

**Environmental Assessment for a Marketing Order for
“Republic Tobacco L.P. OCB XPERT 1-1/4”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

April 5, 2018

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This environmental assessment (EA) is for a marketing order for a roll-your-own (RYO) tobacco rolling paper product manufactured by Republic Tobacco L.P. 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 submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

Republic Tobacco L.P.

2. Address

2301 Ravine Way
Glenview, IL 60025

3. Manufacturer

(b) (4)

4. Description of Proposed Action

The 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 tobacco product into interstate commerce for commercial distribution in the United States.

The order is based on the finding that the new product is substantially equivalent to the predicate product (SE0003298) that was that was previously found substantially equivalent by the FDA and granted a marketing order on October 9, 2013. The applicant claimed that the new product differs from the predicate product in ingredients and product design (Confidential Appendix 1).

The applicant intends to market the new and predicate products simultaneously after receiving a marketing order for the new product, and provided the current year market volume of the predicate product, and first-, and fifth-year marketing projections for the new and predicate products.

4.1 Requested Action

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

4.2 Need for Action

Republic Tobacco L.P. wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the United States. The applicant claims that the new and predicate products have different characteristics but 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, 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 are the Subject of the Proposed Action

4.3.1 Type of Tobacco Product

RYO tobacco rolling paper

4.3.2 Product Name and Their Original Submission Tracking Number

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 SE Report and amendments for the new product.

STN	New Product	Predicate Product
SE0014036	OCB XPERT 1-1/4	OCB Organic Hemp King Size Slim

4.3.3 Description of the Product Package

The packaging materials of the new and predicate products are identical in composition and packaging weights. Details of the weights of each packaging component for the new and predicate products are described in Appendix 1.

4.3.4 Location of Manufacturing

(b) (4)

The location where the final product is made is in France. The manufacturing facility is located on the southernmost border of an industrial area that is bounded to the south by a residential area (Figure 1). The facility is in a mixed-use area, with a building materials showroom to the west, a marble works to the east, multifamily housing and a produce wholesaler 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 (Figure 2) (Google, 2018).

Figure 1. Location of the Rolling Paper Manufacturing Facility

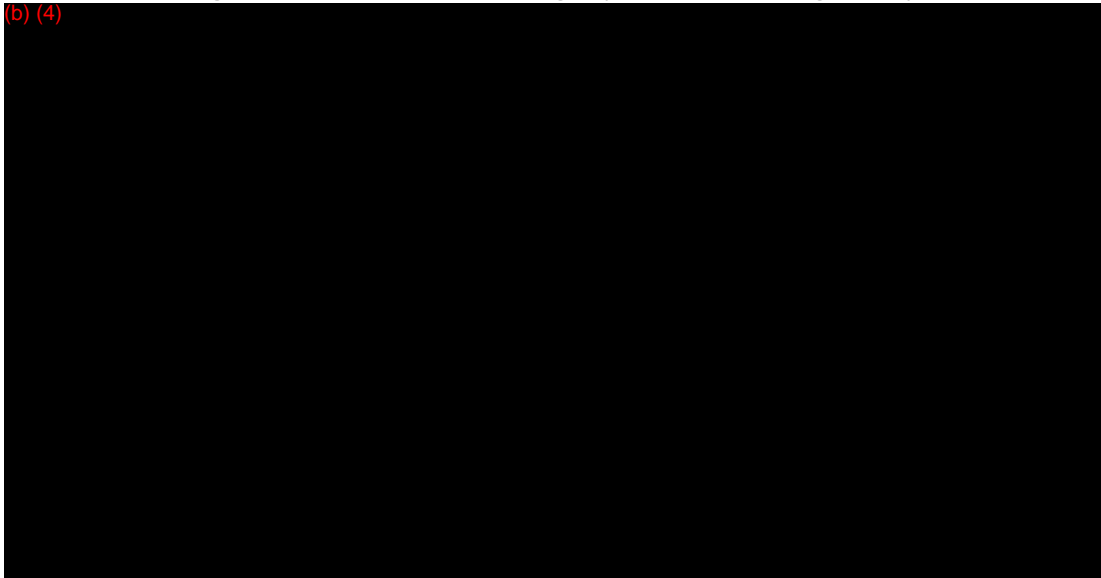
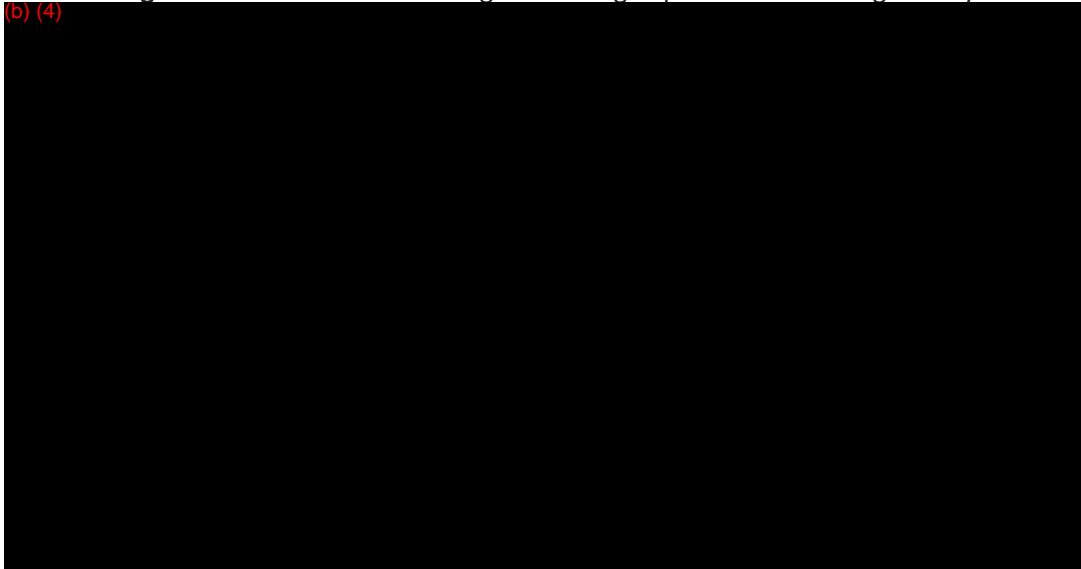


Figure 2. Land Use Surrounding the Rolling Paper Manufacturing Facility¹



4.3.5 Location of Use

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

4.3.6 Location of Disposal

Once used, the new tobacco product will be disposed of 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

¹ Manufacturer address via Google Map. Accessed January 19, 2017.

Agency anticipates 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 new and predicate products differ in certain additives and design features. There are differences in ingredients and ingredient levels, paper dimensions, paper porosity, and total rolling paper mass. (Confidential Appendix 1).

5. Potential Environmental Impacts Due to the Proposed Action

5.1 Potential Environmental Impacts due to Manufacturing the New Tobacco Product

The Agency anticipates the environmental releases generated by manufacturing the new RYO tobacco product will be emitted to the air, discharged in wastewater to waterways directly or through publicly owned treatment works (POTWs), and disposed of in the solid waste stream as municipal solid waste. These releases would occur in the same manner as the releases and waste generated from any other products manufactured in the same facility and in a similar manner to other RYO tobacco products manufactured in the United States.

The applicant stated that manufacturing the new product would not require additional capacity for disposal of manufacturing waste, would not require an expansion of the manufacturing facility, would not emit any new compounds, would not require any additional environmental controls, and would not have any significant impact on greenhouse gas (GHG) emissions. These conclusions are consistent with applicant-provided information that forecasts manufacturing of the new products to comprise, cumulatively, only a fraction of a percent of the total production at the product manufacturing facility (Confidential Appendix 2, Confidential Appendix 3).

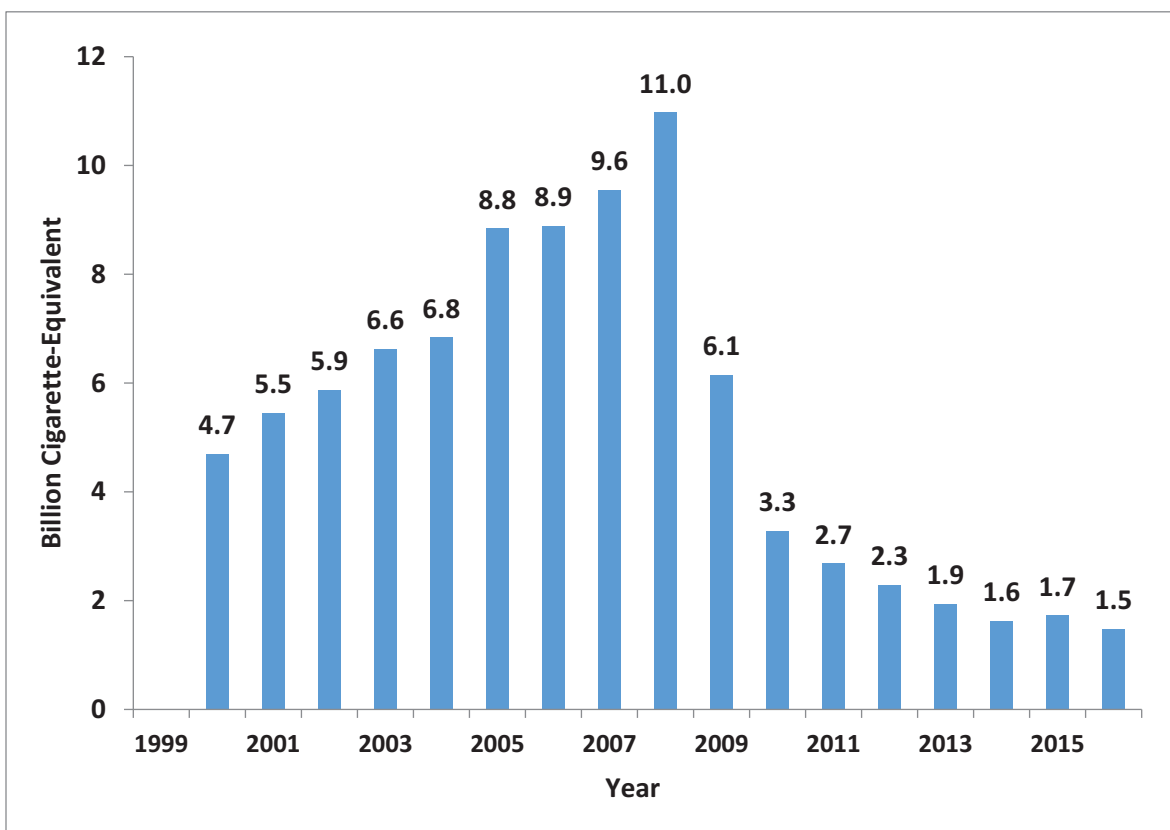
The product modifications include changes to the ingredients and ingredient levels, paper dimensions, paper porosity, and total rolling paper mass. Additionally, the new product contains (b) (4) that is derived from (b) (4) while the predicate product contains (b) (4) that is derived from (b) (4). While ingredient modification has the highest potential for changing the chemical compounds emitted during manufacturing, the applicant stated that no new compounds would be emitted. The applicant claimed that the new ingredients (Confidential Appendix 1) are conventional cigarette rolling paper ingredients found in factory-made cigarettes and cigarette rolling papers. The new ingredients do not raise environmental concerns relative to manufacturing the new products due to these existing uses.

The applicant stated that manufacturing the new product will replace other production at the facility and the production volume of the new product is a small fraction of total production at the manufacturing facility (Confidential Appendix 3). Therefore, no effects from increased GHG emissions are anticipated from the proposed action.

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

According to the United States Alcohol and Tobacco Tax and Trade Bureau's *Tobacco Statistical Release* report, the use of RYO tobacco products in the United States increased from 4.7 billion cigarette-equivalents in 2000 to 11.0 billion cigarette-equivalents in 2008. This was followed by a decrease in use from 6.1 billion cigarette-equivalents(1, 2) in 2009 to 1.5 billion cigarette-equivalents in 2016 (Figure 3).

Figure 3. Use of RYO Tobacco Products in the United States in 2000-2016

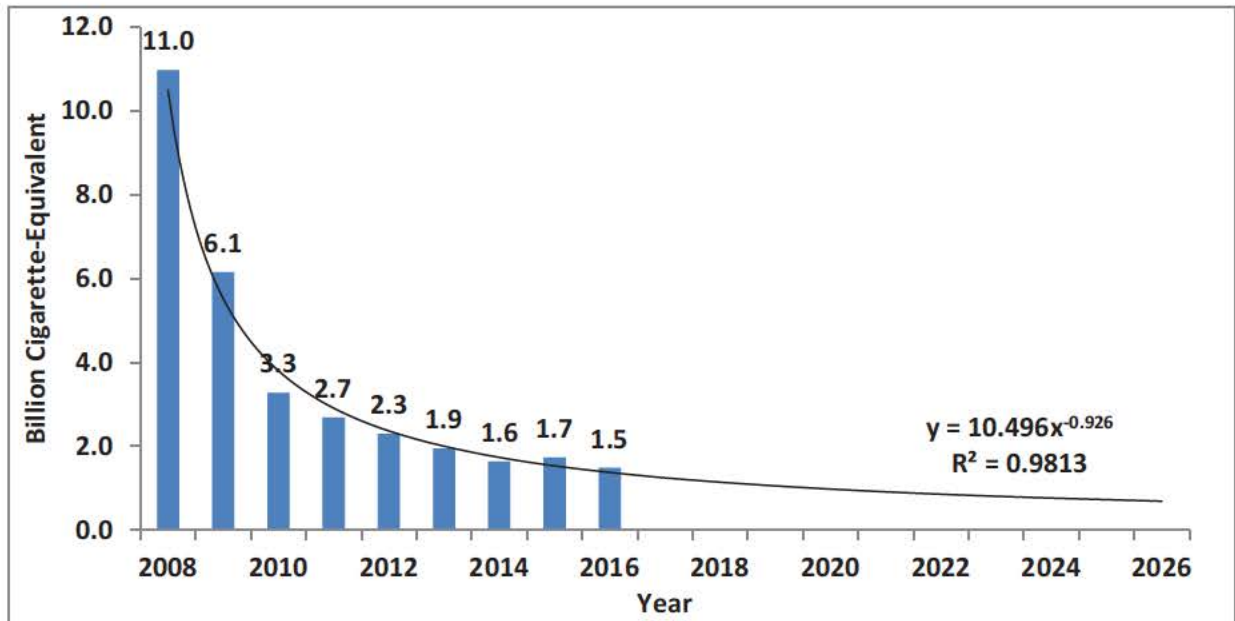


To evaluate the environmental impact of the proposed action due to use of the new product, the Agency analyzed the historical use data for 2008–2016 to forecast the future use of RYO tobacco products in the United States. This was achieved by using one best-fit power trend line with the R^2 value of 0.9813² (Figure 4). Using trend lines, the forecast of use of RYO tobacco products in the United States was estimated mathematically. Accordingly, the forecasted number of RYO tobacco products to be used in the United States is estimated to be 1.2 billion cigarette-equivalents (1,120 metric tons) in 2017 and 0.9 billion cigarette-equivalents (820 metric tons) in 2021.³ The number of RYO tobacco products used in the United States is estimated to be 1.5 billion cigarette-equivalents (1,334 metric tons) in 2016 by TTB.

² Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 15, 2017.

³ Billion cigarette-equivalent value is calculated based on the assumption that approximately 0.9 grams of tobacco is used per cigarette. Billion cigarette-equivalent = $\frac{(X \text{ million pounds tobacco} \times 10^6) \times \left(\frac{453.59 \text{ g}}{0.9 \text{ g}}\right)}{10^9}$

Figure 4. Projected Use of RYO Tobacco Products in the United States in 2017-2021



Year ⁴	RYO Tobacco Products (Billion Cigarette-Equivalent)	RYO Tobacco Products (Metric Tons)
2016	1.5	1,334
First-Year (2017)	1.2	1,120
Fifth-Year (2021)	0.9	820

The new product is intended to be rolled into cigarettes by the consumer. When burned, cigarettes release tobacco smoke to the environment, referred to as secondhand smoke. There is no safe level of exposure to secondhand smoke (3, 4). Even low levels of secondhand smoke can harm children and adults in many ways, including the following:

- The United States Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (5).
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness (3, 4).
- Secondhand smoke causes more than 40,000 deaths a year (5).

The applicant intends to market the new and predicate products after receiving a marketing order for the new product. Because the new product is expected to compete with the predicate product and other RYO products on the market, and represent a small fraction of the total RYO products marketed in the United States (Confidential Appendix 4), the Agency anticipates minimal or no net increase in the use of all RYO products. Thus, the Agency does not anticipate new or increased amounts of substances

⁴ First-Year in billion cigarette-equivalent = $10.496 \times 10\text{EXP}(-0.926) = 1.2$

Fifth-Year in billion cigarette-equivalent = $10.496 \times 14\text{EXP}(-0.926) = 0.9$

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 the same and released in the same manner as the combustion products of the predicate product and other RYO tobacco products. The amount of carbon dioxide generated during combustion that contributes to GHG emissions is miniscule 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

The environmental consequences from disposal of RYO tobacco products are associated with disposal of packaging and discarding the used RYO tobacco products. The Agency believes that the disposal of the new product will be the same as the disposal of other RYO tobacco products that are currently being marketed. After using the new product, the users may recycle the packaging material or dispose of it as MSW or litter. Used RYO tobacco products, consisting of cigarette butts,⁵ are usually disposed of as MSW or litter.

Packaging disposal and properly discarded used products contribute to using landfill capacity and air emissions from landfills. Improperly discarded used products generate litter.

5.3.1 Disposal of Packaging Materials

Following use, the packaging materials either would enter the recycling stream or be disposed of as MSW or litter. Information about trash generation in the United States, including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packaging materials. Specifically, in 2014, approximately 258.46 million tons (234.47 metric tons) of trash was generated in the United States, and approximately 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 5 and 6). Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Plastics account for 33.25 million tons (12.9%) of total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW, 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. Figure 7 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. 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 (6).

⁵ Cigarette butt is defined in this EA as cigarette rolling paper containing remainder tobacco that is disposed of after the product is used. The cigarette butt may or may not also include a filter, depending if the RYO cigarette had one.

Figure 5. MSW Generation Rates in the U.S, 1960 – 2014

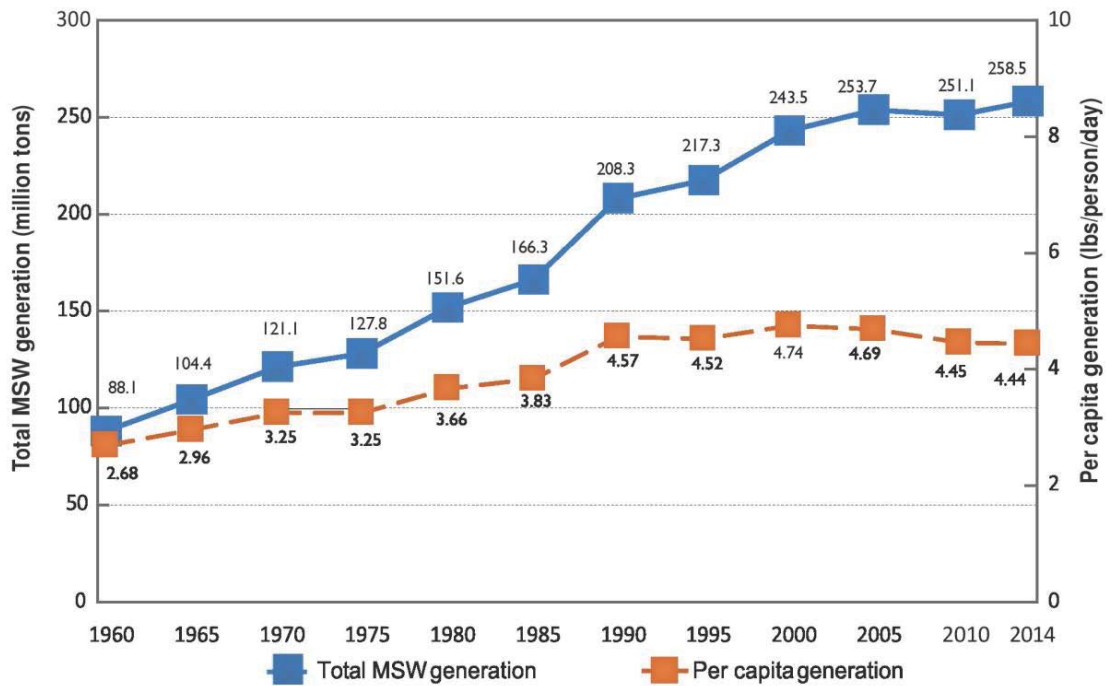


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet" (7)

Figure 6. MSW Recycling Rates in the United States, 1960 – 2014

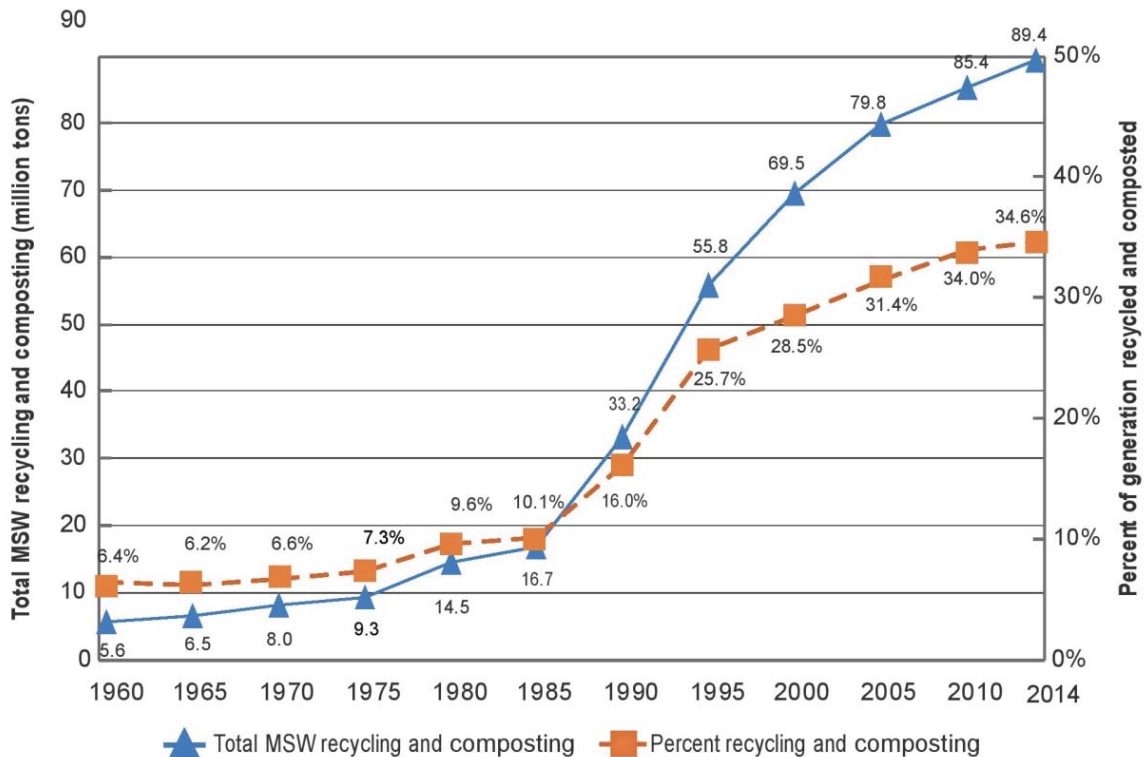
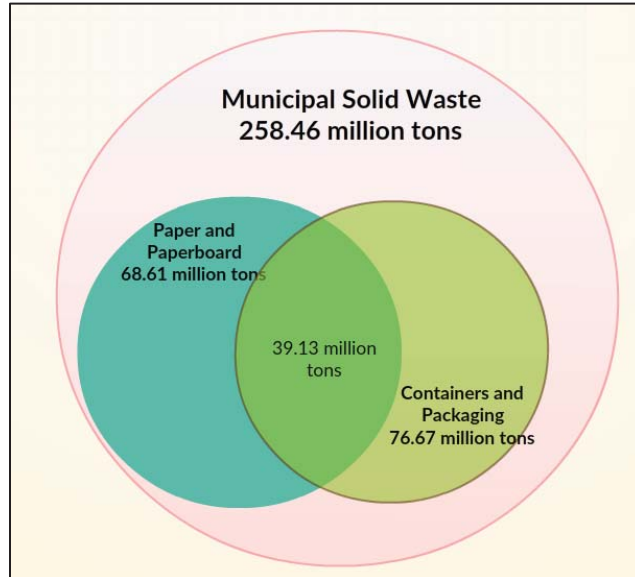


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet" (7)

**Figure 7. Overview of Contents of Municipal Solid Waste:
Highlighting Waste Related to Product Packaging**



The Agency used the projected market volumes for the first and fifth years of marketing the new and predicate products after the new product receives a marketing order, to estimate the waste from disposal of packaging, accounting for recycling of product waste and overall recycling rates for MSW in the United States. The estimated waste from packaging would be miniscule compared to the total MSW forecasted to be discarded. (Confidential Appendix 5). The new RYO tobacco product will compete with the predicate product and other similar RYO tobacco products on the market and the waste estimated from disposal of the new product's packaging is a negligible contribution to overall MSW, therefore, construction of new solid waste landfills or incinerators is not anticipated due to the proposed action.

5.3.2 Disposal of Used RYO Tobacco Product

Used RYO tobacco products, cigarette butts, are usually disposed of in MSW landfills or as litter. Cigarette butt 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. Managed waste is treated as MSW and either incinerated with energy recovery or landfilled. Unmanaged waste consists of littered cigarette butts. Novotny and coworkers characterized cigarette butts as the most commonly discarded piece of waste and the most frequent item of litter picked up on beaches and water edges worldwide (8). 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 (9). For the managed waste, 80.4% by weight enters landfills, and the remaining 19.6% by weight is incinerated for energy recovery (7). The Agency used the projected market volumes for the first and fifth years of marketing to estimate the waste from disposal of used product material (cigarette butts), accounting for recycling of product waste and overall recycling rates for MSW in the United States. The estimated waste from product disposal after use would be miniscule compared to the total MSW forecasted to be discarded in the United States. (Confidential Appendix 5).

Introducing the new product into the U. S. commercial market is not expected to increase the nationwide use of RYO tobacco; instead, it would compete for market share with existing products.

Thus, authorizing 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 RYO products.

6. Use of Resources and Energy

The new product will compete with and replace other currently marketed RYO tobacco products. The applicant stated that the proposed action will not require an expansion of the manufacturing facility. The applicant provided quantitative information on energy that would be 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. Additionally, the applicant stated that all ingredients used to manufacture the new product, as well as the predicate product, are from renewable and sustainable resources, in accordance with the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification Schemes (PEFC); and the manufacture of the new product is carried out under controls and standards that do not threaten any endangered species or critical habitat, as listed by the Endangered Species Act (ESA) or the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

7. Mitigation

The Agency did not identify significant adverse environmental effects for the new product. Therefore, no mitigation measures were developed.

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 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 of RYO tobacco products, as the predicate product and many other similar RYO tobacco products will continue to be marketed.

Alternative B (Proposed action). There is no significant environmental effect due to the proposed action of authorizing the new product and the associated manufacturing, use, and disposal of the product.

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 programmatic environmental assessment.

Preparer:

Susana Addo Ntim, PhD, Center for Tobacco Products

Education: PhD in Environmental Science

Experience: 6 years in various scientific activities

Expertise: Fate, transport and ecotoxicology of new and emerging contaminants, applications and environmental implications of nanotechnology

Reviewer:

Hoshing W. Chang, PhD, Center for Tobacco Products

Education: MS 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. Appendix List

Appendix 1: Submission Tracking Numbers and Related Amendments for the SE Report, Package Sizes, and Weights of Packaging Materials for the New and Predicate Products Covered Under this Environmental Assessment

12. Confidential Appendix List

Confidential Appendix 1: Changes in Composition as Compared to the Predicate Product

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

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

Confidential Appendix 4: Percentage of the Current Market Occupation of the Predicate Product and Projected Total RYO Market in the United States Occupied by the New and Predicate Products in 2017 and 2021

Confidential Appendix 5: Projected Product and Packaging Waste from Disposal after Use

13. References

1. *U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau, Tobacco Statistics* (<https://www.ttb.gov/statistics/2017/201710tobacco.pdf> Accessed January 17, 2018).
2. *Centers for Disease Control and Prevention, Economic Facts about Tobacco Production and Use* (http://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/ Accessed January 17, 2018).
3. *U.S. Department of Health and Human Services, The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General.* (2006).

4. U.S. Department of Health and Human Services, *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General Secondhand Smoke: What It Means to You (Consumer Booklet)* (2006).
5. U.S. Department of Health and Human Services, *The Health Consequences of Smoking 50 Years of Progress. A Report of the Surgeon General* (2014).
6. U. S, Environmental Protection Agency EPA, *Materials and Waste Management in the United States Key Facts and Figures*. (<https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures> Accessed January 17, 2018).
7. *Advancing Sustainable Materials Management: 2014 Fact Sheet* (2016).
8. T. E. Novotny *et al.*, The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. *Bulletin of the World Health Organization* **93**, 877-880 (2015).
9. W. Schultz, "Littering Behavior in America Results of a National Study. Keep America Beautiful," (2009).

APPENDIX 1: Submission Tracking Numbers and Related Amendments for the SE Report, Package Sizes, and Weights of Packaging Materials for the New and Predicate Products Covered Under this Environmental Assessment

New and Predicate Product Information							
STN	Product Name	Packaging Size			Weight of Packaging Materials (g)		Amendment
		Leaves per Booklet	Booklets per Retail Box	Retail Boxes per Shipping Case	Retail Box	Shipping Case	
SE0014036	OCB XPERT 1-1/4	32	50	40	16.7	378	SE0014351
Predicate	OCB Organic Hemp King Size Slim	32	50	20	16.7	378	

CONFIDENTIAL APPENDIX 1: Changes in Composition as Compared to the Predicate Product

The new and predicate products differ in certain additives and design features. There are differences in ingredients and ingredient levels, paper dimensions, paper porosity, and total rolling paper mass.

The applicant provided the product material details for the new and predicate products as listed in the following table.

Changes in Composition as Compared to the Predicate Product					
STN	Product	Ingredient Changes	Paper Dimensions	Paper Porosity	Total Rolling Paper Mass
SE0014036	OCB XPERT 1-1/4	(b) (4) - increased (b) (4) content - decreased (b) (4) - decreased (b) (4) slightly decreased (b) (4) - slightly decreased (b) (4) - eliminated (b) (4) - new ingredient (b) (4) - new ingredient	The new product is shorter than the predicate product	Increased in new product	Decreased in new product

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

STN	Unit	Current-Year (2016) Market Volume	First - Year Market Volume Projection		Fifth - Year Market Volume Projection	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0014036	Leaves	(b)(4)				
	Metric Tons					

CONFIDENTIAL APPENDIX 3: Percentage of the Facility's Total Production Dedicated to the New Product

The projected first- and fifth-year market volumes (Confidential Appendix 2) of the new product were compared to the total 2016 cigarette paper production at the RTF manufacturing facility in order to evaluate the percentage of the manufacturing facility's overall production that would be used to manufacture the new product. The percentage of the facility's total production dedicated to the new product was estimated by the following equation:

Production Fraction of New Product (%)

$$= \frac{\text{Market Volume Projection (metric tons)}}{\text{Total Cigarette Paper Production at RTF (2016)}^6} \times 100\%$$

STN	Percentage of the Facility's Total Production Dedicated to the New Product	
	First - Year	Fifth - Year
SE0014036	(b) (4)	(b) (4)

The new RYO tobacco product is projected to account for (b) (4) and (b) (4) of the facility's total production in the first- and fifth-year, respectively.

⁶ Total Cigarette Paper Production at RTF (2016) – 2150.79 metric tons

CONFIDENTIAL APPENDIX 4: Percentage of the United States Total RYO Market Currently Occupied by the Predicate Product and Projected Occupation by the New and Predicate Products in 2017 and 2021

The current-year, first-year, and fifth-year market volumes (Confidential Appendix 2) of the new and predicate products occupying the United States RYO market were compared to the total current US market and the projected RYO tobacco market (Figures 3 and 4 in section 5.2) in the United States.

Current Year (2016) Market Occupation of Predicate Products (%)

$$= \frac{\text{Current-Year (2016) Market Volume of Predicate Product}}{\text{RYO Used in the United States in 2016}^7} \times 100\%$$

First Year Market Occupation of New (or Predicate) Product (%)

$$= \frac{\text{First-Year Market Volume Projection}}{\text{Forecasted Use of RYO in the United States for 2017}^8} \times 100\%$$

Fifth Year Market Occupation of New (or Predicate) Product (%)

$$= \frac{\text{Fifth-Year Market Volume Projection}}{\text{Forecasted Use of RYO in the United States for 2021}^9} \times 100\%$$

STN	Projected Market Occupation of the New and Predicate Products in the United States (%)		
	Current Year	First - Year	Fifth - Year
SE0014036	0.0000	(b)(4)	
Predicate	(b)(4)		

⁷ RYO Used in the United States in 2016 – 1334 metric tons

⁸ Forecasted Use of RYO in the United States for 2017 – 1120 metric tons

⁹ Forecasted Use of RYO in the United States for 2021 – 820 metric tons

CONFIDENTIAL APPENDIX 5: Projected Product and Packaging Waste from Disposal after Use

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 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, and shipping case waste generation of the products.

$$\sum_{i=1}^5 A_i = \sum_{i=1}^5 (B_i + C_i + D_i + E_i)$$

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

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

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

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

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

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

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

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

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

E_i : Projected cigarette butt¹⁰ waste of the products (metric tons)

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

G_i : Number of rolling papers per booklet

H_i : Weight of empty booklet cover (grams)

I_i : Number of booklets per retail unit

J_i : Weight of empty retail outer box (grams)

K_i : Number of retail units per shipping case

L_i : Weight of empty shipping case (grams)

M_i : Length of rolling paper (millimeters)

N_i : Cigarette butt ratio (%)¹¹

O_i : Weight of rolling paper (milligrams per leaf)

Z : 1.0×10^{-6} metric tons/gram

¹¹ 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.

Current Year	STN	Weight per Leaf (mg)	Cigarette Butt Ratio	Length of Rolling Paper	Weight of Shipping Case (g)	Retail Boxes per Shipping Case	Weight of Retail Box (g)	Booklets per Retail Box	Weight of Booklet Cover (g)	Rolling Papers per Booklet	Projected Market Volume (leaves)	Cigarette Butt Waste (metric tons)	Shipping Case Waste (metric tons)	Retail Box Waste (metric tons)	Booklet Cover Waste (metric tons)	Total Waste (metric tons)
		O_i	N_i	M_i	L_i	K_i	J_i	I_i	H_i	G_i	F_i	E_i	D_i	C_i	B_i	A_i
	Predicate	71.1	24.8	109	378	20	16.7	50	3.02	32	(b) (4)	■	■	■	■	■
First - Year	STN	Weight per Leaf (mg)	Cigarette Butt Ratio	Length of Rolling Paper	Weight of Shipping Case (g)	Retail Boxes per Shipping Case	Weight of Retail Box (g)	Booklets per Retail Box	Weight of Booklet Cover (g)	Rolling Papers per Booklet	Projected Market Volume (leaves)	Cigarette Butt Waste (metric tons)	Shipping Case Waste (metric tons)	Retail Box Waste (metric tons)	Booklet Cover Waste (metric tons)	Total Waste (metric tons)
		O_i	N_i	M_i	L_i	K_i	J_i	I_i	H_i	G_i	F_i	E_i	D_i	C_i	B_i	A_i
	SE0014036	50.2	35.1	77	378	40	16.7	50	3.02	32	(b) (4)	■	■	■	■	■
	Predicate	71.1	24.8	109	378	20	16.7	50	3.02	32	(b) (4)	■	■	■	■	■
Fifth - Year	STN	Weight per Leaf (mg)	Cigarette Butt Ratio	Length of Rolling Paper	Weight of Shipping Case (g)	Retail Boxes per Shipping Case	Weight of Retail Box (g)	Booklets per Retail Box	Weight of Booklet Cover (g)	Rolling Papers per Booklet	Projected Market Volume (leaves)	Cigarette Butt Waste (metric tons)	Shipping Case Waste (metric tons)	Retail Box Waste (metric tons)	Booklet Cover Waste (metric tons)	Total Waste (metric tons)
		O_i	N_i	M_i	L_i	K_i	J_i	I_i	H_i	G_i	F_i	E_i	D_i	C_i	B_i	A_i
	SE0014036	50.2	35.1	77	378	40	16.7	50	3.02	32	(b) (4)	■	■	■	■	■
	Predicate	71.1	24.8	109	378	20	16.7	50	3.02	32	(b) (4)	■	■	■	■	■

If all the projected cigarette butt and packaging waste generated from the use of the new and predicate products is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new and predicate products would be (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021. 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 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 boxes 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) metric tons (b) (4) metric tons) in the first year and (b) (4) metric tons (b) (4) metric tons) in the fifth year of marketing the new and predicate products.