

Programmatic Environmental Assessment for Market Authorizations of “Largo Sun Grown Natural 8 oz Bag, Largo Sun Grown Natural 0.35 oz Pouch, Largo Full Flavor 0.35 oz Pouch, Largo Gold 0.35 oz Pouch, Largo Sun Grown Natural 3 oz Bag, Largo Menthol 0.35 oz Pouch, 4 Aces Turkish 3.5 oz Canister, 4 Aces Turkish 0.35 oz Pouch”

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

October 3, 2016

Table of Contents

1.	Name of Applicant.....	3
2.	Address of Applicant.....	3
3.	Manufacturer.....	3
4.	Description of the Proposed Action.....	3
4.1.	Requested Action	3
4.2.	Need for Action	3
4.3.	Identification of the New Tobacco Products that are Subjects of the Proposed Action	4
4.3.1	<i>Type of Tobacco Products</i>	4
4.3.3	<i>Description of the Product Package</i>	4
4.3.5	<i>Location of Use</i>	6
4.3.6	<i>Location of Disposal</i>	6
4.4.	Modification(s) Identified as Compared to the Predicate Products	6
5.	Environmental Introduction Due to the Proposed Action.....	6
5.1.	Introduction as a Result of Manufacturing the New Products	6
5.2.	Environmental Introduction as a Result of Use of the New Products	8
5.2.1	<i>Use of RYO Tobacco and Rolling Papers</i>	8
5.2.2	<i>Environmental introduction from use of the new products</i>	9
5.3.	Environmental Introduction as a Result of Disposal Following Use	11
5.3.1	<i>Disposal following use of RYO tobacco and rolling papers</i>	11
5.3.2	<i>Environmental introduction of disposal following use of RYO tobacco and rolling papers</i>	13
6.	Fate of Materials Released into the Environment Due to the Proposed Action.....	13
7.	Environmental Effects of New Materials Released into the Environment Due to the Proposed Action.....	14
8.	Use of Resources and Energy.....	14
9.	Mitigation.....	15
10.	Alternatives to the Proposed Action.....	15
11.	List of Preparers.....	15
13.	Appendix List.....	15
14.	Confidential Appendix List.....	16

This programmatic environmental assessment (PEA) is for the market authorizations of multiple roll-your-own (RYO) tobacco products and booklets of rolling papers manufactured by Top Tobacco, L.P. Information presented in the PEA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This PEA 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

Top Tobacco, L.P.

2. Address of Applicant

2301 Ravine Way
Glenview, Illinois 60025

3. Manufacturer

RYO Tobacco Facility:
Top Tobacco, LP
204 Top Tobacco Road
Lake Waccamaw, NC 28450

Subcontractor

(b) (4) :

Information on the supplier of this complex ingredient is assessed in this PEA but included in Confidential Appendix 1 to protect confidential business information.

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 multiple new roll-your-own (RYO) tobacco products and booklets of rolling papers into interstate commerce. These authorizations are based on the finding that these new products are substantially equivalent to their corresponding predicate products that were on the market as of February 15, 2007. The applicant intends to continue marketing the predicate and new products simultaneously after the new products are authorized.

4.1. Requested Action

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

4.2. Need for Action

Top Tobacco, L.P. wishes to introduce the new tobacco products (as described in Section 4.3) into interstate commerce for commercial distribution in the U.S. The applicant claims that the new products and corresponding predicate products have different characteristics but the new products do not raise different questions of public health (sec. 910(a)(3)(A)(ii))

as described in an FDA guidance to industry issued on September 8, 2015.¹ After considering the SE Reports, the Agency shall issue orders pursuant to section 910(a)(2) 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 Subjects of the Proposed Action

4.3.1. Type of Tobacco Products

Roll-your-own (RYO), tobacco and rolling papers

4.3.2 Product Names and Their Original STNs

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

STN	New Products	Predicate Products
SE0007297	Largo Sun Grown Natural 8 oz Bag	Top Regular 6 oz Canister
SE0007298	Largo Sun Grown Natural 0.35 oz Pouch	Top Regular 0.6 oz Pouch
SE0007299	Largo Full Flavor 0.35 oz Pouch	Top Regular 0.6 oz Pouch
SE0007300	Largo Gold 0.35 oz Pouch	Top Gold 0.6 oz Pouch
SE0007301	Largo Sun Grown Natural 3 oz Bag	Top Regular 6 oz Canister
SE0007302	Largo Menthol 0.35 oz Pouch	Top Menthol 0.6 oz Pouch
SE0007303	4 Aces Turkish 3.5 oz Canister	Top Regular 6 oz Canister
SE0007304	4 Aces Turkish 0.35 oz Pouch	Top Regular 0.6 oz Pouch

4.3.3 Description of the Product Package

The new products that are the subject of SE0007298, SE0007299, SE0007300, SE0007302, and SE0007304 are RYO tobacco in pouches packaged with rolling papers. The new product that is the subject of SE0007303 is RYO tobacco in canisters packaged with rolling papers. Additionally, new products that are the subject of SE0007297 and SE0007301 are RYO tobacco in bags not packaged with rolling papers. The different types of packaging for the new products are described below.

STNs	New Product	Package Description
SE0007297	Largo Sun Grown Natural 8 oz Bag	8 oz plastic bag
SE0007298	Largo Sun Grown Natural 0.35 oz Pouch	0.35 oz plastic pouch with one 32-count gummed flat booklet
SE0007299	Largo Full Flavor 0.35 oz Pouch	0.35 oz plastic pouch with one 32-count gummed flat booklet
SE0007300	Largo Gold 0.35 oz Pouch	0.35 oz plastic pouch with one 32-count gummed flat booklet

¹ FDA Guidance for Industry. Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2). Issued September 8, 2015. Available at: <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf>. Accessed September 27, 2016.

SE0007301	Largo Sun Grown Natural 3 oz Bag	3 oz plastic bag
SE0007302	Largo Menthol 0.35 oz Pouch	0.35 oz plastic pouch with one 32-count gummed flat booklet
SE0007303	4 Aces Turkish 3.5 oz Canister	3.5 oz paper and metal canister with two 100-count gummed flat booklets
SE0007304	4 Aces Turkish 0.35 oz Pouch	0.35 oz plastic pouch with one 32-count gummed flat booklet

4.3.4 Location of Manufacturing

The manufacturer location of the tobacco portion of the RYO product is Top Tobacco, LP and is 204 Top Tobacco Road, Lake Waccamaw, NC 28450 (Figure 1).² The facility is located in a light commercial area surrounded by woodlands and agricultural areas.

Figure 1. Location of RYO Tobacco Manufacturer



The manufacturer location of the (b) (4) of the RYO product is located (b) (4) in a heavily industrialized area that is bounded by commercial and residential areas. Additional information, including an aerial map of the location, is included in Confidential Appendix 1.

² Manufacturer address via aerial photo, Google Earth. Accessed 08/29/2016.

4.3.5 Location of Use

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

4.3.6 Location of Disposal

The used ashes and unused tobacco and rolling paper will be disposed of as municipal solid waste (MSW) in the landfills or trashed as litter, in the same manner as any other marketed RYO cigarette. 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 Products

The applicant claims that the new and corresponding predicate products have different characteristics, but that the changes do not cause the new products to raise different questions of public health. The applicant states that all of the new products differ from the corresponding predicate products in the following ways: changes in the product weight, changes to the tobacco blend, and changes to the flavorings and filler ingredients. (Confidential Appendix 2 and 4).

Additionally, the applicant stated the new products that are the subject of SE0007297 and SE0007301 do not include rolling papers and have different RYO tobacco container packaging than their corresponding predicate products shown below.

STN	New Products	Predicate Products
SE0007297	Largo Sun Grown Natural 8 oz Bag	Top Regular 6 oz Canister (with two 100-count TOP gummed flat booklets)
SE0007301	Largo Sun Grown Natural 3 oz Bag	Top Regular 6 oz Canister (with two 100-count TOP gummed flat booklets)

5. Environmental Introduction Due to the Proposed Action

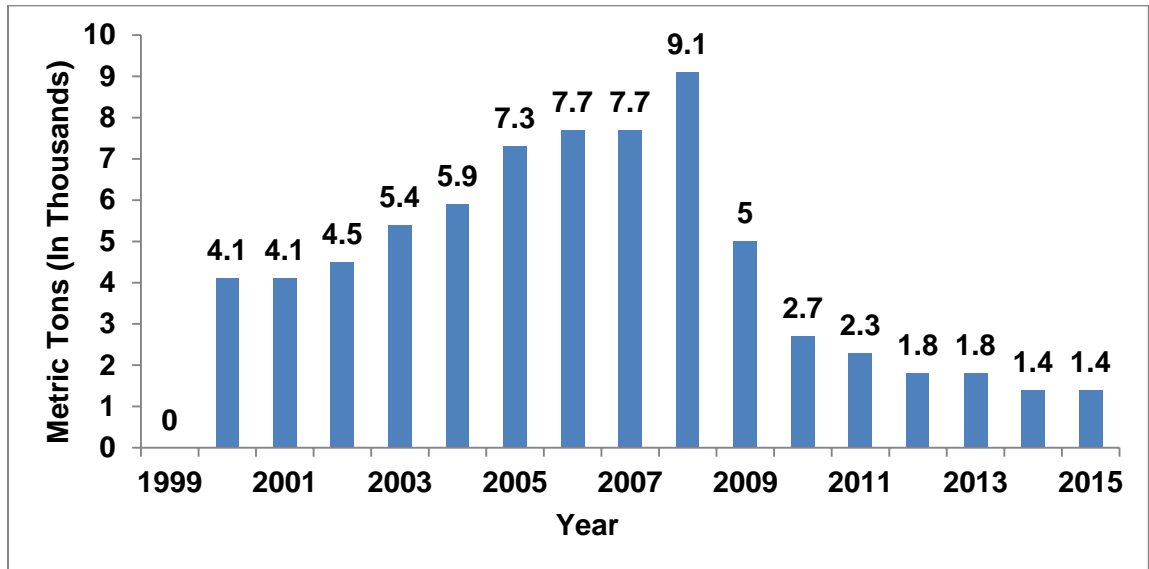
5.1. Introduction as a Result of Manufacturing the New Products

5.1.1. RYO Tobacco Manufactured in the U.S.

Based on U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) data, RYO tobacco manufacturing in the U.S. increased from 4,100 metric tons in 2000 to 9,100 metric tons in 2008. TTB data also show a decline in U.S. manufacturing of RYO tobacco from 9,100 metric tons in 2008 to 1,400 metric tons in 2015 (Figure 2).³

³ U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 30, 2015.

Figure 2. Manufactured RYO Tobacco in the U.S.



5.1.2. Tobacco Products Imported to the U.S. from the Subcontractor's Country

Detailed information is located in Confidential Appendix 1. The data show more than a five-fold increase in the import of total tobacco products to the U.S. from this country over the period from 2006 to 2015.

Compared to total tobacco products, the import of cigarette papers to the U.S from this country over the same time period was nearly half the metric tons in 2015 as compared to 2006. The 2015 import of paper from this country represents over 20 percent of the total amount of tobacco products imported from there.

5.1.3. Environmental introduction from manufacturing the new products

Introduction from manufacturing new products in the proposed actions. The Agency anticipates the waste generated as a result of manufacturing the new products 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 RYO cigarette tobacco and rolling papers manufactured in the U.S. and the non-U.S. location of the subcontractor. The applicant stated that the proposed action will not require an expansion of the existing manufacturing facilities. In addition, the applicant stated additional resources are not expected to be added and no new substances created for waste disposal. Furthermore, the applicant stated no new substances will be emitted and no new environmental controls will be needed for the proposed action. Lastly, the applicant stated there will be

no net increase in energy use from the proposed action as the new products will compete with and replace existing market shares of products that are already being manufactured in the same manner. The Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all RYO tobacco products in the U.S. and the subcontractor's country.

In the U.S., RYO tobacco manufacturing increased from 4,100 metric tons in 2000 to 9,100 metric tons in 2008. The data also show a decline in U.S. manufacturing of RYO tobacco from 9,100 metric tons in 2008 to 1,400 metric tons in 2015.⁴ The applicant stated they comply with relevant federal, state, and local environmental regulations. In addition, the applicant stated they comply with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

Although no particular market trend pattern is observed using data regarding cigarette paper importation to the U.S. from the subcontractor's country from 2000 to 2015, there was an overall decline of cigarette paper imports from the subcontractor's country from 1,180 metric tons in 2000 to 579 metric tons in 2015.⁵ The applicant stated that the RYO paper ingredients are produced from sustainable resources and do not impact critical habitats or endangered species in accordance with the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification Schemes (PEFC).

The new products are anticipated to compete with other RYO tobacco and cigarette papers 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 Reports, the characteristics of the cigarette papers are within the traditional range found throughout the industry. The applicant stated that the differences between the new and corresponding predicate products would be in the product weight, changes to the tobacco blend, and changes to the flavorings and filler ingredients. Additionally, new products that are the subject of SE0007297 and SE0007301 do not include rolling papers and have different RYO tobacco container packaging than their corresponding predicate products (Confidential Appendix 2 and 4). 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.

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

5.2.1 Use of RYO Tobacco and Rolling Papers

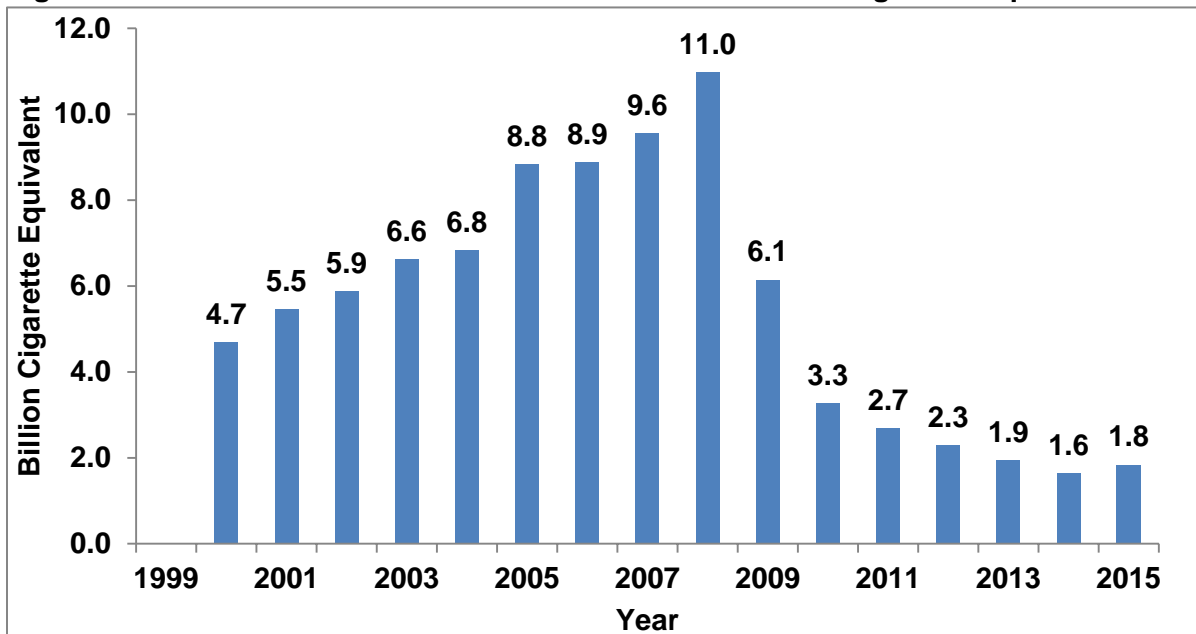
Data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistics reports

⁴ 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 September 27, 2016.

⁵ Unit is defined by USITC, available at: http://dataweb.usitc.gov/scripts/tariff_current.asp?Phase=List_items&lookfor=481310. Accessed on March 23, 2016

showed a gradual linear increase in the use of RYO tobacco in the U.S. from 4.7 billion cigarette-equivalents to 11 billion cigarette-equivalents during the years 2000 to 2008, respectively (Figure 3).⁶ This was followed by a decline in its use to 3.3 billion cigarette-equivalents in 2010 and to 1.8 billion cigarette-equivalents in 2015.

Figure 3. Use of RYO in the U.S. from 2000 – 2015 in Billion Cigarette-Equivalents



5.2.2 Environmental introduction from use of the new products

As noted, the primary differences between the new products and corresponding predicate tobacco products are: changes in the product weight, changes to the tobacco blend, and changes to the flavorings and filler ingredients. Additionally, new products that are the subject of SE0007297 and SE0007301 do not include rolling papers and have different RYO tobacco container packaging than their corresponding predicate products.

When using RYO tobacco with rolling paper, similar to conventional manufactured cigarettes, the users inhale the main stream smoke and release environmental tobacco smoke (secondhand smoke) to the environment. Secondhand smoke (SHS) is classified as a “known human carcinogen” by EPA, the US National Toxicology Program, and the International Agency for Research on Cancer (IARC – the specialized cancer agency of the World Health Organization (WHO)).⁷ Tobacco smoke contains more than 7,000 chemical compounds; many are known to be harmful, with at least 69 known or probable carcinogens and at least 5 reproductive or developmental toxins, including: lead, nicotine, carbon monoxide, and toluene. SHS has been linked to lung cancer with some

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 September 27, 2016.

⁷ International Agency for Research on Cancer (IARC). Second-Hand Tobacco Smoke Monograph. Available at: <http://monographs.iarc.fr/ENG/Monographs/vol100E/mono100E-7.pdf>. Accessed May 20, 2014.

evidence suggesting it might be linked to other forms of cancer in children and cancers of the larynx, pharynx (throat), nasal sinuses, brain, bladder, rectum, stomach, and breast in adults.⁸ About 40 percent of all children are regularly exposed to SHS at home, and almost a third of the deaths attributable to SHS are in children.⁹ A recent study found SHS led to a thickening of children's artery walls, adding some 3.3 years to the age of blood vessels by adulthood.¹⁰ Additionally, cigarette users also release tobacco specific nitrosamines through excretion into the water.¹¹

As noted in the SE Reports, the differences between the new and corresponding predicate products is in the product weight, changes to the tobacco blend, and changes to the flavorings and filler ingredients. Additionally, new products that are the subject of SE0007297 and SE0007301 do not include rolling papers and have different RYO tobacco container packaging than their corresponding predicate products. During use, the combustion products from the new products are released in a similar manner to the predicate products and other RYO tobacco and rolling papers.

To evaluate the environmental impact of the proposed action due to use of the new products, historical data regarding consumption of all RYO in the U.S. from 2005 to 2015 was used. This was achieved by using one best-fit power trend line with the R2 value of 0.9739 for the total RYO cigarette equivalents used in the U.S. Accordingly, the forecasted amounts of all cigarettes to be used in the U.S. are estimated to be 1.4 billion pieces and 1.0 billion pieces in 2016 and 2020, respectively (Appendix 2).¹²

During use, the new products are 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 products are released in a similar manner to those from the predicate products and other RYO, tobacco and rolling paper products. The substances released during use of the new products are negligible from the environmental viewpoint.

Essentially, the Agency anticipates no new substances to be released into the environment as a result of use of the new products, in comparison to the substances released by the predicate products already on the market and all other rolling papers.

⁸ EPA. Health effects of exposure to second hand smoke. Available at: <http://www.epa.gov/smokefree/healtheffects.html>. Accessed May 20, 2014

⁹ World Health Organization (WHO). Tobacco Facts Sheet. July 2013. Available at: <http://www.who.int/mediacentre/factsheets/fs339/en/>. Accessed May 20, 2014

¹⁰ Gall S, Huynh QH, Magnussen GC, Juonala M, Viikari J S-A, Kähönen M, Dwyer T, Raitakari OT, and Venn A. Exposure to parental smoking in childhood or adolescence is associated with increased carotid intima-media thickness in young adults: Evidence from the cardiovascular risk in young Finns study and the childhood determinants of adult health study. *European Heart Journal*. Advance Access May 20, 2014.

¹¹ Andra S and Makris KC. Tobacco-specific nitrosamines in water: An unexplored environmental health risk. *Environmental International*. 2011; 37(2):412-417.

¹² 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 September 27, 2016.

5.3. Environmental Introduction as a Result of Disposal Following Use

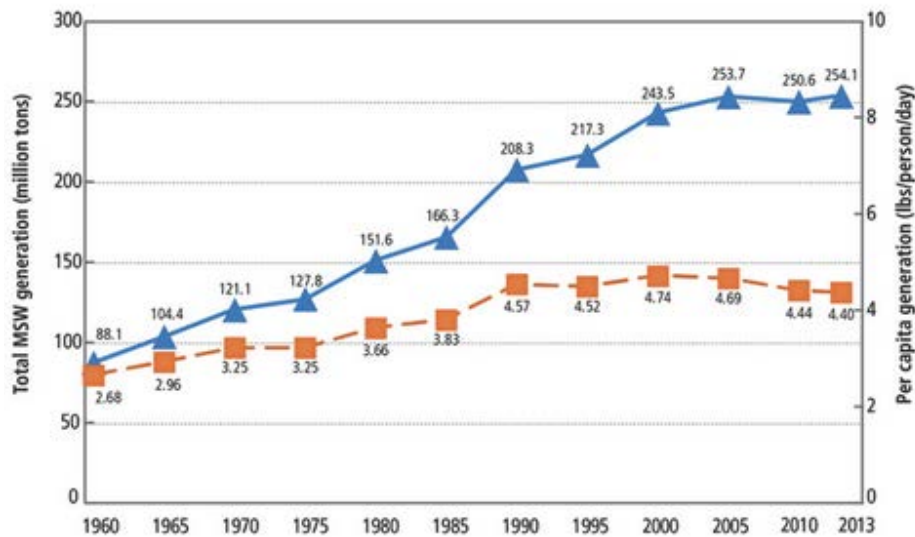
The waste that is generated following use of the new and corresponding predicate RYO products consists of the disposed packaging materials along with the discarded ash, unused tobacco and rolling paper. The unused rolling paper along with the cardboard booklet cover and paper insert material is biodegradable, and could also be recycled or thrown away as trash in MSW landfills or as litter. The plastic and metal packaging components are not readily biodegradable, but could be recycled or thrown away as trash in MSW landfills or as litter.

5.3.1 Disposal following use of RYO tobacco and rolling papers

As noted above, the used RYO tobacco and rolling papers will be disposed of in MSW landfills or as litter. Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2013, the amount of waste generated in the U.S. was approximately 254.1 million tons and approximately 87 million tons of this material was recycled and composted, equivalent to a 34.3 percent recycling rate (Figure 4 and 5).

Paper and paperboard account for 27 percent, plastics comprise about 13 percent and metals make up 9 percent of MSW. On average, in 2013 4.40 pounds per person per day of waste was generated, of which 1.51 pounds was recycled and composted in the U.S.¹³ Of the 87 million tons of MSW recovered in 2013, paper and paperboard had a recovery rate of 50 percent, metals 9 percent and plastics 3.5 percent (Figure 6).¹⁴

Figure 4. Municipal Solid Waste (MSW) Generation Rates in the U.S, 1960 – 2013



¹³ <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures>. Accessed September 26, 2016.

¹⁴ https://www.epa.gov/sites/production/files/2015-09/documents/2013_advncng_smm_fs.pdf. Accessed September 26, 2016.

Figure 5. MSW Recycling Rates in the U.S., 1960 – 2013

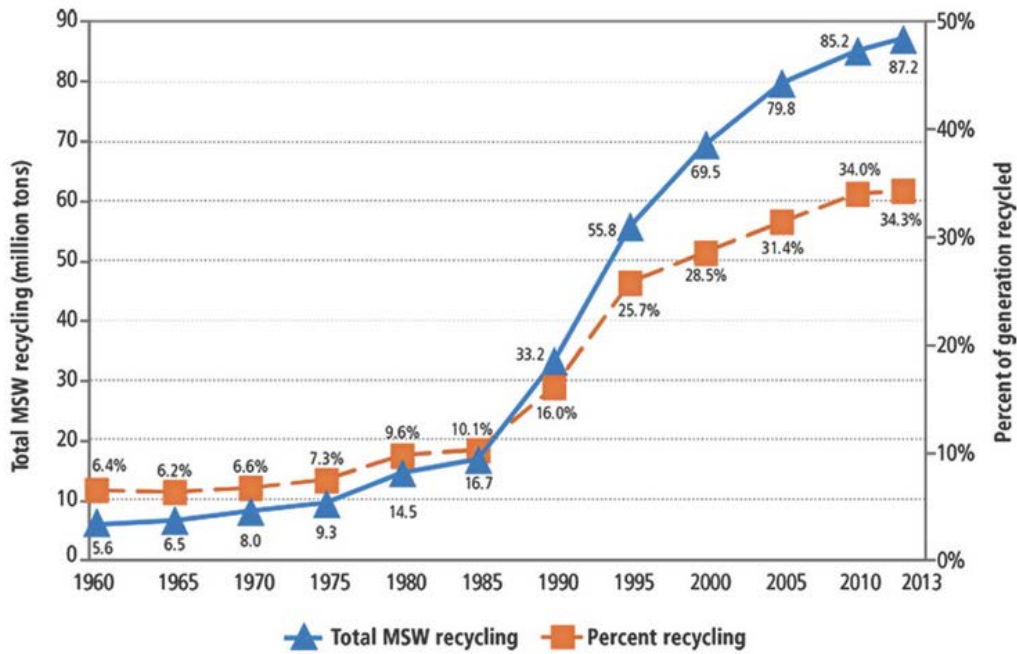
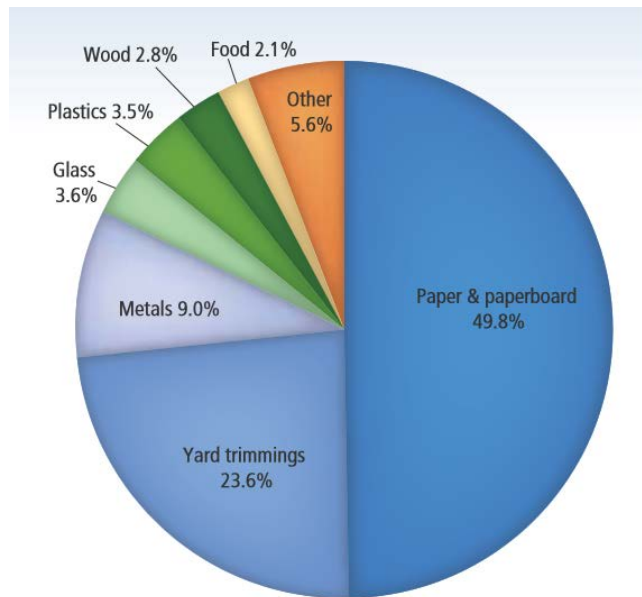


Figure 6. Total 87 Million Tons MSW Recovery Percentage (by material), 2013



5.3.2 Environmental introduction of disposal following use of RYO tobacco and rolling papers

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other RYO tobacco and rolling paper products that are currently being marketed. After using the new products, the users may dispose of or recycle the paper, plastic or metal packaging material. Users may also discard the unused RYO tobacco, rolling paper and ashes as MSW or as litter.

5.3.3 Disposal of packaging material

The Agency assumes that all packaging material of the new products will be disposed of as MSW. However, paper, metal and plastic materials can be recycled, with paper products being more likely to be recycled than any other type of MSW. According to the information presented in the SE Reports, the new products that are the subject of SE0007298, SE0007299, SE0007300, SE0007302, and SE0007304, and their corresponding predicate products, use the same packaging material for the resealable pouch components and for the rolling paper booklet cover included inside the container. The new product that is the subject of SE0007303 and its corresponding predicate product use the same packaging material for the composite canister components and for the rolling paper booklet covers included inside the container. The new products that are the subject of SE0007297 and SE0007301 do not include rolling paper booklets with covers and use resealable pouch components, while their corresponding predicate products contain rolling paper booklets with covers inside a composite canister.

To determine the amount of waste from disposal of paper, metal and plastic packaging material, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products (Confidential Appendix 3 to 8). The calculated cumulative waste of the paper, metal and plastic packaging material is miniscule compared to all municipal solid waste generated and at least a portion of the waste is likely to be recycled. The Agency anticipates no new construction of MSW landfills as a result of disposal of the paper, metal and plastic packaging material.

Furthermore, the anticipated release of new substances into the environment as a result of disposal of the new products is miniscule compared to that of all tobacco products that are already on the market. The Agency anticipates no new construction of MSW landfills as a result of disposal of the new RYO tobacco and rolling paper products following use.

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 predicate products (RYO tobacco and rolling papers with similar attributes and characteristics as the new products) have been sold and continue to be sold in the U.S. The new products are anticipated to be manufactured the same way as other products in the same facilities in the U.S. and the subcontractor's country. Therefore, the fate of additional materials emitted to the air, water and land is anticipated to be

the same as other products manufactured in the facilities. No new types of materials are anticipated to be emitted and no new environmental controls will be needed since the new products will be made using the essentially the same materials and processes as the predicate products.

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

The new products are anticipated to compete with other RYO tobacco and cigarette papers and therefore, the Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all RYO cigarette tobacco and cigarette papers. In addition, the applicant stated additional resources are not expected to be added and no new substances created for waste disposal. Furthermore, the applicant stated no new substances will be emitted and no new environmental controls will be needed for the proposed action. The applicant stated that they comply with relevant federal, state, and local environmental regulations. Therefore, cumulative introduction is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

Consequently, the environmental effects of the materials released due to the manufacturing of the new products are anticipated to be no more than the potential maximum effects to the environment due to the manufacturing facility. Environmental protection laws generally are based on risk to sensitive populations and threshold limits are set using safety factors to address uncertainty. Therefore, if the manufacturer remains in compliance with the existing laws, the environmental effects are expected to be below the level that would cause environmental harm and no substantial effects are anticipated.

Furthermore, the amount of materials anticipated to enter the environment due to use and disposal following use of the new products is negligible. Therefore, the environmental effects of the materials released due to the use and disposal following use of the new products are negligible. Consequently, no new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The applicant stated that the proposed action will not require an expansion of the existing manufacturing facilities. The applicant also stated that the paper used to manufacture the rolling papers is produced from sustainable resources and does not impact critical habitats or endangered species in accordance with the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification Schemes (PEFC). In addition, the applicant stated they comply with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). Lastly, the applicant stated there will not be a net increase in energy use from the proposed action as the new products will compete with and replace existing market shares of products that are already being manufactured in the same manner.

9. Mitigation

During our review of the available data and information, we did not identify adverse environmental effects for the new products and their proposed use as RYO tobacco and rolling papers. 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 products in the U.S. The environmental impact of this action would not change the existing condition of the manufacturing, use, and disposal following use of the tobacco products as the predicate products, as well as many other RYO cigarette tobacco and paper 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 products and the associated manufacture, use, and disposal from use of the new tobacco products.

Therefore, the difference between the environmental impacts of these two alternatives is not substantial.

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.

Preparer:

Ronald L. Edwards Jr., MS, Center for Tobacco Products

Education: MS in Biology

Experience: 22 years in environmental regulation and laboratory toxicology

Expertise: Heavy metal analysis, water quality, environmental remediation and FDA, EPA and USDA investigator

Reviewer:

Gregory Gagliano, MS, Center for Tobacco Products

Education: MS, in Environmental Science

Experience: 33 years in environmental toxicology, environmental risk assessment

Expertise: Environmental toxicology, risk assessment, NEPA analysis

12. List of Agencies and Persons Consulted

Not Applicable

13. Appendix List

Appendix 1: List of SE Reports and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA).

Appendix 2: Forecasted Use of RYO Cigarette-Equivalents in the US

14. Confidential Appendix List

Confidential Appendix 1: Relevant Information Regarding the Provider of the Complex Ingredient of the Rolling Paper

Confidential Appendix 2: Changes Between Predicate and New Products

Confidential Appendix 3: The First- and Fifth-Year Market Volume Projections of the New and Predicate Products

Confidential Appendix 4: Packaging Weight for New and Predicate Products

Confidential Appendix 5: Packaging Weight for Paper, Metal and Plastic for New and Predicate Products

Confidential Appendix 6: The First-Year and Fifth-Year Projections of Paper Waste Associated with Marketing the New Products

Confidential Appendix 7: The First-Year and Fifth-Year Projections of Metal Waste Associated with Marketing the New Products

Confidential Appendix 8: The First-Year and Fifth-Year Projections of Plastic Waste Associated with Marketing the New Products

APPENDIX 1

List of SE Report Submission Tracking Numbers with Names of the New and Predicate Products, and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

STN	New Products	Predicate Products	Amendments
SE0007297	Largo Sun Grown Natural 8 oz Bag	Top Regular 6 oz Canister	SE0008201 SE0009609 SE0009616 SE0010029 SE0010057 SE0010085 SE0010091 SE0010148 SE0010705 SE0013313 SE0013567
SE0007298	Largo Sun Grown Natural 0.35 oz Pouch	Top Regular 0.6 oz Pouch	SE0008202 SE0009609 SE0009616 SE0010023 SE0010057 SE0010085 SE0010092 SE0010148 SE0010705 SE0013313 SE0013567
SE0007299	Largo Full Flavor 0.35 oz Pouch	Top Regular 0.6 oz Pouch	SE0008203 SE0009609 SE0009616 SE0010023 SE0010057 SE0010085 SE0010092 SE0010148

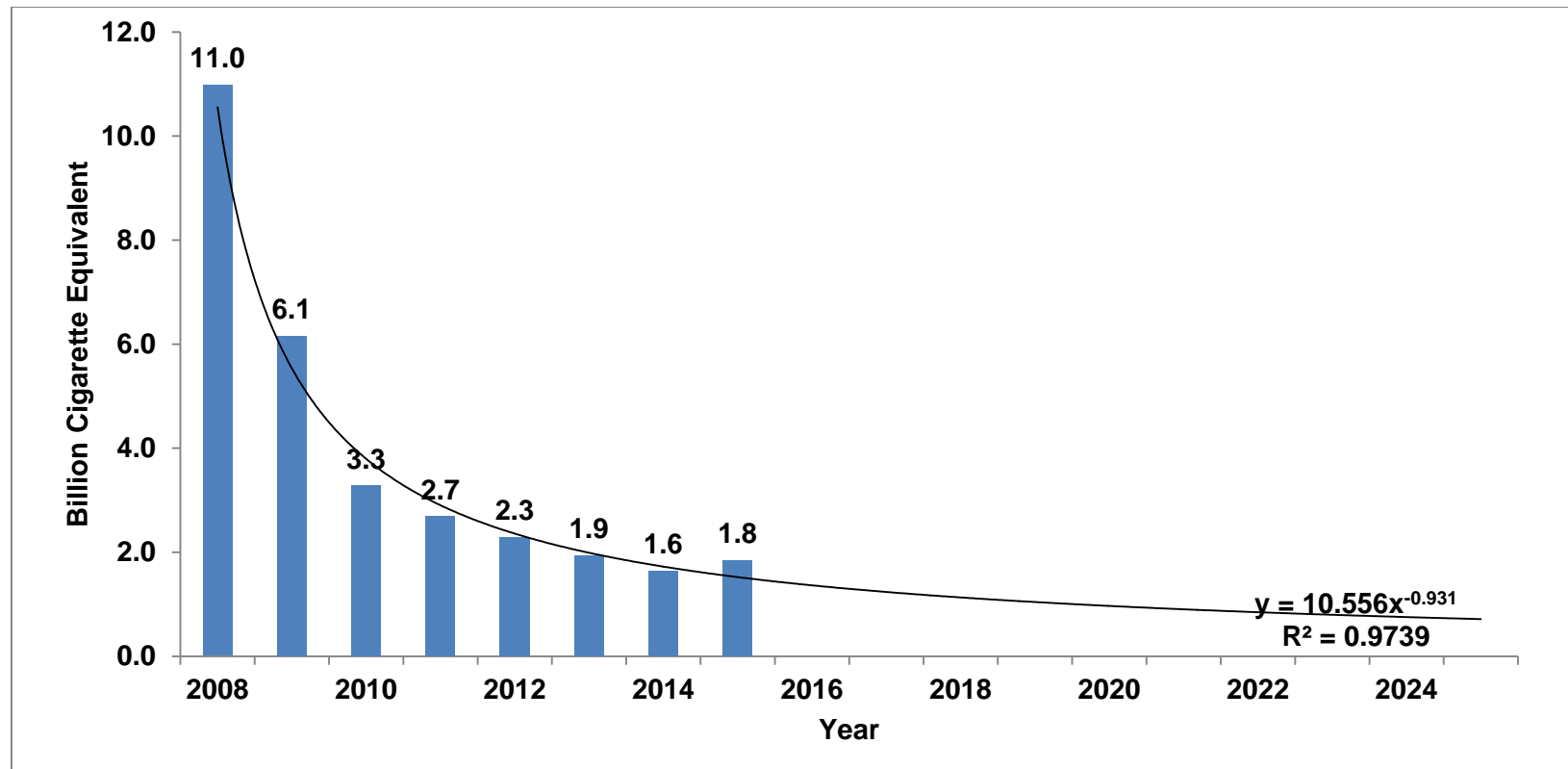
			SE0010705 SE0013313 SE0013567
SE0007300	Largo Gold 0.35 oz Pouch	Top Gold 0.6 oz Pouch	SE0008204 SE0009609 SE0009616 SE0010028 SE0010057 SE0010085 SE0010094 SE0010148 SE0010705 SE0013313 SE0013567
SE0007301	Largo Sun Grown Natural 3 oz Bag	Top Regular 6 oz Canister	SE0008205 SE0009609 SE0009616 SE0010029 SE0010057 SE0010085 SE0010091 SE0010148 SE0010705 SE0013313 SE0013567
SE0007302	Largo Menthol 0.35 oz Pouch	Top Menthol 0.6 oz Pouch	SE0008206 SE0009609 SE0009616 SE0010022 SE0010057 SE0010085 SE0010093 SE0010148 SE0010705 SE0013313 SE0013567

SE0007303	4 Aces Turkish 3.5 oz Canister	Top Regular 6 oz Canister	SE0008207 SE0009609 SE0009616 SE0010029 SE0010057 SE0010085 SE0010091 SE0010148 SE0010705 SE0013313 SE0013567
SE0007304	4 Aces Turkish 0.35 oz Pouch	Top Regular 0.6 oz Pouch	SE0008208 SE0009609 SE0009616 SE0010023 SE0010057 SE0010085 SE0010092 SE0010148 SE0010705 SE0013313 SE0013567

APPENDIX 2

Forecasted Use of RYO Cigarette-Equivalents in the US

To evaluate the environmental impact of the proposed action due to use of the new products, historical data regarding use of RYO from 2008 to 2015 was used to forecast the use of RYO for the ten year period from 2016 to 2025.¹⁵ This was achieved by using one best-fit power trend line with the R^2 value of 0.9739. Accordingly, the forecasted amounts of cigarette-equivalent use in the U.S. are estimated to be 1.4 billion cigarette-equivalents in 2016 and 1.0 billion cigarette-equivalents in 2020.



¹⁵ 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 September 27, 2016.

CONFIDENTIAL APPENDIX 1

Relevant Information Regarding the Provider of the Complex Ingredient of the Rolling Paper

Manufacturer

(b) (4)

A small, irregularly shaped grey redaction box covering a few lines of text in the top left corner of the page.

(b) (4)

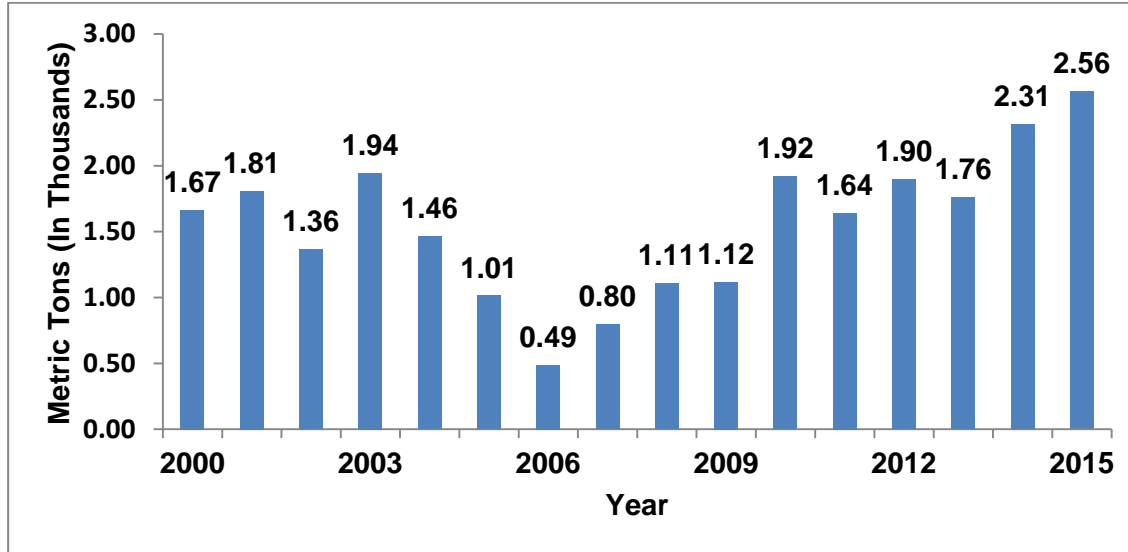
A large, solid grey rectangular redaction box covering the majority of the page's content, starting below the first redaction and extending nearly to the bottom of the page.

¹⁶ Manufacturer address via aerial photo, Google Earth. Accessed 08/29/2016.

Tobacco Products Imported to the U.S. from France

Based on information collected by the U.S. International Trade Commission (USITC), the import of total tobacco products to the U.S. from France increased from 490 metric tons in 2006 to 2,563 metric tons in 2015 (Figure below).¹⁷

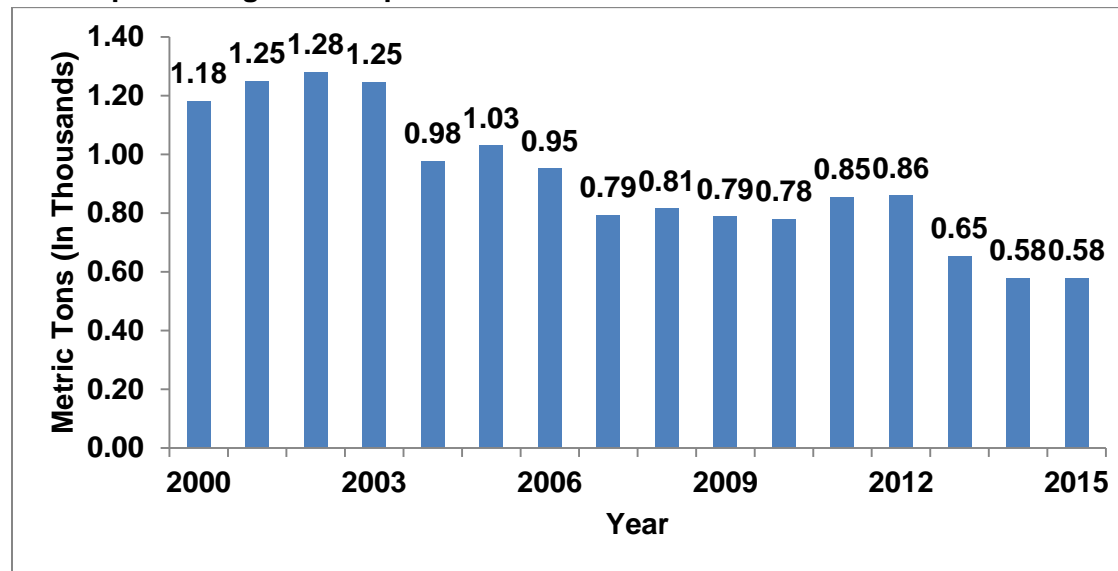
Total Tobacco Products Imported from France into the U.S. 2000 – 2015



¹⁷ Unit is defined by USITC, available at: http://dataweb.usitc.gov/scripts/tariff_current.asp?Phase=List_items&lookfor=481310. Accessed on March 23, 2016

Compared to total tobacco products, the import of cigarette papers to the U.S from France over the same time period decreased from 951 metric tons in 2006 to 579 metric tons in 2015 (Figure below).

U.S. Import of Cigarette Papers from France 2000 – 2015



The cigarette paper imported to the U.S. from France in 2015 (579 metric tons) represents 23 percent of the total amount of tobacco products imported from France in 2015 (2,563 metric tons).

Environmental introduction from manufacturing the new products

Although no particular market trend pattern is observed using data regarding cigarette paper importation to the U.S. from France from 2000 to 2015, there was an overall decline of cigarette paper imports from France from 1,180 metric tons in 2000 to 579 metric tons in 2015.¹⁸

¹⁸ Unit is defined by USITC, available at: http://dataweb.usitc.gov/scripts/tariff_current.asp?Phase=List_items&lookfor=481310. Accessed on March 23, 2016

CONFIDENTIAL APPENDIX 2

Changes Between Predicate and New Products

The applicant stated that the differences between the new and corresponding predicate products would be in the product weight, changes to the tobacco blend, and changes to the flavorings and filler ingredients. Additionally, the new products that are the subject of SE0007297 and SE0007301 do not include rolling papers and have different RYO tobacco container packaging than their corresponding predicate products. Modifications that are relevant to this environmental review are listed in the table below.

STN	New Product	Predicate Product	Mass of Tobacco (grams)		Mass of Rolling Paper (grams)	
			New Product	Predicate Product	New Product	Predicate Product
SE0007297	Largo Sun Grown Natural 8 oz Bag	Top Regular 6 oz Canister (with two 100-count TOP gummed flat booklets)	227	170	N/A	11.8
SE0007298	Largo Sun Grown Natural 0.35 oz Pouch (with one 32-count Gummed flat booklet)	Top Regular 0.6 oz Pouch (with one 32-count TOP gummed flat booklet)	10	17	1.9	1.9
SE0007299	Largo Full Flavor 0.35 oz Pouch (with one 32-count Gummed flat booklet)	Top Regular 0.6 oz Pouch (with one 32-count TOP gummed flat booklet)	10	17	1.9	1.9
SE0007300	Largo Gold 0.35 oz Pouch (with one 32-count Gummed flat booklet)	Top Gold 0.6 oz Pouch (with one 32-count TOP gummed flat booklet)	10	17	1.9	1.9

STN	New Product	Predicate Product	Mass of Tobacco (grams)		Mass of Rolling Paper (grams)	
			New Product	Predicate Product	New Product	Predicate Product
SE0007301	Largo Sun Grown Natural 3 oz Bag	Top Regular 6 oz Canister (with two 100-count TOP gummed flat	85	170	N/A	11.8
SE0007302	Largo Menthol 0.35 oz Pouch (with one 32-count Gummed flat booklet)	Top Menthol 0.6 oz Pouch (with one 32-count TOP gummed flat booklet)	10	17	1.9	1.9
SE0007303	4 Aces Turkish 3.5 oz Canister (with two 100- count Gummed flat booklets)	Top Regular 6 oz Canister (with two 100-count TOP gummed flat booklets)	99	170	11.8	11.8
SE0007304	4 Aces Turkish 0.35oz Pouch (with one 32-count Gummed flat booklet)	Top Regular 0.6 oz Pouch (with one 32-count TOP gummed flat booklet)	10	17	1.9	1.9

CONFIDENTIAL APPENDIX 3

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

STN	Package	First-Year Market Volume		Fifth-Year Market Volume	
		New Product	Predicate Product	New Product	Predicate Product
SE0007297	Bags or (Canisters)	(b) (4)			
SE0007298	Pouches				
SE0007299	Pouches				
SE0007300	Pouches				
SE0007301	Bags or (Canisters)				
SE0007302	Pouches				
SE0007303	Canisters				
SE0007304	Pouches				

STN	First-Year Market Volume				Fifth-Year Market Volume			
	New Product		Predicate Product		New Product		Predicate Product	
	Cigarette Equivalent	Number of Booklets	Cigarette Equivalent	Number of Booklets	Cigarette Equivalent	Number of Booklets	Cigarette Equivalent	Number of Booklets
SE0007297	(b) (4)							
SE0007298								
SE0007299								
SE0007300								
SE0007301								
SE0007302								
SE0007303								
SE0007304								
Totals								

Compared to the forecasted manufactured RYO cigarette-equivalents in the U.S. in 2016 and 2020, 1.2 billion and 1 billion equivalents, the first-and fifth-year market volume for the new product projections occupy (b) (4) of the forecasted market volume in the U.S. for both years.

CONFIDENTIAL APPENDIX 4

Packaging Weight for New and Predicate Products

STN	Packaging Component	New Product	Predicate Product	Weight of Component (grams)	
				New Product	Predicate Product
SE0007297	Resealable Bag	(b) (4)		1.8	N/A
				21.8	N/A
	Paper Insert			0.6	N/A
	Composite Canister			N/A	45.1
				N/A	1.1
				N/A	9.1
	Canister Bottom			N/A	16.5
	Overcap			N/A	6.7
	Insert			N/A	0.8
	Seal			N/A	0.8
Rolling Paper Booklet Cover	N/A	1.4			
SE0007298	Resealable Pouch			0.4	0.4

STN	Packaging Component	New Product	Predicate Product	Weight of Component (grams)		
				New Product	Predicate Product	
SE0007299 SE0007300 SE0007302 SE0007304		(b) (4)		4.8	4.8	
	Rolling Paper Booklet Cover			0.7	0.7	
	Reseal Tab			0.05	0.05	
	Reseal Zipper			0.8	0.8	
	Overwrap Film			1.0	1.0	
SE0007301	Resealable Bag			1.4	N/A	
				14.2	N/A	
	Paper Insert			0.6	N/A	
	Composite Canister				N/A	45.1
					N/A	1.1
					N/A	9.1
	Canister Bottom			N/A	16.5	
Overcap	N/A			6.7		

STN	Packaging Component	New Product	Predicate Product	Weight of Component (grams)			
				New Product	Predicate Product		
		(b) (4)					
	Insert			N/A	0.8		
	Seal			N/A	0.8		
	Rolling Paper Booklet Cover			N/A	1.4		
SE0007303	Composite Canister					36.5	45.1
						1.1	1.1
						9.1	9.1
	Canister Bottom					16.5	16.5
	Overcap					6.7	6.7
	Insert					0.8	0.8
	Seal					0.8	0.8
	Rolling Paper Booklet Cover					1.4	1.4

CONFIDENTIAL APPENDIX 5

Packaging Weight for Paper, Metal and Plastic for New and Predicate Products

STN	New Product				Predicate Product			
	Weight of Component				Weight of Component			
	Paper (grams)	Metal (grams)	Plastic (grams)	Booklet Cover (grams)	Paper (grams)	Metal (grams)	Plastic (grams)	Booklet Cover (grams)
SE0007297	(b) (4)							
SE0007298	(b) (4)							
SE0007299	(b) (4)							
SE0007300	(b) (4)							
SE0007302	(b) (4)							
SE0007304	(b) (4)							
SE0007301	(b) (4)							
SE0007303	(b) (4)							

CONFIDENTIAL APPENDIX 6

The First-Year and Fifth-Year Projections of Paper Waste Associated with Marketing the New Products

The applicant stated that the material used to make the paper components of the packaging are: the insert, composite canister, peelable blend paper, and rolling paper booklet cover. The Agency estimated the first-year and fifth-year weights of the paper waste (in metric tons) generated from disposal after use of the new and corresponding predicate products. Projected paper waste generation is the summation of the projected insert, composite canister, and rolling paper booklet cover waste of the eight new and corresponding predicate products. The following equation was used to calculate the amount of paper waste:

$$\sum_{i=1}^{12} = \sum_{i=1}^{12} (\quad + \quad)$$

$$= (\quad + \quad + \quad) (\quad) (\quad)$$

$$= (\quad \times \quad) (J)$$

where,

= Projected paper container and booklet cover material waste generation of a given product (metric tons)

= Projected paper container waste generation for the product (metric tons)

= Projected paper booklet cover waste generation for the product (metric tons)

= Weight of insert (grams)¹⁹

= Weight of composite canister (grams)¹⁸

= Weight of peelable blend paper (grams)¹⁸

= Number of projected containers²⁰

H_i = Weight of rolling paper booklet cover (grams)¹⁸

I_i = Number of projected rolling paper booklet covers²¹

$J = 10^{-6}$ (metric tons/gram)

¹⁹ Refer to Confidential Appendix 3 and 4 for data used for calculations.

²⁰ Refer to Confidential Appendix 2 for data used for calculations.

²¹ Refer to Confidential Appendix 2 for data used for calculations.

STN	Product Name	First-Year			Fifth-Year		
		B (metric Tons)	C (metric Tons)	A (metric Tons)	B (metric Tons)	C (metric Tons)	A (metric Tons)
SE0007297	Largo Sun Grown Natural 8 oz Bag	(b) (4)					
SE0007298	Largo Sun Grown Natural 0.35 oz Pouch						
SE0007299	Largo Full Flavor 0.35 oz Pouch						
SE0007300	Largo Gold 0.35 oz Pouch						
SE0007301	Largo Sun Grown Natural 3 oz Bag						
SE0007302	Largo Menthol 0.35 oz Pouch						
SE0007303	4 Aces Turkish 3.5 oz Canister						
SE0007304	4 Aces Turkish 0.35 oz Pouch						
Predicate	Top Regular 6 oz Canister						
Predicate	Top Regular 0.6 oz Pouch						
Predicate	Top Gold 0.6 oz Pouch						
Predicate	Top Menthol 0.6 oz Pouch						
Total Paper Waste for New Products							

Paper Waste. Estimation for generated total paper waste 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 (b) (4) in the U.S. according to US EPA.²² Therefore, if (b) (4) of the package is disposed of as waste based on the 2013 waste generation data in the U.S., the estimated cumulative paper waste will be (b) (4) metric tons in the first year of marketing the products and the estimated cumulative paper waste will be (b) (4) metric tons in the fifth year of marketing the products.

If the entire packaging paper is disposed of as waste, in the worst case scenario, the projected cumulative paper waste in the first year of marketing the products is (b) (4) metric tons and (b) (4) metric tons in the fifth year of marketing the products of total paper waste. This is a negligible fraction of the 254.1 million tons of total waste reported in the U.S. in 2013.

²² https://www.epa.gov/sites/production/files/2015-09/documents/2013_advncng_smm_fs.pdf. Accessed September 26, 2016.

CONFIDENTIAL APPENDIX 7

The First-Year and Fifth-Year Projections of Metal Waste Associated with Marketing the New Products

The applicant stated that the material used to make the metal components of the packaging are: the foil, kraft liner, and bead profile. The Agency estimated the first-year and fifth-year weights of the metal waste (in metric tons) generated from disposal after use of the new and corresponding predicate products. Projected metal waste generation is the summation of the foil, kraft liner, and bead profile waste of the eight new and corresponding predicate products. The following equation was used to calculate the amount of metal waste:

$$\sum_{i=1}^{12} = \sum_{i=1}^{12} (\quad + \quad + \quad) (\quad) (\quad)$$

where,

= Projected metal material waste generation of a given product (metric tons)

= Weight of foil (grams)²³

= Weight of kraft liner (grams)²²

= Weight of bead profile (grams)²²

= Number of projected containers²⁴

$F = 10^{-6}$ (metric tons/gram)

²³ Refer to Confidential Appendix 3 and 4 for data used for calculations.

²⁴ Refer to Confidential Appendix 2 for data used for calculations.

STN	Product Name	First-Year	Fifth-Year
		A metric tons	A metric tons
SE0007297	Largo Sun Grown Natural 8 oz Bag	(b) (4)	(b) (4)
SE0007298	Largo Sun Grown Natural 0.35 oz Pouch	(b) (4)	(b) (4)
SE0007299	Largo Full Flavor 0.35 oz Pouch	(b) (4)	(b) (4)
SE0007300	Largo Gold 0.35 oz Pouch	(b) (4)	(b) (4)
SE0007301	Largo Sun Grown Natural 3 oz Bag	(b) (4)	(b) (4)
SE0007302	Largo Menthol 0.35 oz Pouch	(b) (4)	(b) (4)
SE0007303	4 Aces Turkish 3.5 oz Canister	(b) (4)	(b) (4)
SE0007304	4 Aces Turkish 0.35 oz Pouch	(b) (4)	(b) (4)
Predicate	Top Regular 6 oz Canister	(b) (4)	(b) (4)
Predicate	Top Regular 0.6 oz Pouch	(b) (4)	(b) (4)
Predicate	Top Gold 0.6 oz Pouch	(b) (4)	(b) (4)
Predicate	Top Menthol 0.6 oz Pouch	(b) (4)	(b) (4)
Total Metal for New Products		(b) (4)	(b) (4)

Metal Waste. Estimation for generated total metal waste is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year. A portion of the generated metal waste is likely to be recycled with an overall recycling rate for metal products at (b) (4) in the U.S. according to US EPA.²⁵ Therefore, if (b) (4) of the package is disposed of as waste based on the 2013 waste generation data in the U.S., the estimated cumulative metal waste will be (b) (4) metric tons in the first year of marketing the products and the estimated cumulative metal waste will be (b) (4) metric tons in the fifth year of marketing the products.

If the entire packaging metal is disposed of as waste, in the worst case scenario, the projected cumulative metal waste in the first year of marketing the products is (b) (4) metric tons and (b) (4) metric tons in the fifth year of marketing the products of total metal waste. This is a negligible fraction of the 254.1 million tons of total waste reported in the U.S. in 2013.

²⁵ https://www.epa.gov/sites/production/files/2015-09/documents/2013_advncng_smm_fs.pdf. Accessed September 26, 2016.

CONFIDENTIAL APPENDIX 8

The First-Year and Fifth-Year Projections of Plastic Waste Associated with Marketing the New Products

The applicant stated that the material used to make the plastic components of the packaging are: the resealable bag, overcap, seal, resealable pouch, reseal tab, reseal zipper, and overwrap film. The Agency estimated the first-year and fifth-year weights of the plastic waste (in metric tons) generated from disposal after use of the new and corresponding predicate products. Projected plastic waste generation is the summation of the resealable bag, overcap, seal, resealable pouch, reseal tab, reseal zipper, and overwrap film waste of the eight new and corresponding predicate products. The following equation was used to calculate the amount of plastic waste:

$$\sum_{i=1}^{12} = \sum_{i=1}^{12} (+ + + + i + i + i) (i) ()$$

where,

= Projected metal material waste generation of a given product (metric tons)

= Weight of resealable bag (grams)²⁶

= Weight of overcap (grams)²⁵

= Weight of seal (grams)²⁵

= Weight of resealable pouch (grams)²⁵

F_i = Weight of reseal tab (grams)²⁵

G_i = Weight of reseal zipper (grams)²⁵

H_i = Weight of overwrap film (grams)²⁵

I_i = Number of projected containers²⁷

$J = 10^{-6}$ (metric tons/gram)

²⁶ Refer to Confidential Appendix 3 and 4 for data used for calculations.

²⁷ Refer to Confidential Appendix 2 for data used for calculations.

STN	Product Name	First-Year	Fifth-Year
		A metric tons	A metric tons
SE0007297	Largo Sun Grown Natural 8 oz Bag	(b) (4)	(b) (4)
SE0007298	Largo Sun Grown Natural 0.35 oz Pouch	(b) (4)	(b) (4)
SE0007299	Largo Full Flavor 0.35 oz Pouch	(b) (4)	(b) (4)
SE0007300	Largo Gold 0.35 oz Pouch	(b) (4)	(b) (4)
SE0007301	Largo Sun Grown Natural 3 oz Bag	(b) (4)	(b) (4)
SE0007302	Largo Menthol 0.35 oz Pouch	(b) (4)	(b) (4)
SE0007303	4 Aces Turkish 3.5 oz Canister	(b) (4)	(b) (4)
SE0007304	4 Aces Turkish 0.35 oz Pouch	(b) (4)	(b) (4)
Predicate	Top Regular 6 oz Canister	(b) (4)	(b) (4)
Predicate	Top Regular 0.6 oz Pouch	(b) (4)	(b) (4)
Predicate	Top Gold 0.6 oz Pouch	(b) (4)	(b) (4)
Predicate	Top Menthol 0.6 oz Pouch	(b) (4)	(b) (4)
Total Plastic for New Products		(b) (4)	(b) (4)

Plastic Waste. Estimation for generated total plastic waste 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 (b) (4) in the U.S. according to US EPA.²⁸ Therefore, if (b) (4) of the package is disposed of as waste based on the 2013 waste generation data in the U.S., the estimated cumulative plastic waste will be (b) (4) metric tons in the first year of marketing the products and the estimated cumulative plastic waste will be (b) (4) metric tons in the fifth year of marketing the products.

If the entire packaging plastic is disposed of as waste, in the worst case scenario, the projected cumulative plastic waste in the first year of marketing the products is (b) (4) metric tons and (b) (4) metric tons in the fifth year of marketing the products of total plastic waste. This is a negligible fraction of the 254.1 million tons of total waste reported in the U.S. in 2013.

²⁸ https://www.epa.gov/sites/production/files/2015-09/documents/2013_advncng_smm_fs.pdf. Accessed September 26, 2016.