Programmatic Environmental Assessment for Market Authorizations of "OCB® Yellow Cigarette Paper with Tips" and "OCB® Slim Long Cigarette Papers with Tips"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

September 20, 2017

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This programmatic environmental assessment (PEA) is for the market authorizations of multiple roll-your-own (RYO) cigarette rolling paper booklets with tips manufactured by "Republic Tobacco, LP". Information presented in the PEA is based on the submissions provided by the applicant (Appendix 1), unless noted or referenced otherwise. This PEA has been prepared in accordance to 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

Republic Tobacco, LP

2. Address

2301 Ravine Way
Glenview, IL 60025

3. Manufacturer

(b) (4)

4. Description of Proposed Actions

The proposed actions are for FDA to issue market authorizations under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of new roll-your-own (RYO) rolling cigarette paper booklets with tips, OCB® Yellow Cigarette Papers with Tips and OCB® Slim Long Cigarette Papers with Tips, in interstate commercial distribution in the U.S. The authorizations are based on finding that the new RYO products are substantially equivalent to their predicate products that were on the market as of February 15, 2007.

4.1 Requested Action

Orders finding the listed tobacco products are substantially equivalent to the respective predicate products.

4.2 Need for Action

Republic Tobacco, LP wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the U.S. The applicant claimed that the new products differ from the predicate products only in product quantity (sec 910(a)(3)(A)(i) of the FD&C Act), as described in the FDA guidance to industry issued on March 4, 2015 (*1*). In addition, the applicant claimed that the new products and predicate products have identical product and packaging composition. After considering the SE Reports (SE0012326 and SE0012327), 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 their corresponding predicate products.

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

4.3.1 Type of Tobacco Products

Roll-your-own (RYO), rolling paper booklets with tips

4.3.2 Product Names and Original STNs of the New Tobacco Products

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

STNs	New Products	Predicate Product
SE0012326	OCB® Yellow Cigarette Papers with Tips	OCB® Yellow Cigarette Papers with Tips
SE0012327	OCB® Slim Long Cigarette Papers with Tips	OCB® Slim Long Cigarette Papers with Tips

4.3.3 Description of the Product Package

The packaging materials of the finished new products are identical to those of the corresponding predicate products. The new product packaging components consist of a cardboard booklet in which the cigarette rolling papers and tips are contained and 24 booklets are enclosed in each cardboard retail box (Appendix 1). Details of the package components and weights of each packaging component for the new products are described in Confidential Appendix 3.

4.3.4 Location of Manufacturing

(b) (4)

(Figure 1)

Figure 1. Location of the Manufacturer[1]

[1] Manufacturer address via Google Map. Accessed June 8, 2016.

4.3.5 Location of Use

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

4.3.6 Location of Disposal

Once used the new tobacco products will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as the predicate products 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 distribution of waste from disposal after use should correspond to the pattern of the product use.

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

The applicant claimed that a change in product quantity is the only difference between the new products and their corresponding predicate products (Appendix 1).

5. Environmental Introduction Due to the Proposed Actions

5.1 Environmental Introduction as a Result of Manufacturing the New Tobacco Products

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 United States 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).

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

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

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

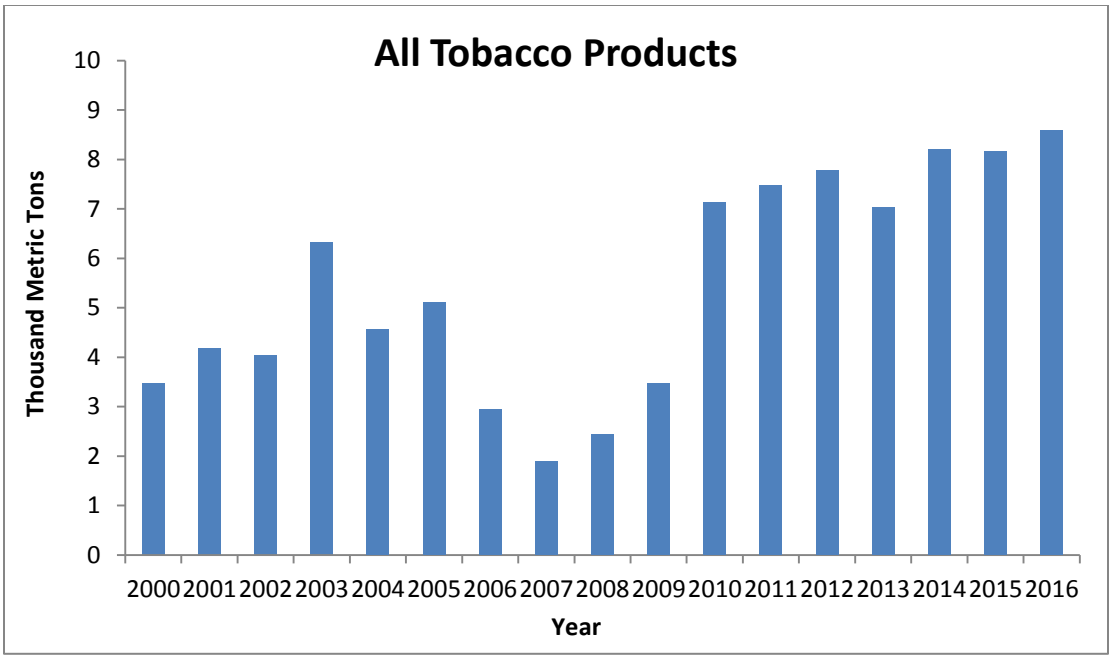
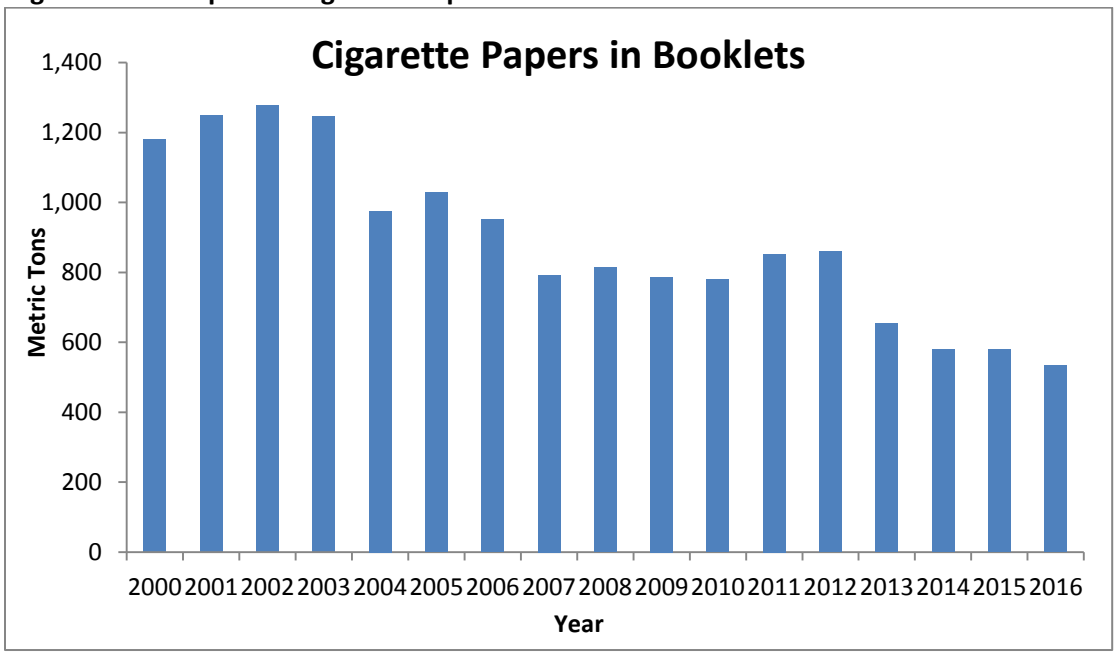


Figure 3. U.S. Import of Cigarette Papers in the Form of Booklets from France in 2000-2016



5.1.2 Environmental Introduction from Manufacturing the New Tobacco Products

Introduction from Manufacturing the New Products in the Proposed Actions. The Agency anticipates the waste generated as a result of manufacturing the new RYO tobacco products 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. In addition, (b) (4)

(b) (4) (Appendix 1) and compete with other currently marketed RYO cigarette paper products. Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new products. There has been a general decline in cigarette rolling paper import from France from 1,180 metric tons in 2000 to 533 metric tons in 2016. Therefore, the Agency does not foresee the introduction of the new products to notably affect the current manufacturing waste generated from the production of all cigarette rolling papers.

Based on information in the SE Reports, the only difference between the new products and the predicate products is in product quantity. 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 products.

The applicant provided the first- and fifth-year market volumes for the new products (Confidential Appendix 1). Comparing the projected market volume of the new products with the forecasted market volume of cigarette papers in the form of booklets imported into the U.S. from France in 2017 and 2021, the cumulative projected market volumes of the new products are a small fraction of the total forecasted market volumes of cigarette papers in the form of booklets in 2017 and 2021 (Appendix 2 and Confidential Appendix 1). 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 environmental laws and regulations. The applicant also stated that the RYO paper and tips are produced from renewable and sustainable sources and their manufacture does not appear to threaten any endangered species or critical habitat.

In 2014, the total greenhouse gas (GHG) emissions generated in the U.S. was estimated at 6,870 million metric tons of CO_2-equivalent (CO_2-eq.). One of the primary sources of the total GHG emissions include the industry sector, which generated 22% of the 2015 GHG emissions(*2*). GHG emissions from industry originate mainly from burning fossil fuels for energy and certain chemical reactions to produce goods from raw materials. The U.S. manufacturing sector generated approximately 1,261 million metric tons of CO_2-eq. in 2006(*3*). EPA released a final rule stating an expectation of methane emission reduction by an estimated 334,000 metric tons, the equivalent of reducing 8.2 million metric tons of CO_2 in 2025 (*5*). Because the new product will compete with other currently marketed RYO products, no addition of GHG emissions is anticipated. In addition, the applicant stated that the manufacturing facility abides by all applicable French regional and federal emissions regulations and requirements.

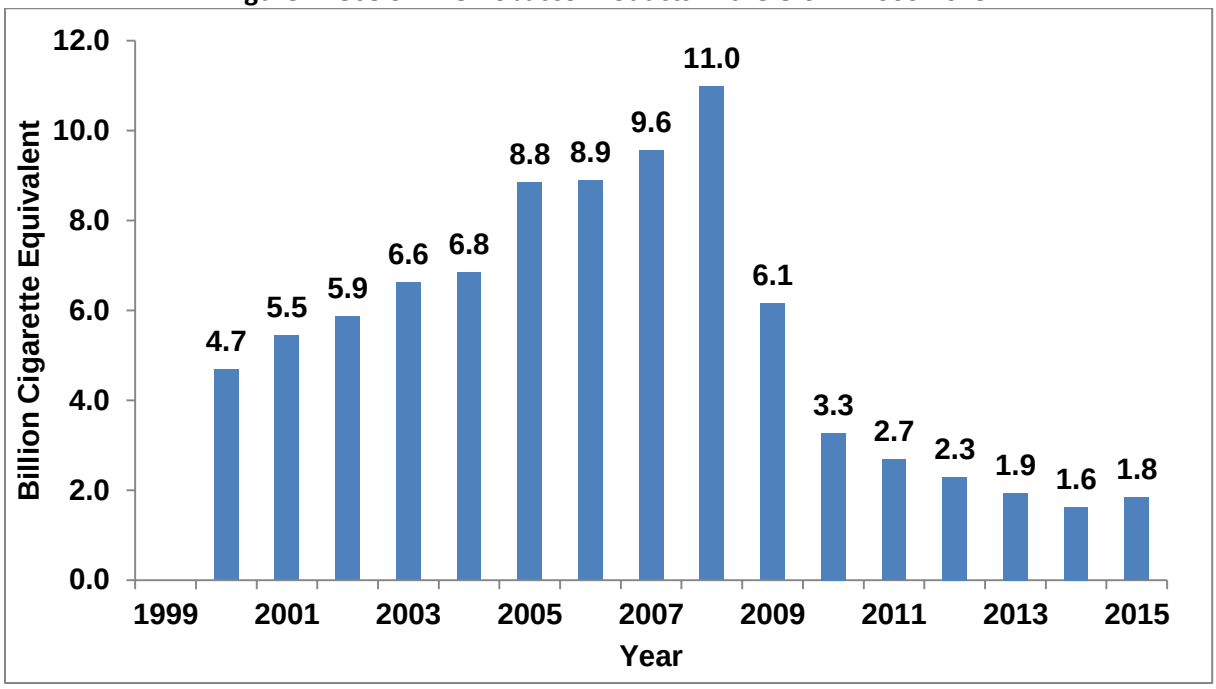
5.2 Environmental Introduction as a Result of Use of the New Tobacco Products

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-equivalents[3] in 2009 to 1.8 billion cigarette-equivalents in 2015 (Figure 4) (*6, 7*).

Figure 4. Use of RYO Tobacco Products in the U.S. in 2000-2015[3]



5.2.2 Environmental Introduction from Use of the New Products

The applicant intends to continue to market the predicate products after receiving market authorizations for the new products. Because the new products are expected to compete with the predicate products as well as 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 products, relative to the substances released by the predicate products and other RYO products already on the market. As noted, the only difference between the predicate products and corresponding new tobacco products is in product quantity. 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 products are released in a similar manner to the corresponding predicate products and other RYO cigarette rolling paper products.

5.3 Environmental Introduction as a Result of Disposal Following Use of the New Tobacco Products

[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. National Association of Attorneys General (1998).

The environmental consequences resulting from disposal following use of RYO cigarette rolling paper and tips are a) disposal of packaging, b) discarding of the used RYO tobacco products, and c) air emissions.

5.3.1 Disposal Following Use of RYO Rolling Cigarette Paper and Tips

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. Plastics account for 33.25 million tons (12.9%) of total MSW generated in 2014. Containers and packaging represented 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(*8*).

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

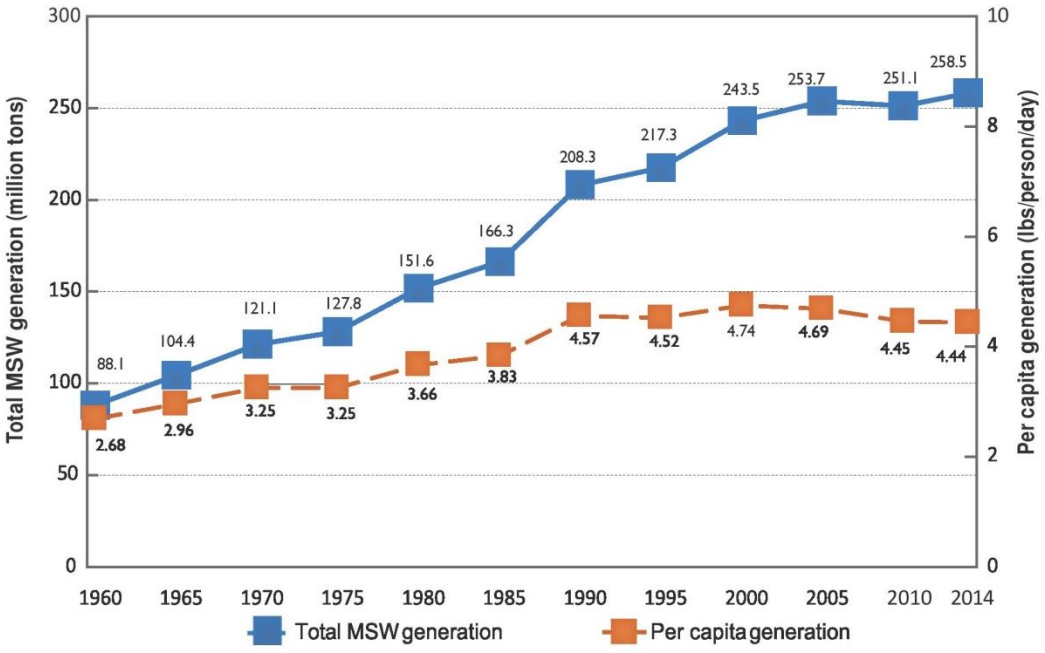


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

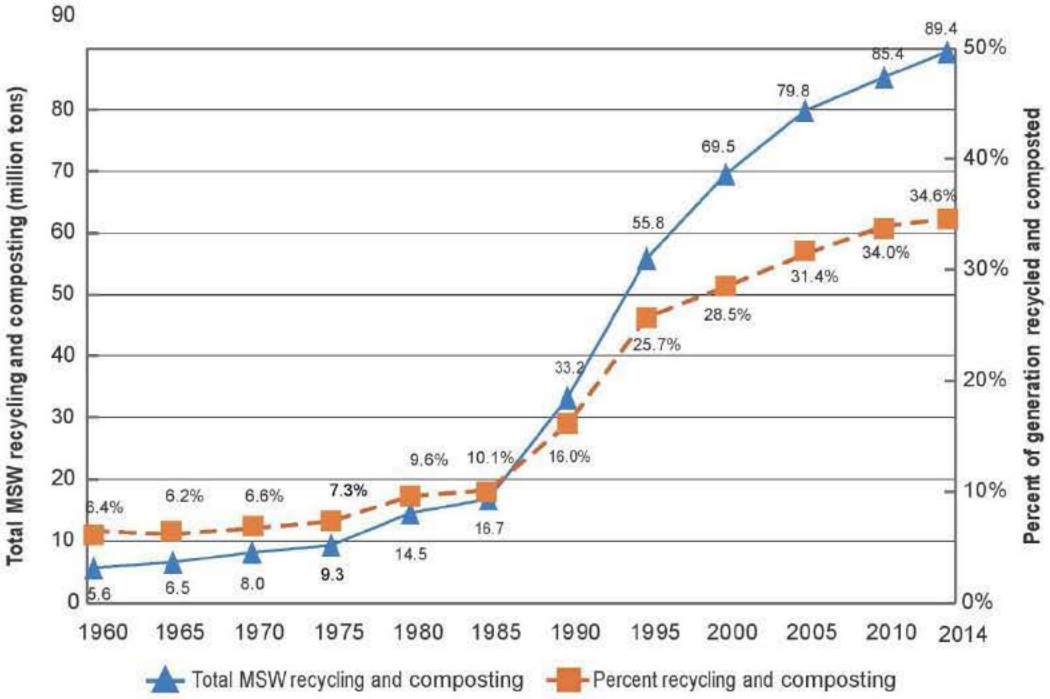


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

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]**
1st Year	1.90	0.000368
5th Year	1.31	0.000254

[a] See Appendix 3

[4] RYO Tobacco Products in percentage:

$$\text{1st Year} = \left(\frac{862.6 \text{ metric tons}}{234{,}470{,}000 \text{ metric tons}}\right) \times 100\% = 0.000368\%$$

$$\text{5th Year} = \left(\frac{595.0 \text{ metric tons}}{234{,}470{,}000 \text{ metric tons}}\right) \times 100\% = 0.000254\%$$

c) Air Emissions

The used RYO tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHG. According to U.S. EPA, from the paper and paperboard waste generated in 2014, 64.7% was recycled, leaving 28.4% disposed of in MSW landfills and 6.9% combusted(*8*).

Global methane (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 CH_4 emissions in the U.S., releasing an estimated 115.7 million metric tons of CO_2-eq, accounting for approximately 15.4% of these emissions in 2015 (*4*). Methane is a potent GHG that has a global warming potential of 28-36 times greater than CO_2, and has an atmospheric life of about 12 years. The decomposition of landfill waste produces approximately 50% biogenic CO_2 and 50% CH_4, by volume, as well as trace amounts of non-methane organic compounds and volatile organic compounds. However, only 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(*9*). As mentioned previously, in 2014, MSW landfills generated roughly 133.1 MMT CO_2-eq. of CH_4 emissions(*4*). Because the new products are not expected to substantially impact the RYO tobacco market volume, no addition of GHG emissions is anticipated.

5.3.2 Environmental Introduction from Disposal Following Use of the New Products

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other RYO cigarette rolling paper, tips, and any other RYO tobacco products that are currently being marketed. After using the new products, the users may dispose of or recycle the packaging material. Users may also discard the combusted tobacco and other ingredients (tips), as discussed above, as MSW or litter.

To determine the amount of waste due to disposal of paper and cardboard 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 products. The calculated waste of the paper and cardboard packaging materials and paper product materials of the new products were determined to be miniscule compared to the forecasted MSW to be generated in the U.S. (Confidential Appendix 3). In addition, paper components are more likely to be recycled; at least a portion of the new products' waste is likely to be recycled.

As previously discussed, because the new RYO rolling cigarette paper and tips 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 landfill is not anticipated due to the proposed actions.

Because the waste generated from using the new products is expected to make up a negligible fraction of the total MSW, no additional control of GHG emissions is anticipated in the landfills.

6. Fate of Materials Released into the Environment due to the Proposed Actions

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment because the new products are anticipated to be manufactured, used, and disposed of in the same way as other RYO tobacco products, including rolling cigarette paper and tips. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other RYO tobacco products, including rolling cigarette paper and tips, manufactured in the facility. No new types of material are anticipated to be emitted to the environment because the new products have identical properties to their corresponding predicate products and will be made using the same materials, ingredients and processes as the predicate products.

7. Environmental Effects of New Materials Released into the Environment due to the Proposed Actions

The applicant stated that the manufacturing operation is in compliance with all regional 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 products are small fractions when compared to that of the projected RYO tobacco products imported from France and used in the U.S. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction of the total forecasted MSWs in the U.S. Consequently, no new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The new products will compete with other currently marketed RYO tobacco products. 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. Additionally, the applicant stated that all ingredients used to manufacture the new products are from 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 products 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 products 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 actions of authorizing the new products and associated manufacture, use, and disposal following use of the new tobacco products.

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 position/title, education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment.

Preparers:

Catherine W. McCollum, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Biochemistry and Cell Biology
- Experience: 10 years in various scientific activities
- Expertise: NEPA analysis, environmental impact analysis, ecotoxicity, developmental toxicology

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

Hoshing W. Chang, PhD, Center for Tobacco Products
- Education: M.S. in Environmental Science and PhD in Biochemistry
- Experience: 8 years in FDA related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

12. List of Agencies and Persons Consulted

Not applicable.

13. Appendix List

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

Appendix 2: Forecast of Cigarette Rolling Papers in the Form of Booklets 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 First- and Fifth-Year Market Volume Projections for the New and Predicate Products

Confidential Appendix 2: 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 3: The First- and Fifth-Year Projection of Paper and Cardboard Waste of Packaging Materials and Product Materials Associated with Marketing the New and Corresponding Predicate 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. 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/2017-02/documents/2017_complete_report.pdf. Accessed February 28, 2017.
3. U.S. Department of Energy. U.S. Manufacturing Energy Use and Greenhouse Gas Emissions Analysis. (2012). Available at https://www.energy.gov/sites/prod/files/2013/11/f4/energy_use_and_loss_and_emissions.pdf. Accessed February 28, 2017.
4. U.S. EPA. Landfill Methane Outreach Program (LMOP). Basic Information about Landfill Gas. Available at https://www.epa.gov/lmop/basic-information-about-landfill-gas. Accessed July 25, 2017.
5. 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 December 1, 2016.
6. 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 May 27, 2016.
7. Centers for Disease Control and Prevention (CDC). Prevention, Economic Facts about Tobacco Production and Use. Available at http://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/. Accessed January 16, 2015.
8. 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 May 17, 2016.
9. Intergovernmental Panel on Climate Change (IPCC). 2006 IPCC Guidelines for National Greenhouse Gas Inventories. Available at http://www.ipcc-nggip.iges.or.jp/public/2006gl/. Accessed January 23, 2017.

APPENDIX 1

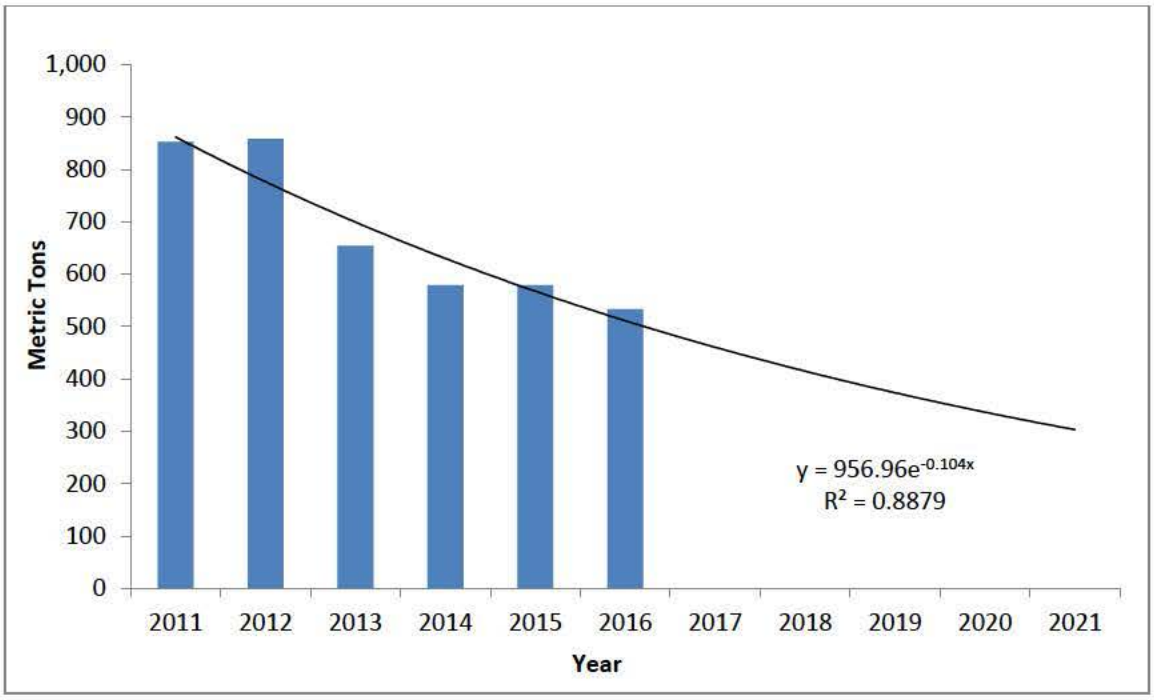
Submission Tracking Numbers for the SE Reports and Package Sizes of the New and Predicate Products and Related Amendments That Are Covered Under this Programmatic Environmental Assessment (PEA)

STN	New Product	Predicate Product	Package Size (Paper and Tip/Booklet)		Package Size (Booklets/Cardboard Retail Box)		Amendments
			New	Predicate	New	Predicate	
SE0012326	OCB® Yellow Cigarette Papers with Tips	OCB® Yellow Cigarette Papers with Tips	32 each	24 each	24 each	24 each	SE0012417, SE0013287, SE0013463
SE0012327	OCB® Slim Long Cigarette Papers with Tips	OCB® Slim Long Cigarette Papers with Tips	50 each	24 each	24 each	24 each	SE0012418, SE0013287, SE0013463

APPENDIX 2

Forecast of Cigarette Rolling Papers in the Form of Booklets 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 cigarette papers in the form of booklets from France into the U.S. from 2011 to 2016 was used to forecast the manufacture of RYO tobacco products[5]. This was achieved by using one best-fit exponential trend line with the R^2 value of 0.8879. Accordingly, the forecasted amount of cigarette papers in the form of booklets to be imported from France into the U.S. is estimated to be 462 metric tons in 2017 and 305 metric tons in 2021. The amount of cigarette papers in the form of booklets imported from France into the U.S. is estimated at 533 metric tons in 2016.



Year[6]	Cigarette Rolling Papers in the form of Booklets Imported from France (Metric Tons)
Current (2016)	533
1st Year (2017)	462
5th Year (2021)	305

[5] Forecast trend lines extrapolated from USITC data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed February 17, 2017.

[6] 1st Year (2017) = $956.96^{(-0.104\times7)}$ = 462; 5th Year (2021) = $956.96^{(-0.104\times11)}$ = 305

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 0.9296.[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 1.90 billion cigarette-equivalents (862.6 metric tons) in 2017 and 1.31 billion cigarette-equivalents (595.0 metric tons) in 2021.[8]

Year[9]	RYO Tobacco Products (Billion Cigarette-Equivalent)	RYO Tobacco Products (Metric Tons)
Current (2016)	1.07	487.3
1st Year (2017)	1.90	862.6
5th Year (2021)	1.31	595.0

[7] Forecast trend lines extrapolated from TTB data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed July 18, 2017.

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

[9] 1st Year (2017) in billion cigarette-equivalent = 11.901 x 10EXP(-1.104) = 1.90
5th Year (2021) in billion cigarette-equivalent = 11.901 x 14EXP(-1.104) = 1.31

CONFIDENTIAL APPENDIX 1

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

STN	Unit	First-Year Market Volume		Fifth-Year Market Volume	
		New Product	Predicate Product	New Product	Predicate Product
SE0012326	Individual Leaves of Rolling Papers	(b) (4)			
	Metric Tons				
SE0012327	Individual Leaves of Rolling Papers				
	Metric Tons				

CONFIDENTIAL APPENDIX 2

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 volume of the new products forecasted to occupy the U.S. market was determined by comparing the projected market volume of the new products to the forecasted use of total RYO tobacco in the U.S. (Appendix 2, 3, and Confidential Appendix 1). The percent of the total cigarette market occupied in the projected first and fifth year of marketing of the new products was calculated using the equations below[10]:

Projected Market Occupation of New Product Imported from France:

$$\text{First Year} = \frac{\text{1st Year Market Volume Projection (metric tons)}}{\text{Forecasted import of cigarette papers in form of bookets from France in 2017 (metric tons)}} \times 100\%$$

$$\text{Fifth Year} = \frac{\text{5th Year Market Volume Projection (metric tons)}}{\text{Forecasted import of cigarette papers in form of bookets from France in 2021 (metric tons)}} \times 100\%$$

Projected Market Occupation of New Product in the U.S.:

$$\text{First Year} = \frac{\text{1st Year Market Volume Projection (metric tons)}}{\text{Forecasted use of RYO in the U.S.for 2017 (metric tons)}} \times 100\%$$

$$\text{Fifth Year} = \frac{\text{5th Year Market Volume Projection (metric tons)}}{\text{Forecasted use of RYO in the U.S.for 2021 (metric tons)}} \times 100\%$$

STN	Year	Forecasted Import of Cigarette Papers in the form of Booklets from France (Metric Tons)[11]	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)[12]	Projected Market Volume of New Product (Metric Tons)[13]	Projected Market Occupation of New Product Imported from France (%)	Projected Market Occupation of New Product in the U.S. (%)
SE0012326	First-Year (2017)	462	872	(b) (4)		
	Fifth-Year (2021)	305	1,228			
SE0012327	First-Year (2017)	462	872			
	Fifth-Year (2021)	305	1,228			

[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

The First- and Fifth-Year Projection of Total Waste of Packaging Materials and Product Materials Associated with Marketing the New and Corresponding Predicate Products

To analyze the environmental effects from total waste due to the proposed actions, the Agency estimated the first- and fifth-year weights of the projected packaging and product materials waste (in tons) that are generated from disposal after use of the new and corresponding predicate products in 2017 and 2021. Projected total waste generation is the summation of the projected booklet cover, cardboard box, and used tip waste generation of the new and corresponding predicate products:

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

$$B_i = \frac{E_i}{F} \times G \times K$$

$$C_i = \frac{E_i}{F \times H} \times I \times K$$

$$D_i = E_i \times J \times K$$

A_i: Projected paper waste generation of the new and corresponding predicate products (metric tons)
B_i: Projected booklet cover waste generation of the new and corresponding predicate products (metric tons)
C_i: Projected retail cardboard box waste generation of the new and corresponding predicate products (metric tons)
D_i: Projected tip waste generation of the new and corresponding predicate products (metric tons)
E_i: Projected market volume of the new and corresponding predicate products (# individual leaves of rolling paper)
F: Number of rolling papers per booklet
G: Weight of booklet cover (grams)
H: Number of booklets per retail cardboard box
I: Weight of empty retail cardboard box (grams)
J: Weight of tip (grams)
K: 1.0×10^{-6} metric tons/gram

	STN	J	I	H	G	F	E	D	C	B	A
First Year	SE0012326	(b) (4)									
	SE0012327										
	Predicate for SE0012326										
	Predicate for SE0012327										
	Total Waste for New and Corresponding Predicate Products										(b) (4)
Fifth Year	SE0012326	(b) (4)									
	SE0012327										
	Predicate for SE0012326										
	Predicate for SE0012327										
	Total Waste for New and Corresponding Predicate Products										(b) (4)

Total Waste. The booklet cover, cardboard box, and tip are disposed of, recycled, or both as waste. Estimation of generated total waste is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing. A portion of the generated total waste is likely to be recycled with an overall recycling rate for paper products at 64.7% in the U.S., according to the U.S. EPA(*6*). Therefore, if 100% of the tips and 35.3% of the booklets and cardboard retail boxes are disposed of as waste based on the 2014 waste generation data in the U.S., the estimated cumulative total 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 corresponding predicate products[14].

If the entire packaging paper, pouch, and cardboard are disposed of as waste, which is a more conservative approach, the projected cumulative total waste in the first and fifth years of marketing the new and corresponding 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 MSW waste reported in the U.S. in 2014.

(b) (4)