Environmental Assessment for Market Authorizations for Republic Tobacco, LP "TOP King Size"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

August 15, 2017

Table of Contents

This environmental assessment (EA) is for the market authorization of a roll-your-own (RYO) filter tip 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 to 21 CFR 25.40 as part of a submission under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

Republic Tobacco, LP

2. Address

2301 Ravine Way,
Glenview, IL 60025

3. Manufacturer

(b) (4)

4. Description of Proposed Action

This proposed action is for FDA to issue a market authorization under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of a brand of RYO filter tips into interstate commercial distribution in the U.S. The authorization is based on the finding that this 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, L.P. 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 differs from the predicate product have different characteristics (sec 910(a)(3)(A)(ii) of the FD&C Act) but that they differ only in product quantity. In addition, the applicant claimed that the new and predicate products have different packaging composition weights. After considering the substantial equivalence (SE) report (SE0011134), the Agency shall issue an order under the provisions of sections 910 and 905(j) of the FD&C Act when finding the new product to be substantially equivalent to the predicate product.

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

4.3.1 Type of Tobacco Product

Roll-your-own (RYO) filter tip

4.3.2 Product Name and 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 product and the predicate product.

STN	New Product	Predicate Product (Grandfathered Product)
SE0011134	TOP King Size	TOP King Size

4.3.3 Description of the Product Package

The packaging weight of the finished new product is different from the predicate product. The new product packaging components consist of a polyethylene pouch in which the RYO filter tips are contained. The pouch is enclosed in a paperboard retail box with an adhesive label and shipped in a paperboard case (Appendix 1). Details of the package components and weights of each packaging component for the new product is described in Confidential Appendix 3 and 4.

4.3.4 Location of Manufacturing

The manufacturer of the RYO filter tip product is (b) (4) (Figure 1). This manufacturing facility is located in an industrial park.

(b) (4)

[1] Manufacturer address via Google Earth. Accessed June 5, 2017.

4.3.5 Location of Use

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

4.3.6 Location of Disposal

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

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

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

5. Environmental Introduction Due to the Proposed Action

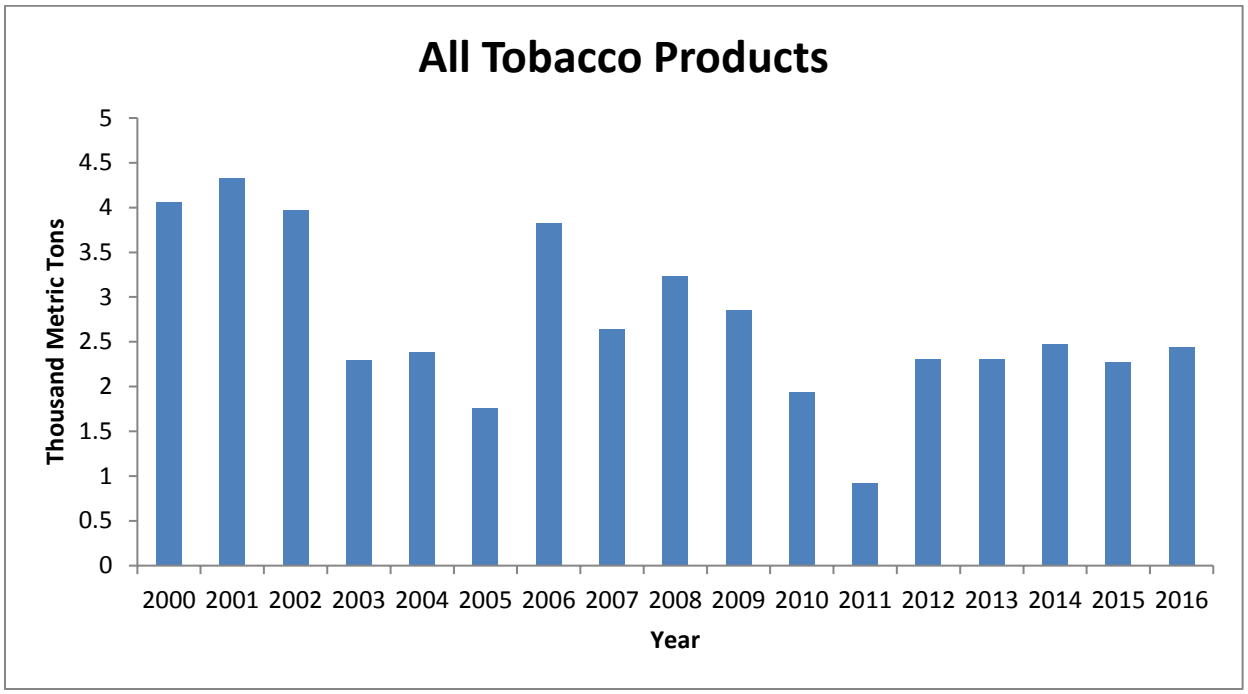
5.1 Introduction as a Result of Manufacturing the New Tobacco Product

5.1.1 Tobacco Products Imported from Spain

Tobacco Import and Tobacco Market Volumes. According to the U.S. International Trade Commission (USITC), the import of total tobacco products to the U.S. from Spain has decreased from 4,057 metric tons in 2000 to 2,435 metric tons in 2016 (Figure 2).[2] When searching for import of RYO filter tips to the U.S. from Spain over the same period of time, there were no data at the time of this review showing total RYO filter tips imported into the U.S.[2]

[2] Unit is defined by the United States International Trade Commission, available at: http://dataweb.usitc.gov/. Accessed on June 6, 2017.

Figure 2. Total Tobacco Products Imported from Spain into the U.S. 2000-2016[2]



Hazardous and Non-Hazardous Waste from the RYO Filter Tip Manufacturing Facility. Emissions and non-hazardous and hazardous waste information associated with industrial facilities in the European Pollutant Release and Transfer Register was not publicly available for this manufacturer.[3] The applicant stated, however, that the manufacturer abides by all applicable Spanish regional and federal emissions, solid waste, and liquid waste regulations and requirements, including any controls on greenhouse gas (GHG) emissions associated with the production of their products.

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 Spain. The new product will compete with other currently marketed RYO filter tip products. In addition, the applicant stated the factory is already equipped to manufacture the new product as the process is identical to the predicate product and will not require any additional environmental controls. Also, the applicant stated the new and predicate products are intended to compete with other RYO tobacco products. Lastly, the applicant stated the manufacture of the new product would not result in an expansion of the manufacturing facility.

[3] European Environment Agency. European Pollutant Release and Transfer Register. Available at http://prtr.ec.europa.eu/#home. Accessed June 6, 2017.

Based on information in the SE Report, the new product differs from the predicate product in product quantity only. The applicant stated the new and predicate products are identical, which would not result in the release of any new substances or emissions into the environment. Furthermore, the applicant stated the new product is intended to compete with and substitute for current marketed RYO products. 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 Spain in 2017 and 2021, the cumulative projected market volumes of the new product are a negligible portion of the total forecasted market volumes in 2017 and 2021 (Appendix 2 and Confidential Appendix 2). Also, the applicant stated, 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 Spain and the applicant stated that the facility is in compliance with the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

In addition, the applicant claimed the projected production volume of the new product (Confidential Appendix 1) will be minimal 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. Furthermore, the applicant claimed that depending on the volume of market acceptance of the new product and market conditions in non-U.S. markets, it is likely that the volume of the new product will replace other production at the factory and thus, result in no increase in production volume and in turn not result in a net increase of energy use at the facility.

The new product will compete with other currently marketed RYO products, and the new product will yield the same emissions as the predicate product because both products are identical filter tips and have been processed using the same, conventional methods. Furthermore, the applicant states that the new product could replace other product production at the factory. In addition, the applicant stated that the manufacturing facility abides by all applicable Spanish regional and federal emissions, regulations and requirements. The European Environmental Agency has reported a decrease of GHG emission in Spain since 2008. The short-term GHG decrease from 2009 to 2010 is due to an increased use of hydro, wind, and nuclear power.[4] Therefore, GHG emission related to the manufacturing of the product is likely to decrease.

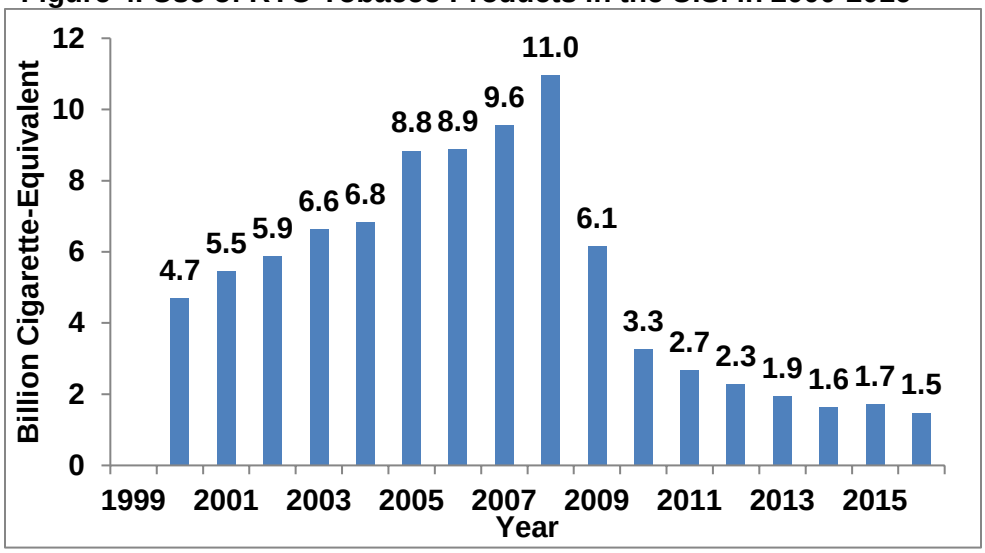
5.2 Environmental Introduction as a Result of Use of the New Tobacco Product

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

[4] https://www.eea.europa.eu/publications/ghg-trends-and-projections-2012/spain.pdf. Accessed July 24, 2017

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[5] in 2009 to 1.5 billion cigarette-equivalents in 2016 (Figure 4)(*1, 2*).

Figure 4. Use of RYO Tobacco Products in the U.S. in 2000-2016[4]



5.2.2 Environmental Introduction from Use of the New Product

The applicant intends to market both new and predicate products after receiving market authorizations for the new product. The new product is filter tip which is not burned at use. No environmental impacts are anticipated to exist at use of the new product.

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 filter tips are a) disposal of packaging, b) discarding of the used RYO filter tip, and c) GHG.

5.3.1 Disposal Following Use of RYO Filter 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

[5] 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.

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(*3*).

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

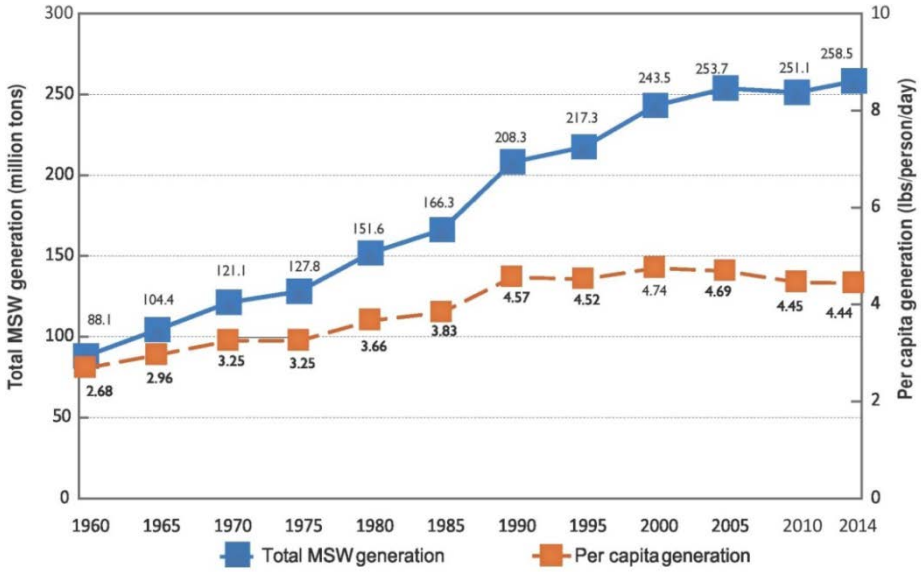


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

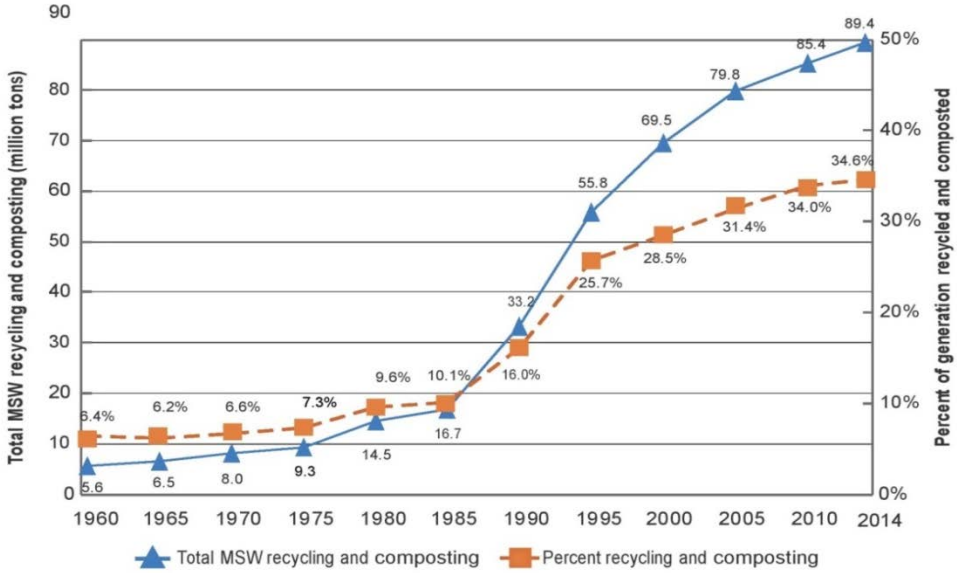


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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. 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.

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. (%)[6]**
1st Year		(b) (4)
5th Year		

[a] See Appendix 3

c) Air Emissions

The used tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHG. 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.

Global methane emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related methane emissions in the U.S., releasing an estimated 115.7 million metric tons of carbon dioxide equivalents, accounting for approximately 17.6% of total methane emissions in 2015 [4]. Methane is a potent GHG that has a global warming potential of 28-36 times greater than carbon dioxide, and has an atmospheric life of about 12 years. The decomposition of landfill waste produces approximately 50% biogenic carbon dioxide and 50% methane, by volume, as well as trace amounts of non-methane organic compounds and volatile organic compounds. However, only methane generation and emissions are estimated and reported for landfills, a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines [5].

[6] RYO Tobacco Products in percentage: (b) (4)

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 filter tips, 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 the product after smoking, such as the remaining filter tip itself, 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 2). In addition, paper and plastic components are more likely to be recycled; at least a portion of the waste is likely to be recycled.

To determine the amount of waste from disposal of filter tips, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products (Confidential Appendix 1). RYO filters can be disposed of in MSW or as litter. In the case of litter, filters could eventually end up in aquatic waterways and pose an environmental concern for aquatic organisms. Although the waste generated from RYO filters remains as an environmental concern, the calculated cumulative waste of the filters due to the new product, is determined to be miniscule compared to the MSW forecasted to be generated in the U.S.

The waste generated from using the new product is expected to make up a negligible fraction of the total MSW (Confidential Appendix 1), construction of new landfills and control of air emissions are not anticipated due to the proposed action.

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 the predicate product and other RYO tobacco products. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from the predicate product and other tobacco products, including RYO filter tips, manufactured in the facility. No new types of material are anticipated to be emitted to the environment during use.

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 Spanish regional and federal emissions, solid waste, and liquid waste regulations and requirements, including any controls on GHG emissions associated with the production of their products. 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 Spain 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 Spain. 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 applicant claimed the projected production volume of the new product (Confidential Appendix 1) will be minimal 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. Furthermore, the applicant claimed it is likely that the volume of the new product will merely replace other production at the factory and thus, result in no increase in production volume and in turn not result in a net increase of energy use at the facility.

The applicant also stated that the proposed action will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total RYO market volumes in the U.S., the Agency found that the projected market volumes of the new product are a small fraction of the total forecasted market volume in 2017 and 2021. Because the new product is intended to compete or replace similar RYO 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. Accordingly, no additional use of resources is anticipated.

9. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for the new product and the proposed use as a RYO tobacco product. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not authorize the marketing of the new tobacco product in the U.S. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products and many other similar RYO tobacco products will continue to be marketed.

Alternative B (Proposed action): There is no substantial environmental effect due to the proposed action of authorizing the new product (Confidential Appendix 1) 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:

Ronald L. Edwards Jr., MS, Center for Tobacco Products
Education: M.S. in Biology
Experience: 22 years in environmental regulation and laboratory toxicology
Expertise: Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

Reviewer:

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 Number for the SE Report and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

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

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 of 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. and with Tobacco Products Imported from Spain

Confidential Appendix 3: The First- and Fifth-Year Projection of Paper Waste of Packaging Materials Associated with Marketing the Products

Confidential Appendix 4: The First- and Fifth-Year Projection of Plastic Waste of Packaging Materials Associated with Marketing the Products

15. References

1. 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 March 15, 2017.
2. Centers for Disease Control and 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.
3. 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.
4. Environmental Protection Agency (EPA). *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015.* 2017(EPA 430-P-17-001). Accessed July 25, 2016
5. Intergovernmental Panel on Climate Change (IPCC) *2006 IPCC Guidelines for National Greenhouse Gas Inventories*. 2006; Available from: http://www.ipcc-nggip.iges.or.jp/public/2006gl/. Accessed July 20, 2017.

APPENDIX 1

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

STN	Product Name	Product	Filter Tips per Pouch	Pouches per Retail Box	Retail Unit	Retail Boxes per Shipping Case	Amendments
SE0011134	TOP King Size	New	100	30	Pouch, packaged in a retail box and shipped in a case	8	SE0011758 SE0012589
	TOP King Size	Predicate	200	16	Pouch, packaged in a retail box and shipped in a case	12	SE0011758 SE0012589

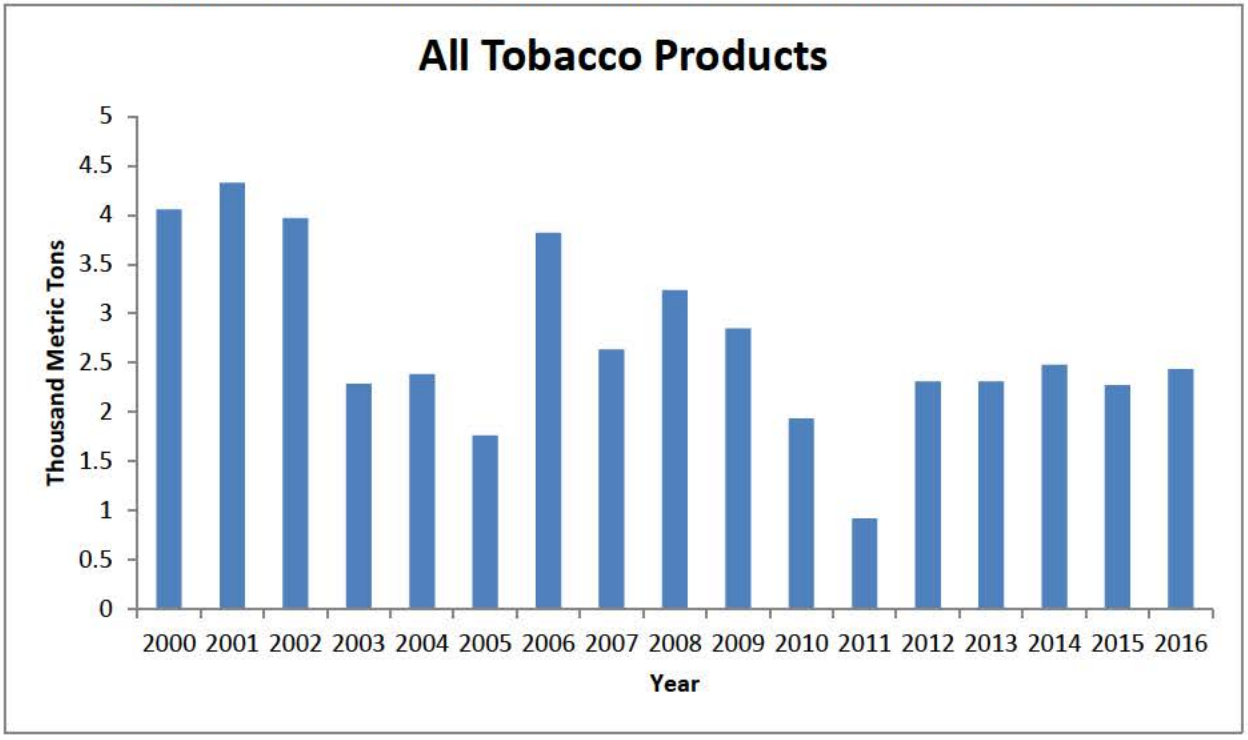
The predicate product is marketed in individual pouches containing 200 filter tips per pouch, and packaged in a retail box containing 16 pouches per retail box and shipped 12 retail boxes per case. The new product is intended to be marketed as individual pouches containing 100 filter tips per pouch, and packaged in a retail box containing 30 pouches per retail box and shipped 8 retail boxes per case.

APPENDIX 2

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

To evaluate the environmental impact of the proposed action due to import of the new product, historical data regarding the import of all tobacco products from Spain into the U.S. was used to forecast the manufacture and import from Spain of RYO tobacco products[7]. This was achieved by averaging 2012 to 2016 metric tons of all tobacco products imported from Spain, a timeframe where the data show a somewhat stable level of importation. Accordingly, the forecasted amount of all tobacco products to be imported from Spain into the U.S. is estimated to be about 2,363 metric tons in 2017 and 2021. The amount of all tobacco products imported from Spain into the U.S. is estimated at 2,435 metric tons in 2016 by USITC.

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



Year[8]	All Tobacco Products Imported from Spain (Metric Tons)
2016	2,435
1st Year (2017)	2,363
5th Year (2021)	2,363

[7] Unit is defined by the United States International Trade Commission, available at: http://dataweb.usitc.gov/. Accessed on June 6, 2017.

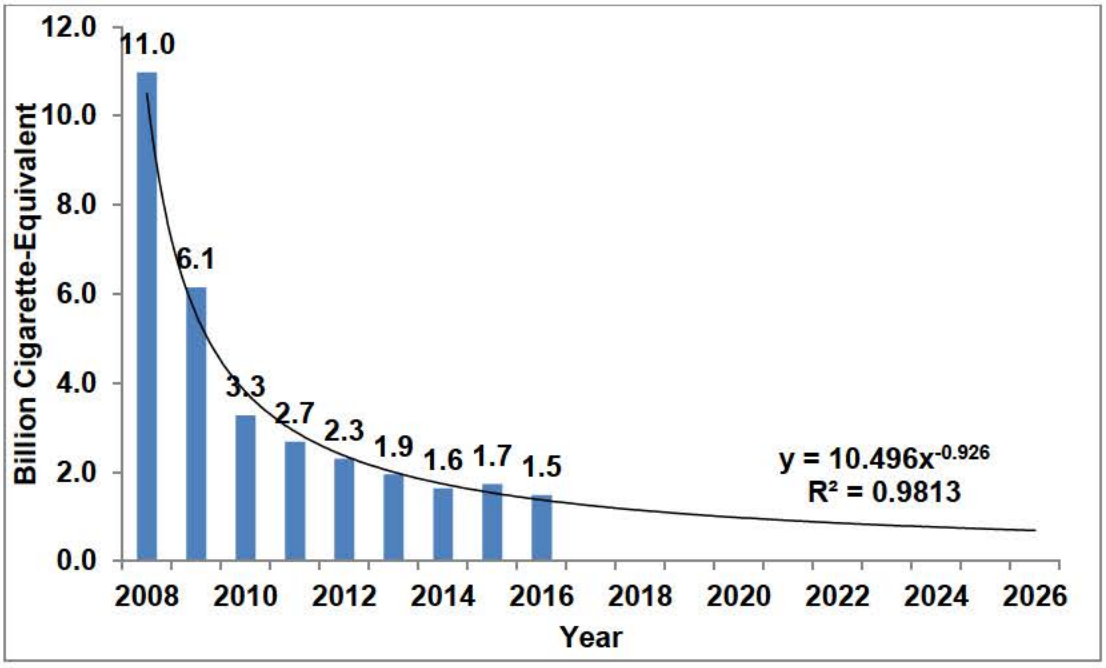
[8] 1st Year (2017) and 5th Year (2021) = average of years 2012 to 2016 in metric tons

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 product, the Agency utilized the historical data of use of RYO tobacco products in 2008–2016 to forecast the use in the U.S.in 2017 and 2021. This was achieved by using one best-fit power trend line with the R^2 value of 0.9813.[9]

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.[10]



Year[11]	RYO Tobacco Products (Billion Cigarette-Equivalent)	RYO Tobacco Products (Metric Tons)
1st Year (2017)	(b) (4)	
5th Year (2021)		

[9] Forecast trend lines extrapolated from TTB data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed June 16, 2017.

[10] Billion cigarette-equivalent value is calculated based on the assumption that approximately (b) (4) of tobacco is used per cigarette. Billion cigarette-equiv (b) (4)

[11] 1st Year in billion cigarette-equivalent = (b) (4)
5th Year in billion cigarette-equivalent =

CONFIDENTIAL APPENDIX 1

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

STN	Measure	First-Year Market Volume		Fifth-Year Market Volume	
		New Product	Predicate Product	New Product	Predicate Product
SE0011134	Number of Tips	(b) (4)			
	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. and with Tobacco Products Imported from Spain

The first- and fifth-year market volumes of the new and predicate products projected to occupy the U.S. market were determined by comparing the projected market volume of the new and predicate product to the forecasted use of total RYO tobacco in the U.S. (Appendices 2, 3, and Confidential Appendix 1). The percent of the total RYO tobacco market occupied in the projected first and fifth year of marketing of the new and predicate products was calculated using the equations below[12]:

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 (%)

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

The percent of the tobacco products imported from Spain projected to be occupied by the new and predicate products in the first and fifth years of marketing was calculated using the equations below:

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

$$= \frac{\text{First-Year Market Volume Projection (metric tons)}}{\text{Forecasted Market Occupation of total tobacco products imported from Spain for 2017 (metric tons)}} \times 100\%$$

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

$$= \frac{\text{Fifth-Year Market Volume Projection (metric tons)}}{\text{Forecasted Market Occupation of total tobacco products imported from Spain for 2021 (metric tons)}} \times 100\%$$

STN	Year	Forecasted Import of Total Tobacco Products from Spain (Metric Tons)[13]	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)[14]	Projected Market Volume (Metric Tons)[15]	Projected Market Occupation of Total Tobacco Products Imported from Spain (%)	Projected Market Occupation in the U.S. (%)
SE0011134	2017	(b) (4)				

[12] Each individual filter tip is anticipated to be used in making a single cigarette unit. Therefore, one filter tip is equal to one cigarette-equivalent.

[13] See Appendix 2.

[14] See Appendix 3.

[15] See Confidential Appendix 1.

STN	Year	Forecasted Import of Total Tobacco Products from Spain (Metric Tons)[13]	Forecasted Use of Total RYO Tobacco in the U.S. (Metric Tons)[14]	Projected Market Volume (Metric Tons)[15]	Projected Market Occupation of Total Tobacco Products Imported from Spain (%)	Projected Market Occupation in the U.S. (%)
	2021	(b) (4)				
Predicate	2017					
	2021					

CONFIDENTIAL APPENDIX 3

The First- and Fifth-Year Projection of Paper Waste of Packaging Materials Associated with Marketing the Products

To analyze the environmental effects from paper waste due to the proposed action, the Agency estimated the first- and fifth-year weights of the projected packaging materials waste (in metric tons) that are generated from disposal after use of the products in 2017 and 2021. Projected paper waste generation is the summation of the retail box, paper label, and shipping case waste generation of the products:

$G = F/D$

$H = G \times B \times L$

$I = G \times A \times L$

$J = G/E \times C \times L$

$K = H + I + J$

$A =$ *Weight of retail box paper label (grams)*
$B =$ *Weight of retail box (grams)*
$C =$ *Weight of shipping case (grams)*
$D =$ *Filter tips per retail box*
$E =$ *Retail Boxes in a shipping case*
$F =$ *Market projection of filter tips*
$G =$ *Projected retail boxes*
$H =$ *Projected retail box paper waste (metric tons)*
$I =$ *Projected paper label waste (metric tons)*
$J =$ *Projected shipping case paper waste (metric tons)*
$K =$ *Projected paper waste generation of the products (metric tons)*
$L = 1.0\ x\ 10 - 6\ metric\ tons/gram$

Year	STN	A	B	C	D	E	F	G	H	I	J	K
First	SE0011134	(b) (4)										
	Predicate											
First-Year Total Paper Waste for New and Predicate Products (metric tons)												(b) (4)
Fifth	SE0011134	(b) (4)										
	Predicate											
Fifth-Year Total Paper Waste for New and Predicate Products (metric tons)												(b) (4)

Paper Waste. The paperboard retail box, paper label, and paperboard shipping case are disposed of, recycled, or both, as paper waste or as litter. Estimation of generated total paper waste for the new and predicate products is (b) (4) metric tons in the first year 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(3). Therefore, if 35.3% of the paperboard retail box, paper label, and paperboard shipping cases are disposed of as waste based on the 2014 waste generation data in the U.S., the estimated cumulative

paper 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.[16]

If the entire packaging paper is disposed of as waste, which is a more conservative approach, the projected cumulative paper 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.

[16] At 35.3% disposal rate as paper waste (on booklets, cardboard boxes, display cartons, and shipping cases) for the (b) (4)

CONFIDENTIAL APPENDIX 4

The First- and Fifth-Year Projection of Plastic Waste of Packaging Materials Associated with Marketing the Products

To analyze the environmental effects from plastic waste due to the proposed action, the Agency estimated the first- and fifth-year weights of the projected packaging materials waste (in metric tons) that are generated from disposal after use of the products in 2017 and 2021. Projected plastic waste generation is the summation of the projected plastic pouch waste used to contain filter tips:

$$D = C/B$$

$$E = A \times D$$

$A = Weight\ of\ plastic\ pouch\ (grams)$
$B = Filter\ tips\ per\ pouch$
$C = Market\ projection\ of\ filter\ tips$
$D = Projected\ plastic\ pouches$
$E = Projected\ plastic\ waste\ generation\ of\ the\ products\ (metric\ tons)$
$F = 1.0\ x\ 10 - 6\ metric\ tons/gram$

Year	STN	A	B	C	D	E
First	SE0011134	(b) (4)				
	Predicate					
First-Year Total Plastic Waste for New and Predicate Products (metric tons)						(b) (4)
Fifth	SE0011134	(b) (4)				
	Predicate					
Fifth-Year Total Plastic Waste for New and Predicate Products (metric tons)						(b) (4)

Plastic Waste. The plastic pouch, constructed out of polyethylene, is disposed of, recycled, or both, as plastic waste or litter. Estimation of generated total plastic waste for the new and predicate products is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year. A portion of the generated plastic waste is likely to be recycled with an overall recycling rate for plastic products at 9.5% in the U.S., according to U.S. EPA(*5*). Therefore, if 90.5% of the plastic pouches are disposed of as waste based on the 2014 waste generation data in the U.S., the estimated cumulative plastic 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.[17]

If the entire packaging plastic waste is disposed of as waste, which is a more conservative approach, the projected cumulative plastic 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.

[17] At 9.5% disposal rate as plastic pouch waste for the 1st Year, (b) (4) on on $metric\ tons.$