Environmental Assessment for Market Authorization of "Silver Tip Extra 250" Manufactured by GIZEH Raucherbedarf GmbH, Found Substantially Equivalent to the Respective Predicate Product, "Silver Tip 250"

Prepared by Center for Tobacco Products U.S.

Food and Drug Administration

October 5, 2015

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This environmental assessment (EA) is for the market authorization of Silver Tip Extra 250 Roll-Your-Own (RYO) tobacco filtered cigarette tubes manufactured by GIZEH Raucherbedarf GmbH. Information presented in the EA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This EA has been prepared in accordance with 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

1. Name of Applicant

GIZEH Raucherbedarf GmbH

2. Address

Bunsenstrasse 12
51647 Gummersbach, Germany

3. Manufacturer

ALPACI (GIZEH Raucherbedarf GmbH)
Zone Industrielle Imbsheim
67330 Bouxwiller, France

4. Description of the Proposed Action

The proposed action is for FDA to issue market authorizations under section 910(a)(2) of the FD&C Act for the introduction of a new RYO filtered cigarette tube product – Silver Tip Extra 250. The Agency has found the new RYO filtered cigarette tube product to be substantially equivalent to the predicate product "Silver Tip 250" that was commercially marketed in the U.S. as of February 15, 2007.

4.1. Requested Action

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

4.2. Need for Action

GIZEH Raucherbedarf GmbH wishes to introduce the new RYO tobacco product into interstate commerce for commercial distribution in the United States (U.S.) and submitted to FDA a Substantial Equivalence (SE) Report to obtain market authorizations pursuant to section 910(a)(2) of the FD&C Act. The applicant claims that the new product is substantially equivalent to the predicate product, Silver Tip 250, which was commercially marketed in the United States on or before February 15, 2007.

After considering the SE Report and amendments, the Agency shall issue an order pursuant to section 910(a)(2) of the FD&C Act when finding the new product 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), Filtered Cigarette Tube

4.3.2 Names of Tobacco Product

The names of the new and predicate products are listed in Table 1.

Table 1. Submission Tracking Numbers (STNs) of the SE Report and Related Amendments with Names of the New and Predicate Products that are Covered Under this EA

STN	New Product	Predicate Product	Amendments
SE0010112	Silver Tip Extra 250	Silver Tip 250	SE0010114 SE0010321 SE0010400 SE0010401 SE0010477 SE0010748 SE0011022 SE0011720 SE0012044 SE0012406

4.3.3 Description of the New Product

The new product is RYO tobacco filtered cigarette tubes.

4.3.4 *Description of Product Package*

The filtered cigarette tubes are sold to retailers in cardboard boxes sealed with polypropylene shrink wrap. There are 250 tubes per retail box and the retail boxes are bundled into packaging units of 4 retail boxes wrapped in plastic. There are 10 packaging units (40 retail boxes) per shipping case.

4.3.5 *Location of Use*

GIZEH Raucherbedarf GmbH intends to distribute and sell the new product to U.S. consumers in the U.S., who will assemble the filtered cigarette tubes into the finished cigarettes.

4.3.6 *Location of Disposal*

Disposal of the used and unused filtered cigarette tubes will be disposed of as municipal solid waste (MSW) in the landfills or as litter, in the same manner as any other marketed filtered cigarette tube. Disposal of the packaging materials following use will either enter

the recycling stream or be deposited in MSW landfills or as litter. The distribution of waste from disposal after use should correspond to the pattern of product use.

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

The applicant claims that the new product is substantially equivalent to the predicate product that was commercially marketed in the U.S. as of February 15, 2007. The differences in the new product compared to the predicate product are those pertaining to product mass, filter length, product name, graphic design and color of the label on the package.

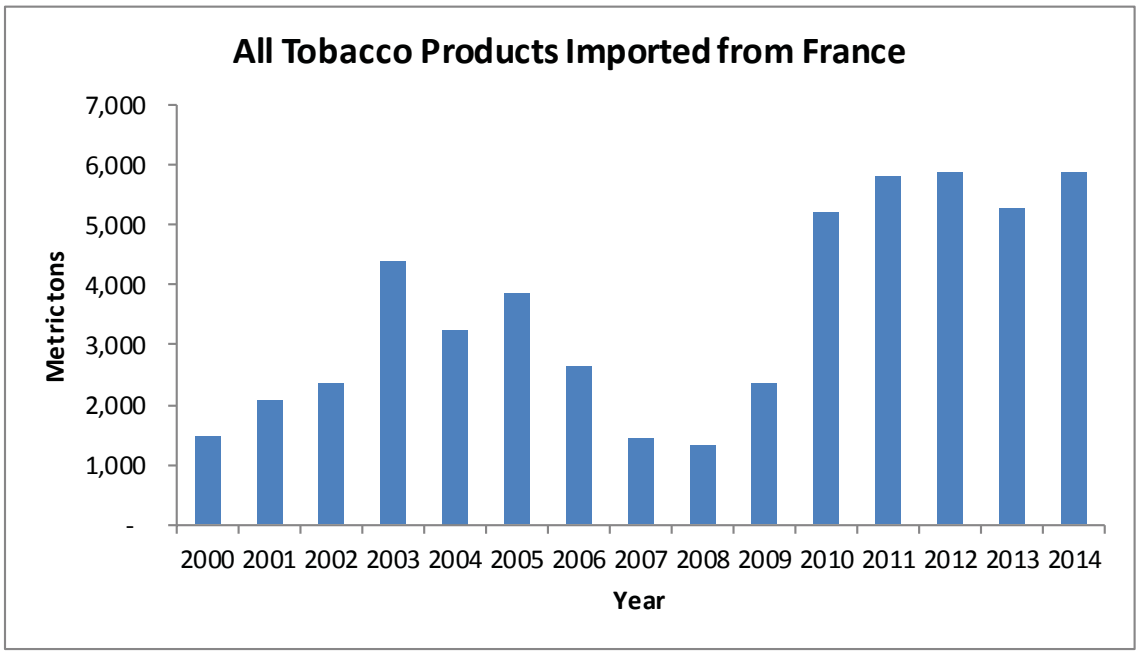
5. Environmental Introduction Due to the Proposed Action

5.1. Introduction as a Result of Manufacturing the New Product

5.1.1 Tobacco Products Imported from France

The import of tobacco products to the U.S. from France has increased sharply from 1,328 metric tons in 2008 to 5889 metric tons in 2014[1] (see Figure 1).

Figure 1. Total Tobacco Products Imported from France into the U.S. 2000 – 2014

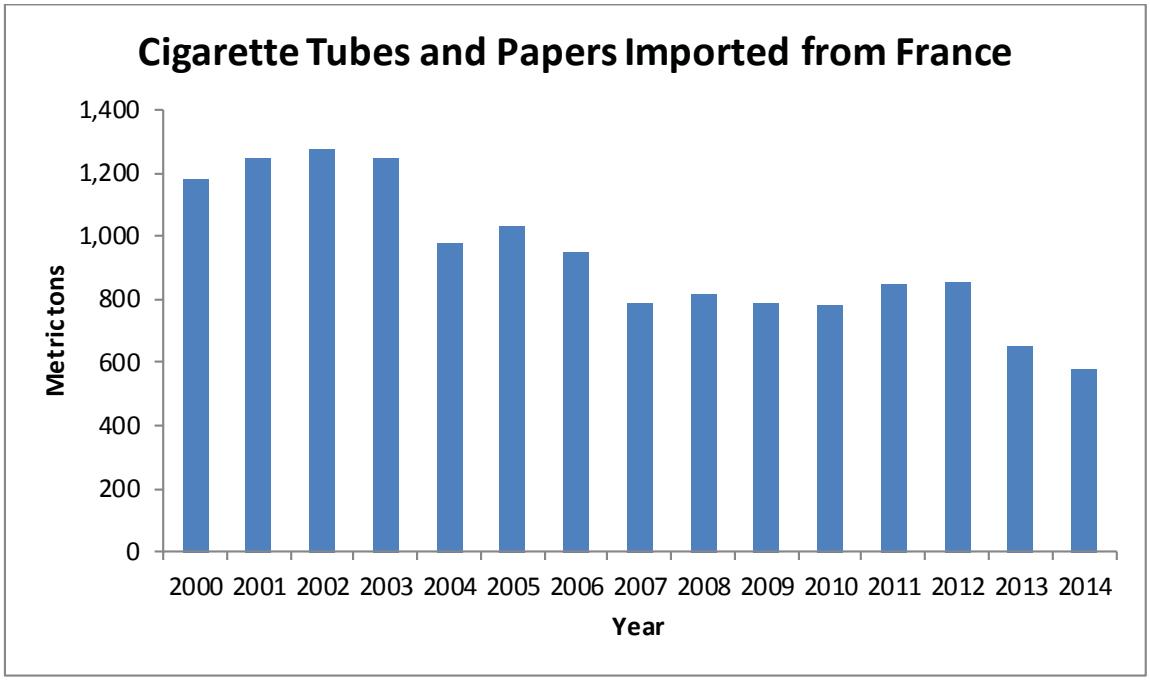


When looking at the change in import of cigarette tubes and papers to the U.S. from France over a longer period of time, notably from 2002 to 2014, there has been a steady

[1] Unit is defined by the United States International Trade Commission, available at: http://dataweb.usitc.gov/scripts/gsp/gsp_tariff.asp. Accessed on July 8, 2015

decline, from 1,278 metric tons in 2002 to 579 metric tons in 2014, as shown in Figure 2.

Figure 2. U.S. Import of Cigarette Papers from France in 2000 – 2014



The cigarette tubes and paper imported to the U.S. from France in 2014 (579 metric tons) represents approximately 10% of the total amount of tobacco products imported from France in 2014 (5,889 metric tons).

5.1.2 Environmental introduction from manufacturing the new product

The agency anticipates the waste generated as a result of manufacturing the new product will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as any other products manufactured in the same facility and in a similar manner to other filtered cigarette tubes manufactured in France. In addition, the new product is anticipated to compete with other filtered cigarette tubes and therefore, the agency does not expect the introduction of the new product to notably affect the current manufacturing waste generated from the production of all cigarette papers.

Based on information in the SE Report and amendments, the characteristics of the filtered cigarette tubes are within the traditional range found throughout the industry. 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 manufacturing facility is located in France and the applicant stated that the facility is in compliance with France's applicable environmental laws and regulations.

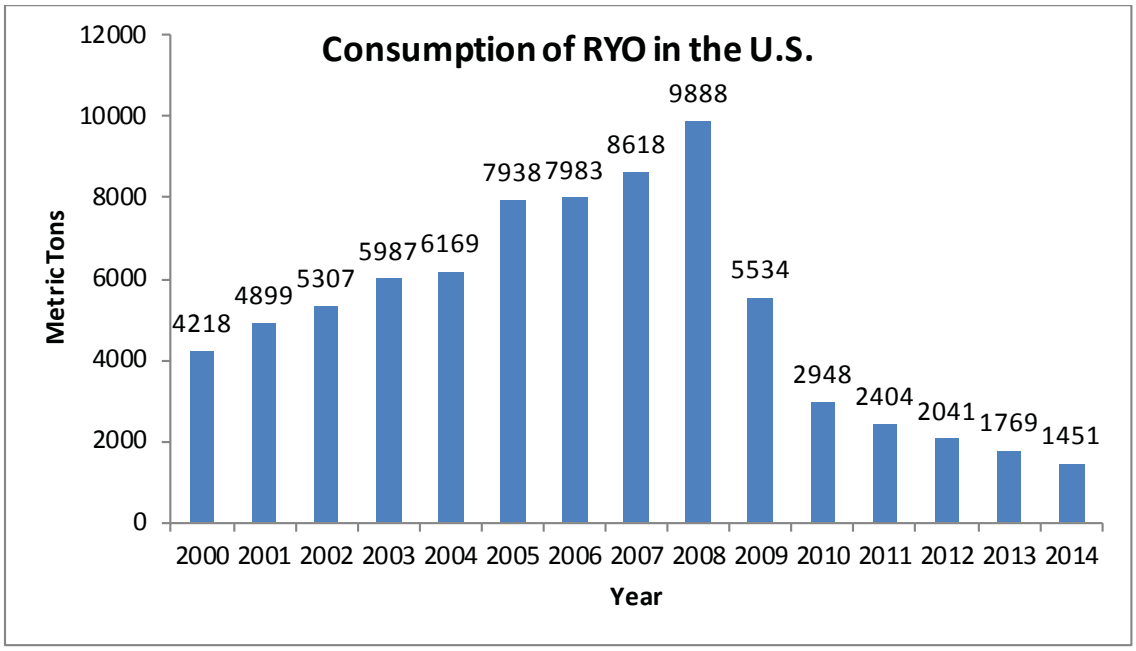
Therefore, the environmental introduction as a result of manufacturing the new product due to the proposed action is negligible.

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

5.2.1 Use of RYO tobacco products in the U.S.

Data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) showed a gradual increase in the use of RYO tobacco products in the U.S. from 4,218 metric tons to 9,888 metric tons during the years 2000 to 2008, respectively (Figure 3).[2] This was followed by a sharp decline in its use to 2,948 metric tons in 2010 and to 1451 metric tons in 2014.

Figure 3. Use of RYO Tobacco Products in the U.S. in 2000 – 2014 in Billion Cigarette Equivalent



5.2.2 Environmental introduction from use of the new product

As noted, the primary difference between the predicate product and corresponding new tobacco product is related to product weight, filter size, and colors and graphic styles on the exterior of the packaging carton. During use, the new product is usually 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

[2] 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 January 16, 2015.

released in a similar manner to the predicate product and other filtered cigarette tube products. The released substances during use of the new product are negligible from the environmental viewpoint. Therefore, the agency does not anticipate new substances to be released into the environment as a result of use of the new product, in comparison to the substances released by the predicate product already on the market and all other RYO cigarette papers.

To evaluate the environmental impact of the proposed action due to use of the new product, the historic data of RYO use in 2008-2014 is used to forecast the amount of use in the future. This was achieved by using one best-fit power trend line with the R-square value of 0.9889 (See Appendix 1). Accordingly, the amount of RYO forecasted to be used in the U.S. is estimated to be 1,124 metric tons in 2016 and 780 metric tons in 2020. This forecast is estimated using a mathematical prediction. No economic models to predict the RYO market forecast in the U.S. are available to the agency. The market volume projections for the first year and fifth year of marketing the new product is a small fraction of the total forecasted volume of RYO use in the U.S. during the same time frame (See Confidential Appendix 2).

The amount of release of material mass into the environment as a result of use of the new product is negligible from the environmental viewpoint.

5.3. Environmental Introduction as a Result of Disposal Following Use of the New Product

5.3.1 Disposal following use of RYO filtered cigarette tube products in the U.S.

a) Disposal of packaging material

As noted above, the used filtered cigarette tubes will be disposed of as MSW in landfills or as litter. Disposal of the packaging materials following use will either enter the recycling stream or be deposited in MSW landfills or as litter. In 2012, the amount of waste generated in the U.S. was approximately 251 million tons and approximately 87 million tons of this material was recycled and composted, equivalent to a 34.5% recycling rate (Figure 4 and Figure 5). The recovery of newspaper/mechanical papers was about 70% (5.9 million tons) and recovery for polypropylene waste was 30.8%. On average, 4.38 pounds per person per day of waste was generated, of which 1.51 pounds was recycled and composted in the U.S. in 2012. [3]

[3] EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: http://www.epa.gov/waste/nonhaz/municipal/. Accessed June 15, 2015.

Figure 4. Municipal Solid Waste Generation Rates in the U.S, 1960 – 2012

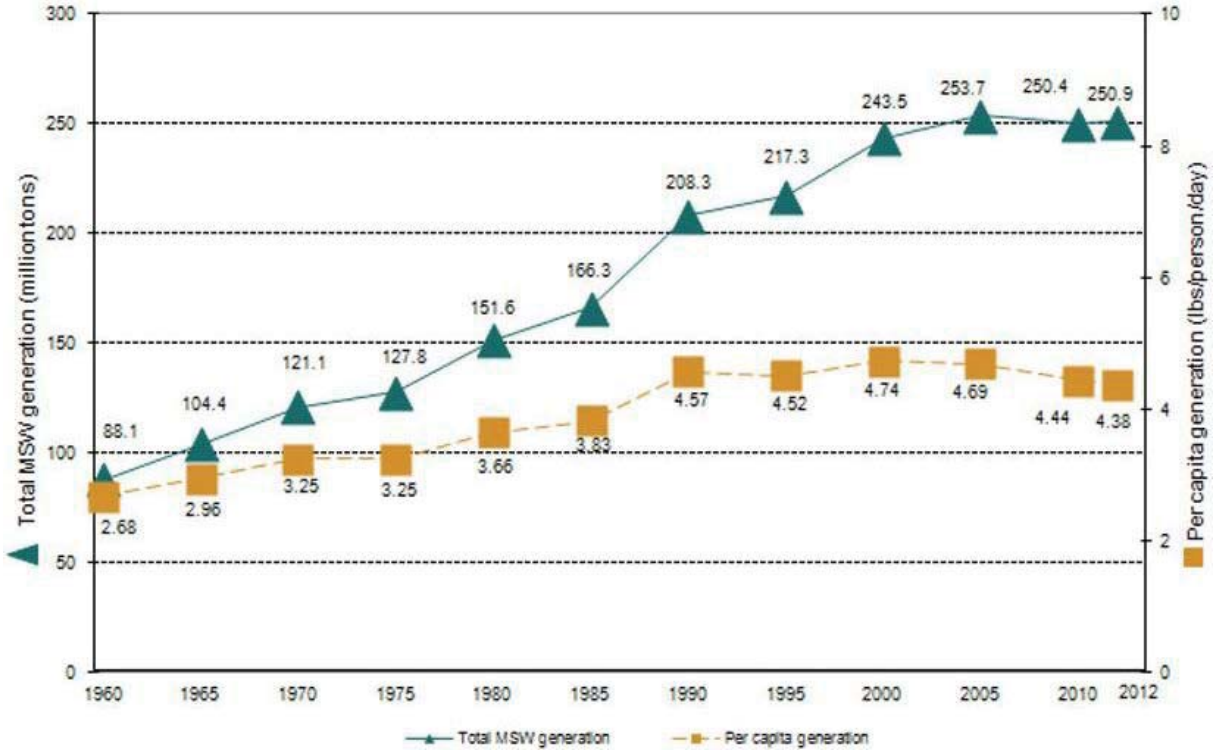
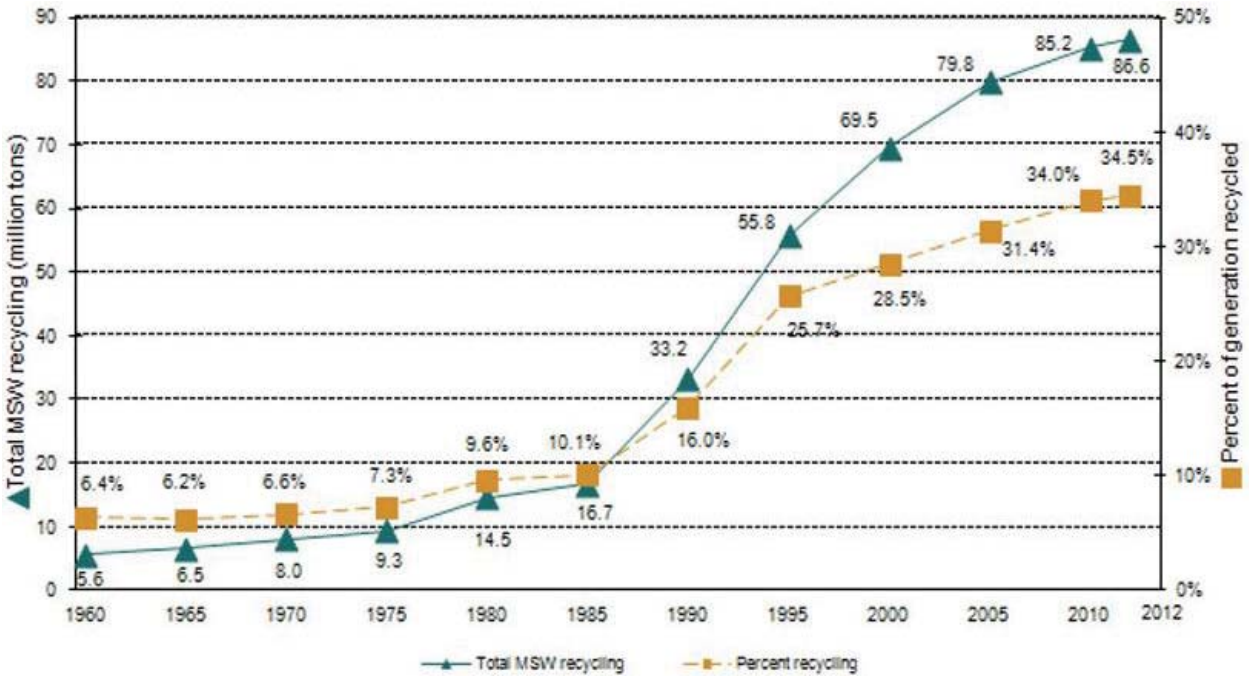


Figure 5. Municipal Solid Waste Recycling Rates in the U.S., 1960 - 2012



b) Disposal of cigarette tube filters following use

A major existing environmental consequence of use of filtered cigarette tubes is the waste disposal of the filters (cigarette butts). Evidence has shown that cigarette butts are the most prevalent items discarded into roads and streets in urban areas. Once dumped onto city streets, they move through the storm drains to streams, into the ocean, and back onto the beaches, while leaching toxicants into the environment along the way. Discarded filters are found to be the most collected item in beach clean-ups and litter surveys. An estimated 30% of the total waste (by count) on U.S. shorelines, waterways and land is cigarette filter waste.[4]

Cigarette tube filters most commonly contain cellulose diacetate, which may persist under normal environmental conditions for 18 months to 10 years.[5] [6] Cigarette filters were found to be a point source for metal contamination, based on research investigating the gradual release of multiple metals from the filter over a 34-day study period.[7] In addition, cigarette filters were found to be a point source for nicotine based on research investigating the release of nicotine from smoked cigarette butts over a 24-hour simulated rainfall event.[8]

6. Fate of New 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 filtered cigarette tubes with similar attributes and characteristics as the new product have been sold and continue to be sold in the U.S.

Furthermore, the material mass released into the environment does not increase compared to the predicate product and other RYO filtered cigarette tube products; the impact due to the proposed action is negligible, or non-existent, as discussed.

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[4] Tobacco Control Legal Consortium. Policy Tools for Minimizing Public Health and Environmental Effects of Cigarette Waste. March 2014. Available at: http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-cigarette-waste-2014.pdf. March 27, 2015.

[5] US Department of Health and Human Services. Reducing the health consequences of smoking: 25 years of progress. A report of the Surgeon General, 1989. Rockville, Maryland: Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1989. (DHHS Publication No (CDC) 89-8411.).

[6] Ach A. Biodegradable plastics based on cellulose acetate. *Journal of Macromolecular Science: Pure and Applied Chemistry* 1993; A30:733–40.

[7] Moerman, JW; Potts, GE. Analysis of metals leached from smoked cigarette litter. *Tobacco Control*. 2011; 20(Suppl. 1):I30-I35.

[8] Roder Green, AL; Putschew, A; Nehls, T. Littered cigarette butts as a source of nicotine in urban waters. *Journal of Hydrology*. 2014; 519:3466-3474.

7. Environmental Effects of New Materials Released into the Environment Due to the Proposed Action

As outlined above, the amount of materials anticipated to enter the environment due to the proposed action is miniscule, especially if the new product competes with and replaces the market share of the predicate product. Therefore, the environmental effects of the materials released due to the manufacturing, use, and disposal after use of the new product are negligible compared to those of marketed filtered cigarette tubes currently on the market.

8. Use of Resources and Energy

The anticipated first- and fifth-year market volumes of the new product are a small fraction of the total tobacco products assumed to be imported from France into the U.S. in 2016. Accordingly, the use of resources and energy due to the proposed action is negligible. The applicant also stated that the cigarette paper used to manufacture the new product is from sustainable sources and their manufacture does not appear to threaten any endangered species or critical habitat.

9. Mitigation

During the review of the available data and information, no adverse environmental effects were identified due to the manufacturing, use, and disposal after use of the new product. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not allow the marketing of the new tobacco product in the U.S. The environmental impact of this action would not change the existing condition of the manufacturing, use, and disposal from use of the tobacco products since the predicate product, as well as many other RYO filtered cigarette tube products, will continue to be marketed.

Alternative B (Proposed action): There is virtually no environmental effect due to the proposed action of authorizing the new product and the associated manufacture, use, and disposal from 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 position/title, education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment.

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

Education: M.S. in Environmental Science
Experience: 32 years in environmental toxicology and risk assessment
Expertise: NEPA Analysis, Environmental Risk Assessment, Environmental Toxicology, Environmental Fate

12. Appendix List

Appendix 1: Projected Use of RYO Tobacco Products in the U.S.

13. Confidential Appendix

Confidential Appendix 1: The First- and Fifth-Year Market Volume Projections of the New Product and the Predicate Product.

Confidential Appendix 2: The First- and Fifth-Year Projections of Waste of Packaging Materials and Cigarette Filters Associated with Marketing the New Product and the Predicate Product.

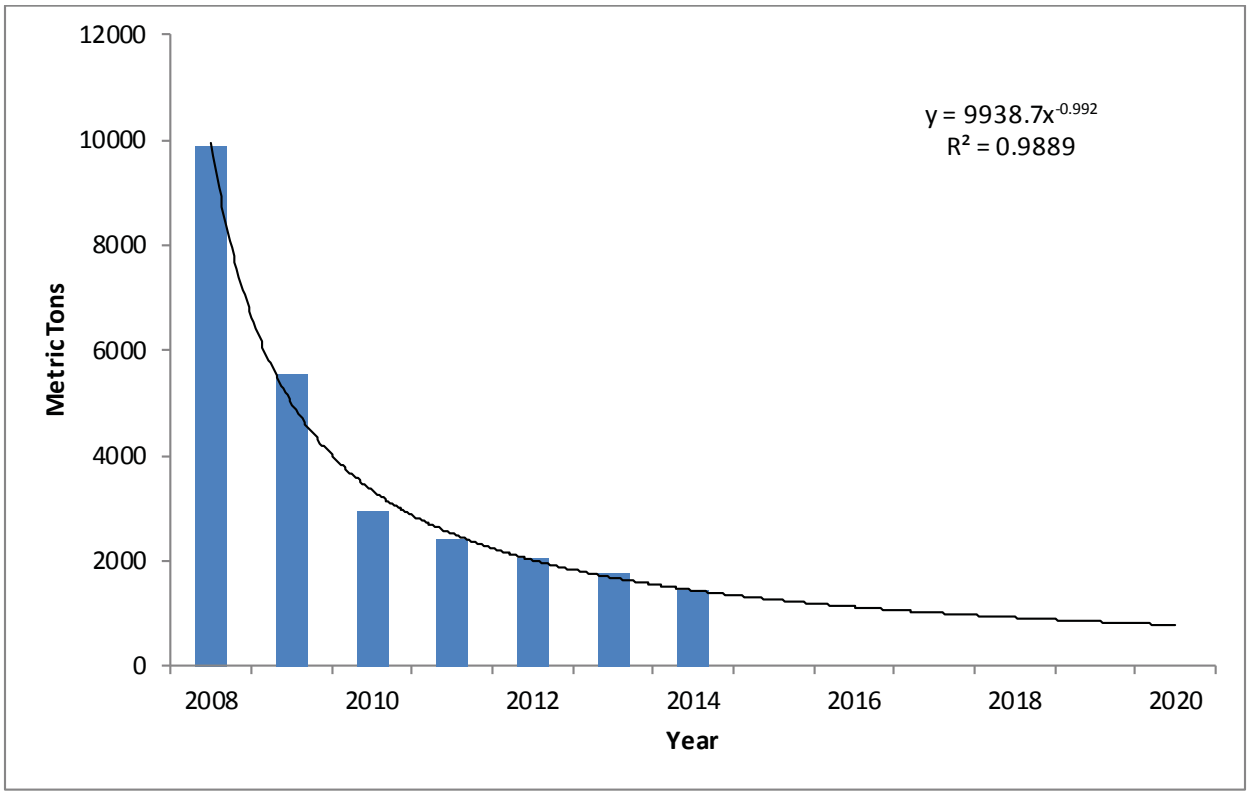
APPENDIX 1

Projected 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, historic data regarding use of RYO from 2008 to 2014 was used to forecast the use of RYO. This was achieved by using one best-fit power trend line with the R^2 value of 0.9889 (see figure below).

Accordingly, the forecasted amount of RYO papers that will be used in the U.S. is estimated to be 1,124 metric tons in 2016 and 780 metric tons in 2020.

Forecast of Use of RYO Paper Products in the U.S.



CONFIDENTIAL APPENDIX 1

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

STN	Type of Product	Product Name	1st-Year Projected Market Volume (# of Tubes)	1st-Year Projected Market Volume (Metric Tons)	5th-Year Projected Market Volume (# of Tubes)	5th-Year Projected Market Volume (Metric Tons)
SE0010112	New	Silver Tip Extra 250	(b) (4)			
	Predicate	Silver Tip 250				

The marketing estimate for the new product in 2016 is (b) (4) metric tons. The marketing estimate for the new product in 2020 is (b) (4) metric tons. The tonnage values represent (b) (4) of the 1,124 tons of RYO products estimated to be consumed in the U.S. in 2016 and (b) (4) of the estimated 780 tons of RYO products estimated to be consumed in the U.S. in 2020 (see section 5.2.1 and Appendix 1).

CONFIDENTIAL APPENDIX 2

The First- and Fifth-Year Projections of Waste of Packaging Materials and Cigarette Filters Associated with Marketing the New Product and the Predicate Product

The agency estimated the first- and fifth-year weights of the projected packaging materials waste and filter waster (in metric tons) that is generated from disposal after use of the new and predicate products as follows:

Retail Box Waste	Plastic Wrap Waste	Shipping Case Waste	Filter Waste
Box waste (metric tons) = (A / B) x C x D	Wrap waste (metric tons) = (A / B) x C x D	Case waste (metric tons) = (A / B)/E x C x D	Filter waste (metric tons) = A x B x C
A= Projected number of cigarette tubes B= Number of tubes per retail box (250) C = Weight of retail box (29.48 g) D= 10^{-6} (metric tons/gram)	A= Projected number of cigarette tubes B= Number of tubes per retail box (250) C = Weight of wrap per box (0.48 g) D= 10^{-6} (metric tons/gram)	A= Projected number of cigarette tubes B= Number of tubes per retail box (250) C= Weight of shipping case (511 g for new, 507 g for predicate) D= 10^{-6} (metric tons/gram) E= Retail boxes per shipper case (40)	A= Projected number of cigarette tubes B= Weight of filter (0.165 g for new, 0.103 g for predicate) C= 10^{-6} (metric tons/gram)

STN	Type of Product	Product Name	1st-Year Max Projected Market Volume (# of Cigarette Tubes)	1st-Year Max Projected Retail Box Waste (Metric Tons)	1st-Year Max Projected Plastic Wrap Waste (Metric Tons)	1st-Year Max Projected Shipping Case Waste (Metric Tons)	1st-Year Max Projected Filter Waste (Metric Tons)
SE0010112	New	Silver Tip Extra 250	(b) (4)				
	Predicate	Silver Tip 250					

STN	Type of Product	Product Name	5th-Year Max Projected Market Volume (# of Cigarette Tubes)	5th-Year Max Projected Retail Box Waste (Tons)	5th-Year Max Projected Plastic Wrap Waste (Tons)	5th-Year Max Projected Shipping Case Waste (Tons)	5th-Year Max Projected Filter Waste (Tons)
SE0010112	New	Silver Tip Extra 250	(b) (4)				
	Predicate	Silver Tip 250					

Paper Waste. The total paper waste generated by the new product and predicate product is estimated to be (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 70% in the U.S according to USEPA[9]. Therefore, if 30% of the cardboard (booklet cover, retail box, shipping case) is disposed of as waste based on the 2012 waste generation data in the U.S., the estimated cumulative cardboard waste will be (b) (4) metric tons in the first year of marketing the product, (b) (4) metric tons from the new product and (b) (4) metric tons from the predicate product. The estimated cumulative cardboard waste will be (b) (4) metric tons in the fifth year of marketing the products, (b) (4) metric tons from the new product and (b) (4) metric tons from the predicate product.

If the entire packaging cardboard is disposed of as waste in the worst case scenario, the projected cumulative cardboard waste in the first year of marketing the products is (b) (4) metric tons, (b) (4) metric tons from the new product and (b) (4) metric tons from the predicate product. In the fifth year of marketing the products the worst case scenario is (b) (4) metric tons of total cardboard waste, (b) (4) metric tons from the new product and (b) (4) metric tons from the predicate product. This is a minute fraction (b) (4) of the 251 million tons (228 million metric tons) of total waste reported in the U.S. in 2012.

Plastic Waste. The total plastic waste generated by the new product and predicate product is estimated to be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year. The projected cumulative plastic wrap waste in the first year of marketing the products is (b) (4) metric tons, (b) (4) metric tons from the new product and (b) (4) metric tons from the predicate product. The projected cumulative plastic wrap waste in the fifth year of marketing the products is (b) (4) metric tons, (b) (4) metric tons from the new product and (b) (4) metric tons from the predicate product. Therefore, the estimated amount of wrap waste is a miniscule fraction of the 251

[9] EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: http://www.epa.gov/waste/nonhaz/municipal/. Accessed June 9, 2015

million tons (228 million metric tons) of total waste reported in the U.S. in 2012.

Filter Waste. The projected cumulative waste of cigarette tube filters in each of the first year and the fifth year of product and the predicate product is [redacted] metric tons and [redacted] metric tons, respectively. This is a minute fraction (b) (4) 251 million tons of total waste (228 million metric tons) reported in the U.S. in 2012. However, it is still important t of cigarette tube filters may end up in landfills, but they may also be discarded on streets and roadsides where th storm drains into surface waters. Ultimately, they can move into the ocean and back onto the beaches. Moreove residues from littered filters may leach into the environment via storm water runoff.