

**Environmental Assessment for Market Authorizations
for Republic Tobacco, LP “JOB® Organic Hemp
Single Wide”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

August 15, 2017

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

1. Name of Applicant

Republic Tobacco, LP

2. Address

2301 Ravine Way
Glenview, IL 60025

3. Manufacturer

(b) (4)


4. Description of Proposed Actions

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 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 claimed that the new product and the predicate product have different characteristics (sec 910(a)(3)(A)(ii) of the FD&C Act), but they differ only in product quantity and labeling. The applicant claimed that the new and predicate products are the same in product and packaging composition. After considering the substantial equivalence (SE) reports, the Agency shall issue orders under the provisions of section 910 and 905(j) of the FD&C Act when finding the new products to be substantially equivalent to the 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

Roll-your-own (RYO) cigarette papers

4.3.2 Product Names and Their 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 (Grandfathered Product)
SE0013890	JOB® Organic Hemp Single Wide	OCB® Organic Hemp Single Wide

4.3.3 Description of the Product Package

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

4.3.4 Location of Manufacturing

The manufacturer, ^{(b) (4)} (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.



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

4.3.5 Location of Use

Republic Tobacco, LP intends to distribute and sell the new cigarette paper RYO 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.

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 and labeling only.

5. Environmental Introduction Due to the Proposed Actions

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 1,889 metric tons in 2007 to 8,588 metric tons in 2016 (Figure 2).² When examining the change in import of cigarette rolling paper in the form of booklets to the U.S. from France over the same period of time, there was a significant decrease from 792 metric tons in 2007 to 533 metric tons in 2016 (Figure 3).³

The cigarette rolling paper in the form of booklets imported to the U.S. from France in 2016 represented 6.2% of the total amount of tobacco products imported from France in 2016.

² Unit is defined by the United States International Trade Commission, available at: <http://dataweb.usitc.gov/>. Accessed on February 17, 2017.

Figure 2. Total Tobacco Products Imported from France into the U.S. 2000-2016³

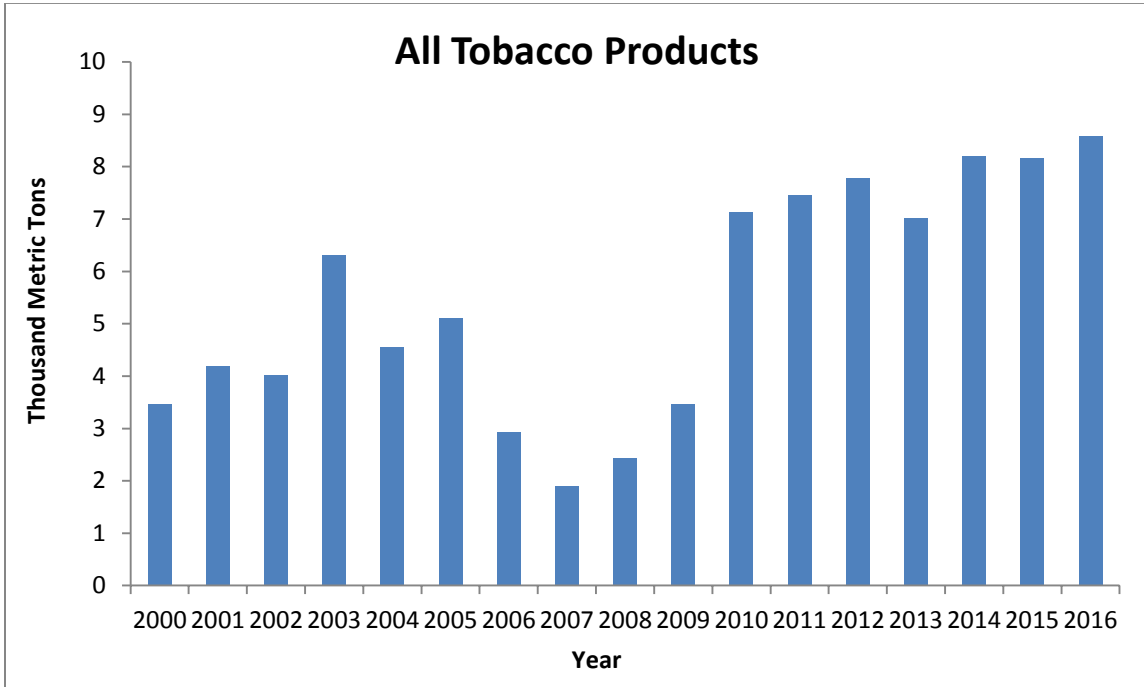
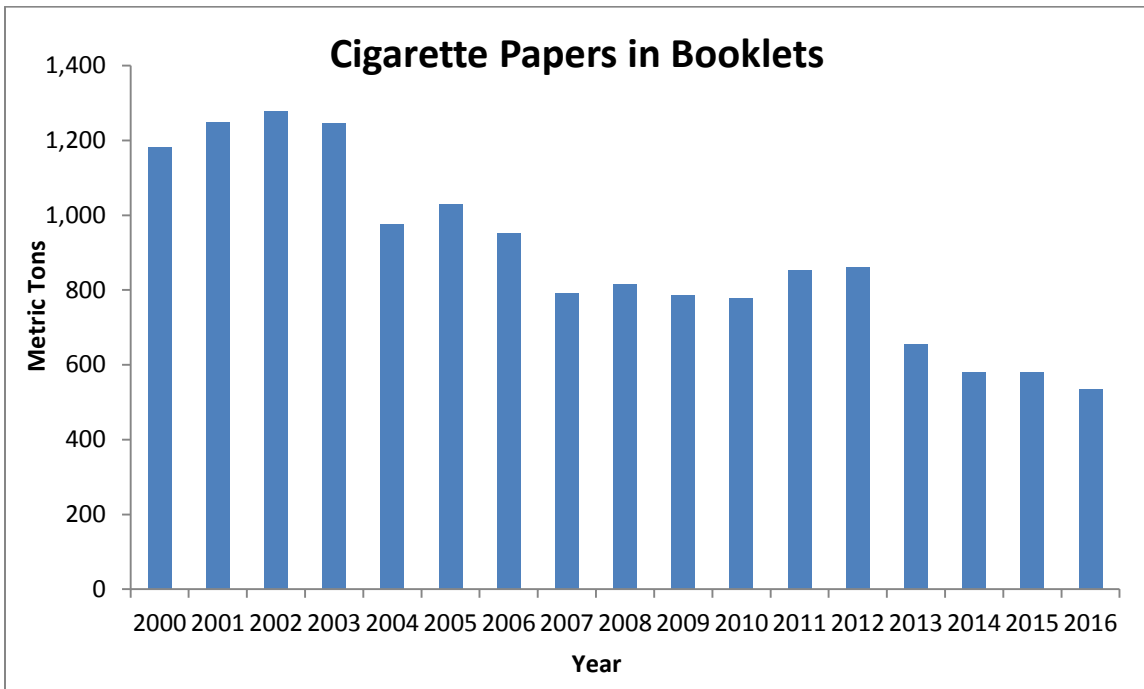


Figure 3. U.S. Import of Cigarette Papers in the Form of Booklets from France in 2000-2016³



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. The new product will compete with and replace other currently marketed RYO cigarette paper products. In addition, the applicant stated that the new product will be manufactured on existing production runs along with the predicate product. The applicant also stated that total manufacturing volume of the facility will not increase due to the new product because the manufacturer will allocate a portion of the facility's existing manufacturing to the manufacture of the new product. Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new product.

Based on information in the SE Report, the new product differs from the predicate product only in product quantity and labeling. 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 provided the first- and fifth-year market volumes for the new product (Confidential Appendix 1). Comparing the projected market volume of the new product with the forecasted market volume of all tobacco products imported into the U.S. from the France in 2017 and 2021, the projected market volume of the new product is a miniscule fraction of the total forecasted market volumes in 2017 and 2021 (Appendix 2 and Confidential Appendix 1). Also, the new product comprises a miniscule fraction of the total volume of rolling papers manufactured at the facility. The waste associated with manufacturing the new product is negligible compared to the facility's total waste. Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed.

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

The applicant claimed the projected production volume of the new product will be negligible relative to the overall production at the factory and most of the energy required to operate the factory is fixed and not incremental to production volumes.

Emissions of carbon dioxide and other greenhouse gases (GHGs), such as methane, nitrous oxide, and fluorinated gases, are a type of air pollution. The applicant stated

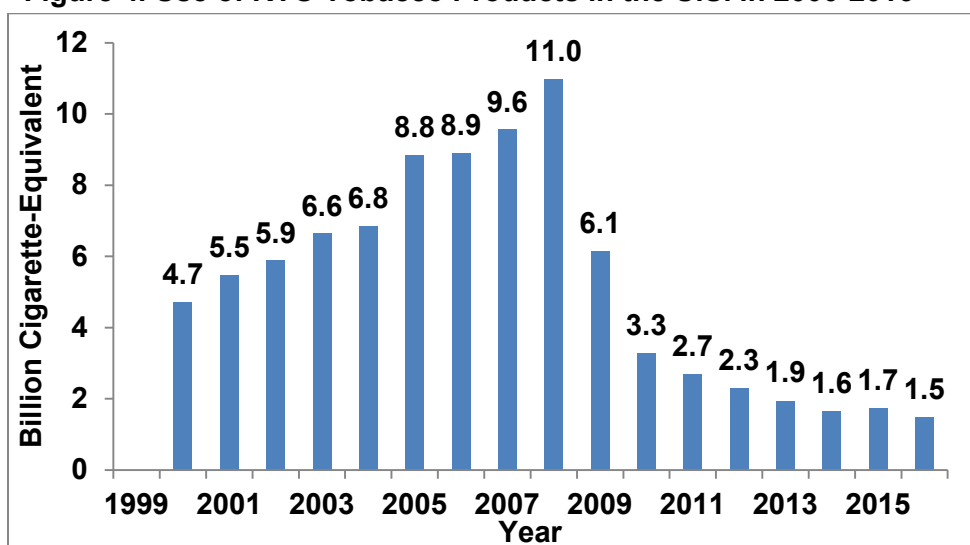
that because the new product will compete with and replace other currently marketed RYO products, no addition of GHG emissions is anticipated.

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

5.2.1 Use of the RYO Tobacco Products in the U.S.

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 was followed by a decrease in use from 6.1 billion cigarette-equivalents³ in 2009 to 1.5 billion cigarette-equivalents in 2016 (Figure 4)(3, 4).

Figure 4. Use of RYO Tobacco Products in the U.S. in 2000-2016⁴



5.2.2 Environmental Introduction from Use of the New Product

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

³ The calculated cigarette-equivalence data is based on the conversion rate in the Master Settlement Agreement is that 0.0325 oz. (0.9 g) of tobacco equals to one cigarette. See Reference #7.

During use, the new products are burned to ash, carbon dioxide, and water vapor, as well as products of incomplete combustion such as carbon monoxide. These combustion products from the new product are released in a similar manner to its predicate product as well as current RYO cigarette rolling paper products. The amount of carbon dioxide generated during combustion which contributes to GHG emissions is miniscule, and because the new products will compete with other currently marketed RYO products, no addition of GHG emissions is anticipated.

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) discarding 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. On average, 4.4 pounds per person of waste was generated, of which 2.1 pounds was recycled, composted, or combusted for energy recovery in the U.S. in 2014(5).

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

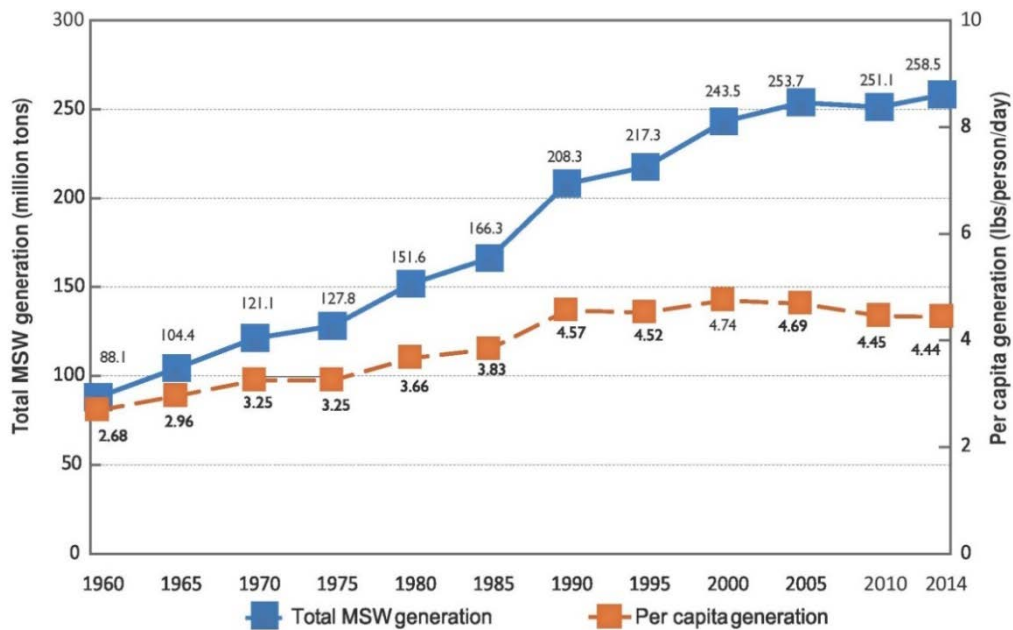


Figure Excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

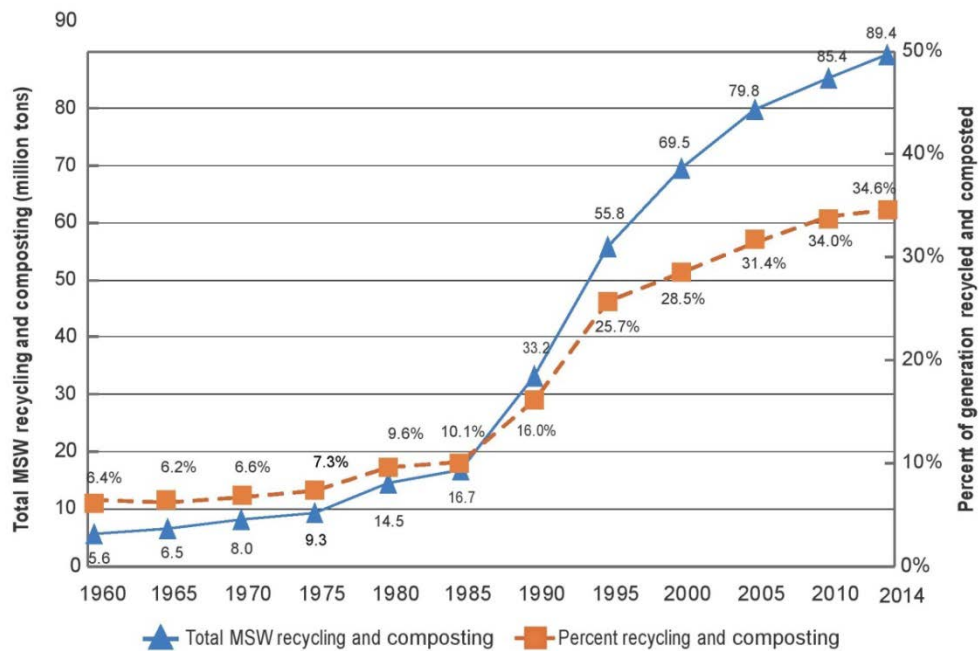


Figure Excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

b) Disposal of Used RYO Tobacco Products Following Use

Used RYO tobacco products are usually disposed of in MSW landfills or as litter. When discarded as litter, the spent products are likely to move by run-off to the ocean and eventually decompose. When discarded as MSW, the products would enter landfills.

The Agency utilized the historical data for use of RYO tobacco products in the U.S. to forecast the future use of RYO tobacco products and calculate the projected tobacco waste accordingly (Appendix 3). Assuming that all used RYO tobacco products will be disposed of as MSW, the estimated waste of used RYO tobacco products is a fraction of a percent of the total 258.46 million tons (234.47 million metric tons) of projected MSW to be generated in the U.S.

Forecast of Waste of Used RYO Tobacco Products as Compared to Total MSW Forecast in the U.S.		
Year	Projected Use (Equivalent to Projected Waste) of RYO Tobacco Products in the U.S. (Billion Cigarette-Equivalent) ^a	Percent of Projected Waste of RYO Tobacco Products to Total MSW Forecasted in the U.S. (%) ⁴
1 st Year	(b) (4)	
5 th Year		

^a See Appendix 3

c) Air Emissions from Disposal

Landfill disposal or incineration of the used RYO tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs. However, 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 to have landfill gas collection-and-control systems installed. Additionally, all landfills must report GHG emissions to the EPA under 40 CFR 98.

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 rolling paper, and any other RYO tobacco products that are currently being marketed. After using the new product, the users may dispose of or recycle the packaging material. Users may also discard what remains of the product after smoking, such as remaining combusted tobacco and cigarette rolling paper, as discussed above, as MSW or litter.

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 and product 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 and plastic components are more likely to be recycled; at least a portion of the new product's waste is likely to be recycled.

⁴ RYO Tobacco Products in percentage:

1st Year = (b) (4)
 5th Year = (b) (4)

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

The waste generated from using the new product is expected to make up a negligible fraction of the total MSW; no additional control of GHG 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.

Because the waste generated from the new product is expected to comprise a negligible fraction of the total MSW, the GHG emitted from the waste associated with the new product is negligible.

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 paper. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other RYO tobacco products, specifically cigarette rolling paper, manufactured in the facility. No new types of material are anticipated to be emitted to the environment 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 operation is in compliance with all local, state 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 that of the projected RYO tobacco products imported from France 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 other currently marketed RYO tobacco products. The applicant also stated that the proposed actions will not require an expansion of the

manufacturing facility. When comparing the market volume projections with the forecasted total RYO market volumes in the U.S., the Agency found that the projected market volumes of the new products are a small fraction of the total forecasted market volume for RYO tobacco products in 2017 and 2021. Because the new product is intended to compete with and replace other currently marketed products, no increase of overall RYO tobacco product market volume and no net increase of energy use will be expected from the proposed action. 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. 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 products. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Actions

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 3 and 4) and many other similar RYO tobacco products will continue to be marketed.

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

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.

Preparers:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: 3 years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

ITC Data Preparer:

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

Education: M.S. in Environmental Science

Experience: 34 years in environmental toxicology and risk assessment

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

RYO Tobacco Products Projection Preparer:

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

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: 23 years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA implementation

Reviewers:

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 Report and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Environmental Assessment (EA)

Appendix 2: Forecast of All Tobacco Products Imported into the U.S. from France

Appendix 3: Forecast of Use of RYO Tobacco Products in the U.S.

14. Confidential Appendix List

Confidential Appendix 1: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products

Confidential Appendix 2: Comparison of the Current-Year Market Volume for the Predicate Product with Total RYO Tobacco Products Used in the U.S.

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.

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. FDA Guidance for Industry. Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3). Issued December 2016.
2. P. Reig, T. Shiao, F. Gassert, Aqueduct Water Risk Framework. *Washington, DC: World Resources Institute Working Paper*, (2013).
3. U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed July 6, 2017.
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5. U.S. EPA. Materials and Waste Management in the United States Key Facts and Figures. Available at <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures>. Accessed July 5, 2017.
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9. U.S. EPA. Stationary Sources of Air Pollution. Municipal Solid Waste Landfills: Proposed and Final Air Regulation Fact Sheets. Available at <https://www.epa.gov/stationary-sources-air-pollution/municipal-solid-waste-landfills-proposed-and-final-air-regulation>. Accessed July 3, 2017.

APPENDIX 1

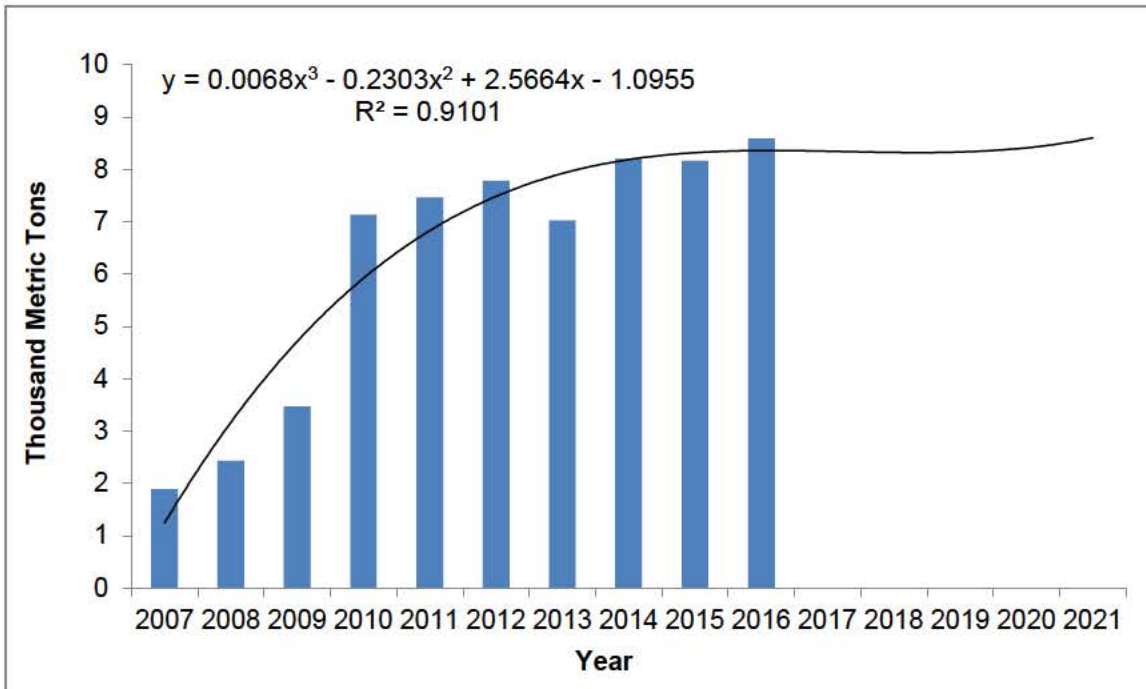
Submission Tracking Numbers for the SE Report and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Environmental Assessment (EA)

STN	Product Name	Product	Leaves per Booklet	Booklets per Retail Unit	Retail Unit	Retail Units per Shipping Case	Amendments
SE0013890	JOB® Organic Hemp Single Wide	New	50	24	Paperboard Box	40	SE0014099
	OCB® Organic Hemp Single Wide	Predicate	100	24	Paperboard Box	40	SE0014099

APPENDIX 2

Forecast of All Tobacco Products Imported into the U.S. from France

To evaluate the environmental impact of the proposed action due to import of the new products, historical data regarding the import of all tobacco products from France into the U.S. from 2007 to 2016 was used to forecast the manufacture of RYO tobacco products in France and imported into the U.S.⁵ This was achieved by using one best-fit polynomial trend line with the R² value of 0.9101. Accordingly, the forecasted amount of all tobacco products to be imported from France into the U.S. is estimated to be 8,319 metric tons in 2017 and 8,533 metric tons in 2021. The amount of all tobacco products imported from France into the U.S. is estimated at 8,588 metric tons in 2016.



Year ⁶	All Tobacco Products Imported from France (Metric Tons)
2016	8,588
1 st Year (2017)	8,319
5 th Year (2021)	8,533

⁵ Forecast trend lines extrapolated from USITC data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed February 17, 2016.

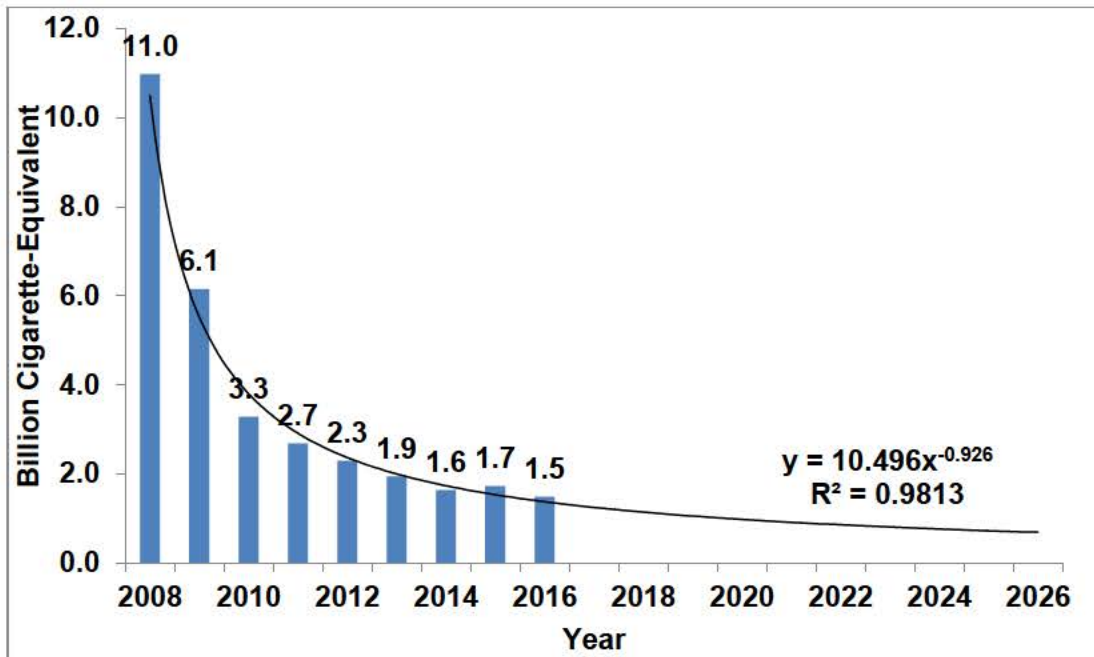
⁶ 1st Year (2017) in thousand tons = $[0.0068 \times (11^3)] - [0.2303 \times (11^2)] + (2.5664 \times 11) - 1.0955 = 8.319$
 5th Year (2021) in thousand tons = $[0.0068 \times (15^3)] - [0.2303 \times (15^2)] + (2.5664 \times 15) - 1.0955 = 8.533$

APPENDIX 3

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 products, the Agency utilized the historical data of RYO tobacco product use in 2008–2016 to forecast the use of RYO tobacco products in the U.S. This was achieved by using one best-fit power trend line with the R^2 value of 0.9813.⁷

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 (1,120 metric tons) in 2017 and 0.9 billion cigarette-equivalents (820 metric tons) in 2021.⁸ The amount of RYO tobacco products used in the U.S. is estimated to be 1.5 billion cigarette-equivalents (1,334 metric tons) in 2016 by TTB.



Year ⁹	RYO Tobacco Products (Billion Cigarette-Equivalent)	RYO Tobacco Products (Metric Tons)
2016	(b) (4)	(b) (4)
1 st Year (2017)	(b) (4)	(b) (4)
5 th Year (2021)	(b) (4)	(b) (4)

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

⁸ Billion cigarette-equivalent value is calculated based on the assumption that approximately (b) (4) of tobacco is used per cigarette. Billion cigarette-equivalent = (b) (4)

⁹ 1st Year in billion cigarette-equivalent = (b) (4)
5th Year in billion cigarette-equivalent = (b) (4)

CONFIDENTIAL APPENDIX 1

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		Fifth-Year Market Volume	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0013890	Booklets	(b) (4)				
	# Leaves					
	Metric Tons					

*See Appendix 1: 100 leaves per booklet (predicate product), 50 leaves per booklet (new product)

CONFIDENTIAL APPENDIX 2

Comparison of the Current-Year Market Volume for the Predicate Product with Total RYO Tobacco Products Used in the U.S.

The current-year market volume of the predicate product occupying the U.S. market was compared to the use of total RYO tobacco in the U.S. (Appendices 2 and 3, and Confidential Appendix 3). The percent of the total RYO tobacco market occupied in the current year of marketing of the predicate product was calculated using the equation below¹⁰:

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

STN	Year	Import of Total Tobacco Products from France (Metric Tons) ¹¹	Use of Total RYO Tobacco in the U.S. (Metric Tons) ¹²	Market Volume of Predicate Product (Metric Tons) ¹³	Market Occupation of Predicate Product in the U.S. (%)
SE0013890	2016	(b) (4)			

¹⁰ 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.

¹¹ See Appendix 2.

¹² See Appendix 3.

¹³ See Confidential Appendix 1.

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 product to the forecasted use of total RYO tobacco in the U.S. (Appendices 2 and 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 below¹⁴:

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 Import of Total Tobacco Products from France (Metric Tons) ¹⁵	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons) ¹⁶	Projected Market Volume of New Product (Metric Tons) ¹⁷	Projected Market Occupation of New Product in the U.S. (%)
SE0013890	First (2017)	(b) (4)			
	Fifth (2021)				
Predicate	First (2017)				
	Fifth (2021)				
Total	First (2017)				
	Fifth (2021)				

Although there is an increase of production identified according the applicant-reported market volume, as noted, the new product will be manufactured on existing production runs along with the predicate product. The applicant stated that the total manufacturing volume of the facility will not increase due to the new product because the manufacturer will allocate a portion of the facility’s existing manufacturing to the manufacture of the new products.

¹⁴ 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.

¹⁵ See Appendix 2.

¹⁶ See Appendix 3.

¹⁷ 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 actions, the Agency estimated the first- and fifth-year weights of the projected packaging and product materials waste (in metric tons) that would be generated from disposal after use of the new and predicate products in 2017 and 2021. Projected paper and “cigarette butt” waste generation is the summation of the projected booklet cover, cardboard box, pouch (used to contain RYO tobacco), cigarette butt¹⁹, and shipping case waste generation of the products:

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

$$B_i = \frac{H_i}{I_i} \times J \times Z$$

$$C_i = \frac{H_i}{I_i \times K_i} \times L \times Z$$

$$D_i = \frac{H_i}{I_i \times K_i \times Q_i} \times R \times Z$$

$$E_i = \frac{H_i}{I_i \times K_i \times M_i} \times P \times Z$$

$$F_i = \left[\left(\frac{H_i}{I_i \times K_i \times M_i} \times N \right) + \left(\frac{H_i}{I_i \times K_i \times M_i} \times O \right) \right] \times Z$$

$$G_i = \frac{H_i \times T_i \times U_i}{100} \times 0.001 \times Z$$

$$T_i = \frac{27}{S_i} \times 100$$

- 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 display carton waste generation of the products (metric tons)
- E_i*: Projected shipping case pouch waste generation of the products (metric tons)
- F_i*: Projected pouch and pouch-related waste generation of the products (metric tons)
- G_i*: Projected cigarette butt¹⁸ waste of the products (metric tons)
- H_i*: Projected market volume of the products (# individual leaves of rolling paper)
- I_i*: Number of rolling papers per booklet
- J*: Weight of empty booklet cover (grams)
- K_i*: Number of booklets per retail unit
- L*: Weight of empty retail outer box (grams)
- M_i*: Number of retail units (pouch or outer box) per shipping case
- N*: Weight of empty pouch (grams)
- O*: Weight of adhesive/tape per pouch (grams)
- P*: Weight of empty shipping case (grams)
- Q_i*: Number of pouch per display case
- R*: Weight of empty display carton (grams)
- S_i*: Length of rolling paper (millimeters)
- T_i*: Cigarette butt ratio (%)¹⁹
- U_i*: Weight of rolling paper (milligrams per leaf)
- Z*: 1.0 x 10⁻⁶ metric tons/gram

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

¹⁹ ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed as solid waste following use.

First Year	STN	U	T	S	R	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
	SE0013890	(b) (4)																				
	Predicate																					
First-Year Total Paper and Cigarette Butt Waste for New and Predicate Products (metric tons)																						(b) (4)

Fifth Year	STN	U	T	S	R	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
	SE0013890	(b) (4)																				
	Predicate																					
Fifth-Year Total Paper and Cigarette Butt Waste for New and Predicate Products (metric tons)																						(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) metric tons in the first year of marketing and (b) (4) metric tons in the fifth year. 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) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new and predicate products.²⁰

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

(b) (4)