Environmental Assessment for a Marketing Order for Scandinavian Tobacco Group Lane Ltd. “Bugler Leaf .65 oz Pouch”

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

April 18, 2018

Contents

This environmental assessment (EA) is for the marketing order for roll-your-own (RYO) tobacco filler manufactured by Scandinavian Tobacco Group Lane Ltd (STG). Information presented in the EA is based on the submission referenced in Appendix 1, unless noted or referenced otherwise. This EA has been prepared in accordance to 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

1. Name of Applicant

Scandinavian Tobacco Group Lane Ltd

2. Address

2280 Mountain Industrial Boulevard
Tucker, Georgia 30084

3. Manufacturer

Scandinavian Tobacco Group Lane Ltd

4. Description of Proposed Action

This proposed action is for FDA to issue a marketing order under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of a RYO tobacco filler into interstate commercial distribution in the United States. The authorization is based on the finding that the new product is substantially equivalent to the predicate product that was on the market as of February 15, 2007.

4.1 Requested Action

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

4.2 Need for Action

Scandinavian Tobacco Group wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the United States. The applicant claims that the new product differs from the predicate product only in product quantity (sec 910(a)(3)(A)(ii) of the FD&C Act). After considering the substantial equivalence (SE) report, 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

RYO tobacco filler

4.3.2 Product Name and Submission Tracking Number

The name of the new product is listed below, along with the original submission tracking number (STN) and the name of the predicate product. See Appendix 1 for additional STNs associated with the new and predicate products.

STN	New Product	Predicate Product
SE0014118	Bugler Leaf 0.65 oz Pouch	Bulk Golden Virginia Cigarette Cut

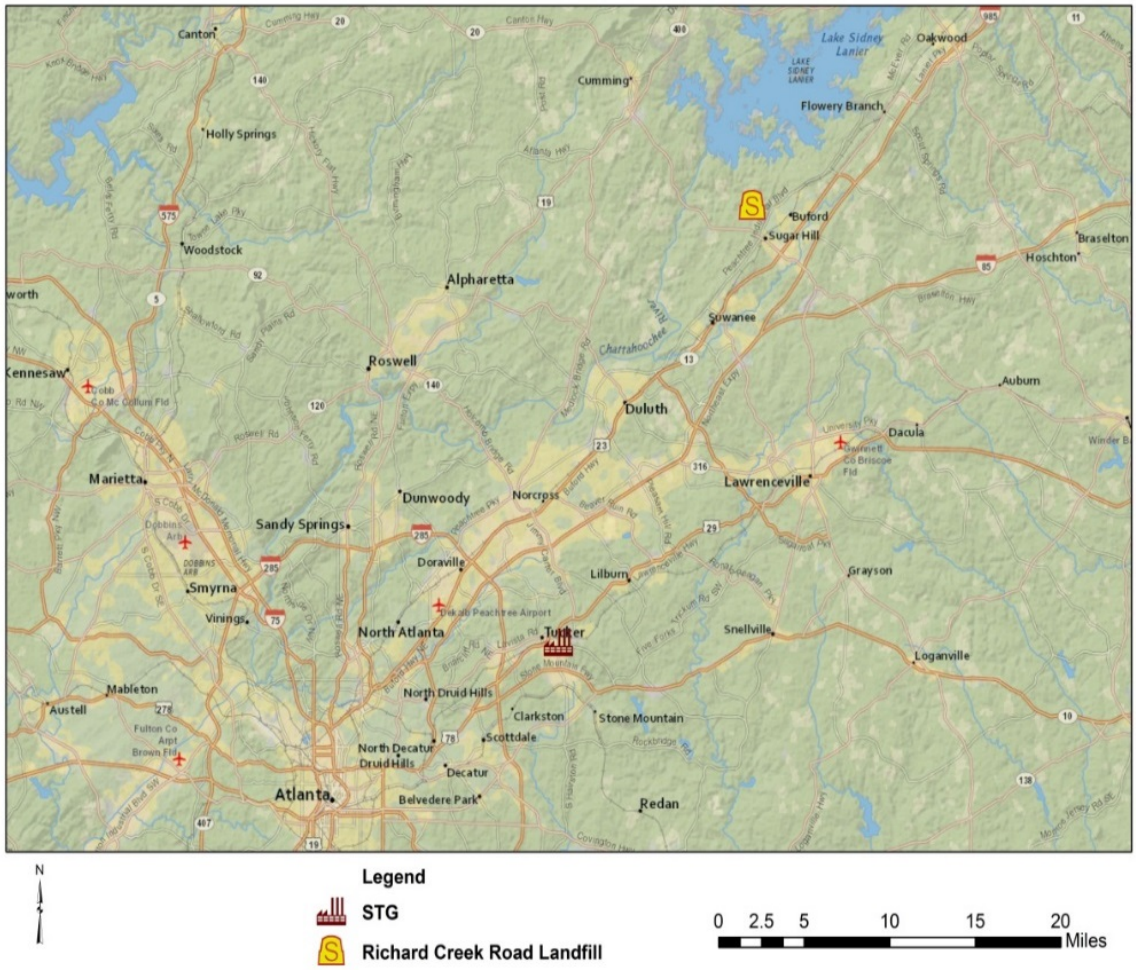
4.3.3 Description of the Product Package

The new product weighs 18.4 g and comes in a pouch; a retail unit is a single pouch which comes in a retail box of 12 pouches; this retail box would display the pouches on the retailers' shelf. Twelve of these retail boxes come in each shipping case. Details of the package components and weights of each packaging component for the new and predicate products are described in Appendix 1.

4.3.4 Location of Manufacturing

2280 Mountain Industrial Boulevard
Tucker, Georgia 30084

Figure 1: Location of the Scandinavian Tobacco Group and Landfill



The facility is located in the Upper Ocmulgee Watershed with the 8-digit hydrologic unit code (HUC): 03070103 (Figure 1) (US EPA , 2017). This watershed covers approximately 982 square miles with land cover breakdown across this watershed accounts for 36% undeveloped (23% forested, 9% agricultural, 4 water/wetlands) and 64% developed (8% commercial, 2%

transportation, 3% industrial and 41% residential) (CH2M, 2017). Administratively, this facility is located in DeKalb county with the population of 691,893 (US Census Bureau , 2010).

4.3.5 Location of Use

Scandinavian Tobacco Group intends to distribute and sell the new tobacco product to consumers in the United States.

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 will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates that 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 weight and packaging characteristics. The new product weighs 18.4 g compared to the predicate product that weighs 2,268 g. The new product comes in a pouch and there are 12 RYO tobacco pouches packed in a retail cardboard box. The predicate product comes in a bag and the retail unit is a single bag of tobacco. There are twelve retail units (boxes) per shipping case for the new product and five retail units (boxes) per shipping case for the predicate product.

5 Potential Environmental Impacts Due to the Proposed Action

5.1 Potential Environmental Impacts Due to Manufacturing the New Product

The Agency anticipates the environmental releases generated by manufacturing the new RYO tobacco product will be emitted to the air, discharged in wastewater to waterways or publicly owned treatment works (POTWs), and disposed of in the solid waste stream. These releases would occur in the same manner as the releases and waste generated from manufacturing other RYO products in the manufacturing facility. The applicant stated that the manufacturing of the new product will not result in the need for additional disposal resources and they expect that all waste tobacco generated from manufacturing the new tobacco product will be disposed of in the same landfill as the waste from all other products manufactured in the facility.

The applicant stated that there would be no increase in manufacturing, facility expansion or equipment modification due to manufacturing the new product. They stated that manufacturing the new product results in no more than a negligible increase in MSW generation and that the air emissions and wastewater discharges from manufacturing the new product are the same types as from the predicate product and any increase in emissions or discharges would have a negligible environmental impact. The applicant also stated that manufacturing the new product would not require a revised or new air emissions or wastewater discharge permit and any changes to greenhouse gas (GHG) emissions would be negligible. These conclusions are consistent with applicant-provided information that forecasts manufacturing the new product to add only a fraction of a percent to the current production of the facility.

Based on information in the SE Report, the product modification consists of a change to the product quantity. The applicant stated that no new compounds would be emitted, compared to compounds currently emitted from the manufacturing facility. In addition, and will be controlled by the facility's

biofilter and dust collectors. Therefore, the Agency does not anticipate that manufacturing the new product will lead to the release of new chemicals into the environment.

Because the new product will compete with other currently marketed RYO products, and the applicant provided data demonstrating that the production volume of the new product is a small fraction of total production at the manufacturing facility, no effects from increased GHG emissions during manufacturing are anticipated from the proposed action.

According to Georgia's Fish and Wildlife Service, as of November 2017, 62 federally-threatened and endangered species exist[1] in Georgia (US FWS, 2017). Of these species, two endangered species (*Isoetes melanospora* and *Rhus michauxii*) and two threatened species (*Elliptoideus sloatianus* and *Amphianthus pusillus*) are observed in DeKalb county (US FWS, 2017). However, the applicant claimed that there is no anticipated adverse effect on endangered species or critical habitats of the species identified under the Endangered Species Act (ESA). Therefore, the agency does not anticipate any adverse effects on the species or the critical habitat of a species identified under the ESA due to the manufacture and commercial introduction of the new product.

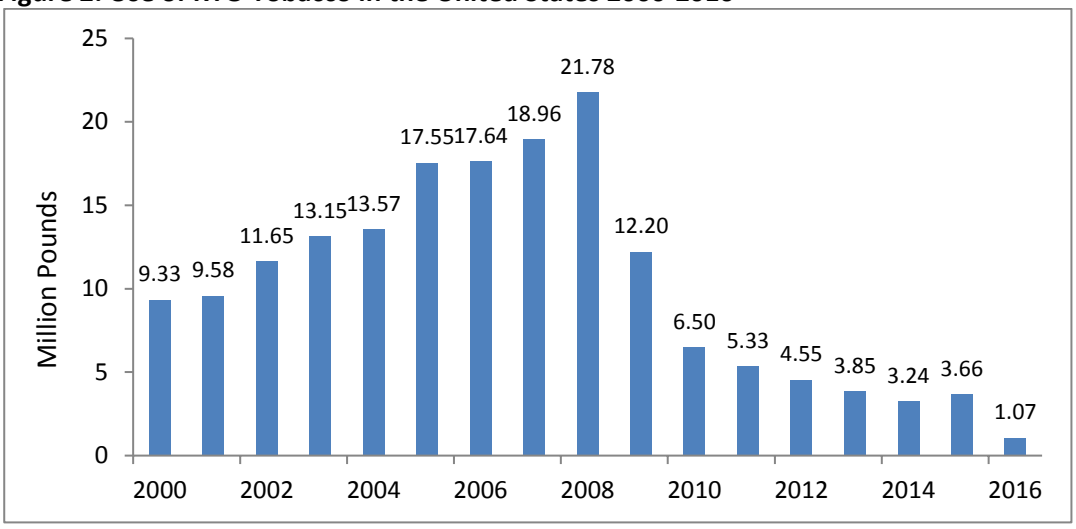
The applicant claims that they maintain two district permits issued by the Georgia Department of Natural Resources for air and storm water. The applicant also claims that the facility is equipped with a biofilter control device that removes 90% of the volatile organic compounds (VOCs) produced by the facility's tobacco product manufacturing operations. The air permit has an annual VOC emission limit of 25 tons; the facility meets this limit. Furthermore, the applicant reports that because all raw materials are stored inside the facility and are not exposed to storm water, the runoff from the storm water would not have adverse effects on the surrounding surface waters.

5.2 Potential Environmental Impacts Due to Use of the New Product

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of RYO tobacco products in the United States increased from 9.33 million pounds in 2000 to 21.78 million pounds in 2008. This was followed by a decrease in use from 12.20 million pounds in 2009 to 1.07 million pounds in 2016 (Figure 2) (US TTB, 2017).

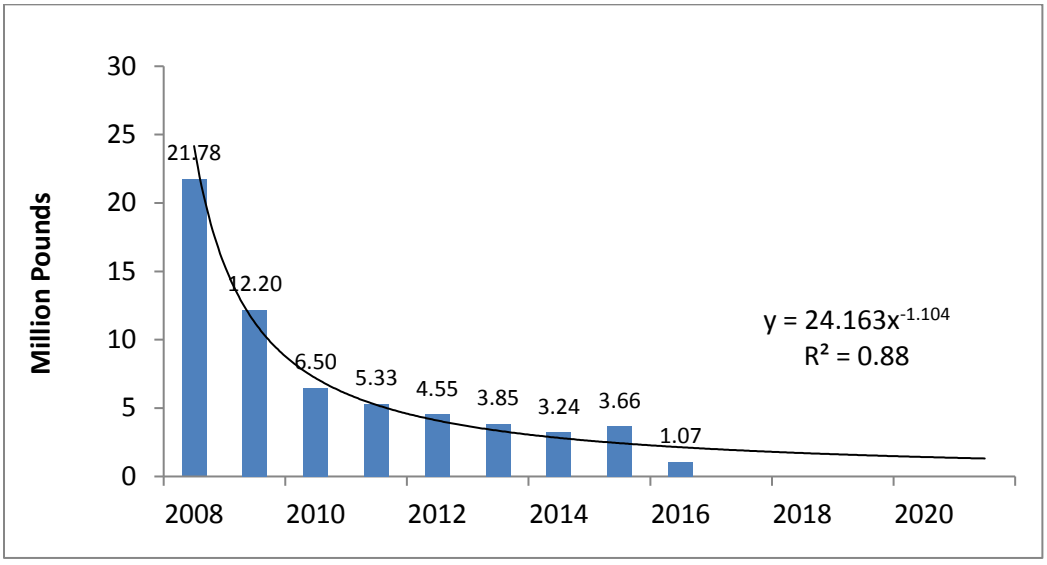
[1] The Endangered Species Act of 1973 (ESA) protects species of plants and animals that are in danger of extinction. The purpose of the ESA is to protect and recover jeopardized species and their habitats. The ESA is administered by the U.S. Fish and Wildlife Service (USFWS) and the Commerce Department's National Marine Fisheries Service (NMFS). The ESA allows the USFWS and the NMFS to list species of plants and animals as threatened or endangered. "endangered" means a species is in danger of extinction throughout all or a significant portion of its range. "threatened" means a species is likely to become endangered within the foreseeable future [FWS].

Figure 2: Use of RYO Tobacco in the United States 2000-2016



To evaluate the environmental impact of the proposed action due to the use of the new product, the Agency analyzed historical use data for 2008-2016 to forecast the future use of RYO tobacco products in the United States. This was achieved by using one best-fit power trend line with the R^2 value of 0.88. Using this approach, the amount of RYO tobacco products forecasted to be used is estimated to be 1.90 million pounds in 2017 and 1.31 million pounds in 2021 (Figure 3).

Figure 3: Forecasted Use of RYO Tobacco in the United States



The projected market volumes for the new product in the first and fifth year of marketing occupy a small portion of the total projected estimate of use of RYO products in the United States (Confidential Appendix 2). However, because the new product is expected to compete with the predicate product and other RYO products on the market, the Agency anticipates minimal increase in the use of all RYO products. Therefore, the Agency does not anticipate more chemicals to be released into the environment from the use of the new RYO product, compared to the chemicals released by the predicate product that is currently on the market.

When burned, a RYO cigarette produces environmental tobacco smoke (ETS) or secondhand smoke. The ETS composed of sidestream smoke (SS), emitted from the smoldering tobacco between puffs, and exhaled mainstream smoke (MS) from the smoker (DHHS, 1991).

ETS contains many of the toxic agents and carcinogens that are present in MS, but in diluted form. The major source of ETS is SS, which contains higher amounts of some toxic and carcinogenic agents than MS in its undiluted form. The primary reason that undiluted SS and MS have different concentrations of toxic and carcinogenic agents is that peak temperatures in the burning cone of a cigarette reach 800° to 900°C during puffing, but only 600°C between puffs, resulting in less complete combustion of tobacco during generation of SS. In addition, most of the burning cone is oxygen deficient during smoldering and produces a strongly reducing environment (DHHS, 1991).

There is no safe level of exposure to secondhand smoke. Even low levels of secondhand smoke can harm children and adults in many ways, as detailed below.

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (DHHS, Surgeon General Report, 2010).
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness (DHHS, Surgeon General Report, 2010).
- Secondhand smoke causes more than 40,000 deaths a year (DHHS, Surgeon General Report, 2010).

As noted, the applicant claimed that the new product differs from the predicate product in the weight per retail unit and packaging weights. Therefore, the Agency does not anticipate new chemicals to be emitted into the environment from the use of the new product, compared to the chemicals released by the predicate product that is currently on the market.

5.3 Potential Environmental Impacts Due to Disposal of the New Tobacco Product

To better understand the potential environmental impacts due to disposal of the new tobacco product, it is important to comprehend the pathways of disposed packaging materials and pathways of discarded cigarette waste.

5.3.1 Disposal of Packaging Materials

Disposal of the packaging materials would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the United States, including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packaging materials. Specifically, in 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the United States, and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 4 and 5) (US EPA, 2014). 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 (US EPA, 2014).

To estimate the waste from the disposal of packaging material, the Agency utilized the projected market volumes for the first and fifth years of marketing the new and predicate products, assuming all packaging is disposed of in MSW. The estimated waste from packaging disposal following product use would be a very small portion of the total MSW forecasted to be disposed of in the United States. (Confidential Appendix 3).

Figure 4: Municipal Solid Waste Generation Rates in the United States, 1960-2014

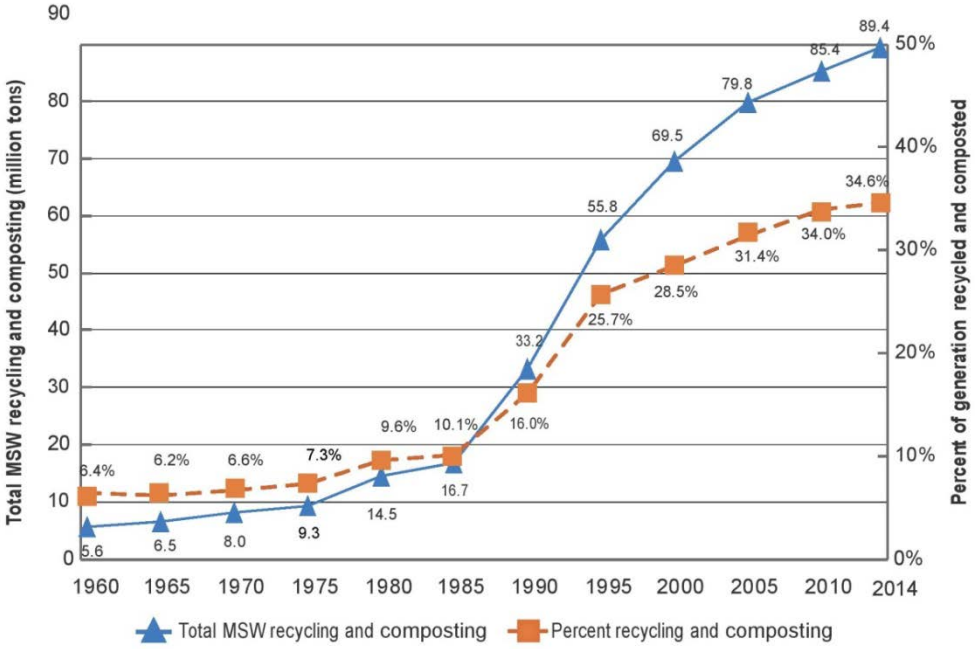


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 5: Municipal Solid Waste Recycling Rates in the United States, 1960-2014

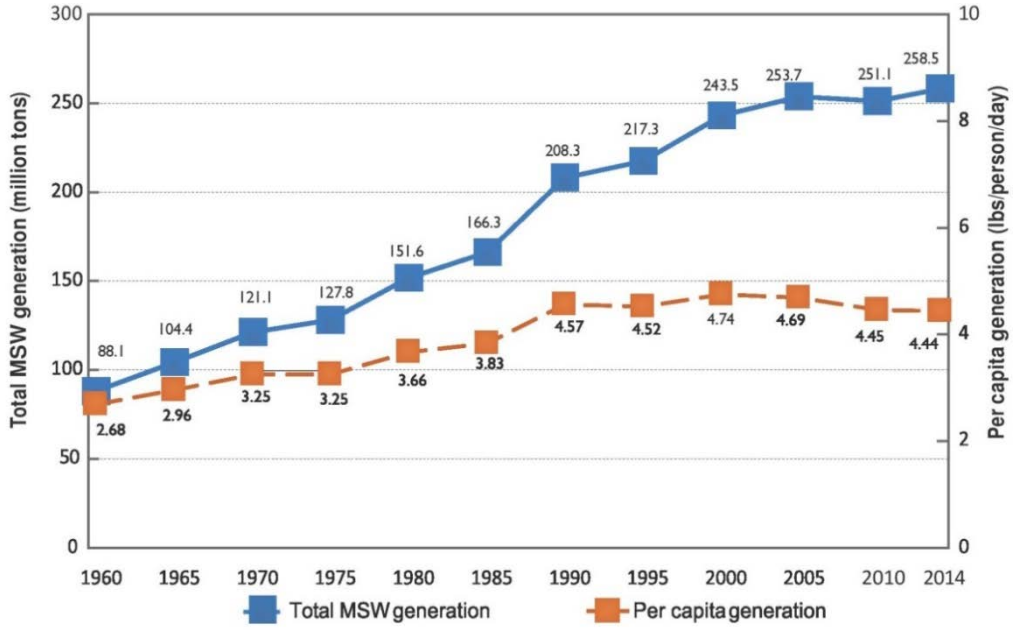


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

As previously discussed, because the applicant stated that the new product will compete with other similar products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfills is not anticipated due to the proposed action.

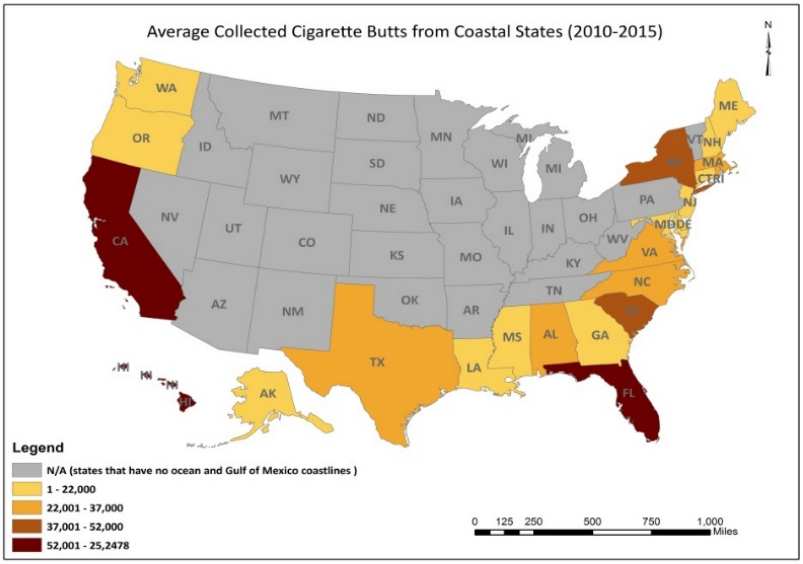
The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment due to manufacturing. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other RYO tobacco fillers manufactured in the facility.

5.3.2 Disposal of RYO Waste

The Agency uses information from the U.S. EPA and "Keep America Beautiful" to estimate the rates of managed and unmanaged RYO tobacco products entering the environment from disposal of RYO tobacco products. The managed waste is treated as MSW and either incinerated with energy recovery or landfilled. As discussed previously, based on the 2014 information by the U.S. EPA (U.S. EPA, 2014) of all of the trash generated in the United States, 34.6% is recycled and composted. This leaves 65.4% of the trash that was moved to landfills and possibly combusted with energy recovery. This is how the managed waste of the used cigarettes would be handled. For 100% of all managed waste, landfilled and combusted, based on this information, 80.4% by-weight enters landfills, and the remaining 19.6% by-weight is incinerated for energy recovery (US EPA, 2014).

The majority of unmanaged cigarette waste ends up in oceans and beaches across the United States and worldwide. The annual Ocean Conservancy's International Coastal Cleanup (ICC) reports that cigarette waste has been the single most collected item since coastal clean-ups began (Novotny, Lum, & Smith, 2009). Using the data from the ICC reports, the average collected cigarette waste (2010-2015) from coastal states (excluding Great Lakes coast) on the international coastal cleanup day is depicted (Figure 6).

Figure 6: Collected Cigarette Waste from Coastal States (2010-2015)



A threat assessment study focusing on the most common types of litter that are found along the world's coastlines, based on data gathered during three decades of international coastal clean-up efforts, was conducted by Wilcox et al., 2016. The study was conducted based on elicited information from experts on the ecological threat of entanglement, ingestion and chemical contamination for three major marine taxa: seabirds, sea turtles and marine mammals (Wilcox & Mallos, 2016). The result of this study shows that cigarette butts are ranked seventh out of 20 marine debris items of interest for which information was elicited.

As previously discussed, the new RYO tobacco product will compete with other similar RYO tobacco products on the market. As such, introducing the new products into the U.S. market is not expected to increase the nationwide use of RYO. Thus, authorizing the new product is not expected to affect the overall level of cigarette butt litter in the United States. Based on this, and the above-mentioned information regarding waste, construction of new POTWs or landfills are not anticipated due to the proposed actions.

6 Use of Resources and Energy

The applicant states that there will be no change in how the new product is manufactured compared to the predicate product. The same raw materials and energy will be used to manufacture the new product compared to the predicate product and the applicant does not anticipate any increased energy or resource needs to manufacture the new product. The applicant states that the proposed action will not require an expansion of the manufacturing facility. Because the applicant states that the new product will compete with other similar RYO products and the predicate product, no increase of overall RYO products market volume and no net increase of energy use will be expected from the proposed action. The applicant states that no adverse effects to endangered or threatened species or critical habitat are expected from manufacturing the new product.

7 Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for manufacturing, use, and disposal of the new product. Therefore, no mitigation measures are discussed.

8 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 United States. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal of tobacco products as many other similar RYO tobacco products will continue to be marketed.

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

9 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:

Mehran Niazi, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Environmental Sciences
- Experience: 12 years in environmental fate and transport and environmental modeling
- Expertise: water quality modeling, environmental fate and transport

Reviewers:

Hoshing W. Chang, Ph.D., Center for Tobacco Products
- Education: M.S. in Environmental Science and Ph.D. in Biochemistry
- Experience: 9 years in FDA-related NEPA review
- Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

10 List of Agencies and Persons Consulted

Not applicable.

11 Appendix List

Appendix 1: Submission Tracking Number and Related Amendments for the SE Report and Package Sizes of the New and Predicate Products Covered Under this Environmental Assessment (EA)

12 Confidential Appendix List

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

Confidential Appendix 2: Percentage of the Projected Total RYO Market in the United States Occupied by the New Product in 2017 and 2021

Confidential Appendix 3: The First- and Fifth-Year Projections of Packaging Materials Waste Associated with Marketing the New and Predicate Products

13 References

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APPENDIX 1

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

SE0014118	Retail Unit Weight (g)	Retail Unit per Retail Box	Retail Unit per Shipping Case	Amendments
New Product	18.4 (pouch)	12	12	SE0014187 SE0014249 SE0014345 SE0014346
Predicate Product	2,268 (bag)	N/A	5	

CONFIDENTIAL APPENDIX 1

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

SE0014118	Name	1st-Year Projected Volume (Pounds)	5th-Year Projected Volume (Pounds)
New Product	Bugler Leaf .65 oz Pouch	(b) (4)	
Predicate Product	Bulk Golden Virginia Cigarette Cut		

CONFIDENTIAL APPENDIX 2

Percentage of the Projected Total RYO Market in the United States Occupied by the New and Predicate Products in 2017 and 2021

SE0014118	Year of Marketing	Forecasted Use of Total RYO Tobacco in the United States (pounds)[2]	Projected Market Volume (pounds)[3]	Projected Market Occupation of New Product in the United States (%)
New Product	First	1,902,000	(b)(4)	
	Fifth	1,312,000		
Predicate Product	First	1,902,000	0	0
	Fifth	1,312,000	0	0

First Year Market Occupation of New Product (%)

$$= \frac{\text{First-Year Market Volume Projection}}{\text{Forecasted Use of RYO in the U.S. for 2017}} \times 100\%$$

Fifth Year Market Occupation of New Product (%)

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

The projected market volume for the new product is (b) (4) and (b) (4) pounds in 2017 and 2021, respectively. Compared to the amount of RYO projected to be used in the United States, the new product would occupy (b) (4) and (b) (4) of the total market of RYO in 2017 and 2021, respectively (see section 5.2). According to the applicant, the predicate product's projected market volume for the first- and fifth- year is zero.

[2] See Figure 5.

[3] See Confidential Appendix 1.

CONFIDENTIAL APPENDIX 3

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

To analyze the environmental effects from total waste due to the proposed action, the Agency estimated the first- and fifth-year projected weight of the packaging materials waste (in metric tons) that would be generated from disposal of the new product in 2017 and 2021. Projected waste generation is the summation of the projected foil inner liner, cardboard retail boxes, and cardboard of the cartons of retail boxes of the new product.

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

$$B_i = \frac{D_i}{E_i} \times F \times I$$

$$C_i = \frac{D_i}{E_i \times G_i} \times H \times I$$

A_i: Projected paper waste generation of the product (metric tons)
B_i: Projected retail cardboard box waste generation of the products (metric tons)
C_i: Projected shipping case waste generation of the products (metric tons)
D_i: Projected market volume of the new product (# pouches)
E_i: Number of pouches per retail box
F: Weight of empty retail box (grams)
G_i: Number of retail boxes per shipping case
K_i: Weight of retail unit package (grams)
H: Weight of empty shipping case (grams)
I: 1.0 x 10^{-6} metric tons/gram

	STN	H	G	F	E	K	D	C	B	A
First Year	SE0014118	487	12	68.7	12	5.25	(b) (4) [redacted]			
Fifth Year	SE0014118	487	12	68.7	12	5.25				

If all of the projected packaging waste generated from use of the new product is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new product would be (b) (4) [redacted] metric tons in 2017 and (b) (4) [redacted] metric tons in 2021. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014. Similarly, the projected retail unit waste of (b) (4) [redacted] metric tons in 2017 and (b) (4) [redacted] metric tons in 2021 is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.

A portion of the generated cardboard waste is likely to be recycled, with an overall recycling rate for paper and paperboard products of 64.7% in the United States. If 64.7% of the cardboard boxes is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed of in landfills would be decreased to (b) (4) metric tons (b) (4) in the first year and (b) (4) metric tons (b) (4) in the fifth year of marketing the new product.