicate products and will be made using the same materials, ingredients and processes as the predicate products.

## **7. Environmental Effects of New Materials Released into the Environment due to the Proposed Action**

The applicant stated that the manufacturing facilities are in compliance with all local and federal environmental laws. Therefore, cumulative introduction of materials released into the environment is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

As discussed above, the amount of materials anticipated to enter the environment due to the manufacturing and use of the new products are a small fraction when compared to the total RYO tobacco products manufactured and used in the U.S. The Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all RYO tobacco products. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction of the total forecasted MSWs in the U.S. Consequently, no new substances or new type of emissions are expected to be released, and therefore no new environmental controls are needed. No new environmental effects are anticipated due to the new products.

## **8. Use of Resources and Energy**

The new products will (b) (4). The applicant also stated that the proposed actions will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total RYO market volumes in the U.S., the Agency found that the projected market volumes of the new products are a small fraction of the total forecasted market volume for RYO tobacco products in 2017 and 2021. Because the applicant stated that (b) (4) no increase of overall RYO tobacco product market volume and no net increase of energy use will be expected from the proposed actions. No additional use of resources and energy is anticipated.

## **9. Mitigation**

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

## **10. Alternatives to the Proposed Actions**

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

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

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

## **11. List of Preparers**

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment.

### **Preparer:**

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

Education: PhD in Environmental Science and Management

Experience: Four years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of heavy metals, and soil, sediment, and water quality

### **Reviewer:**

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

Education: PhD, in Biochemistry and M.S. in Environmental Science

Experience: Nine years in NEPA practice

Expertise: Waste water treatment, environmental impact analysis

## **12. List of Agencies and Persons Consulted**

Not applicable.

## **13. Appendix List**

- Appendix 1: Submission Tracking Numbers for the SE Reports and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)
- Appendix 2: Forecast of Use of RYO Tobacco Products in the U.S.

## **14. Confidential Appendix List**

- Confidential Appendix 1: The First- and Fifth-Year Projection of Paper and Cigarette Butt Waste of Packaging Materials and Product Materials Associated with Marketing the New and Predicate Products
- Confidential Appendix 2: Location of RYO Paper Manufacturing Facility
- Confidential Appendix 3: Comparison of the New Products to the Manufacturer's Total Annual Production
- Confidential Appendix 4: Comparison of the First- and Fifth-Year Market Volume Projections for the New and Predicate Products with Total RYO Tobacco Products Used in the U.S.
- Confidential Appendix 5: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products

## 15. References

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9. Intergovernmental Panel on Climate Change (IPCC) *2006 IPCC Guidelines for National Greenhouse Gas Inventories*. 2006; Available from: <http://www.ipcc-nggip.iges.or.jp/public/2006gl/>. Accessed July 20, 2017.

## APPENDIX 1

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

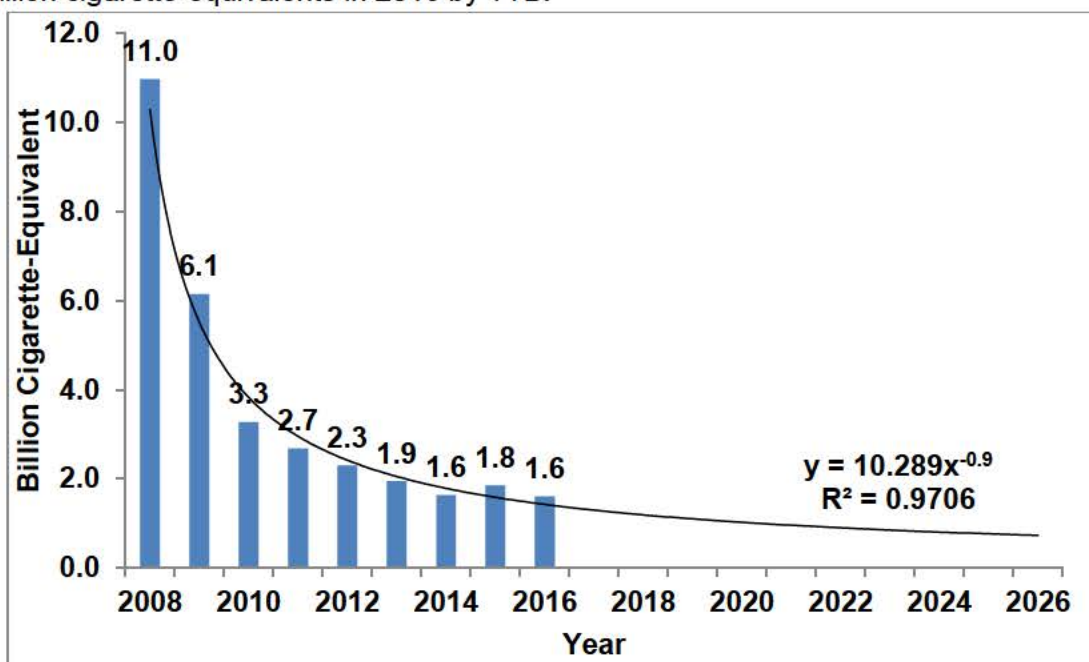
STN	New Product Name	Product	Weight of Tobacco (oz)	Papers per Booklet	Amendments
SE0011172	Top® Gold 0.6 oz Pouch	New	0.6	32	SE0011721 SE0011752 SE0011759 SE0011895 SE0014028 SE0014220
		Predicate	0.75	32	
SE0011173	Top® Regular Plain-Vu 0.65 oz Pouch	New	0.65	32	
		Predicate	0.75	32	
SE0011174	Top® Regular 0.6 oz Pouch	New	0.6	32	
		Predicate	0.75	32	
SE0011175	Top® Menthol 0.6 oz Pouch	New	0.6	32	
		Predicate	0.75	32	
SE0011176	Top® Menthol Plain-Vu 0.65 oz Pouch	New	0.65	32	
		Predicate	0.75	32	
SE0011177	Gambler® Full Flavor 0.6 oz Pouch	New	0.6	32	
		Predicate	0.65	32	
SE0011179	Gambler® Menthol 0.6 oz Pouch	New	0.6	32	
		Predicate	0.65	32	
SE0011180	Drum® Halfzware Shag 5 oz Canister	New	5	200	
		Predicate	5.29	200	
SE0011181	Drum® Halfzware Shag 1.14 oz Pouch	New	1.14	50	
		Predicate	1.41	50	

## APPENDIX 2

### Forecast of Use of RYO Tobacco Products in the U.S.

To evaluate the environmental impact of the proposed action due to use of the new products, the Agency utilized the historical data of RYO tobacco product use in 2008–2016 to forecast the use of RYO tobacco products in the U.S. This was achieved by using one best-fit power trend line with the  $R^2$  value of 0.97.<sup>9</sup>

Using trend lines, the forecast of use of RYO tobacco products in the U.S. was estimated mathematically. Accordingly, the forecasted amount of RYO tobacco products to be used in the U.S. is estimated to be 1.2 billion cigarette-equivalents in 2017 and 0.9 billion cigarette-equivalents in 2021.<sup>10</sup> The amount of RYO tobacco products used in the U.S. is estimated to be 1.5 billion cigarette-equivalents in 2016 by TTB.



Year <sup>11</sup>	RYO Tobacco Products (Billion Cigarette-Equivalent)	RYO Tobacco Products (Metric Tons)
2016	1.5	1,334
1 <sup>st</sup> Year (2017)	1.2	1,120
5 <sup>th</sup> Year (2021)	0.9	820

<sup>9</sup> Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 20, 2017.

<sup>10</sup> Billion cigarette-equivalent value is calculated based on the assumption that approximately 0.9 grams of tobacco is used per cigarette. Billion cigarette-equivalent =  $\frac{(X \text{ million pounds tobacco} \times 10^6) \times (\frac{453.59 \text{ g}}{0.9 \text{ g}})}{10^9}$

<sup>11</sup> 1<sup>st</sup> Year in billion cigarette-equivalent =  $10.496 \times 10 \text{EXP}(-0.926) = 1.2$

5<sup>th</sup> Year in billion cigarette-equivalent =  $10.496 \times 14 \text{EXP}(-0.926) = 0.9$

## CONFIDENTIAL APPENDIX 1

### The First- and Fifth-Year Projection of Paper and Cigarette Butt Waste of Packaging Materials and Product Materials Associated with Marketing the New and Predicate Products

To analyze the environmental effects from packaging and cigarette butt waste due to the proposed actions, the Agency estimated the first- and fifth-year weights of the projected packaging and product materials waste (in metric tons) that would be generated from disposal after use of the RYO products in 2017 and 2021. Projected waste generation is the summation of the projected booklet cover, plastic, pouch or canister, and cigarette butt<sup>19</sup> waste generation of the new and corresponding predicate products:

$$\sum_{i=1}^9 A_i = \sum_{i=1}^9 (B_i + C_i + D_i + E_i + F_i)$$

$$B_i = G_i \times H_i \times I_i \times P$$

$$C_i = G_i \times J \times P$$

$$D_i = G_i \times K_i \times P$$

$$E_i = G_i \times L_i \times P$$

$$F_i = G_i \times I_i \times (N_i \times 0.9 + N_i \times O_i) \times P$$

$$N_i = \frac{27}{M_i}$$

$A_i$ : Projected total waste generation of the products (metric tons)  
 $B_i$ : Projected booklet cover waste generation of the products (metric tons)  
 $C_i$ : Projected plastic waste generation of the products (metric tons)  
 $D_i$ : Projected pouch waste generation of the products (metric tons)  
 $E_i$ : Projected canister waste generation of the products (metric tons)  
 $F_i$ : Projected cigarette butt<sup>12</sup> waste of the products (metric tons)  
 $G_i$ : Projected market volume of the products (# of units)  
 $H_i$ : Weight of empty booklet cover (grams)  
 $I_i$ : Number of rolling papers per booklet  
 $J_i$ : Weight of overwrap (grams)  
 $K_i$ : Weight of empty pouch (grams)  
 $L_i$ : Weight of empty canister (grams)  
 $M_i$ : Length of rolling paper (millimeters)  
 $N_i$ : Cigarette butt ratio (%)<sup>13</sup>  
 $O_i$ : Weight of rolling paper (grams per leaf)  
 $P$ :  $1.0 \times 10^{-6}$  metric tons/gram

<sup>12</sup> Cigarette butt in this EA is defined as cigarette rolling paper containing remainder tobacco that is disposed of following use. The cigarette butt waste takes into account the weight of the paper and the tobacco (one cigarette is assumed to have 0.9 g of tobacco).

<sup>13</sup> 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 as solid waste following use.

First Year	STN	Weight of rolling paper $O_i$	Cigarette butt ratio $N_i$	Length of rolling paper $M_i$	Weight of canister $L_i$	Weight of pouch $K_i$	Weight of overwrap $J_i$	# rolling papers per booklet $I_i$	Weight of booklet $H_i$	Market volume $G_i$	Cigarette butt waste $F_i$	Canister waste $E_i$	Pouch waste $D_i$	Plastic waste $C_i$	Booklet cover waste $B_i$	Total waste $A_i$
	SE0011172	0.060	38.57	70	-	6.6	1	32	0.7	(b) (4)						
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011173	0.060	38.57	70	-	3.8	1	32	0.7							
	Predicate	0.060	38.57	70	-	3.8	1	32	0.7							
	SE0011174	0.060	38.57	70	-	6.6	1	32	0.7							
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011175	0.060	38.57	70	-	6.6	1	32	0.7							
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011176	0.060	38.57	70	-	3.8	1	32	0.7							
	Predicate	0.060	38.57	70	-	3.8	1	32	0.7							
	SE0011177	0.060	38.57	70	-	6.6	1	32	0.7							
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011179	0.060	38.57	70	-	6.6	1	32	0.7							
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011180	0.060	39.13	69	108.8	-	-	200	1.2							
	Predicate	0.060	39.13	69	108.8	-	-	200	1.2							
	SE0011181	0.060	39.13	69	-	6.6	1	50	1.2							
	Predicate	0.060	39.13	69	-	6.6	1	50	1.2							
	First-Year Total Paper, Plastic, Steel, and Cigarette Butt Waste for New and Predicate Products (metric tons)															(b) (4)

Fifth Year	STN	Weight of rolling paper $O_i$	Cigarette butt ratio $N_i$	Length of rolling paper $M_i$	Weight of canister $L_i$	Weight of pouch $K_i$	Weight of overwrap $J_i$	# rolling papers per booklet $I_i$	Weight of booklet $H_i$	Market volume $G_i$	Cigarette butt waste $F_i$	Canister waste $E_i$	Pouch waste $D_i$	Plastic waste $C_i$	Booklet cover waste $B_i$	Total waste $A_i$
	SE0011172	0.060	38.57	70	-	6.6	1	32	0.7	(b) (4)						
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011173	0.060	38.57	70	-	3.8	1	32	0.7							
	Predicate	0.060	38.57	70	-	3.8	1	32	0.7							
	SE0011174	0.060	38.57	70	-	6.6	1	32	0.7							
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011175	0.060	38.57	70	-	6.6	1	32	0.7							
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011176	0.060	38.57	70	-	3.8	1	32	0.7							
	Predicate	0.060	38.57	70	-	3.8	1	32	0.7							
	SE0011177	0.060	38.57	70	-	6.6	1	32	0.7							
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011179	0.060	38.57	70	-	6.6	1	32	0.7							
	Predicate	0.060	38.57	70	-	6.6	1	32	0.7							
	SE0011180	0.060	39.13	69	108.8	-	-	200	1.2							
	Predicate	0.060	39.13	69	108.8	-	-	200	1.2							
	SE0011181	0.060	39.13	69	-	6.6	1	50	1.2							
	Predicate	0.060	39.13	69	-	6.6	1	50	1.2							
	Fifth-Year Total Paper, Plastic, Steel, and Cigarette Butt Waste for New and Predicate Products															(b) (4)

**Packaging and Cigarette Butt Waste.** The booklet cover and metal canister are disposed of, recycled, or both, as paper waste and metal waste, respectively. The pouch and overwrap, as well as the cigarette butts, are disposed of as waste or litter. Estimation of generated total paper and cigarette butt waste for the new and predicate products is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper products at (b) (4) in the U.S., according to U.S. EPA [7]. Therefore, if 35.3% of the booklets are disposed of as waste based on the 2014 waste generation data in the U.S., the estimated cumulative paper waste (booklets + cigarette butts) will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new and predicate products.<sup>14</sup> This is a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. in 2014.

## CONFIDENTIAL APPENDIX 2

### Location of RYO Paper Manufacturing Facility

(b) (4)



Manufacturer address via Google Maps. Accessed August 16, 2017.

The cigarette rolling papers are manufactured in (b) (4) and shipped to the (b) (4) in the U.S. for final packaging. The (b) (4) factory is located at:

(b) (4)



### CONFIDENTIAL APPENDIX 3

Comparison of the New Products to the Manufacturer's Total Annual Production

STN	Year 1 (metric tons)	Year 5 (metric tons)	Manufacturer's Total Annual Production (metric tons)	Total Manufacturer's Production Year 1 (%)	Total Manufacturer's Production Year 5 (%)
SE0011172	(b) (4)				
Predicate to SE0011172					
SE0011173					
Predicate to SE0011173					
SE0011174					
Predicate to SE0011174					
SE0011175					
Predicate to SE0011175					
SE0011176					
Predicate to SE0011176					
SE0011177					
Predicate to SE0011177					
SE0011179					
Predicate to SE0011179					
SE0011180					
Predicate to SE0011180					
SE0011181					
Predicate to SE0011181					
<b>Total</b>				(b) (4)	

## CONFIDENTIAL APPENDIX 4

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

The first- and fifth-year market volumes of the new and corresponding predicate products projected to occupy the U.S. market were determined by comparing the projected market volume of the new and corresponding predicate products to the forecasted use of total RYO tobacco in the U.S. (Appendix 2 and Confidential Appendix 1). The percent of the total RYO tobacco market occupied in the projected first and fifth year of marketing of the new and predicate products was calculated using the equations below<sup>15</sup>:

#### First Year Market Occupation of New and Predicate Products (%)

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

#### Fifth Year Market Occupation of New and Predicate Products (%)

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

STN	Year	Forecasted Use of Total RYO Tobacco in the U.S. (Billion Cigarette-Equivalent) <sup>16</sup>	Projected Market Volume of New Products <sup>17</sup> (Billion Cigarette-Equivalent)	Projected Market Occupation of New Products in the U.S. (%)
SE0011172	2017	-	(b) (4)	
	2021	-		
SE0011173	2017	-		
	2021	-		
SE0011174	2017	-		
	2021	-		
SE0011175	2017	-		
	2021	-		
SE0011176	2017	-		
	2021	-		
SE0011177	2017	-		
	2021	-		
SE0011179	2017	-		
	2021	-		
SE0011180	2017	-		
	2021	-		
SE0011181	2017	-		
	2021	-		
Total	2017	(b) (4)		
	2021			

<sup>15</sup> Each individual leaf of rolling paper is anticipated to be used in making a single cigarette unit. Therefore, one leaf of rolling paper is equal to one cigarette-equivalent.

<sup>16</sup> See Appendix 2.

<sup>17</sup> See Confidential Appendix 5.

## CONFIDENTIAL APPENDIX 5

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

STN	Unit	Current-Year Market Volume	First-Year Market Volume		Fifth-Year Market Volume	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0011172	Number of units	(b) (4)				
	Metric Tons					
SE0011173	Number of units					
	Metric Tons					
SE0011174	Number of units					
	Metric Tons					
SE0011175	Number of units					
	Metric Tons					
SE0011176	Number of units					
	Metric Tons					
SE0011177	Number of units					
	Metric Tons					
SE0011179	Number of units					
	Metric Tons					
SE0011180	Number of units					
	Metric Tons					
SE0011181	Number of units					
	Metric Tons					
Total number of units						
Total metric tons						