

**Environmental Assessment for Market Authorization of  
“Ventura® Whites”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

August 8, 2017

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This environmental assessment (EA) is for the market authorization of a Roll-Your-Own (RYO) cigarette paper manufactured by Republic Tobacco, LP. Information presented in the EA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This EA has been prepared in accordance with 21 CFR 25.40 as part of a submission under section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

**1. Name of Applicant**

Republic Tobacco, LP

**2. Address**

2301 Ravine Way  
Glenview, Illinois 60025

**3. Manufacturer**

(b) (4)  


**4. Description of the Proposed Action**

This proposed action is for FDA to issue a market authorization under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of a brand of RYO cigarette papers into interstate commercial distribution in the U.S. The authorization is based on the finding that the new product is substantially equivalent to the 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 market authorization for the new product.

**4.1. Requested Action**

An order finding the listed tobacco product is substantially equivalent to the predicate product.

**4.2. Need for Action**

Republic Tobacco, LP wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the U.S. The applicant claims that the new product and the predicate product have different characteristics (sec 910(a)(3)(A)(ii) of the FD&C Act), but that they differ only in product quantity. In addition, the applicant claimed that the new and predicate products are the same in product and packaging composition. After considering the SE Report, 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 Subject of the Proposed Action

#### 4.3.1. Type of Tobacco Products

Roll-your-own (RYO) cigarette papers

#### 4.3.2. Product Name and Its Original STN

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

STN	New Product	Predicate Product
SE0011188	Ventura® Whites	Ventura® Whites

#### 4.3.3. Description of the Product Package

The packaging materials of the new and predicate products are identical in materials and composition. However, the new product contains more rolling papers per box, therefore the retail display box is larger for the new product compared to the predicate product.

#### 4.3.4. Location of Manufacturing

The manufacturer, <sup>(b) (4)</sup> [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.

(b) (4)



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

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

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

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

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

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

The applicant claims that the new product differs from the predicate product in product quantity only.

### **5. Environmental Introduction Due to the Proposed Action**

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

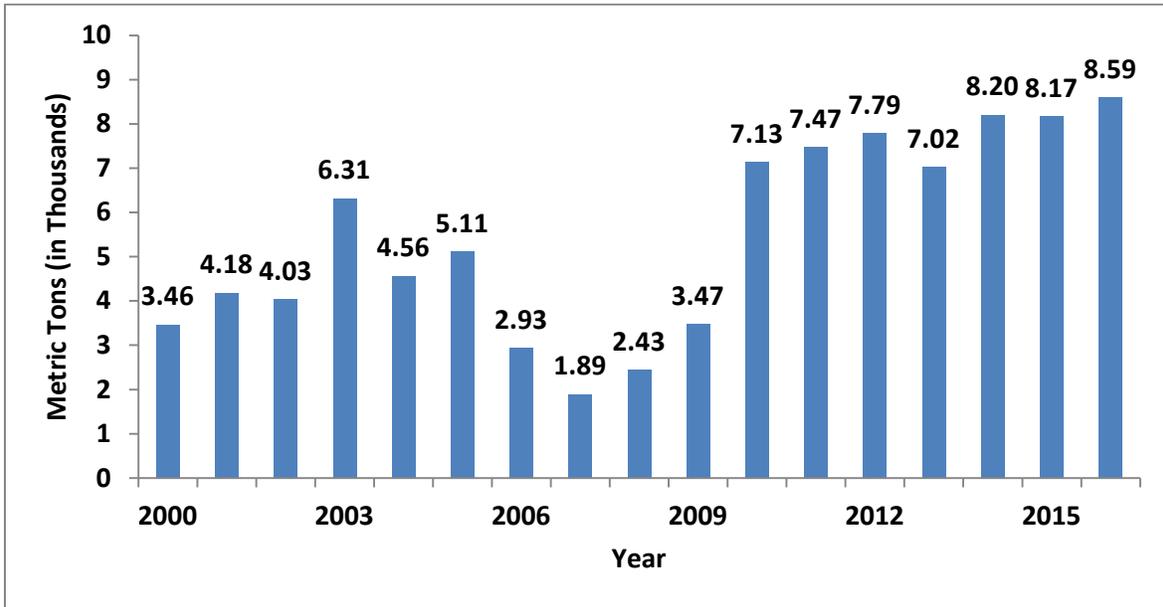
##### **5.1.1. Tobacco Products Imported from France**

Tobacco Import and Tobacco Market Volumes. According to the U.S. International Trade Commission (USITC), the import of tobacco products to the U.S. from France has increased from 3,463 metric tons in 2000 to 8,588 metric tons in 2016 (Figure 2).<sup>2</sup> When examining the change in import of cigarette papers to the U.S from France over the same period of time, there was a significant decrease from 1,180 metric tons in 2000 to 533 metric tons in 2016, as shown in (Figure 3).

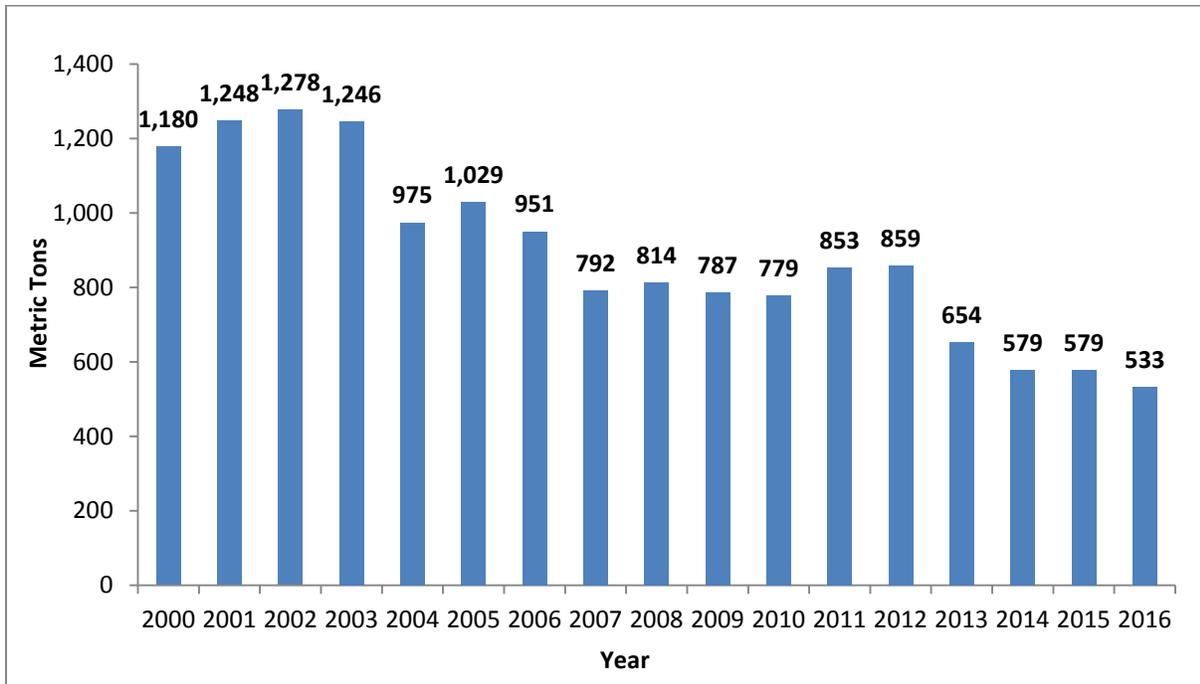
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<sup>2</sup> Unit is defined by USITC, available at: <http://dataweb.usitc.gov/>. Accessed on March 23, 2017.

**Figure 2. Total Tobacco Products Imported from France into the U.S. 2000 – 2016**



**Figure 3. U.S. Import of Cigarette Papers from France 2000 – 2016**



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

*Introduction from Manufacturing the New Product in the Proposed Action.* The Agency anticipates the waste generated as a result of manufacturing the new RYO tobacco product 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.

Based on information in the SE Report, the only difference between the new product and the predicate product is the quantity of cigarette papers. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new product.

The applicant stated that the new product comprises a very small fraction of the total volume of cigarette papers manufactured at the facility (confidential appendix 1). In addition, the applicant claimed that the new product is intended to compete with and replace other currently marketed RYO cigarette paper products. The applicant claimed that no expansion of the manufacturing facility is anticipated for manufacturing the new product, despite continuing to market the predicate product. Therefore, the Agency does not foresee the introduction of the new product to notably affect the current manufacturing waste generated from the production of all cigarette papers.

Because the applicant claimed that the new product is intended to compete with and replace other currently marketed RYO products, no addition of air emissions (e.g., greenhouse gases (GHG), SO<sub>x</sub> and NO<sub>x</sub>) is anticipated. In addition, the manufacturing facility is located in France and the applicant claimed that the facility is in compliance with applicable French environmental laws and regulations. Additionally, France has shown a decrease of GHG emissions since 1990.<sup>3</sup>

The applicant also claimed that the RYO papers are produced from renewable and sustainable sources, certified by 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 concluded that the manufacturing of the new product will be operated under controls and standards that protect the environment including those species and habitats listed under the Convention on International Trade and Endangered Species (CITES).

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

### **5.2.1 Use of RYO Rolling Papers**

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of RYO tobacco products in the U.S. increased from 4.7 billion cigarette-equivalents in 2000 to 11.0 billion cigarette-equivalents in 2008. This

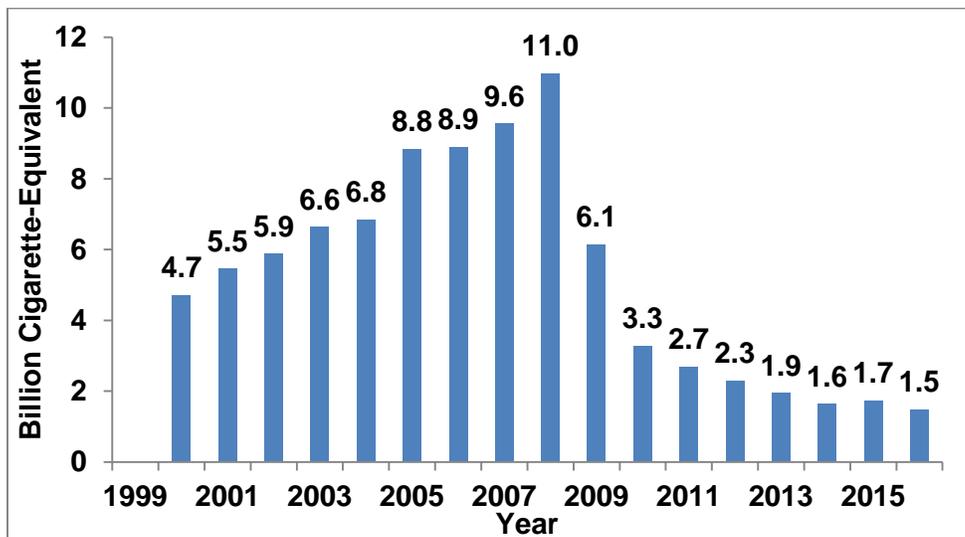
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<sup>3</sup> United Nations Climate Change Secretariat, Summary of GHG Emissions for France.

[https://unfccc.int/files/ghg\\_emissions\\_data/application/pdf/fra\\_ghg\\_profile.pdf](https://unfccc.int/files/ghg_emissions_data/application/pdf/fra_ghg_profile.pdf). Accessed on Aug 1, 2017

was followed by a decrease in use from 6.1 billion cigarette-equivalents [1] in 2009 to 1.5 billion cigarette-equivalents in 2016 (Figure 4).

**Figure 4. Use of RYO in the U.S. in 2000 – 2016 in Billion Cigarette-Equivalents**



### **5.2.2 Environmental Introduction from the Use of the New Product**

The applicant intends to market the new and predicate products after receiving market authorization for the new product. Because the new product is expected to compete with and replace 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 product, relative to the substances released by the predicate product already on the market because the only change is in product quantity with the new product. There are no physical property changes between the new and predicate products resulting in no new substances being released into the environment.

As noted, the only difference between the new and predicate products is the quantity of rolling papers per box. During use, the new product is usually burned to ash, carbon dioxide (CO<sub>2</sub>), and water vapor, as well as products of incomplete combustion such as carbon monoxide (CO). These emissions from the new product are released in a similar manner to those from its predicate product and other RYO paper products. The amount of carbon dioxide generated during combustion which contributes to GHG emissions is miniscule, and because the new product will compete with and replace other currently marketed RYO products, no addition of GHG emissions is anticipated.

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

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

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

#### **5.3.1 Disposal Following Use of RYO Rolling Cigarette Paper**

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

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the U.S., and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 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 [2].

**Figure 5. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960-2014**

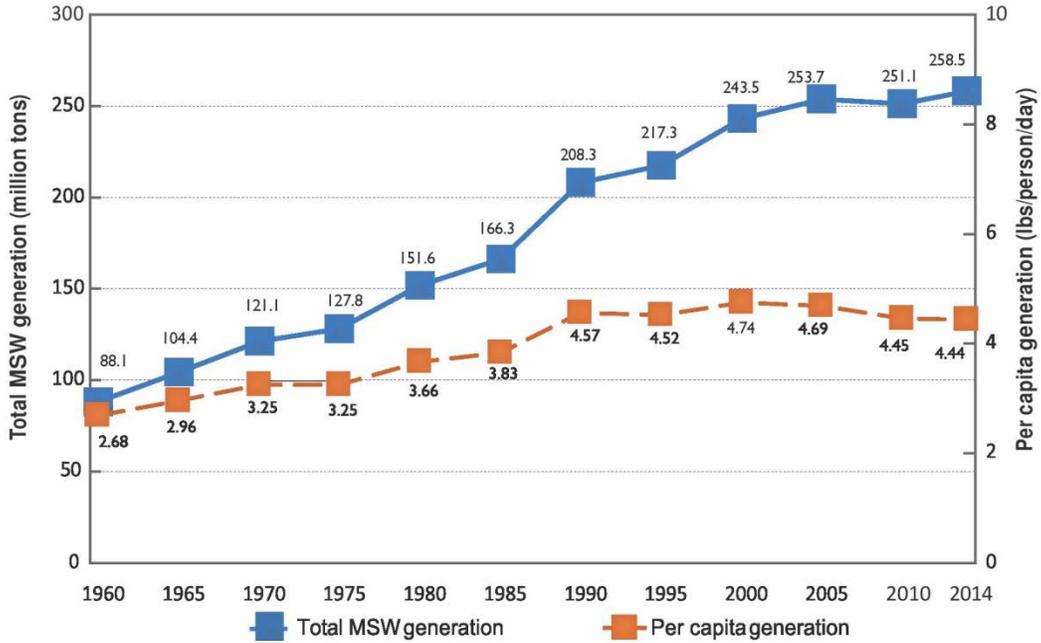


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

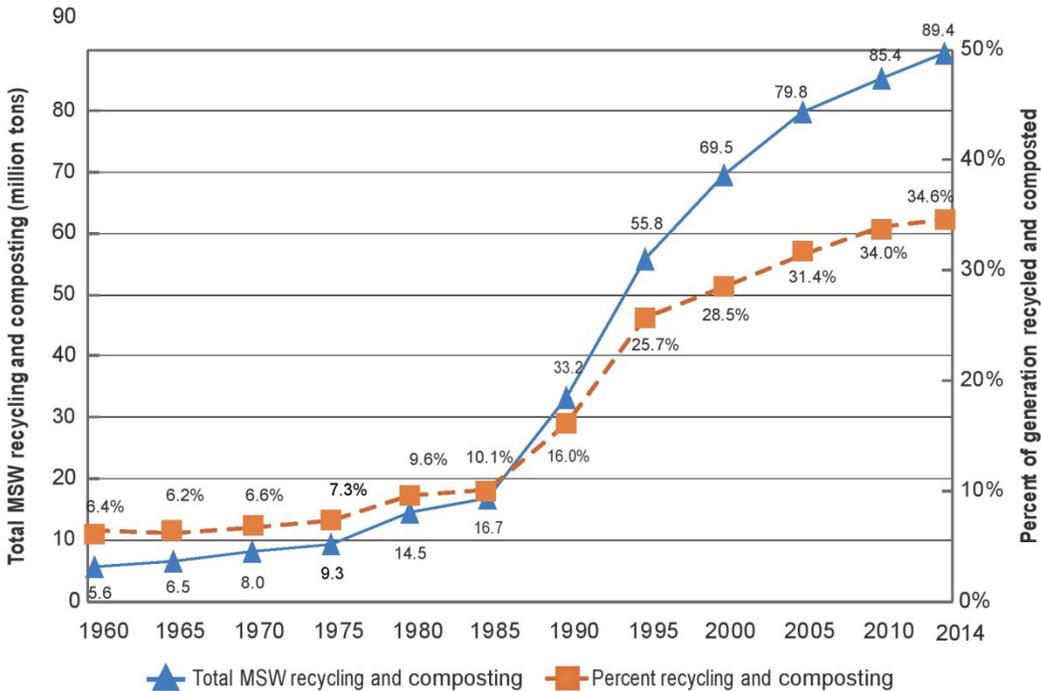


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

## (b) Disposal of Used RYO Tobacco Paper Following Use

Because RYO papers can be consumed with filters, like cigarettes, the end of life pathway of RYO papers is assumed to have the same pathway as the filtered cigarette waste (cigarette butts). Additionally, when RYO papers are not consumed with filters, the end of life pathway can be like unfiltered cigarettes.

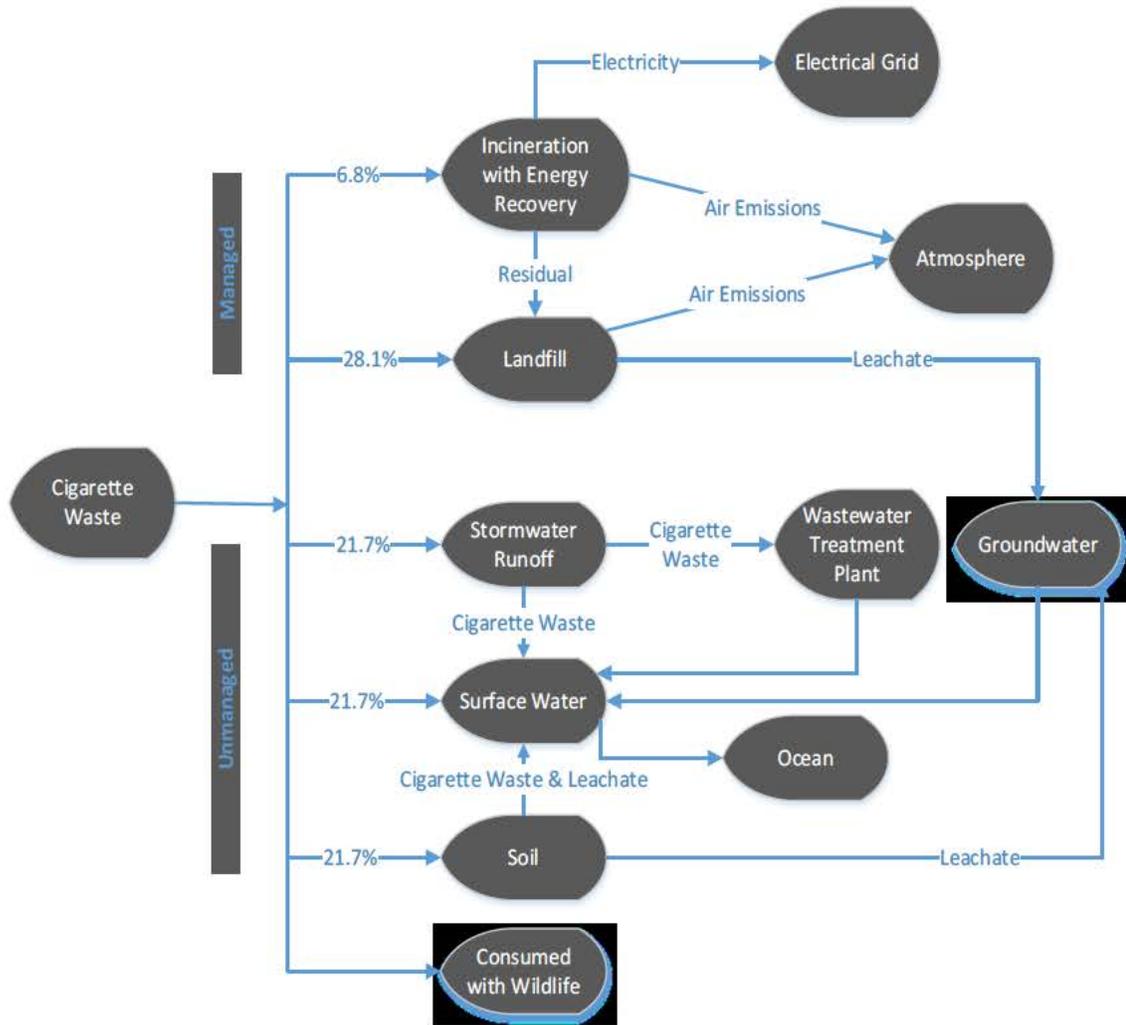
At the end of life, cigarette butt waste usually undergoes a series of scenarios for both managed and unmanaged waste (Figure 7). The managed waste is the waste that is handled by an organized solid waste collection and management system. The managed waste is treated as municipal solid waste (MSW) and either incinerated with energy recovery or landfilled. The unmanaged waste is the result of users littering cigarettes. According to a report published by “Keep America Beautiful”, a study of 767 smokers showed 35% of used cigarettes were disposed of properly (with MSW) with a resulting 65% littering rate for cigarette butts[3]. This study is done by observing the cigarettes users’ behavior in 44 locations.<sup>4</sup>

For the managed waste, 80.4% by-weight of the managed waste enters landfills, and the remaining 19.6% by-weight is incinerated for energy recovery [4]; that is, approximately 28.1% by-weight ( $80.4\% \times 35\%$ ) of the total cigarette waste enters the landfills and 6.8% by-weight ( $19.6\% \times 35\%$ ) of the total cigarette waste enters the incinerators. For the unmanaged waste, the Agency assumes that cigarette butt waste enters the storm water runoff, surface water, and soil in equal amounts; that is, 21.7% each by-count of total cigarette butt waste (Figure 7).

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<sup>4</sup> Including city center, retail, medical/hospital, gas station, bar/restaurant, recreational, and rest area settings.

**Figure 7. End of life pathways for cigarette waste**



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

(c) Air Emissions

The used tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs. Methane ( $\text{CH}_4$ ) is a potent GHG that has a global warming potential of 28-36 times greater than  $\text{CO}_2$ , and has an atmospheric life of about 12 years. Global  $\text{CH}_4$  emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related  $\text{CH}_4$  emissions in the U.S., releasing an estimated 115.7 million metric tons of  $\text{CO}_2$ -equivalents, accounting for approximately 15.4% of total  $\text{CH}_4$  emissions in 2015 [5]. The decomposition of landfill waste produces approximately 50% biogenic  $\text{CO}_2$  and 50%  $\text{CH}_4$ , by volume, as well as trace amounts of non- $\text{CH}_4$  organic compounds and volatile organic compounds. However, only  $\text{CH}_4$  generation and emissions are

estimated and reported for landfills, a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines [6].

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

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

To determine the amount of waste due to disposal of packaging material and product material, the Agency used the projected market volumes in the first and fifth years after issuance of an authorization order for the new product. 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 U.S. (Confidential Appendix 4). In addition, paper components are more likely to be recycled; at least a portion of the new product's waste is likely to be recycled.

As previously discussed, because the new product will compete with and replace other similar RYO tobacco products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfills is not anticipated due to the proposed action.

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

Comparing the projected market volume of the new product with the forecasted total U.S. MSW, the projected waste generated from use of the new product is negligible.

The waste generated from using the new product is expected to make up a negligible fraction of the total MSW. Therefore, the GHG emitted from the waste associated with the new product is negligible and no additional control of air emissions is anticipated in the landfills.

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

The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment because the new product is anticipated to be manufactured, used, and disposed of in the same way as other RYO tobacco products, including cigarette rolling papers. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other RYO tobacco products, including cigarette rolling papers,

manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use because the new product has identical properties to its predicate product and will be made using the same materials, ingredients and processes as the predicate product.

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

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

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

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

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

## **9. Mitigation**

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

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

*Alternative A (No-action alternative):* The no-action alternative is to not authorize the marketing of the new tobacco product in the U.S. The environmental impact of the no-action

alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products as the predicate product (Confidential Appendices 1 and 4) and many similar RYO tobacco products would continue to be marketed.

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

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

## 11. List of Preparers

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

Mehran Niazi, PhD, Center for Tobacco Products

Education: PhD, in Environmental Science

Experience: 12 years in environmental fate and transport and environmental modeling

Expertise: Environmental risk assessment, water quality modeling, environmental fate & transport

Gregory G. Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: 34 years in environmental toxicology and risk assessment

Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

## 12. List of Agencies and Persons Consulted

Not applicable.

## 13. Appendix List

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

Appendix 2: Forecast of Use of RYO Tobacco Products in the U.S.

## 14. Confidential Appendix List

Confidential Appendix 1:	Comparison of the New Product to the Manufacturer's Total Annual Production
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 Product with Total RYO Tobacco Products Used in the U.S.
Confidential Appendix 4:	The First- and Fifth-Year Projection of Paper and Cigarette Butt Waste of Packaging Materials and Product Materials Associated with Marketing the Products

## 15. References

1. U.S. Dept of Treasury Alcohol and Tobacco Tax and Trade Bureau. (2017, April 10). *Tobacco Statistics*. Accessed <http://www.ttb.gov/tobacco/tobacco-stats.shtml>
2. U.S. Environmental Protection Agency. (2016). *Advancing Sustainable Material Management: Facts and Figures*. Available at [www.epa.gov/sites/production/files/2016-11/documents/2014\\_smmfactsheet\\_508.pdf](http://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf)
3. Keep America Beautiful, "Littering Behavior in America Results of a National Study," San Marcos, CA, 2009.
4. U.S EPA Office of Resource Conservation and Recovery, "EPA Advancing Sustainable Materials Management: Facts and Figures 2013," 2016.
5. U.S. EPA. Draft Report: Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2014. EPA 430-P-17-001. Issued February 15, 2017. Available at [https://www.epa.gov/sites/production/files/201702/documents/2017\\_complete\\_report.pdf](https://www.epa.gov/sites/production/files/201702/documents/2017_complete_report.pdf)
6. Intergovernmental Panel On Climate change (IPCC). (2017, January 23). *2006 IPCC Guidelines for National Greenhouse Gas Inventories*. Available at <http://www.ipcc-nggip.iges.or.jp/public/2006gl/>

**APPENDIX 1**

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

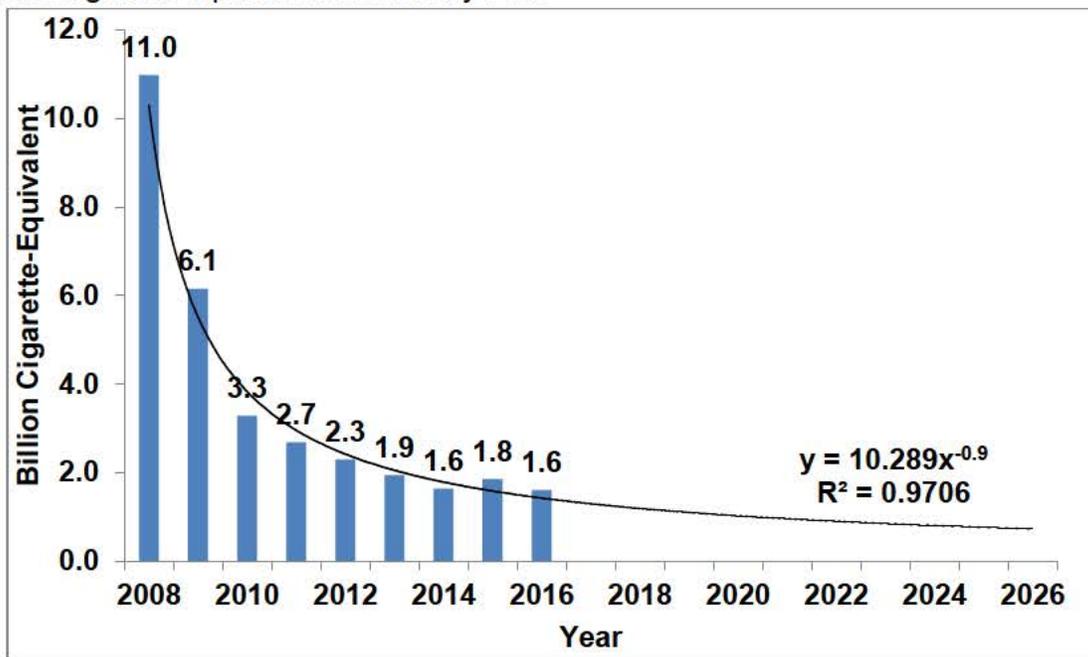
STN	Product Name	Product	Papers per box	Amendments
SE0011188	Ventura® Whites	New	200	SE0011758 SE0011919
		Predicate	32	SE0013570 SE0014086

## APPENDIX 2

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

To evaluate the environmental impact of the proposed action due to use of the new product, the Agency utilized the historical data of RYO tobacco product use in 2008–2016 to forecast the use of RYO tobacco products in the U.S. This was achieved by using one best-fit power trend line with the  $R^2$  value of 0.97.<sup>5</sup>

Using trend lines, the forecast of use of RYO tobacco products in the U.S. was estimated mathematically. Accordingly, the forecasted amount of RYO tobacco products to be used in the U.S. is estimated to be 1.2 billion cigarette-equivalents in 2017 and 0.9 billion cigarette-equivalents in 2021.<sup>6</sup> The amount of RYO tobacco products used in the U.S. is estimated to be 1.5 billion cigarette-equivalents in 2016 by TTB.



Year <sup>7</sup>	RYO Tobacco Products (Billion Cigarette-Equivalent)	RYO Tobacco Products (Metric Tons)
2016	(b) (4)	
1 <sup>st</sup> Year (2017)		
5 <sup>th</sup> Year (2021)		

<sup>5</sup> Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 20, 2017.

(b) (4) [Redacted] of tobacco

**CONFIDENTIAL APPENDIX 1**

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

Item	Unit	New Product	Manufacturer's Total Annual Production	% of the New Product to Total Manufacturer's Production
Market Volume	# Leaves	(b) (4)		

**Confidential Appendix 2**

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

STN	Unit	First-Year Market Volume		Fifth-Year Market Volume	
		New Product	Predicate Product	New Product	Predicate Product
SE0011188	# Leaves	(b) (4)			
	Metric Tons	(b) (4)			

### CONFIDENTIAL APPENDIX 3

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

The first- and fifth-year market volumes of the new and predicate products projected to occupy the U.S. 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 U.S. (Appendices 2, 3, and Confidential Appendix 3). The percent of the total RYO tobacco market occupied in the projected first and fifth year of marketing of the new and predicate products was calculated using the equations below<sup>8</sup>:

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

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

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

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

STN	Year	Forecasted Use of Total RYO Tobacco in the U.S. (Billion Cigarette-Equivalent) <sup>9</sup>	Projected Market Volume of New Product (Billion Cigarette-Equivalent) <sup>10</sup>	Projected Market Occupation of New Product in the U.S. (%)
SE0011188	2017	(b) (4)		
	2021			
Predicate	2017			
	2021			
Total	2017			
	2021			

<sup>8</sup> Each individual leaf of rolling paper is anticipated to be used in making a single cigarette unit. Therefore, one leaf of rolling paper is equal to one cigarette-equivalent.

<sup>9</sup> See Appendix 3.

<sup>10</sup> See Confidential Appendix 1.

## CONFIDENTIAL APPENDIX 4

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

To analyze the environmental effects from paper and cigarette butt waste due to the proposed action, 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<sup>19</sup>, and shipping case waste generation of the products:

$\sum_{i=1}^1 A_i = \sum_{i=1}^1 (B_i + C_i + E_i + G_i)$ $B_i = \frac{H_i}{I_i} \times J \times Z$ $C_i = \frac{H_i}{I_i \times K_i} \times L \times Z$ $E_i = \frac{H_i}{I_i \times K_i \times M_i} \times P \times Z$ $G_i = \frac{H_i \times T_i \times U_i}{100} \times 0.001 \times Z$ $T_i = \frac{27}{S_i} \times 100$	<p><i>A<sub>i</sub></i>: Projected paper waste generation of the products (metric tons)  <i>B<sub>i</sub></i>: Projected booklet cover waste generation of the products (metric tons)  <i>C<sub>i</sub></i>: Projected retail cardboard unit waste generation of the products (metric tons)  <i>E<sub>i</sub></i>: Projected shipping case pouch waste generation of the products (metric tons)  <i>F<sub>i</sub></i>: Projected pouch and pouch-related waste generation of the products (metric tons)  <i>G<sub>i</sub></i>: Projected cigarette butt<sup>11</sup> waste of the products (metric tons)  <i>H<sub>i</sub></i>: Projected market volume<sup>11</sup> of the products (# individual leaves of rolling paper)  <i>I<sub>i</sub></i>: Number of rolling papers per booklet  <i>J</i>: Weight of empty booklet cover (grams)  <i>K<sub>i</sub></i>: Number of booklets per retail unit  <i>L</i>: Weight of empty retail outer box (grams)  <i>M<sub>i</sub></i>: Number of retail units (pouch or outer box) per shipping case  <i>P</i>: Weight of empty shipping case (grams)  <i>S<sub>i</sub></i>: Length of rolling paper (millimeters)  <i>T<sub>i</sub></i>: Cigarette butt ratio (%)<sup>12</sup>  <i>U<sub>i</sub></i>: Weight of rolling paper (milligrams per leaf)  <i>Z</i>: 1.0 x 10<sup>-6</sup> metric tons/gram</p>
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<sup>11</sup> Cigarette butt in this EA is defined as cigarette rolling paper containing remainder tobacco that is disposed of following use.

<sup>12</sup> ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed as solid waste following use.

First Year	STN	U	T	S	P	M	L	K	J	I	H	G	E	C	B	A
	SE0011188	(b) (4)														
	Predicate	(b) (4)														
First-Year Total Paper and Cigarette Butt Waste for New and Predicate Products																(b) (4)

Fifth Year	STN	U	T	S	P	M	L	K	J	I	H	G	E	C	B	A
	SE0011188	(b) (4)														
	Predicate	(b) (4)														
Fifth-Year Total Paper and Cigarette Butt Waste for New and Predicate Products																(b) (4)

**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). 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 U.S., 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 U.S., the estimated cumulative paper and cardboard waste will be (b) (4) in the fifth year of marketing the new product.<sup>13</sup>

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, respectively. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. in 2014.