Programmatic Environmental Assessment for Marketing Orders for Two Republic Tobacco, LP Products Named, "Top Standard"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

March 30, 2018

Contents

This programmatic environmental assessment (PEA) is for marketing orders for two roll-your-own (RYO) paper products manufactured by Republic Tobacco, LP. Information presented in the PEA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This PEA has been prepared in accordance 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. Manufacturers

The RYO manufacturing location of the suppliers is in a foreign country and that location is provided in Confidential Appendix 1.

The RYO paper mill is in a foreign country and that location is provided in Confidential Appendix 1.

4. Description of Proposed Action

The proposed actions are for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of multiple RYO paper products into interstate commercial distribution in the United States. 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 currently markets the predicate products and 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 products.

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 claims that the new and corresponding predicate products differ only in packaged quantities (sec 910(a)(3)(A)(ii) of the FD&C Act). In addition, the applicant claims that the new and corresponding predicate products have the same packaging composition. After considering the substantial equivalence (SE) reports, the Agency shall issue an order under the provisions of sections 910 and 905(j) of the FD&C Act when finding the new products to be substantially equivalent to the predicate products.

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

4.3.1 Type of Tobacco Product

RYO paper

4.3.2 Product Names and STNs

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

STN	New Product	Predicate Product
SE0014367	Top Standard	Top Cig Paper 24's
SE0014368	Top Standard	Top Standard

4.3.3 Description of the Product Package

The packaging materials for the new and corresponding predicate products are the same in composition packaging material.

4.3.4 Location of Use

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

4.3.5 Location of Disposal

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

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

The applicant claims that the new products differ from the corresponding predicate products only in product quantity.

5 Potential Environmental Impacts Due to the Proposed Action

5.1 Potential Environmental Impacts Due to Manufacturing the New Products

The applicant stated that the manufacturing of the new products would not generate new emissions, solid waste or liquid waste. Also, the applicant stated that the new products will not require additional resources for disposal of manufacturing waste such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity. In addition, the applicant stated that waste generated by manufacturing the new products will be released

to the environment, transferred to publicly owned treatment works and disposed of in landfills in the same manner as other cigarette papers manufactured in the foreign country listed in Confidential Appendix 1.

The applicant stated that the new products will not require additional environmental controls and the manufacturing facility abides by all federal and regional emissions, solid waste and liquid waste regulations, and requirements applicable to their facility. Moreover, the applicant stated that the new products will not result in an expansion of the manufacturing facility because the facility is already equipped to manufacture the new products. Furthermore, the applicant stated that there will not be any impact on greenhouse gas (GHG) emissions due to manufacturing the new products and that the energy that would be used to manufacture the new products would be a fraction of the energy use of the facility.

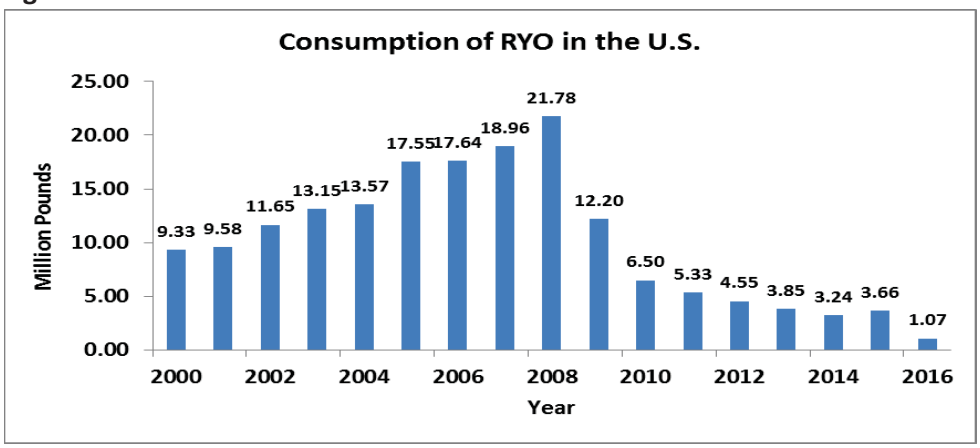
The applicant stated that the manufacturing of the new products is carried out under controls and standards that protect the environment, including those species and habitats addressed under the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

The applicant stated that the rolling paper suppliers for the manufacturing facility 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. Furthermore, the applicant stated that PEFC certification confirms the commitment to curbing deforestation, maintaining biodiversity, and protecting ecologically important forest areas. Lastly, the applicant stated that the manufacturing facility holds ISO 9001 ("Quality management systems Requirements") and ISO 14001 ("Environmental management systems Requirements with Guidance") certifications, showing that the facility has effective quality management and environmental management systems in place.

5.2 Potential Environmental Impacts Due to Use of the New Products

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of RYO tobacco in the United States increased from 9.33 million pounds in 2000 to 21.78 million pounds in 2008. This was followed by a decrease in use from 12.20 million pounds in 2009 to 1.07 million pounds in 2016 (Figure 1) (US TTB, 2017).

Figure 1. Use of RYO Tobacco in the United States in 2000-2016



Overall, the use of RYO tobacco in the United States has decreased since 2008 and the Agency anticipates the same pattern will continue for at least the next few years. Furthermore, the applicant claimed that the new products will compete with and replace other currently marketed RYO products. Therefore, quantitatively the Agency does not anticipate more chemicals to be emitted into the environment from the use of the new products, compared to the chemicals released from the use of the predicate products that are currently on the market.

As noted, the applicant claimed that the new products differ from the predicate products in only quantity. Therefore, the Agency does not anticipate new chemicals to be emitted into the environment from the use of the new products, compared to the chemicals released by use of the predicate products that are currently on the market.

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

5.3.1 Environmental Impacts Due to Disposal of Packaging Materials

The applicant stated that the cigarettes made from this cigarette paper will burn to ash during use and the remaining portion will be disposed of in the same manner as other marketed RYO tobacco products, through deposit in municipal solid waste (MSW) landfills or as litter. Also, the applicant stated that the distribution of waste from disposal is anticipated to correspond to the pattern of product use. In addition, the applicant stated that disposal of the new products will not require additional resources (e.g., new landfills, recycling centers, etc.) for waste disposal. Furthermore, the applicant stated that no new chemicals are anticipated to be released into the environment due to the proposed actions because the ingredients in the new products are the same as the ingredients used to manufacture the corresponding predicate products.

The applicant stated that following use, the consumer will either place the new products' packaging in the recycling stream, deposit it in MSW landfills or dispose of it as litter. The applicant provided an analysis of the amount of used packaging and product material waste from the new and corresponding predicate products in the SE Reports.

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 (Figures 2 and 3) (US EPA, 2014). Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), out of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW generated, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery (US EPA, 2014). Figure 4 shows the overlap of MSW that is paper or paperboard, as well as container and packaging material. These are the types of materials that will be disposed of from the new product packaging.

Figure 2. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014

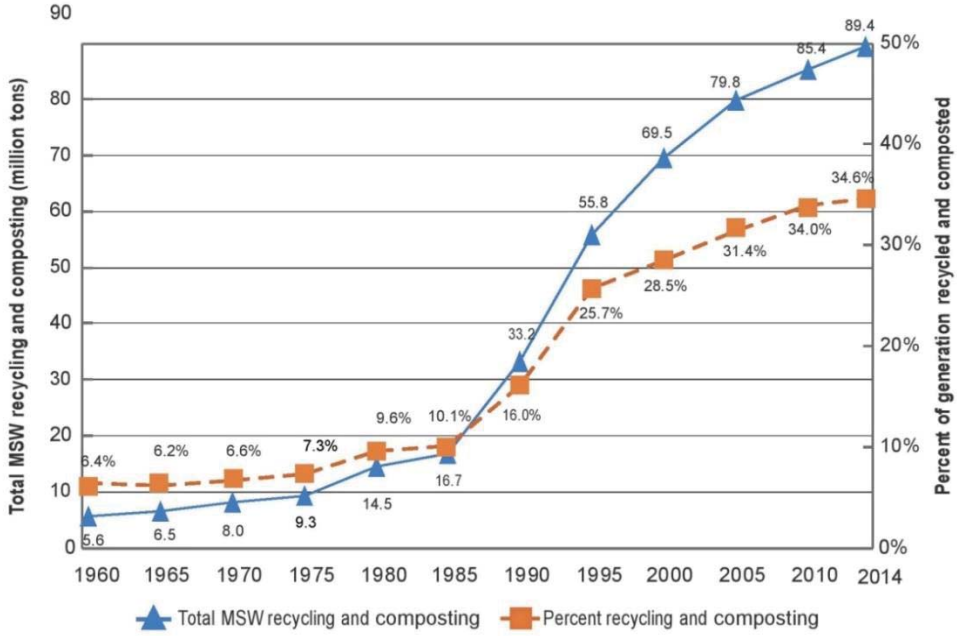


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 3. MSW Recycling Rates in the United States, 1960-2014

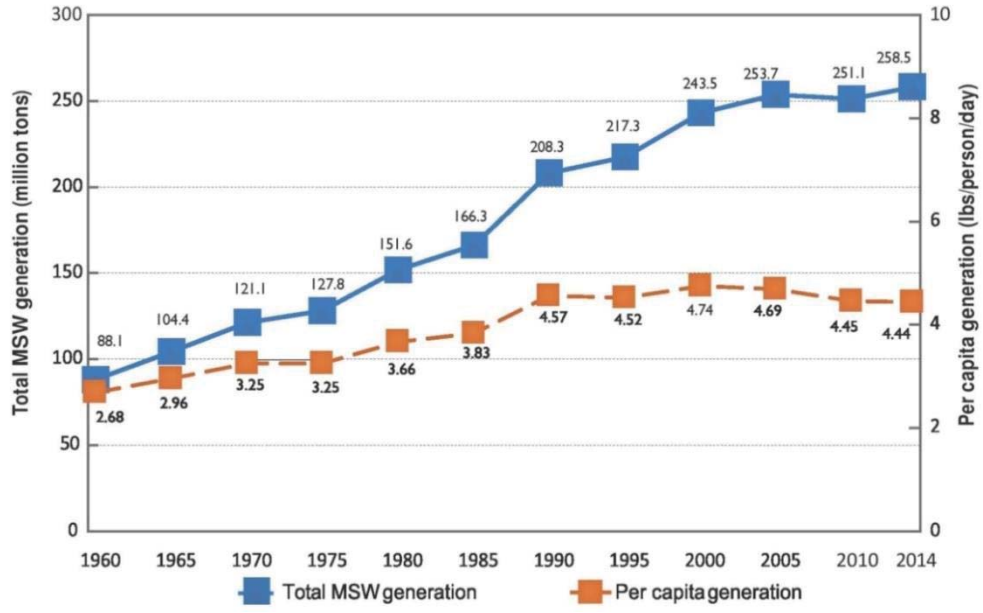
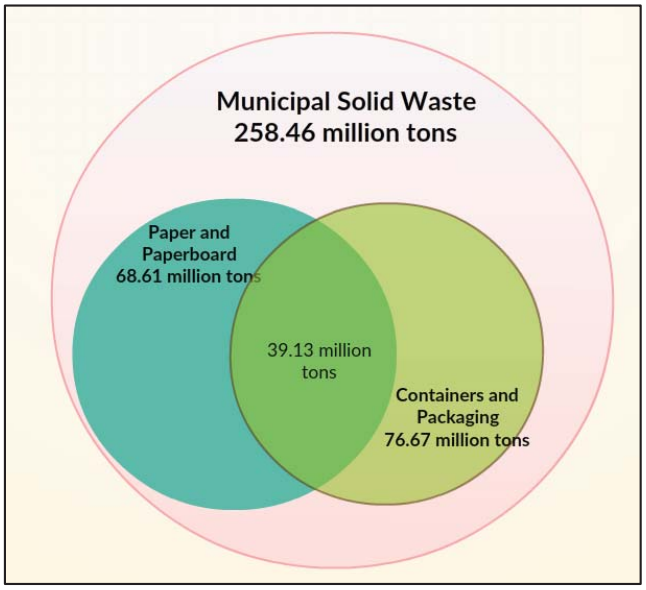


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 4. Overview of Contents of Municipal Solid Waste: Highlighting Waste Related to Product Packaging



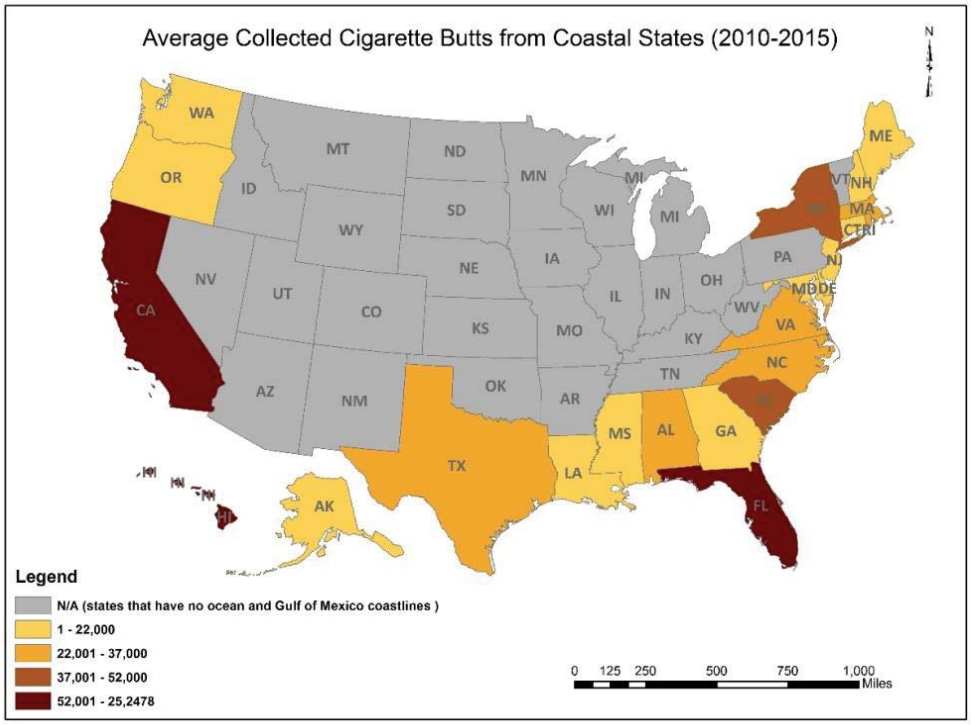
To estimate the waste from the disposal of packaging material, the agency utilized the projected market volumes for the first and fifth years of marketing the new and predicate products, and assumed all used product material is disposed of in MSW. The estimated waste from disposal of the packaging and the used product would be a miniscule portion of the total MSW forecasted to be disposed of in the United States. (Confidential Appendixes 4 and 5).

5.3.2 Environmental Impacts due to Disposal of RYO Waste

Once the consumer is done using the product, like combusted cigarettes, RYO cigarettes usually undergo a series of scenarios for both managed and unmanaged waste. The managed waste is the waste that is handled by an organized solid waste collection. The unmanaged waste is the result of users littering cigarettes. 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 5).

Figure 5. Collected Cigarette Waste from Coastal States (2010-2015)



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

As previously discussed, the new RYO cigarette tubes will compete with other similar RYO tobacco products on the market 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 applicant stated that there will be no change in how the new products are manufactured compared to the corresponding predicate products. In addition, the applicant stated that the factory is already equipped to manufacture the new products and thus, no energy will be required to install or calibrate new or existing manufacturing equipment. The same raw materials and energy will be used to manufacture the new products compared to the predicate products and the applicant does not anticipate any significant increase in energy or resource needs to manufacture the new products. Because the applicant stated that the new products will compete with other similar RYO products and with the predicate products, no increase in total market volume for RYO tobacco products and no net increase of energy use will be expected from the proposed actions. Energy use estimates were provided by the applicant (Confidential Appendix 3).

7 Mitigation

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

8 Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco 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 of tobacco products as 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 actions of authorizing the new products (Confidential Appendix 1) and associated manufacture, use, and disposal 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.

Preparer:

Ronald L. Edwards Jr., M.S., Center for Tobacco Products
Education: M.S. in Biology
Experience: 23 years in environmental regulation and laboratory toxicology
Expertise: Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products
Education: M.S. in Environmental Science and Ph.D. in Biochemistry
Experience: 9 years in FDA-related NEPA review
Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

10 List of Agencies and Persons Consulted

Not applicable.

11 Appendix List

Appendix 1: Submission Tracking Numbers for the SE Reports, Related Amendments, and Package Sizes of the New and Predicate Products Covered Under this Programmatic Environmental Assessment (PEA)

12 Confidential Appendix List

Confidential Appendix 1:	Location of Suppliers
Confidential Appendix 2:	The Current-, First-, and Fifth-Year Market Volume Projections and Unit Weights of the New and Predicate Products
Confidential Appendix 3:	Estimate of Energy Use for the Manufacturing of the New and Predicate Products
Confidential Appendix 4:	The First- and Fifth-Year Projection of Paper Waste Associated with Marketing the New and Predicate Products
Confidential Appendix 5:	The First- and Fifth-Year Projection of Cardboard Waste from the Packaging Materials Associated with Marketing the New and Predicate Products

13 References

Agency, E. E. (2017, November 1). *NPRI. (2017). Retrieved 10 20, 2017, from Environment and Climate Change Canada: https://www.ec.gc.ca/inrp-npri/*. Retrieved from E-PRTR : http://prtr.ec.europa.eu/#/facilitylevels

E-PRTR. (2017, November 1). Retrieved from European Environment Agency: http://prtr.ec.europa.eu/#/facilitylevels

Heikkila, T. (2007). *The Great Lakes-St Lawrence River Basin Water Resources Compact.*

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Statistics Canada. (2011). Retrieved 10 20, 2017, from http://www12.statcan.gc.ca/census-recensement/2011/dp-pd/index-eng.cfm

US EPA. (2014). Retrieved 10 20, 2017, from Materials and Waste Management in the United States Key Facts and Figures: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures

US TTB. (2017). Retrieved 10 20, 2017, from https://ttb.gov/tobacco/index.shtml

Wilcox, C., & Mallos, N. (2016). Using Expert Elicitation to Estimate the Impacts of Plastic Pollutionon on Marine Wildlife. *Marine Policy*, 107-114.

APPENDIX 1

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

STN	Package Size Leaves		New	Predicate	Amendments
	New	Predicate			
SE0014367	125	100	Top Standard	Top Cig Paper 24's	SE0014457
SE0014368	125	100	Top Standard	Top Standard	

CONFIDENTIAL APPENDIX 1
Location of Suppliers

The RYO paper manufacturing location is listed below and shown in Figure 6. The RYO paper manufacturing facility is in an industrial park.

(b) (4)

(b) (4)

RYO paper mill location is listed below and shown in Figure 7. The RYO paper mill facility is in a rural wooded area.

(b) (4)

(b) (4)

CONFIDENTIAL APPENDIX 2

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

STN	Measure	Weight of Individual Unit (grams)	Current-Year Market Volume (# RYO)	First-Year Market Volume (# RYO)		Fifth-Year Market Volume (#RYO)	
			Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0014367	Leaves	0.0597	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Booklets	3.02	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Retail Boxes	16.7	[redacted]	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]
	Shipping Cases	378	[redacted]	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]
SE0014368	Leaves	0.0597	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Booklets	3.02	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Retail Boxes	16.7	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Shipping Cases	378	(b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

CONFIDENTIAL APPENDIX 3

Estimate of Energy Use for the Manufacturing of the New and Predicate Products

Energy Description	SE0014367 (kWh)	SE0014368 (kWh)
Energy per Production Unit	(b) (4) [redacted]	
First-Year Energy Used New Product[a]		
First-Year Energy Used Predicate Product[b]		
Fifth-Year Energy Used New Product[c]		
Fifth-Year Energy Used Predicate Product[d]		

[a] New product first year market volume multiplied by energy per production unit

[b] Predicate product first year market volume multiplied by energy per production unit

[c] New product fifth year market volume multiplied by energy per production unit

[d] Predicate product fifth year market volume multiplied by energy per production unit

The applicant claimed that it is possible that the volume of the new products will merely replace other production at the factory and thus, result in no actual increase in production volume or energy usage. As a multi-national manufacturing facility, the market acceptance of the new products and market conditions in non-U.S. markets for other tobacco products manufactured at the same facility would factor into the overall energy use by the manufacturing facility.

The applicant also stated that the energy used to manufacture the new products is negligible compared to the total energy used by the factory. For example, based on the fifth-year projected market volumes, each of the new products alone account for approximately (b) (4) of the total site's energy (b) (4) [redacted]. The proposed actions, therefore, would account for approximately (b) (4) of the total energy used at the manufacturing facility, based on the fifth-year market volume projections (b) (4) [redacted].

CONFIDENTIAL APPENDIX 4

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

To analyze the environmental effects from the total waste due to the proposed actions, the Agency estimated the first- and fifth-year projected weight of the product materials waste (in metric tons) that would be generated from disposal after use of the new and predicate products in 2018 and 2022. Projected waste generation is the total of the projected paper leaves of the new and predicate products.

$$\sum_{i=1}^{2} A_i = \sum_{i=1}^{2} B_i \times C_i \times D$$

A: Projected paper waste generation of the products (metric tons)
B: Projected market volume of paper leaves
C: Weight of individual paper (grams)
D: 1.0 x 10^6 metric tons/gram

	STN Predicate	C	B	A
Current Year	SE0014367	(b) (4)		
	SE0014368			
	Total Predicate Products		(b) (4)	
	STN New	C	B	A
First Year	SE0014367	(b) (4)		
	SE0014368			
	Total New Products		(b) (4)	
	STN Predicate	C	B	A
	SE0014367	(b) (4)		
	SE0014368			
	Total New Products		(b) (4)	
	STN New	C	B	A
Fifth Year	SE0014367	(b) (4)		
	SE0014368			
	Total New Products		(b) (4)	
	STN Predicate	C	B	A
	SE0014367	(b) (4)		
	SE0014368			
	Total Predicate Products		(b) (4)	

If all the projected paper waste generated from use of the new products is disposed of in landfills, the projected cumulative paper waste generated in the first and fifth years of marketing the new products would be (b) (4) metric tons in 2018 and (b) (4) metric tons in 2022. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.

A portion of the generated paper waste is likely to be burnt to ash, which would reduce the amount of waste paper going to landfills or disposed as litter and varies by use of the consumer.

CONFIDENTIAL APPENDIX 5

The First- and Fifth-Year Projection of Cardboard Waste from the Packaging Materials Associated with Marketing the New and Predicate Products

To analyze the environmental effects from total waste due to the proposed actions, the Agency estimated the first- and fifth-year projected weight of the packaging materials waste (in metric tons) that would be generated from disposal after use of the new and predicate products in 2018 and 2022. Projected waste generation is the total of the projected cardboard booklets, retail boxes and shipping cases of the new and predicate products.

$$\sum_{i=1}^{2} A_i = \sum_{i=1}^{2} [(B_i \times C_i) + (D_i \times E_i) + (F_i \times G_i)]H$$

A: Projected cardboard waste generation of the products (metric tons)
B: Projected market volume of booklets
C: Weight of booklet (grams)
D: Projected market volume of retail boxes
E: Weight of retail box (grams)
F: Projected market volume of shipping cases
G: Weight of shipping case (grams)
H: 1.0 x 10-6 metric tons/gram

	STN Predicate	G	F	E	D	C	B	A
Current	SE0014367	378	(b) (4)	16.7	(b) (4)	3.02	(b) (4)	
	SE0014368	378		16.7		3.02		
	Total Predicate Products							(b) (4)
	STN New	G	F	E	D	C	B	A
First Year	SE0014367	378	(b) (4)	16.7	(b) (4)	3.02	(b) (4)	
	SE0014368	378		16.7		3.02		
	Total New Products							(b) (4)
	STN Predicate	G	F	E	D	C	B	A
	SE0014367	378	(b) (4)	16.7	(b) (4)	3.02	(b) (4)	
	SE0014368	378		16.7		3.02		
	Total Predicate Products							(b) (4)
	STN New	G	F	E	D	C	B	A
Fifth Year	SE0014367	378	(b) (4)	16.7	(b) (4)	3.02	(b) (4)	
	SE0014368	378		16.7		3.02		
	Total New Products							(b) (4)
	STN Predicate	G	F	E	D	C	B	A
	SE0014367	378	(b) (4)	16.7	(b) (4)	3.02	(b) (4)	
	SE0014368	378		16.7		3.02		
	Total Predicate Products							(b) (4)

If all the projected packaging waste generated from use of the new products is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new products would be (b) (4) metric tons in 2018 and (b) (4) metric tons in 2022. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the United State in 2014.

A portion of the generated cardboard waste is likely to be recycled, with an overall recycling rate for paper and paperboard products of 64.7% in the United States. If 64.7% of the cardboard waste is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed of in landfills would be decreased to (b) (4)) in the first year and (b) (4) metric tons (b) (4) in the fifth year of marketing the new products.