

# **Environmental Assessment for Marketing Order for Republic Tobacco LP “Rolling Standard”**

**Prepared by Center for Tobacco Products**

**U.S. Food and Drug Administration**

**May 15, 2018**

**Table of Contents**

1. Name of Applicant..... 3

2. Address..... 3

3. Manufacturer ..... 3

4. Description of Proposed Action ..... 3

4.1. Requested Action ..... 3

4.2. Need for Action ..... 3

4.3. Identification of the New Tobacco Product that is the Subject of the Proposed Action ..... 4

4.3.1. Type of Tobacco Product ..... 4

4.3.2. Product Name and Submission Tracking Number ..... 4

4.3.3. Description of the Product and Packaging..... 4

4.3.4. Location of Use..... 4

4.3.5. Location of Disposal ..... 4

4.4. Modification(s) Identified as Compared to the Predicate Product ..... 5

5. Potential Environmental Impacts Due to the Proposed Action ..... 5

5.1. Potential Environmental Impacts Due to Manufacturing the New Product ..... 5

5.2. Potential Environmental Impacts Due to Use of the New Product..... 5

5.3. Potential Environmental Impacts Due to Disposal of the New Product ..... 7

5.3.1. Disposal of Packaging Material ..... 7

5.3.2. Disposal of Used Products ..... 9

5.3.3. Air Emissions from Disposal ..... 10

6. Use of Resources and Energy ..... 10

7. Mitigation ..... 11

8. Alternatives to the Proposed Action ..... 11

9. List of Preparers ..... 11

10. List of Agencies and Persons Consulted ..... 11

11. Confidential Appendix List ..... 11

12. References..... 12

13. Confidential Appendix List ..... 14

This environmental assessment (EA) is for the marketing order for one roll-your-own (RYO) rolling paper product manufactured by Republic Tobacco LP. Information presented in the EA is based on the submission referenced in Section 4.3.2, unless noted or referenced otherwise. This EA has been prepared in accordance with 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

**1. Name of Applicant**

Republic Tobacco LP

**2. Address**

2301 Ravine Way  
Glenview, IL 60025

**3. Manufacturer**

The RYO paper supplier for the new and predicate product is currently located in a foreign country, and location details are provided in Confidential Appendix 1.

**4. Description of Proposed Action**

This proposed action is for the Food & Drug Administration (FDA) to issue a marketing order under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of a RYO rolling paper product into interstate commercial distribution in the United States. The marketing order is based on the finding that this new product is substantially equivalent to a grandfathered predicate product. The authorization is based on the finding that the new product is 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 predicate products after receiving a marketing order for the new product. The applicant provided marketing projections for the new and predicate products for the current, first, and fifth years after a marketing order is issued (Confidential Appendix 2).

**4.1. Requested Action**

Order finding that the listed tobacco product is substantially equivalent to the corresponding predicate product.

**4.2. Need for Action**

Republic Tobacco, LP intends to introduce the new tobacco product into interstate commerce for commercial distribution in the United States. The applicant claims that the new product and predicate products are identical in characteristics and that the new product does not raise different questions of public health (sec 910(a)(3)(A)(ii) of the FD&C Act). After considering the substantial equivalence (SE) report (SE0012826), the Agency shall issue an order under the provisions of sections 910 and 905(j) of the FD&C Act when finding the new product to be substantially equivalent to the predicate product.

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

**4.3.1. Type of Tobacco Product**

RYO rolling paper

**4.3.2. Product Name and Submission Tracking Number**

The name of the new product is listed in Table 1, along with the original submission tracking number (STN), the name of the predicate product, and STNs for amendments in support of this application.

Table 1: The New and Predicate Products and Supporting Amendments

New Product		Predicate Product		Amendments
STN	Name	STN	Name	STN
SE0012826	ROLLING™ STANDARD	NA	TOP® STANDARD	SE0012986 SE0013017 SE0013035 SE0014538 SE0014600

**4.3.3. Description of the Product and Packaging**

The packaging details of the finished new product are the same as those of the predicate product (Table 2).

Table 2: Packaging Information of the New and Predicate Product

STN	New Product			Predicate Product		
	Name	Leaves per booklet	Packaging	Name	Leaves per booklet	Packaging
SE0012826	ROLLING™ STANDARD	125	24 booklets per box and 40 boxes per shipping case	TOP STANDARD	100	24 booklets per box and 40 boxes per shipping case

**4.3.4. Location of Use**

Republic Tobacco LP intends to distribute and sell the new tobacco product in the United States.

**4.3.5. Location of Disposal**

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

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

The applicant claims that the new product differs from the corresponding predicate product only in product quantity (See 4.3.3).

### **5. Potential Environmental Impacts Due to the Proposed Action**

#### **5.1. Potential Environmental Impacts Due to Manufacturing the New Product**

The applicant stated that waste generated by manufacturing the new product 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 manufacturing of the new product would not generate new emissions, solid waste or liquid waste. Also, the applicant stated that the new product 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 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 product will not result in an expansion of the manufacturing facility because the facility is already equipped to manufacture the new product.

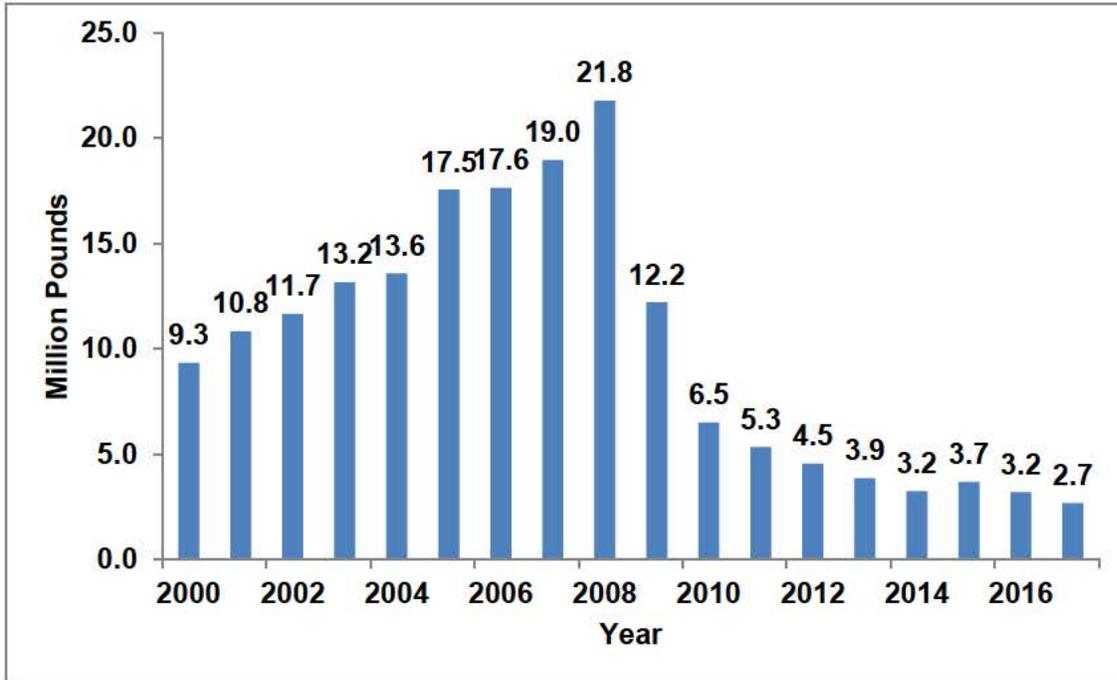
The applicant stated that no effects from increased greenhouse gas (GHG) emissions during manufacturing are anticipated from the proposed action as the new product will compete with other currently marketed RYO products. The applicant provided data demonstrating that the production volume of the new product is a small fraction of total production at the manufacturing facility (SE0014538) (see Confidential Appendix 3).

#### **5.2. Potential Environmental Impacts Due to Use of the New Product**

Per the U.S. Alcohol and Tobacco Tax and Trade Bureau's Tobacco Statistical Release Reports, the use of RYO tobacco products in the United States increased from 9.33 million pounds (4.23 million kilograms) in 2000 to 21.8 million pounds (9.89 million kilograms) in 2008. This was followed by a decrease from 12.2 million pounds (5.53 million kilograms) in 2009 to 1.07 million pounds (0.485 million kilograms) in 2016 (Figure 1) (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2017).

To evaluate the environmental impact of the proposed action due to use of the new product, the Agency analyzed the historical use data for 2008–2016 to forecast the future use of RYO tobacco products in the United States. This was achieved by applying one best-fit power trend line with an  $R^2$  value of 0.9708. Using this approach, the forecasted amount of RYO tobacco products to be used in the United States is estimated to be 2.354 million pounds (1.068 million kilograms) in 2018 and 1.780 million pounds (0.8074 million kilograms) in 2022 (Table 3). Although the data from 2000 to 2007 showed a trend of annual increases in RYO consumption, there has been a clear overall downward trend in RYO consumption since 2008 (Figure 1). Therefore, the Agency did not account for the historical data from 2000 to 2007 to forecast the future use of RYO tobacco products.

Figure 1. Consumption of RYO Tobacco Products in the United States, 2000–2017



The results also forecast cigarette-equivalent units, based on the assumption that 0.0325 ounces (0.921 grams) of tobacco is used per cigarette (National Association of Attorneys General, 1998) (Figure 2). In addition, the agency also analyzed the historical data for U.S. imports of cigarette papers from country of manufacture (Confidential Appendix 4).

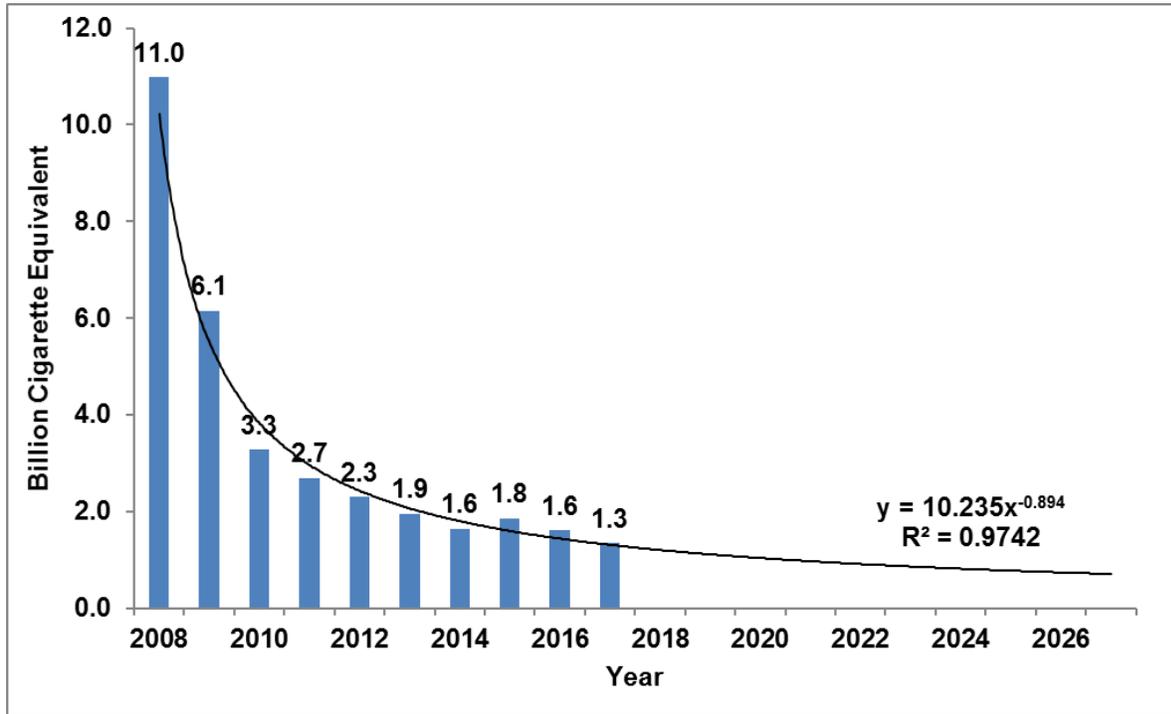
Table 3. Forecasted estimates of RYO tobacco products in the U. S.

Year	RYO Tobacco Products (million pounds) <sup>a</sup>	RYO Tobacco Products (billion cigarette-equivalents) <sup>b</sup>
2018	2.38	1.20
First year (2019)	2.20	1.11
Fifth year (2023)	1.70	0.86

<sup>a</sup> Projected first year and fifth year pounds RYO products:  $20.421 (\text{year} - 2007)^{-0.901}$

<sup>b</sup> Cigarette-equivalents = RYO tobacco (pounds) x 16 ounces/pound x cigarette/0.0325 ounces RYO tobacco

**Figure 2.** Projected Use of RYO Cigarette-Equivalents in the United States, 2019–2023



Because the new product is expected to compete with other RYO products on the market, and represents a small fraction of the total RYO products market in the United States, the Agency anticipates minimal or no net increase in the use of all RYO products. Thus, the Agency also does not anticipate more substances to be released into the environment from use of the new RYO products relative to the substances released by the predicate product and other RYO products already on the market.

During use, the new product is burned to ash, carbon dioxide, and water vapor, as well as products of incomplete combustion such as carbon monoxide. The combustion products from the new product would be similar and released in a similar manner as the predicate product and other RYO rolling paper products. Therefore, the Agency does not anticipate that the use of the new product will lead to the release of new chemicals into the environment. The amount of carbon dioxide generated during combustion of RYO cigarettes that contributes to GHG emissions is miniscule (Confidential Appendix 5) and, because the new product will compete with other currently marketed RYO products, no net addition to GHG emissions is anticipated.

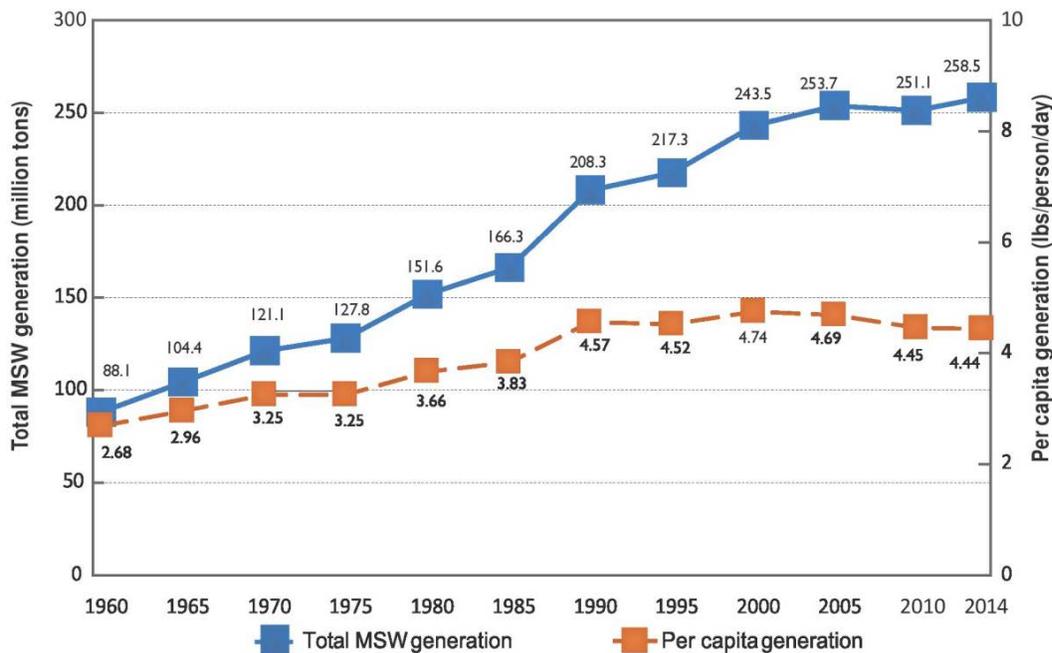
### **5.3. Potential Environmental Impacts Due to Disposal of the New Product**

#### **5.3.1. Disposal of Packaging Material**

After using the new product, the users may recycle the packaging material or dispose of it as MSW or litter. Packaging disposal contributes to using landfill capacity.

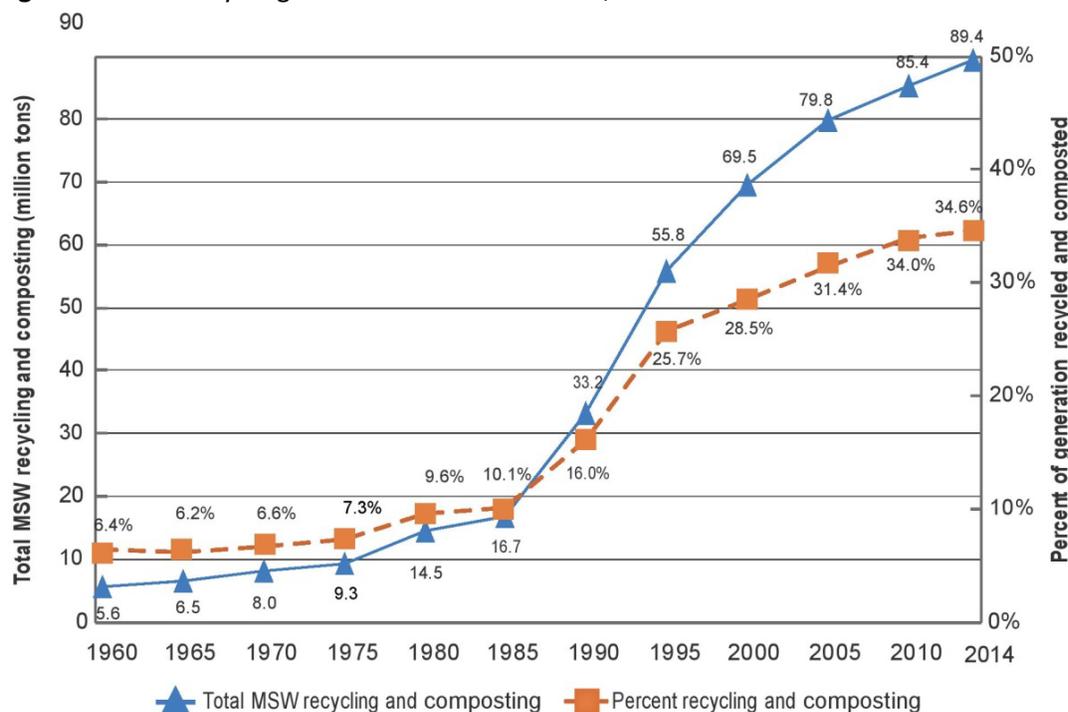
Following use, the packaging materials either would enter the recycling stream or be disposed of as MSW or litter. In 2014, approximately 258.46 million tons (234.47 metric tons) of trash was generated in the United States, and approximately 89.4 million tons (81.1 million metric tons) of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 3 and 4). Paper and paperboard account for 68.61 million tons (62.24 million metric 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 (69.55 million metric tons) (29.7%), of which 39.13 million tons (35.50 million metric tons) was made of paper and paperboard. Of the total paper and paperboard MSW, 44.4 million tons (40.3 million metric tons) (64.7%) was recycled, 19.47 million tons (17.66 million metric tons) (28.4%) was disposed of in landfills, and 4.74 million tons (4.30 million metric tons) (6.9%) was combusted with energy recovery. On average, 4.4 pounds (2.0 kilograms) of waste was generated per person per day in the United States, of which 2.1 pounds (0.95 kilograms) was recycled, composted, or combusted for energy recovery (U.S. Environmental Protection Agency, 2016a).

**Figure 3. MSW Generation Rates in the U.S, 1960 – 2014**



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

**Figure 4. MSW Recycling Rates in the United States, 1960 – 2014**



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

The Agency used the projected market volumes for the first and fifth years of marketing the new product to estimate the waste from disposal of packaging, accounting for recycling of packaging waste as part of overall U.S. recycling of MSW. The estimated waste from packaging disposal after use would be miniscule compared to the total MSW generated at the production facility (Confidential Appendix 6). The materials comprising the packaging elements are commonly found in U.S. MSW and, therefore, the Agency does not anticipate that disposal of packaging from the new product will lead to the release of new chemicals into the environment.

Because the new rolling paper product will compete with other similar rolling paper products on the market and the estimates described above and detailed in Confidential Appendix 6 indicate a negligible contribution to U.S. MSW, construction of new solid waste landfills or incinerators is not anticipated due to disposal of packaging material under the proposed action.

### 5.3.2. Disposal of Used Product

Cigarette butt<sup>1</sup> waste may have an end-of-life-cycle scenario as either managed or unmanaged waste. Managed waste is handled by an organized solid waste collection and management system. For the managed waste, 80.4% by weight enters landfills, and the remaining 19.6% by weight is incinerated for energy recovery (U.S. Environmental Protection Agency, 2016a). The Agency used the projected market volumes for the first and fifth years of marketing the new product to estimate the waste from discarding

<sup>1</sup> “Cigarette butt” is defined in this EA as the cigarette rolling paper containing remainder tobacco that is disposed of following use. The cigarette butt may or may not also include a filter, depending if the RYO cigarette had one.

used product items (RYO cigarette butts). The estimated waste from RYO cigarette butt disposal as MSW would be miniscule compared to the total MSW forecasted to be discarded in the United States (Confidential Appendix 6). Because the new rolling paper product will compete with other similar rolling paper products on the market and the estimates described above and detailed in Confidential Appendix 6 indicate a negligible contribution to U.S. MSW, construction of new solid waste landfills or incinerators is not anticipated due to disposal of used product items under the proposed actions.

Unmanaged waste consists of littered cigarette butts. Globally, cigarette butts are the most commonly discarded piece of waste and one of the most frequently picked up litter item from beaches and water edges (Novotny & Slaughter, 2014, Novotny et al. 2015). These discarded, non-biodegradable cigarette butts leach hazardous substances including arsenic, lead, nicotine and ethyl phenol into aquatic environments and soil (Novotny & Slaughter, 2014, Novotny et al. 2015). Threat assessment surveys among marine experts identified cigarette butts as a threat to seabirds, sea turtles, and marine mammals through entanglement, ingestion and chemical contamination (Wilcox et al. 2016).

Introducing the new product into the U.S. market is not expected to increase the nationwide use of cigarettes; instead, it would compete for market share with existing products. Thus, issuing a marketing order for the new product is not expected to affect the overall level of cigarette butt litter in the United States, but may displace the level of litter from other cigarette products. Based on information in the SE Report, the product modification consists of changes to material composition and the new product will still be the cigarette paper element of a complete cigarette. Therefore, the Agency does not anticipate that disposal of the new product after use will lead to the release of new chemicals into the environment.

### **5.3.3. Air Emissions from Disposal**

Landfill disposal or incineration of used product items and packaging materials will produce GHGs. Methane is a potent GHG that has a global warming potential 28–36 times greater than carbon dioxide and persists in the atmosphere for about 12 years. Landfills are the third largest source of human-related methane emissions in the United States, accounting for approximately 15.4% of these emissions in 2015 (U.S. Environmental Protection Agency, 2017). Estimated GHG emissions from disposal of used product items and packaging associated with the new and predicate products are miniscule (Confidential Appendix 4).

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

The SE Report stated that the manufacture, use, and disposal of the new and predicate products are not expected to jeopardize the continued existence of any endangered species, nor result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. Endangered Species Act. The applicant also confirmed that no plants used for the manufacture of the new and predicate products are listed as an endangered plant under the Convention on International Trade in Endangered Species of Wild Flora and Fauna.

The applicant provided quantitative information on energy used to manufacture the new product and the fraction of total production for the new product at the manufacturing facility. No significant impacts from emissions of GHGs were indicated based on these data (Confidential Appendix 5).

## 7. Mitigation

The Agency did not identify significant adverse environmental effects for the new product. 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 RYO rolling paper product 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 RYO tobacco products, as many other similar RYO tobacco products will continue to be marketed.

Alternative B (Proposed action). The Agency did not identify any significant environmental effects due to the proposed action of issuing a marketing order for the new product and the associated manufacturing, use, and disposal following use of the product.

## 9. List of Preparers

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

### **Preparers:**

Dilip Venugopal, Ph.D., Center for Tobacco Products (product-specific analyses)

Education: M.S. in Ecology and PhD in Entomology

Experience: 16 years in various scientific activities

Expertise: NEPA analysis, environmental impact analysis, applied ecology, geo-statistics

### **Reviewer:**

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

Education: M.S. in Environmental Science and PhD 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. Confidential Appendix List

Confidential Appendix 1: Location of manufacturing facility

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

Confidential Appendix 3: Percentage of the Manufacturing Facility's Total Production Dedicated to the New Product

Confidential Appendix 4: U.S. Imports of Cigarette Papers from Country of Manufacture for the Current and Predicate Products.

Confidential Appendix 5: Greenhouse Gas Emissions from Manufacturing, Use, and Disposal of the New and Predicate Products

Confidential Appendix 6: Projected Product and Packaging Waste from Disposal

## 12. References

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Wilcox, C., Mallos, N. J., Leonard, G. H., Rodriguez, A., & Hardesty, B. D. (2016). Using expert elicitation to estimate the impacts of plastic pollution on marine wildlife. *Marine Policy*, 65, 107-114.

**13. Confidential Appendix List**

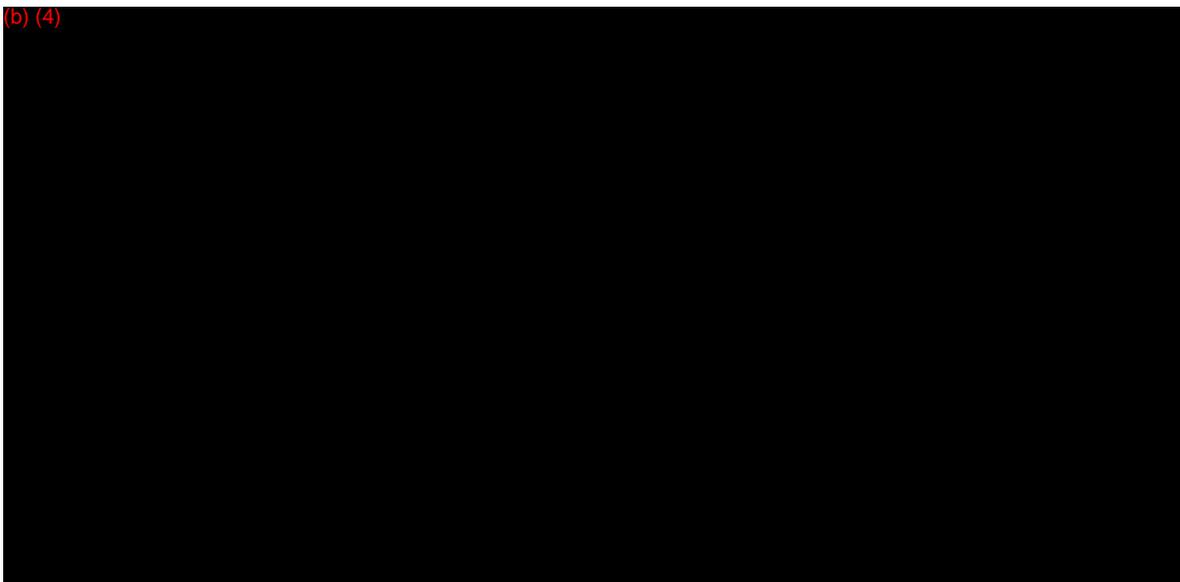
**CONFIDENTIAL APPENDIX 1: Location of Manufacturing Facility**

The new and predicate products are manufactured at (b) (4) (Figure 1). The facility is in a mixed land use area (Figure 2), with a showroom for building materials to the west, a marble works to the east, multifamily housing and a wholesale shipping operation across a two-lane highway to the south, and the (b) (4) river with a 50- to 100-foot vegetated buffer immediately to the north (Google Map, 2018).

**Figure 1:** Location of the Rolling Paper Manufacturing Facility



**Figure 2:** Land Use Surrounding the Rolling Paper Manufacturing Facility



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

STN	Name	Unit	Market Volume (units)		
			Current Year	First Year	Fifth Year
SE0012826	ROLLING™ STANDARD	Leaves	(b) (4)		
		Booklets			
Predicate	TOP® STANDARD	Leaf			
		Booklets			

The applicant intends to simultaneously market the new and predicate products.

**CONFIDENTIAL APPENDIX 3: (b) (4) 2017's Total Production Percentage Occupied by the First and Fifth Year Market Volumes after Issuance of the Marketing Order**

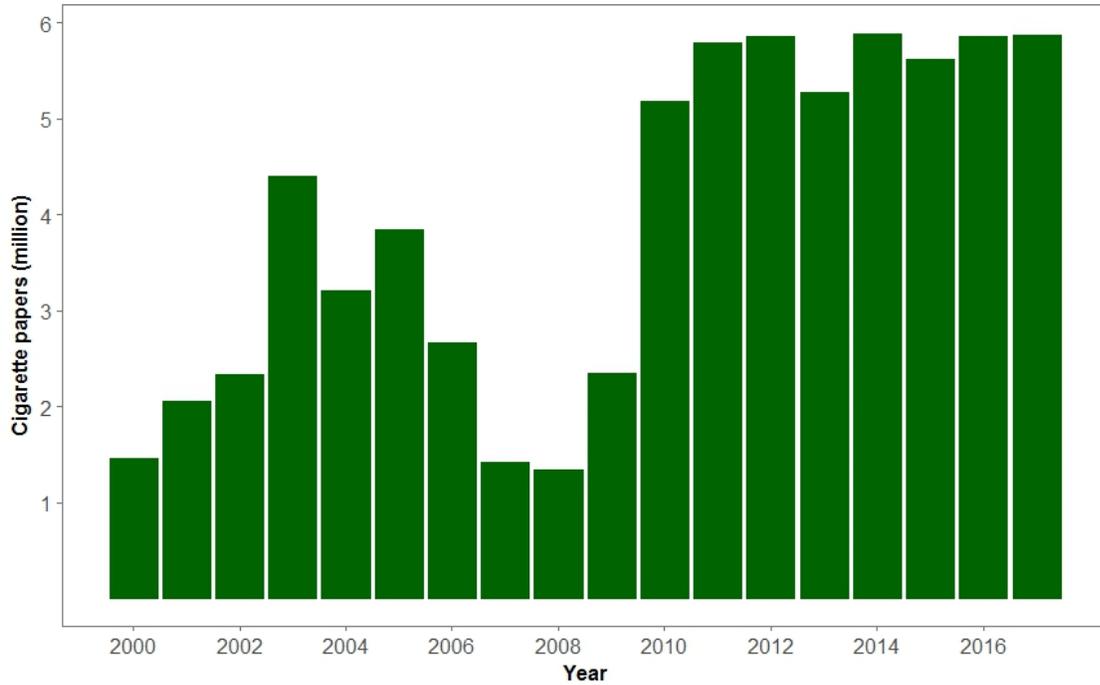
STN	Name	Year	Market Volume (Leaves)	(b) (4) Factory 2017 Production (Leaves)	Percent Occupied by the New Product (%)
SE0012826	Rolling™ Standard	1	(b) (4)		
		5			

The applicant claimed that the new RYO tobacco paper products are intended to account for approximately (b) (4) of the facility's total production

**CONFIDENTIAL APPENDIX 4: U.S. Imports of Cigarette Papers from the Country where the New and Predicate Products were Manufactured (2000-2017)**

Based on data from the U.S. International Trade Commission (USITC), the import of cigarette paper from France, the country where the predicate and new products were manufactured, has increased from 1.5 million units in 2000 to 5.9 million units in 2017 (Figure 1).<sup>2</sup>

**Figure 1. Total Cigarette Papers Imported from France into the United States (2000-2017)**



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<sup>2</sup> Unit is defined by the United States International Trade Commission, available at: <http://dataweb.usitc.gov/>. Accessed on March 13, 2018.

**CONFIDENTIAL APPENDIX 5: Greenhouse Gas Emissions from Manufacturing, Use, and Disposal of the New and Predicate Products**

***GHG Emissions from Manufacturing the Product***

The applicant stated that the energy that will be used to manufacture the new product is negligible compared to the total energy used by the facility. The applicant provided the example that in year 5, energy for manufacturing the new product accounts for approximately (b) (4) of the total site’s energy (b) (4). The applicant also stated that the new and predicate products are intended to compete with each other as well as other RYO papers that are on the market. Thus, they reasoned that there will not be an increase in the overall market volume of RYO papers based on the marketing of the new product and, as Republic uses energy to manufacture the new product, less energy is expected to be needed to manufacture the predicate product. Because the change in energy use is minuscule, any change in resulting GHG emissions from manufacturing the new product would likely be negligible.

***GHG Emissions from Use of Product***

The amount of CO<sub>2</sub>-equivalent gases (CO<sub>2</sub>-eq) emitted from the use of cigarettes has been estimated to be 45–65 mg per cigarette (Geiss & Dimitrios, 2007). As a conservative approach, the high end of this range was used to calculate the GHG emissions from use of each cigarette-equivalent containing 0.0325 ounces (90.921 grams) of RYO tobacco (National Association of Attorneys General, 1998) rolled with one rolling paper leaf from the new and predicate products. The total GHG emissions from the new product were estimated to be (b) (4) metric tons of CO<sub>2</sub>-eq in each of the first and fifth years of marketing, respectively. Even when combined with GHG emissions from use of the predicate product, this is a negligible fraction (approximately (b) (4)) of the 6.87 billion metric tons of CO<sub>2</sub>-eq estimated to have been generated in the United States in 2014 (Table 1).

**Table 1: Relative contribution of GHG emissions from the use of new and predicate products to overall U.S. total**

STN	Name	Metric Tons of CO <sub>2</sub> -eq		
		Current Year	First Year	Fifth Year
SE0012826	Rolling™ Standard	(b) (4)	(b) (4)	(b) (4)
Predicate	Top• Standard	(b) (4)	(b) (4)	(b) (4)
<b>Total, new and predicate products:</b>		(b) (4)	(b) (4)	(b) (4)
<b>Total U.S. (2014):</b>		6,870,000,000		
<b>New and predicate products as a % of total U.S.:</b>		(b) (4)	(b) (4)	(b) (4)

***GHG Emissions from Disposal of Product***

GHG emissions from the product waste and packaging were calculated using the GHG emission rates from the Waste Reduction Model (WARM), v. 14 (U.S. Environmental Protection Agency, 2016c). WARM estimates GHG emissions across different material types commonly found in MSW. Taking into account the rates for recycling, landfill disposal, and combustion with energy recovery of the various material types in the new and predicate products, the total amount of GHG emissions from product waste and packaging disposal was estimated to be (b) (4) metric tons of CO<sub>2</sub>-eq in each of the first and fifth years of marketing, respectively. Even when combined with GHG emissions from disposal of the

predicate product, this is a negligible fraction (approximately (b) (4) of the 6.87 billion metric tons of CO<sub>2</sub>-eq estimated to have been generated in the United States in 2014 (Table 2).

**Table 2:** Relative contribution of GHG emissions from the disposal of new and predicate products to overall U.S. total

STN	Name	Metric Tons of CO <sub>2</sub> -eq		
		Current Year	First Year	Fifth Year
SE0012826	Rolling™ Standard	(b) (4)		
Predicate	Top• Standard			
<b>Total, new and predicate products:</b>				
Total U.S. (2014):		6,870,000,000		
<b>New and predicate products as a % of total U.S.:</b>		(b) (4)		

## CONFIDENTIAL APPENDIX 6: Projected Product and Packaging Waste from Disposal

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

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

$$B_i (\text{tons}) = E \times F_i (\text{leaves}) \times G_i (\text{ounces}) \times \frac{\text{ton}}{32,000 \text{ ounces}}$$

$$C_i (\text{tons}) = F_i (\text{leaves}) \times \left[ \frac{J_i (\text{grams})}{K_i} + \frac{L_i (\text{grams})}{M_i \times K_i} + \frac{N_i (\text{grams})}{O_i \times M_i \times K_i} \right] \times R \times \frac{\text{ton}}{907,184.74 \text{ grams}}$$

$$G_i (\text{ounces}) = \frac{H (\text{millimeters})}{P_i (\text{millimeters})} \times \left[ \frac{0.0325 \text{ ounces RYO tobacco}}{\text{leaf}} + \left( \frac{Q_i (\text{grams})}{\text{leaf}} \times \frac{\text{ounce}}{28.35 \text{ grams}} \right) \right]$$

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

$B_i$  = cigarette butt MSW generated by the used products (tons)

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

$D$  = fraction of cigarette butts disposed in MSW = 0.66 (34% littered)

$E_i$  = leaves (cigarette-equivalents) for market projection of product

$F_i$  = weight per cigarette butt (ounces)

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

$H_i$  = booklet (grams)

$I_i$  = leaves per booklet

$J_i$  = display box (grams)

$K_i$  = booklets per box

$L_i$  = shipping case (grams)

$M_i$  = boxes per case

$N_i$  = cigarette rolling paper length (millimeters)

$O_i$  = leaf (grams)

$P$  = fraction of cardboard paper waste not recycled = 1 - 0.647 = 0.353 (U.S. Environmental Protection Agency 2016a)

The product packaging elements are disposed of as MSW or recycled, and the cigarette butts are disposed of as MSW or litter. The Agency estimated the amount of MSW that would be disposed of in landfills or incinerated, after accounting for portions of the paper and cardboard packaging being recycled at a rate of 64.7% (U.S. Environmental Protection Agency, 2016a). The total estimated MSW generated from the new and predicate products is (b) (4) tons (b) (4) metric tons) in the current, first, and fifth years, respectively. This is a negligible fraction (less than (b) (4) ; see table below) of the 192,080,000 tons (174,250,000 metric tons) of total MSW generated and not recycled in the United States in 2014, estimated as follows:

$$258,460,000 \text{ million tons generated} - 66,380,000 \text{ million tons recycled} = 192,080,000 \text{ tons disposed of as MSW}$$

Table 3 details the parameters used in the calculations for MSW generation from the new and predicate products in the current, first, and fifth years.

**Table 3: Relative contribution of MSW generated from the new and predicate products to overall U.S. total**

	STN	Name	Fraction cardboard/paper in MSW	Rolling paper mass (g)	Paper length (mm)	Display boxes/shipping case	Shipping case (g)	Booklets per box	Display box (g)	Leaves per booklet	Booklet cover (g)	Butt length (mm)	Butt (oz)	Cig-eq	Frac butts in MSW	Cardboard/paper	Butts	Total waste
			P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
Current Year	SE0012826	Rolling™ Standard	0.353	0.05000	70	40	378	24	16.7	125	3.02	27	0.0132	(b) (4)				
	Predicate	Top* Standard	0.353	0.05000	70	40	378	24	16.7	100	3.02	27	0.0132					
	MSW from disposal of new and predicate products after use (tons)																	(b) (4)
	Total MSW disposed (not recycled) in U.S. (2014) (tons)																	192,080,000
MSW from product disposal as a % of total U.S.																	(b) (4)	
First Year	SE0012826	Rolling™ Standard	0.353	0.05000	70	40	378	24	16.7	125	3.02	27	0.0132	(b) (4)				
	Predicate	Top* Standard	0.353	0.05000	70	40	378	24	16.7	100	3.02	27	0.0132					
	MSW from disposal of new and predicate products after use (tons)																	(b) (4)
	Total MSW disposed (not recycled) in U.S. (2014) (tons)																	192,080,000
MSW from product disposal as a % of total U.S.																	(b) (4)	
Fifth Year	SE0012826	Rolling™ Standard	0.353	0.05000	70	40	378	24	16.7	125	3.02	27	0.0132	(b) (4)				
	Predicate	Top* Standard	0.353	0.05000	70	40	378	24	16.7	100	3.02	27	0.0132					
	MSW from disposal of new and predicate products after use (tons)																	(b) (4)
	Total MSW disposed (not recycled) in U.S. (2014) (tons)																	192,080,000
MSW from product disposal as a % of total U.S.																	(b) (4)	