Programmatic Environmental Assessment for Two Marketing Orders for Republic Tobacco, LP "OCB Virgin 1-1/4 and OCB Virgin Slim"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

April 25, 2018

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This programmatic environmental assessment (PEA) is for the marketing orders for two roll-your-own (RYO) cigarette papers manufactured by Republic Technologies, France. 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 to 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

Republic Tobacco, LP

2. Address

2301 Ravine Way
Glenview, IL 60025

3. Manufacturer

(b) (4) [redacted]

4. Description of Proposed Actions

The proposed actions are for FDA to issue two marketing orders under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of RYO cigarette papers into interstate commercial distribution in the United States. The authorizations are based on the finding that each new product is substantially equivalent to a corresponding predicate product that was on the market as of February 15, 2007. The applicant intends to market the new and predicate products simultaneously after receiving marketing orders for the new products.

4.1 Requested Action

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

4.2 Need for Action

Republic Tobacco, LP wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the United States. The applicant claimed that the two new products and the corresponding predicate products have different characteristics (sec 910(a)(3)(A)(ii) of the FD&C Act) but do not raise different questions of public health; there are minor differences in ingredients and ingredient levels, paper porosity, basis weight, and total rolling paper mass. Additionally, the new products contain (b) (4) [redacted] that is (b) (4) [redacted], while the predicate products contain (b) (4) [redacted] that is (b) (4) [redacted]. After considering the SE Reports, 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 product.

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

4.3.1 Type of Tobacco Product

Roll-your-own (RYO) cigarette papers

4.3.2 Product Names and STNs

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

STN	New Product	Predicate Product
SE0013972	OCB Virgin 1-1/4	OCB Organic Hemp 1-1/4 Size
SE0013973	OCB Virgin Slim	OCB Organic Hemp King Size

4.3.3 Description of the Products' Package

The packaging materials of the finished new products are the same as those of the predicate products. The new products' packaging components consist of a paperboard booklet inside of a paperboard box in which the cigarette rolling papers are contained.

4.3.4 Location of Manufacturing

The manufacturer, (b) (4) [redacted], is located at (b) (4) [redacted] (see Figure 1). This is the location where the final product is made. The manufacturing facility is located on the southernmost border of an industrial area that is bounded to the south by a residential area.

Figure 1. Location of the RYO Tobacco Manufacturing Facility[1]

(b) (4) [redacted]

[1] Manufacturer address via Google Map. Accessed June 30, 2017.

4.3.5 Location of Use

Republic Tobacco, LP intends to distribute and sell the new RYO cigarette paper products to consumers in the United States.

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 predicate products and any other RYO products. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates the distribution of waste from disposal after use will correspond to the pattern of the product use.

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

The applicant claims that the new products differ from the predicate products in minor differences in ingredients and ingredient levels, paper porosity, basis weight, and total rolling paper mass. Additionally, the new products contain (b) (4) that is (b) (4), while the predicate products contain (b) (4) that is (b) (4) (Confidential Appendix 1).

5. Potential Environmental Impacts Due to the Proposed Actions

5.1 Potential Environmental Impacts due to Manufacturing the New Tobacco Products

According to the U.S. International Trade Commission (USITC), the import of tobacco products to the United States from France has increased from 1,889 metric tons in 2007 to 8,588 metric tons in 2016 (Figure 2).[2] When examining the change in import of cigarette rolling paper in the form of booklets to the United States from France over the same period of time, there was a significant decrease from 792 metric tons in 2007 to 533 metric tons in 2016 (Figure 3).[3]

Cigarette rolling papers in the form of booklets imported to the United States from France in 2016 represented 6.2% of the total amount of tobacco products imported from France in 2016.

[2] Unit is defined by the United States International Trade Commission, available at: http://dataweb.usitc.gov/. Accessed on March 23, 2018.
[3] Ibid.

Figure 2. Total Tobacco Products Imported from France into the United States 2000-2016[3]

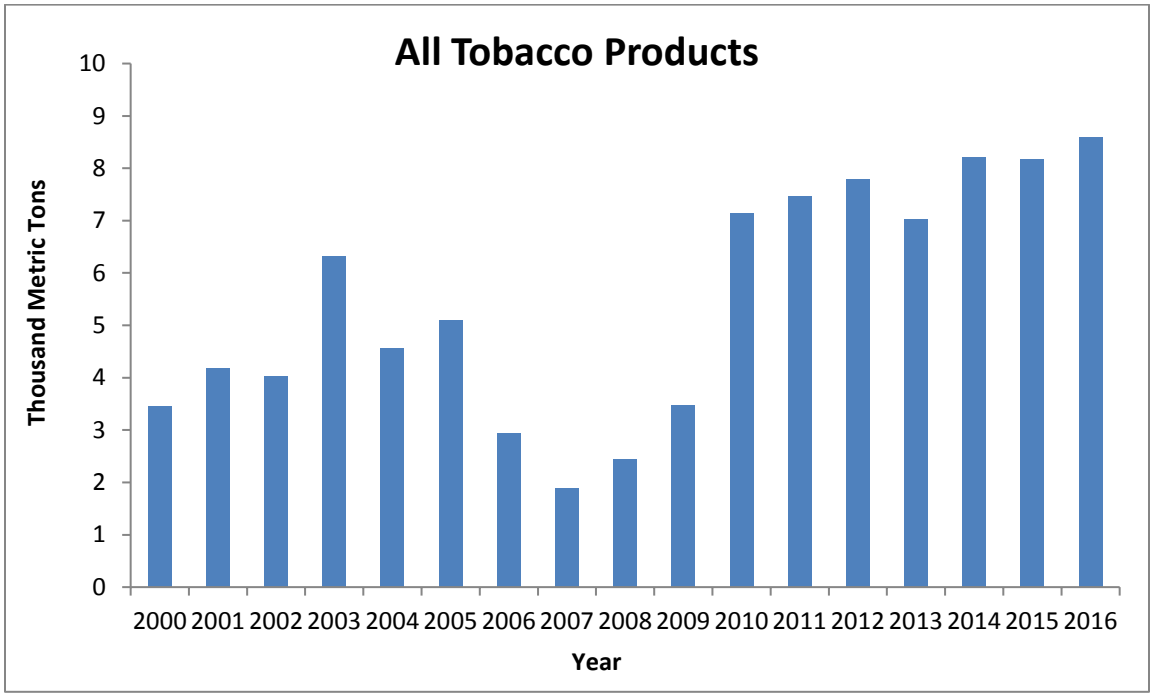
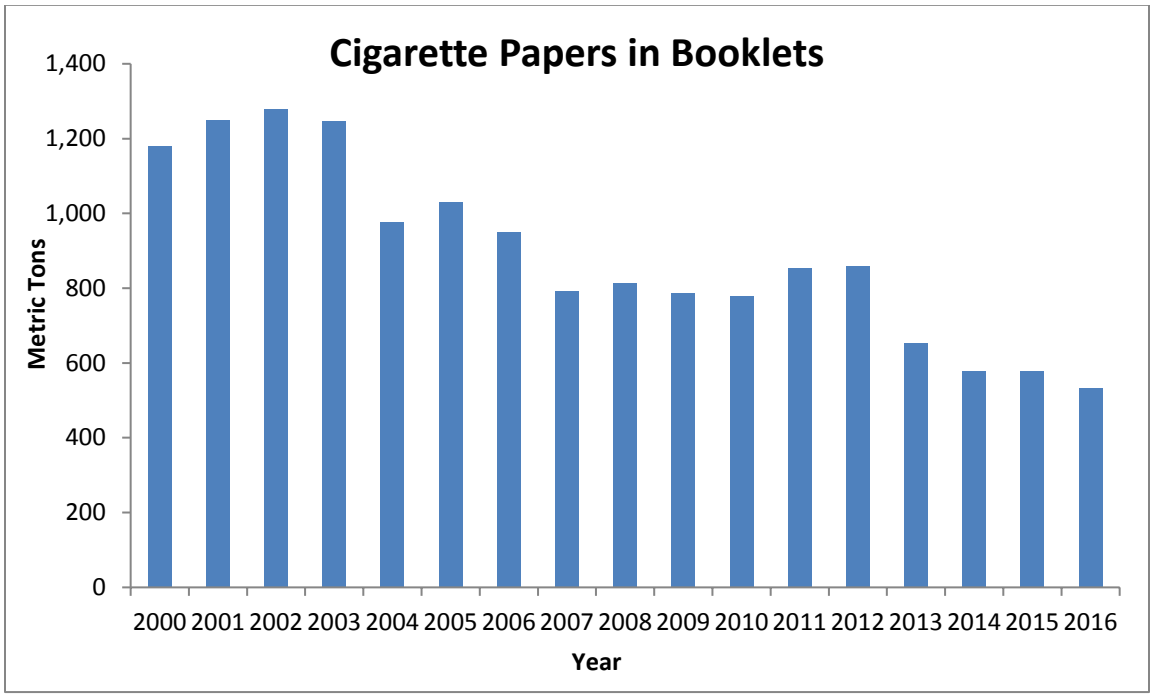


Figure 3. United States Import of Cigarette Papers in the Form of Booklets from France in 2000-2016[3]



The Agency anticipates the waste generated as a result of manufacturing the new RYO tobacco products will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other RYO tobacco products manufactured in France. The new products will compete with and replace other currently marketed RYO cigarette paper products. In addition, the applicant stated that the new products will be manufactured on existing production runs along with the predicate products. The applicant also stated that total manufacturing volume of the facility will not increase due to the new products because the manufacturer will allocate a portion of the facility's existing manufacturing to the manufacture of the new products. Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new products.

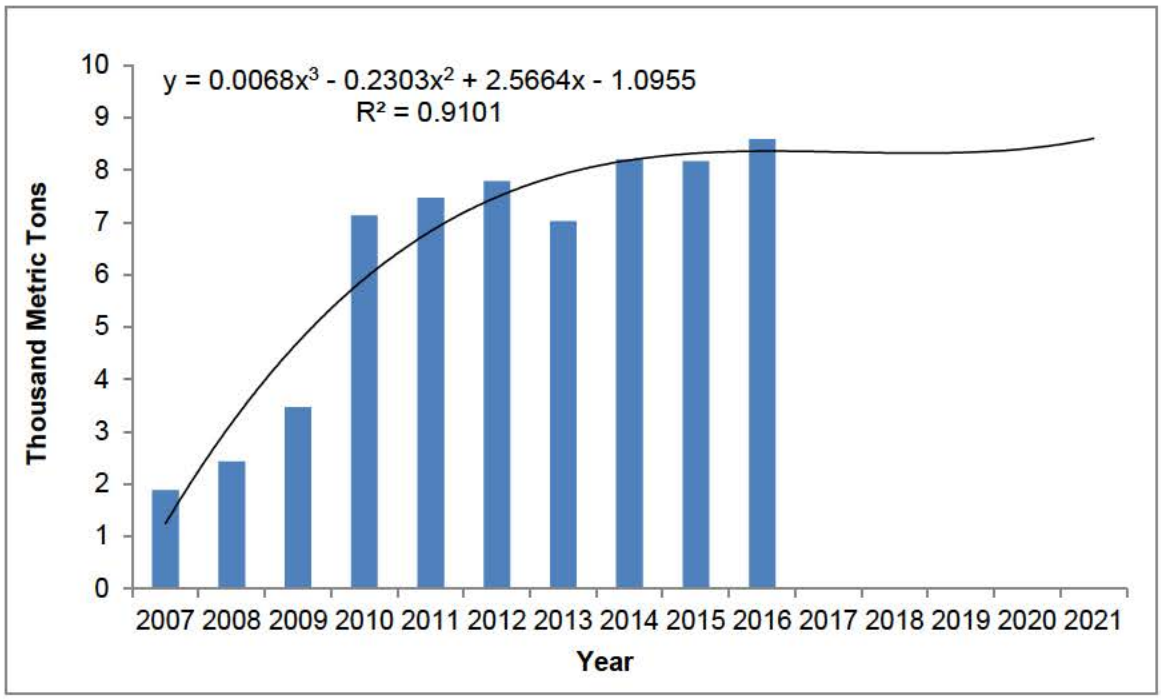
Based on information in the SE Reports, the new products differ from the corresponding predicate products only with minor differences in ingredients and ingredient levels, paper porosity, basis weight, and total rolling paper mass. Additionally, the new products contain (b) (4) that is (b) (4) and the predicate product contains (b) (4) that is (b) (4) (Confidential Appendix 1). The applicant stated that the changes are conventional ingredients found in machine-made cigarettes, injector tubes, and cigarette rolling papers. Therefore, the Agency does not anticipate any new type of emissions to be released into the environment as a result of manufacturing the new products.

The applicant provided the first- and fifth-year market volume projections for the new products (Confidential Appendix 2). Comparing the projected market volume of the new products with the forecasted market volume of all tobacco products imported into the United States from France in 2017 and 2021, the projected market volume of the new products is a miniscule fraction of the total forecasted market volumes in 2017 and 2021 (Confidential Appendix 2). Also, the new products comprise a miniscule fraction of the total volume of rolling papers manufactured at the facility (Confidential Appendix 4). The waste associated with manufacturing the new products is negligible compared to the facility's total waste. Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed.

To evaluate the environmental impact of the proposed actions due to import of the new products, historical data regarding the import of all tobacco products from France into the United States from 2007 to 2016 was used to forecast the manufacture of RYO tobacco products in France and imported into the United States.[4] This was achieved by using one best-fit polynomial trend line with the R^2 value of 0.9101. Accordingly, the forecasted amount of all tobacco products to be imported from France into the United States is estimated to be 8,319 metric tons in 2017 and 8,533 metric tons in 2021. The amount of all tobacco products imported from France into the United States is estimated at 8,588 metric tons in 2016.

[4] Forecast trend lines extrapolated from USITC data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed March 22, 2018.

Figure 4. Forecast of All Tobacco Products Imported into the United States from France



Year[5]	All Tobacco Products Imported to the United States from France (Metric Tons)
2016	8,588
1st Year (2017)	8,319
5th Year (2020)	8,533

The manufacturing facility is located in France and the applicant stated that the facility is in compliance with applicable French federal and regional emissions, solid waste, and liquid waste regulations and requirements. The applicant also stated that the RYO papers are produced from renewable and sustainable sources, according to the Endorsement of Forest Certification (PEFC) and Forest Stewardship Council (FSC). Furthermore, the manufacturing facility holds ISO 9001 and ISO 14001 certifications showing the facility has effective quality management and environmental management systems in place. The applicant stated that their manufacture does not threaten any endangered species or critical habitat, as listed by the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES) and the Endangered Species Act (ESA).

[5] 1st Year (2017) in thousand tons = $[0.0068\times(11^3)] - [0.2303\times(11^2)] + (2.5664\times11) - 1.0955 = 8.319$
5th Year (2021) in thousand tons = $[0.0068\times(15^3)] - [0.2303\times(15^2)] + (2.5664\times15) - 1.0955 = 8.533$

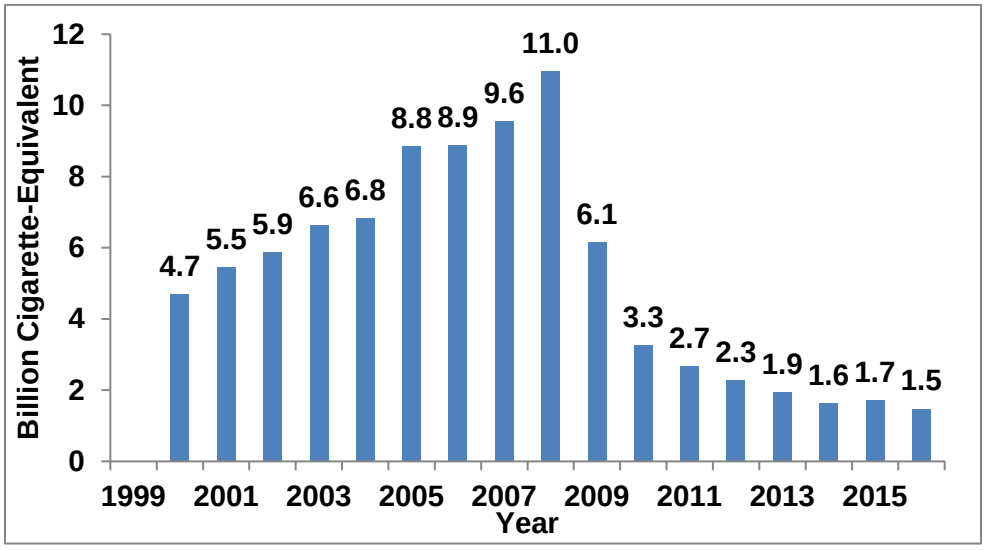
The applicant claimed the projected market volumes of the new products will be negligible relative to the overall production at the factory and most of the energy required to operate the factory is fixed and not incremental to production volumes. Emissions of carbon dioxide and other greenhouse gases (GHGs), such as methane, nitrous oxide, and fluorinated gases, are a type of air pollution. The applicant stated that because the new products will compete with and replace other currently marketed RYO products, no addition of GHG emissions is anticipated.

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

5.2.1 Use of the RYO Tobacco Products in the United States

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of RYO tobacco products in the United States increased from 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[6] in 2009 to 1.5 billion cigarette-equivalents in 2016 (Figure 5) (*6, 7*).

Figure 5. Use of RYO Tobacco Products in the United States in 2000-2016[4]



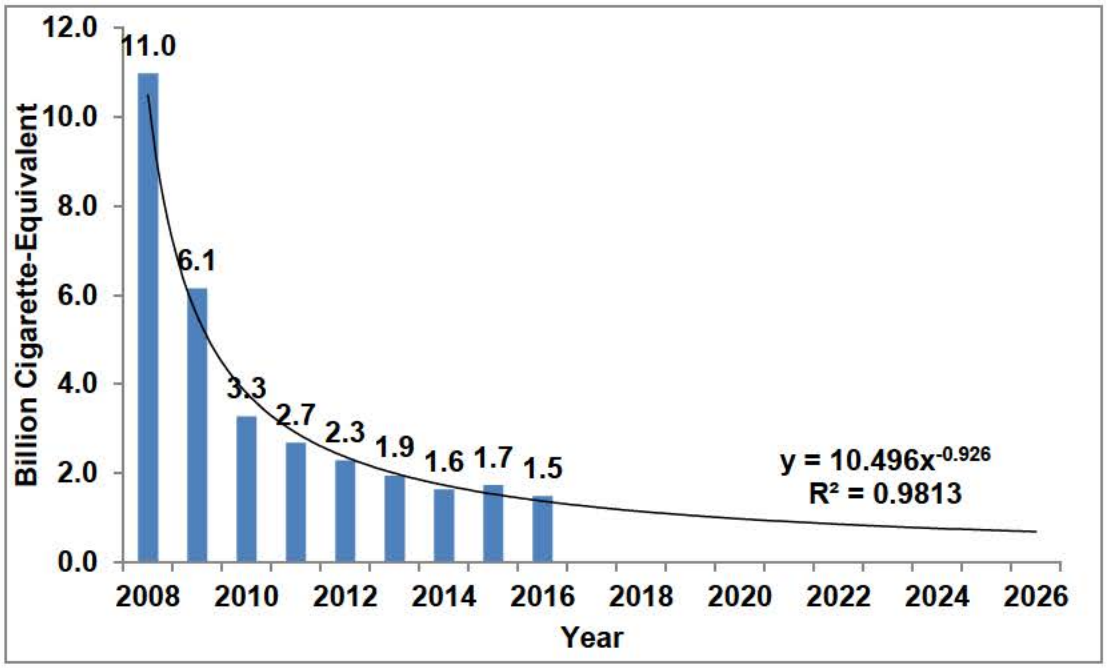
To evaluate the environmental impact of the proposed actions due to use of the new products, the Agency utilized the historical data of RYO tobacco product use in 2008–2016 to forecast the use of RYO tobacco products in the United States. This was achieved by using one best-fit power trend line with the R^2 value of 0.9813.[7]

[6] The calculated cigarette-equivalence data is based on the conversion rate in the Master Settlement Agreement is that 0.0325 oz. (0.9 g) of tobacco equals to one cigarette. See Reference #7.

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

Using trend lines, the forecast of use of RYO tobacco products in the United States was estimated mathematically. Accordingly, the forecasted number of RYO tobacco products to be used in the United States is estimated to be 1.2 billion cigarette-equivalents (1,120 metric tons) in 2017 and 0.9 billion cigarette-equivalents (820 metric tons) in 2021.[8] The number of RYO tobacco products used in the United States is estimated to be 1.5 billion cigarette-equivalents (1,334 metric tons) in 2016 by TTB.

Figure 6. Forecast of Use of RYO Tobacco Products in the United States



Year[9]	RYO Tobacco Products (Billion Cigarette-Equivalent)	RYO Tobacco Products (Metric Tons)
2016	1.5	1,334
1st Year (2017)	1.2	1,120
5th Year (2021)	0.9	820

The applicant intends to market both the new and predicate products after receiving marketing orders for the new products. Because the new products are expected to compete with other RYO products on the market, the Agency anticipates minimal or no net increase in the use of all RYO products. Subsequently, the Agency does not anticipate new substances to be released into the environment as a result of use of the new RYO products, relative to the substances released by the predicate products 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. These combustion

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

[9] 1st Year in billion cigarette-equivalent = 10.496 x 10EXP(-0.926) = 1.2
5th Year in billion cigarette-equivalent = 10.496 x 14EXP(-0.926) = 0.9

products from the new products are released in the same manner as the combustion products from the predicate products, as well as those from current RYO cigarette rolling paper products.

5.3 Potential Environmental Impacts Due to Disposal of the New Products

5.3.1 Disposal of Packaging Materials

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the United States, including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packaging materials. Specifically, in 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the United States, and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 5 and 6). 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. On average, 4.4 pounds per person of waste was generated, of which 2.1 pounds was recycled, composted, or combusted for energy recovery in the United States in 2014(*8*).

Figure 7. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014

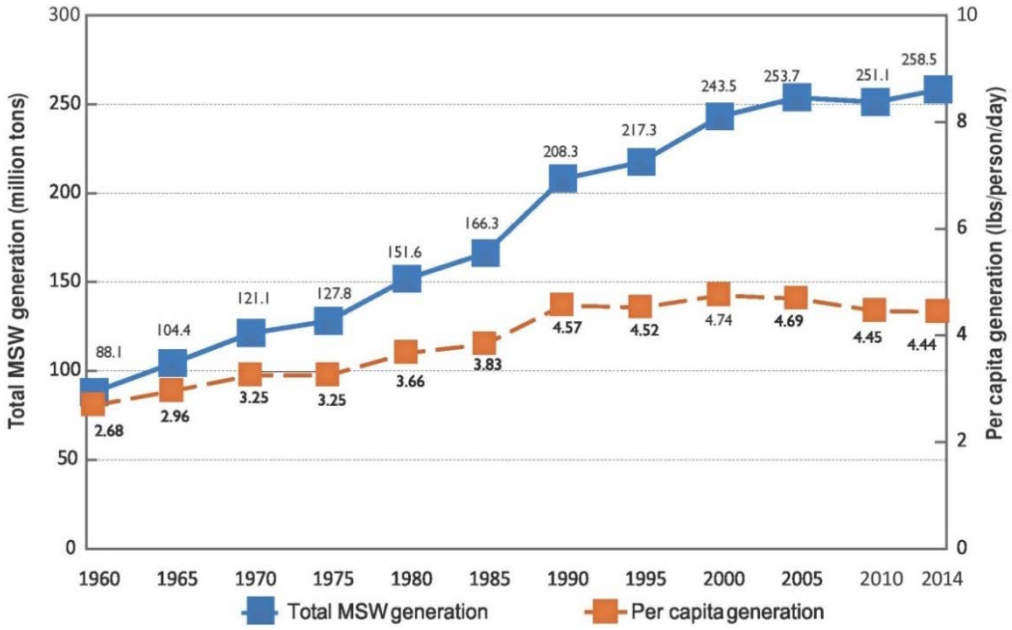


Figure Excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 8. MSW Recycling Rates in the United States, 1960-2014

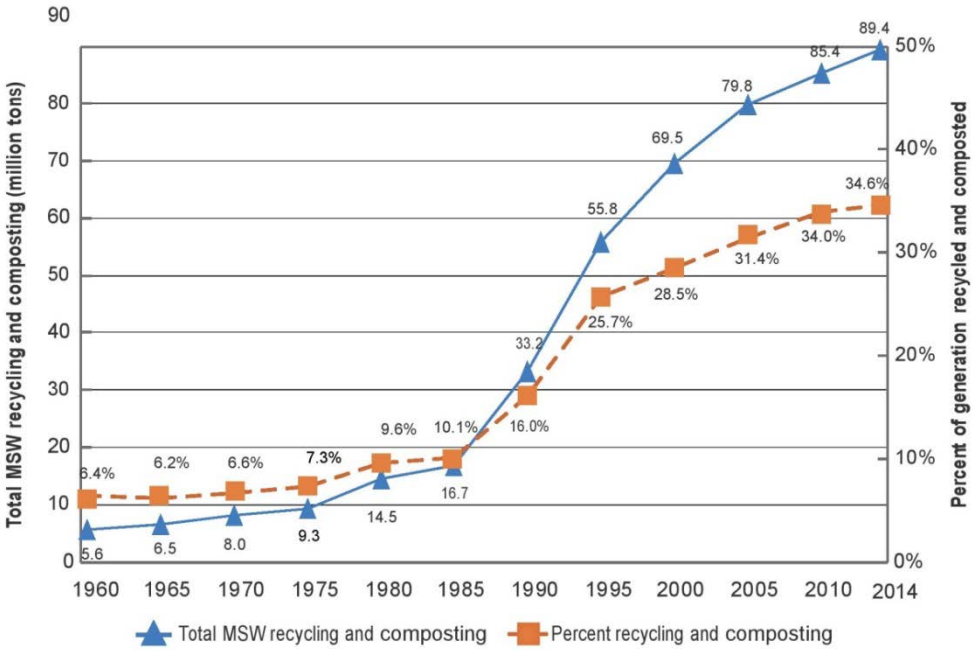


Figure Excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the new products will be the same as the disposal conditions of other RYO cigarette rolling papers. After using the new products, the users may dispose of or recycle the packaging material.

To determine the amount of waste due to disposal of packaging material the Agency used the projected market volumes in the first and fifth years after issuance of marketing orders for the new products. The calculated waste of the packaging materials of the new product were determined to be miniscule compared to the forecasted MSW to be generated in the United States (Confidential Appendix 5). In addition, paper and plastic 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 new RYO cigarette papers will compete with other similar RYO tobacco products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfills are not anticipated due to the proposed actions. The waste generated from the packaging material for the new products is expected to make up a negligible fraction of the total MSW.

5.3.2 Disposal of Used RYO Tobacco Products Following Use

Users may discard what remains of the products after smoking, such as remaining combusted tobacco and cigarette rolling paper, as MSW or litter. When discarded as litter, the spent products are likely to move by run-off to the ocean and eventually decompose. When discarded as MSW, the products would enter landfills. The Agency utilized the historical data for use of RYO tobacco products in the United States to forecast the future use of RYO tobacco products and calculate the projected tobacco waste accordingly. Assuming that all used RYO tobacco products will be disposed of as MSW, the estimated

waste of used RYO tobacco products is a fraction of a percent of the total 258.46 million tons (234.47 million metric tons) of projected MSW to be generated in the United States.

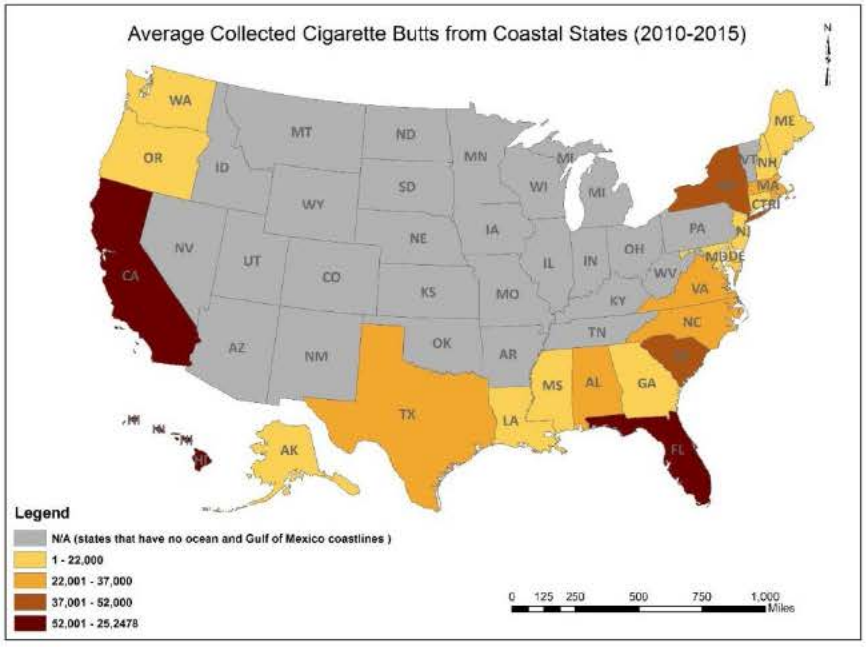
Forecast of Waste of Used RYO Tobacco Products as Compared to Total MSW Forecast in the United States		
Year	**Projected Use (≈ Projected Waste) of RYO Tobacco Products in the U.S. (Billion Cigarette-Equivalent)[a]**	**Percent of Projected Waste of RYO Tobacco Products to Total MSW Forecasted in the U.S. (%)[10]**
1st Year	1.2	0.000520
5th Year	0.9	0.000350

[a] See Figure 6

According to a report published by "Keep America Beautiful", an observational study of 767 smokers conducted in 44 locations, showed 35% of used cigarettes were disposed of properly (with MSW) with a resulting 65% littering rate for cigarette butts (Schultz, 2009).

The majority of unmanaged cigarette waste ends up in oceans and on beaches across the United States and worldwide. The annual Ocean Conservancy's International Coastal Cleanup (ICC) reports that cigarette waste has been the single most collected item since coastal clean-ups began (Novotny, Lum, & Smith, 2009). Using the data from the ICC, the Agency produced a map displaying the average collected cigarette waste (2010-2015) from coastal states (excluding Great Lakes coast) on the international coastal cleanup day (Figure 9).

Figure 9. Collected Cigarette Waste from Coastal States (2010-2015)



[10] RYO Tobacco Products in percentage:

$$\text{1st Year} = \left(\frac{1{,}220 \text{ metric tons}}{234{,}470{,}000 \text{ metric tons}}\right) \times 100\% = 0.000520\%$$

$$\text{5th Year} = \left(\frac{820 \text{ metric tons}}{234{,}470{,}000 \text{ metric tons}}\right) \times 100\% = 0.000350\%$$

A threat assessment study focusing on the most common types of litter that are found along the world's coastlines, based on data gathered during three decades of international coastal clean-up efforts, was conducted by Wilcox et al., 2016. The study was conducted based on elicited information from experts on the ecological threat of entanglement, ingestion and chemical contamination for three major marine taxa: seabirds, sea turtles and marine mammals (Wilcox & Mallos, 2016). The result of this study shows that cigarette butts are ranked seventh out of 20 marine debris items of interest for which information was elicited.

As previously discussed, the new RYO cigarette tubes will compete with other similar RYO tobacco products on the market and based on the above-mentioned information regarding waste, construction of new publicly owned treatment works (POTWs) or landfills are not anticipated due to the proposed actions.

6. Use of Resources and Energy

The new products will compete with other currently marketed RYO tobacco products. The applicant also stated that the proposed actions will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total RYO market volumes in the United States, 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 new product is intended to compete with and replace other currently marketed products, no increase of overall RYO tobacco product market volume and no net increase of energy use will be expected from the proposed actions. Additionally, the applicant stated that all ingredients used to manufacture the new products, as well as the predicate products, are from renewable and sustainable resources. Accordingly, no additional use of resources and energy is anticipated.

7. 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.

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 the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products as the predicate product (Confidential Appendices 3 and 4) and many other similar RYO tobacco products will continue to be marketed.

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

9. List of Preparers

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

Preparers:

William E. Brenner, B.S., Center for Tobacco Products
- Education: B.S. in Biology
- Experience: 4 years in various scientific activities
- Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

ITC Data Preparer:

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

RYO Tobacco Products Projection Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products
- 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

Reviewers:

Hoshing Chang, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Biochemistry and M.S. in Environmental Science
- Experience: 9 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 Covered Under this Programmatic Environmental Assessment (PEA)

12. Confidential Appendix List

Confidential Appendix 1: Comparison of (b) (4) Sources Between the New and Predicate Products
Confidential Appendix 2: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products
Confidential Appendix 3: Comparison of the Current-Year Market Volume for the Predicate Products with Total RYO Tobacco Products Used in the United States
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 United States
Confidential Appendix 5: The First- and Fifth-Year Projections of Paper and Cigarette Butt Waste of Packaging Materials and Product Materials Associated with Marketing the New and Predicate Products

13. References

1. FDA Guidance for Industry. Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3). Issued December 2016.
3. Novotny, T. E., Lum, K., Smith, E., Wang, V., & Barnes, R. (2009). Cigarettes Butts and the Case for an Environmental Policy on Hazardous Cigarette Waste. International Journal of Environmental Research and Public Health, 6(5), 1691–1705.
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12. U.S. EPA. Stationary Sources of Air Pollution. Municipal Solid Waste Landfills: Proposed and Final Air Regulation Fact Sheets. Available at https://www.epa.gov/stationary-sources-air-

pollution/municipal-solid-waste-landfills-proposed-and-final-air-regulation. Accessed July 3, 2017.
13. Wilcox, C., & Mallos, N. (2016). Using Expert Elicitation to Estimate the Impacts of Plastic Pollutionon on Marine Wildlife. *Marine Policy*, 107-114.

APPENDIX 1

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

STN	Product	Product Name	Leaves per Booklet	Booklets per Retail Unit	Retail Units per Shipping Case	Amendments
SE0013972	New Product	OCB Virgin 1-1/4	50	50	20	SE0014219, SE0014397, and SE0014503
	Predicate Product	OCB Organic Hemp 1-1/4 Size	50	25	40	
SE0013973	New Product	OCB Virgin Slim	32	50	20	
	Predicate Product	OCB Organic Hemp King Size Slim	32	50	20	

CONFIDENTIAL APPENDIX 1

Comparison of (b) (4) Sources Between the New and Predicate Products

STN	Product	(b) (4) Source	Agricultural Species	Sustainable or Renewable
SE0013972	New Product	(b) (4)		Sustainable
	Predicate Product	(b) (4)		Renewable
SE0013973	New Product	(b) (4)		Sustainable
	Predicate Product	(b) (4)		Renewable

CONFIDENTIAL APPENDIX 2

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

STN	Unit	Current-Year[a] Market Volume	First-Year Market Volume		Fifth-Year Market Volume	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0013972	# Leaves	(b) (4)				
	Metric Tons					
SE0013973	# Leaves					
	Metric Tons					

[a] Current year refers to 2016

CONFIDENTIAL APPENDIX 3

Comparison of the Current-Year Market Volume for the Predicate Products with Total RYO Tobacco Products Used in the United States

The current-year market volume of the predicate products occupying the United States market was compared to the use of total RYO tobacco in the United States. The percent of the total RYO tobacco market occupied in the current year of marketing of the predicate product was calculated using the equation below.[11]

$$\text{2016 Market Occupation of Predicate Product (\%)} = \frac{\text{2016 Market Volume (metric tons)}}{\text{Use of RYO in the United States for 2016 (metric tons)}} \times 100\%$$

STN	Year	Import of Total Tobacco Products from France (Metric Tons)[12]	Use of Total RYO Tobacco in the United States (Metric Tons)[13]	Market Volume of Predicate Product (Metric Tons)[14]	Market Occupation of Predicate Product in the United States (%)
SE0013972	2016	8,588	1,334	(b) (4)	
SE0013973	2016	8,588	1,334		

[11] 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.

[12] See Figure 5.

[13] See Figure 6.

[14] See Confidential Appendix 2.

CONFIDENTIAL APPENDIX 4

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

The first- and fifth-year market volumes of the new and predicate products projected to occupy the United States market were determined by comparing the projected market volume of the new and predicate products to the forecasted use of total RYO tobacco in the United States. 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.[15]

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

$$= \frac{\text{First–Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of RYO in the United States for 2017 (metric tons)}} \times 100\%$$

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

$$= \frac{\text{Fifth–Year Market Volume Projection (metric tons)}}{\text{Forecasted Use of RYO in the United States for 2021 (metric tons)}} \times 100\%$$

STN	Year	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)[16]	Projected Market Volume of New Product (Metric Tons)[17]	Projected Market Occupation of New Product in the U.S. (%)
SE0013972	First (2017)	1,120	(b) (4) [redacted]	[redacted]
	Fifth (2021)	820		
SE0013973	First (2017)	1,120		
	Fifth (2021)	820		
New Product Total	**First (2017)**	1,120		
	Fifth (2021)	820		
SE0013972 Predicate	First (2017)	1,120		
	Fifth (2021)	820		
SE0013973 Predicate	First (2017)	1,120		
	Fifth (2021)	820		
Overall Total	**First (2017)**	1,120		
	Fifth (2021)	820		

Although there is an increase of production identified according the applicant-reported market volumes, as noted, the new products will be manufactured on existing production runs along with the predicate products. The applicant stated that the total manufacturing volume of the facility will not increase due to the new products because the manufacturer will allocate a portion of the facility's existing manufacturing to the manufacture of the new products. Current manufacturing volume for the RTF facility in 2016 is (b) (4) [redacted] leaves which also equates to (b) (4) [redacted] booklets. The new products will make up only (b) (4) [redacted] of the total production from the manufacturing facility based on the number of leaves manufactured for the new products compared to the overall production from the factory.

[15] 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.

[16] See Figure 6.

[17] See Confidential Appendix 2.

CONFIDENTIAL APPENDIX 5

The First- and Fifth-Year Projections 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 paper 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 new and predicate products in 2017 and 2021. Projected paper and cigarette butt waste generation is the summation of the projected booklet cover, cardboard box, pouch (used to contain RYO tobacco), cigarette butt[19], and shipping case waste generation of the products.

$$\sum_{i=1}^{3} A_i = \sum_{i=1}^{3} (B_i + C_i + D_i + E_i)$$

$$B_i = \frac{F_i}{G_i} \times H_i \times Z$$

$$C_i = \frac{F_i}{G_i \times I_i} \times J_i \times Z$$

$$D_i = \frac{F_i}{G_i \times I_i \times K_i} \times L_i \times Z$$

$$E_i = \frac{F_i \times N_i \times O_i}{100} \times 0.001 \times Z$$

$$N_i = \frac{27}{M_i} \times 100$$

A_i: Projected paper and cigarette butt waste generation of the new and predicate products (metric tons

B_i: Projected booklet cover waste generation of the new and predicate products (metric tons)

C_i: Projected retail cardboard unit waste generation of the new and predicate products (metric tons)

D_i: Projected shipping case waste generation of the new and predicate products (metric tons)

E_i: Projected cigarette butt[18] waste of the new and predicate products (metric tons)

F_i: Projected market volume of the new and predicate products (# individual leaves of rolling paper)

G_i: Number of rolling papers per booklet

H_i: Weight of empty booklet cover (grams)

I_i: Number of booklets per retail unit

J_i: Weight of empty retail outer box (grams)

K_i: Number of retail units per shipping case

L_i: Weight of empty shipping case (grams)

M_i: Length of rolling paper (millimeters)

N_i: Cigarette butt ratio (%)[19]

O_i: Weight of rolling paper (milligrams per leaf)

Z: 1.0 x 10^{-6} metric tons/gram

[18] Cigarette butt in this EA is defined as cigarette rolling paper containing remainder tobacco that is disposed of following use.

[19] 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 following use.

First Year	STN	Weight per leaf O_i	Cigarette butt ratio N_i	Length of rolling paper M_i	Weight of shipping case L_i	Retail boxes per shipping case K_i	Weight of retail box J_i	Booklets per retail unit I_i	Weight of booklet cover H_i	Rolling papers per booklet G_i	Projected market volume of new product F_i	Cigarette butt waste E_i	Shipping case waste D_i	Retail box waste C_i	Booklet cover waste B_i	Total waste A_i
	SE0013972	42.97	35.1	77	378	20	16.7	50	3.02	50	(b) (4)					
	SE0013973	60.82	24.8	109	378	20	16.7	50	3.02	32						
	First-Year Total Paper and Cigarette Butt Waste for New Products (metric tons)															

Fifth Year	STN	Weight per leaf O_i	Cigarette butt ratio N_i	Length of rolling paper M_i	Weight of shipping case L_i	Retail boxes per shipping case K_i	Weight of retail box J_i	Booklets per retail unit I_i	Wright of booklet cover H_i	Rolling papers per booklet G_i	Projected market volume of new product F_i	Cigarette butt waste E_i	Shipping case waste D_i	Retail box waste C_i	Booklet Cover Waste B_i	Total Waste A_i
	SE0013972	42.97	35.1	77	378	20	16.7	50	3.02	50	(b) (4)					
	SE0013973	60.82	24.8	109	378	20	16.7	50	3.02	32						
	Fifth-Year Total Paper and Cigarette Butt Waste for New Products (metric tons)															

First Year	STN	Weight per leaf O_i	Cigarette butt ratio N_i	Length of rolling paper M_i	Weight of shipping case L_i	Retail boxes per shipping case K_i	Weight of retail box J_i	Booklets per retail unit I_i	Wright of booklet cover H_i	Rolling papers per booklet G_i	Projected market volume of predicate product F	Cigarette butt waste E_i	Shipping case waste D_i	Retail box waste C_i	Booklet cover waste B_i	Total waste A_i
	SE0013972	50.20	35.1	77	378	40	16.7	25	3.02	50	(b) (4)					
	SE0013973	71.07	24.8	109	378	20	16.7	50	3.02	32						
	First-Year Total Paper and Cigarette Butt Waste for Predicate Product (metric tons)															

Fifth Year	STN	Weight per leaf O_i	Cigarette butt ratio N_i	Length of rolling paperM_i	Weight of shipping case L_i	Retail boxes per shipping case K_i	Weight of retail box J_i	Booklets per retail unit I_i	Wright of booklet cover H_i	Rolling papers per bookletG_i	Projected market volume of predicate product F_i	Cigarette butt waste E_i	Shipping case waste D_i	Retail box waste C_i	Booklet Cover Waste B_i	Total Waste A_i
	SE0013972	50.20	35.1	77	378	40	16.7	25	3.02	50	(b) (4)					
	SE0013973	71.07	24.8	109	378	20	16.7	50	3.02	32						
	Fifth-Year Total Paper and Cigarette Butt Waste for Predicate Product (metric tons)															

Paper and Cigarette Butt Waste. The booklet cover, retail cardboard box, and shipping case are disposed of, recycled, or both, as paper waste; 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 the new products. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper products at 64.7% in the United States, according to U.S. EPA (*5)*. Therefore, if 35.3% of the booklets, retail cardboard boxes, and shipping cases are disposed of as waste based on the 2014 waste generation data in the United States, the estimated cumulative paper and cardboard waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new products.

If the entire packaging paper and cigarette butt are disposed of as waste, which is a more conservative approach, the projected cumulative paper and cigarette butt waste in the first and fifth years of marketing the new and predicate products is (b) (4) metric tons and (b) (4) metric tons, respectively. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.