Environmental Assessment for a Marketing Order for Scandinavian Tobacco Group Lane Ltd. “Samson Halfzware”

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

October 27, 2017

Table of Contents

This environmental assessment (EA) is for the marketing order for a roll-your-own (RYO) cigarette tobacco filler manufactured by [redacted] for Scandinavian Tobacco Group Lane Ltd. 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 a submission under section 905(j) 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

(b) (4) [redacted]

4. Description of Proposed Action

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

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 Lane Ltd. (STG Lane) wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the United States. The applicant claimed that the new product has a quantity change from the predicate product. This is a change in characteristics from the predicate product, but the applicant claims the new product does not raise different questions of public health (sec 910(a)(3)(A)(ii) of the FD&C Act). In addition, the applicant claimed that the new and predicate products have identical product and packaging composition. After considering the substantial equivalence (SE) report (SE0014067), the Agency shall issue a marketing order under the provisions of sections 910 and 905(i) of the FD&C Act when finding the new product to be substantially equivalent to the predicate product.

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

4.3.1 Type of Tobacco Product

Roll-your-own (RYO) cigarette tobacco filler

4.3.2 Product Name and STN

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

STN	New Product	Predicate Product
SE0014067	Samson Halfzware	Samson Halfzware

4.3.3 Description of the Product Package

The packaging materials of the finished new product are identical to those of the predicate product. Both product packaging components consist of a pouch in which the cigarette tobacco filler is contained; however, the new product does not contain the 60-leaf booklet of cigarette papers that the predicate product contains. Details of the package components and weights of each packaging component for the new product are described in Confidential Appendix 4.

4.3.4 Location of Manufacturing

The manufacturer of the RYO cigarette tobacco filler component of the new product is (b) (4) and is located at (b) (4) (Figure 1).

Figure 1. Location of the RYO Tobacco Product Manufacturing Facility[1]

[1] Manufacturer address via Google Map. Accessed September 20, 2017.

(b) (4)

4.3.5 Location of Use

STG Lane 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 following use 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 Identified as Compared to the Predicate Product

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

5. Potential Environmental Impacts Due to the Proposed Action

5.1 Potential Environmental Impacts due to Manufacturing the New Product

Tobacco Import and Tobacco Market Volumes. According to the U.S. International Trade Commission (USITC), the import of total tobacco products to the United States from the Netherlands has decreased from 902 metric tons in 2000 to 140 metric tons in 2016 (Figure 2).[2] When examining the change in import of RYO cigarette tobacco to the United States from the Netherlands over the last five years of reported data, there has been a fluctuation from 25 metric tons in 2012 to 16 metric tons in 2016 (Figure 3).[2]

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

RYO cigarette tobacco imported to the United States from the Netherlands in 2016 represented 11.4% by weight of the total amount of tobacco products imported from the Netherlands in 2016.

Figure 2. Total Tobacco Products Imported from the Netherlands into the United States 2000-2016[2]

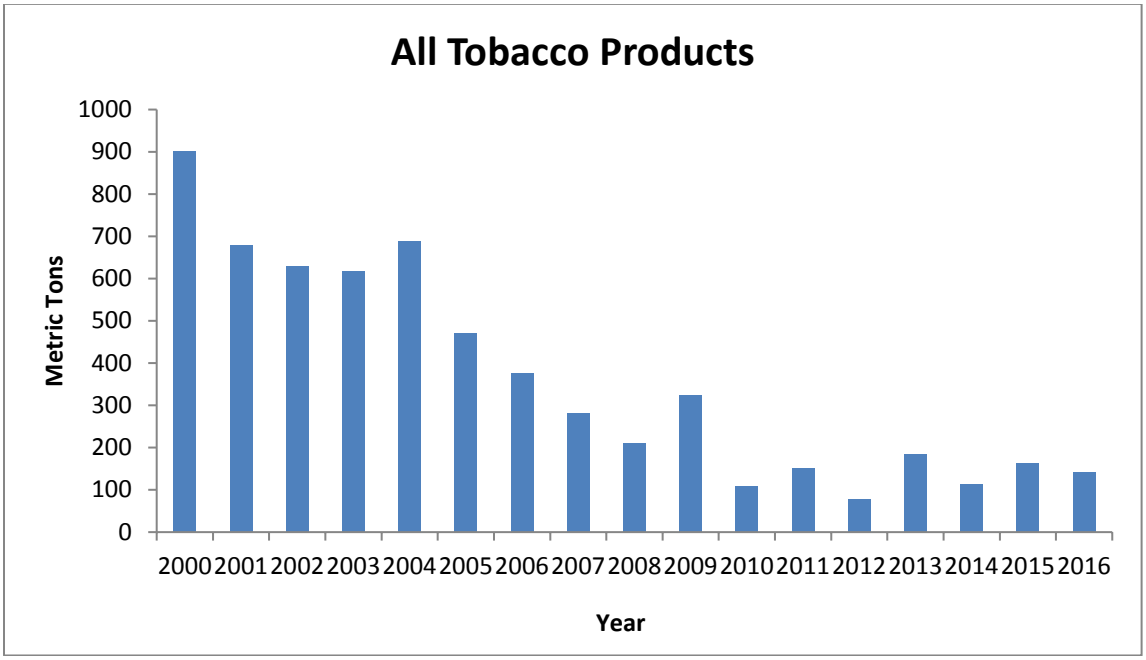
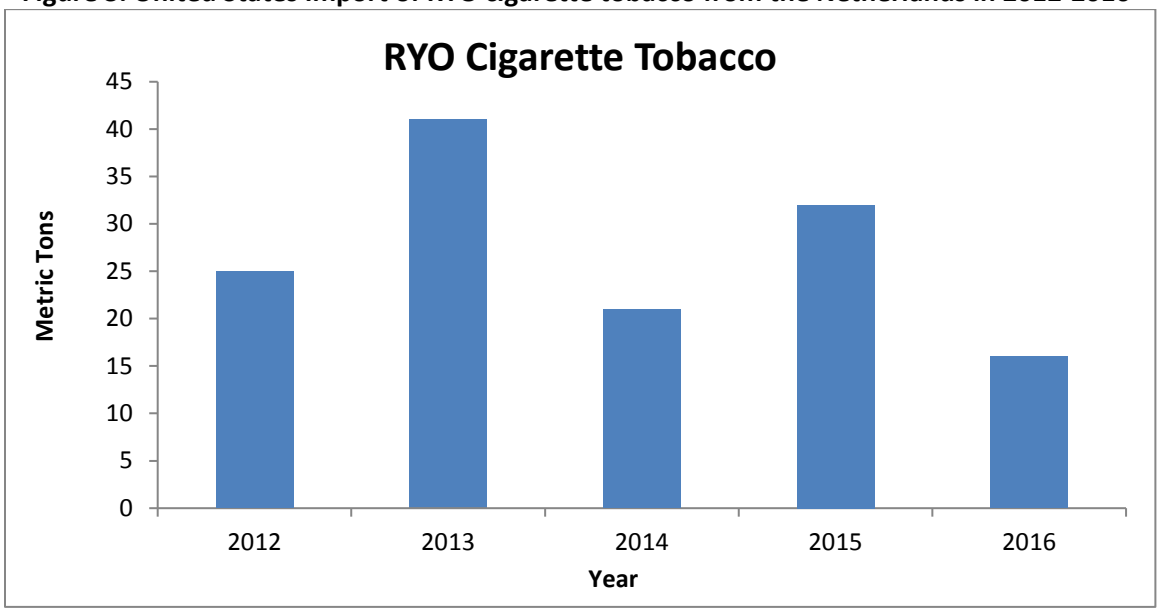


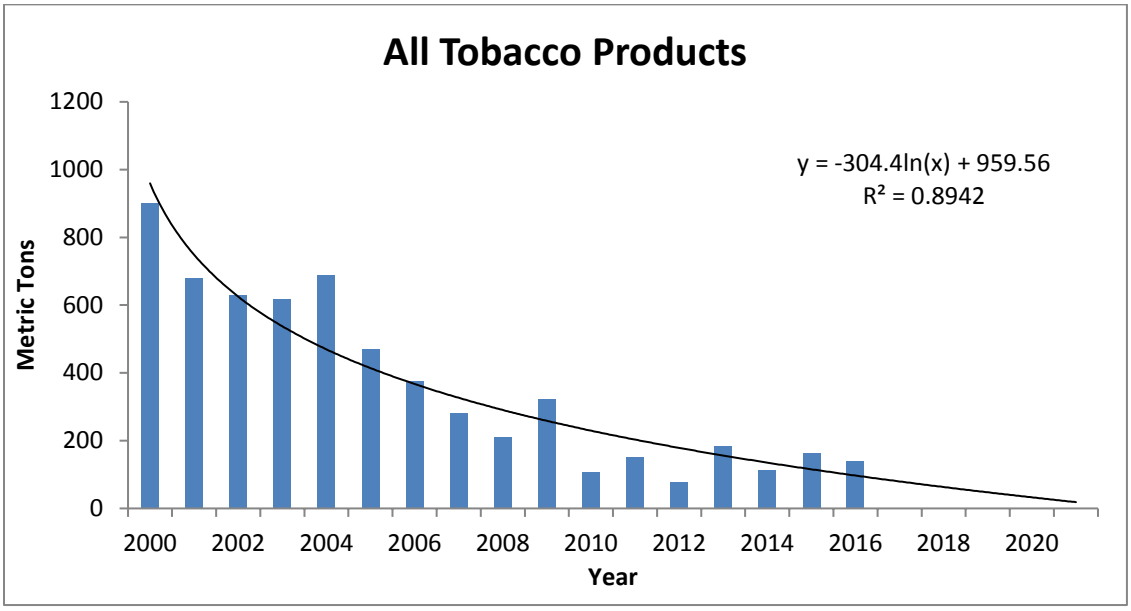
Figure 3. United States Import of RYO cigarette tobacco from the Netherlands in 2012-2016[2]



Potential Environmental Introduction from Manufacturing the New Product in the Proposed Action. The Agency anticipates the waste generated by manufacturing the new RYO tobacco product will be emitted to the air, discharged in wastewater to waterways or publicly owned treatment works, and disposed of in the solid waste stream. These releases could occur in the same manner as the waste generated from manufacturing other products manufactured in the same facility and other RYO tobacco products manufactured in the Netherlands. The new product will compete with other currently marketed RYO cigarette tobacco filler products. The applicant provided the first- and fifth-year market volumes for the new product (Confidential Appendix 1).

To evaluate the environmental impact of the proposed action due to the import of the new product, historical data regarding the import of all tobacco products from the Netherlands into the United States from 2000 to 2016 was used to forecast the manufacture of RYO tobacco products in The Netherlands and then imported into the United States[3]. This was achieved by using a logarithmic trend line with the R^2 value of 0.8942. Accordingly, the forecasted amount of all tobacco products to be imported from the Netherlands into the United States is estimated to be about 97 metric tons in 2017 and 33 metric tons in 2021. The amount of all tobacco products imported from the Netherlands into the United States is estimated at 140 metric tons in 2016 by USITC (Figure 4).

Figure 4. Forecast of All Tobacco Products Imported into the United States from the Netherlands into the United States 2000-2016[3]



Comparing the projected market volume of the new product with the forecasted market volume of all tobacco products imported into the United States from the Netherlands in 2017

[3] Forecast trend lines extrapolated from USITC data. Available from http://dataweb.usitc.gov. Accessed February 17, 2017.

and 2021, the cumulative projected market volumes of the new products are a small fraction of the total forecasted market volumes in 2017 and 2021 (Figure 4 and Confidential Appendix 1). Additionally, the applicant stated that an environmental summary report of the [redacted] factory from 2011-2015 shows that the manufacturing of the new product will comprise a small fraction of the total production at the manufacturing facility. Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new product. The applicant stated that the manufacturing process for the new product is identical to that of all other production at the manufacturing facility. The applicant also stated that the waste associated with manufacturing the new product is negligible compared to the facility's total waste. Therefore, no additional resources will be required for waste disposal, and no new control practices of air emission, water discharge, and solid waste disposal are needed.

Based on information in the SE Report, the new product differs from the predicate product only in product quantity, or more specifically, with the removal of the 60-leaf booklet of cigarette papers. All of the ingredients used to manufacture the new and predicate products and their physical characteristics are identical. 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 the Netherlands and the applicant stated that there are no anticipated adverse effects in respect to the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). The applicant also stated that the manufacturing facility complies with applicable Netherlands national legislation implementing CITES.

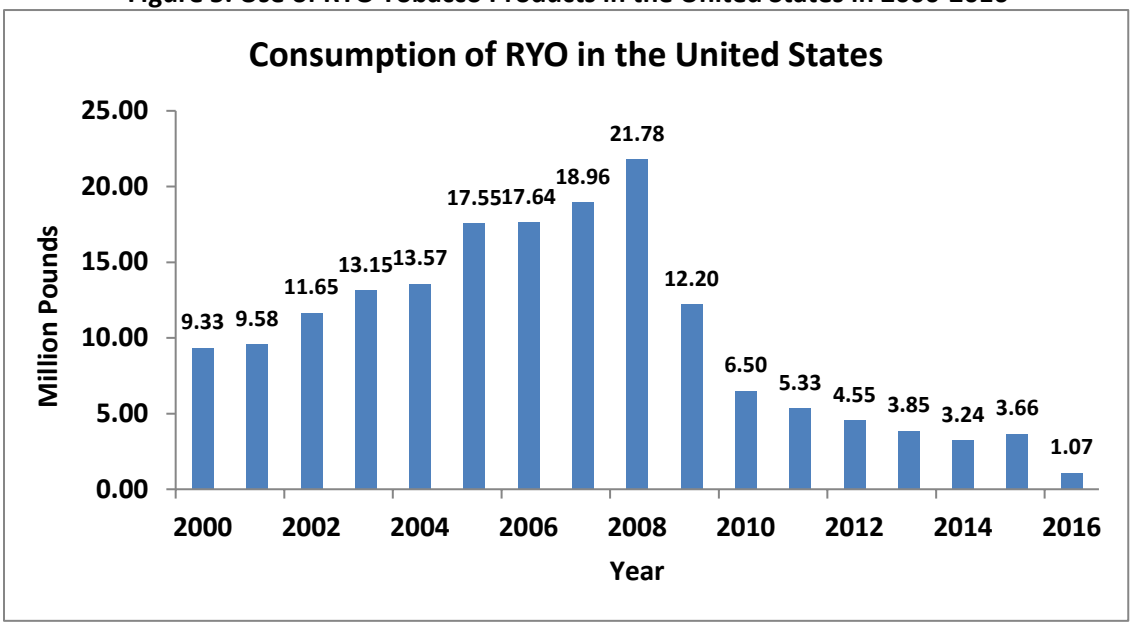
Because the new product comprises a miniscule fraction of the total manufacturing volume at the facility (Confidential Appendix 1), manufacturing the new product will not result in a significant net increase of energy use at the facility.

Additionally, the applicant stated that no different greenhouse gases (GHGs) will be emitted because the new and predicate products are identical in manufacturing and packaging components. Furthermore, because the new product will compete with other currently marketed RYO products, no increase in GHG emissions is anticipated from the proposed action. Additionally, the applicant stated that the manufacturing facility is in compliance with all environmental laws applicable in the territory of the Netherlands and it holds any permits required.

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 5) (U.S. Dept of Treasury Alcohol and Tobacco Tax and Trade Bureau, 2017).

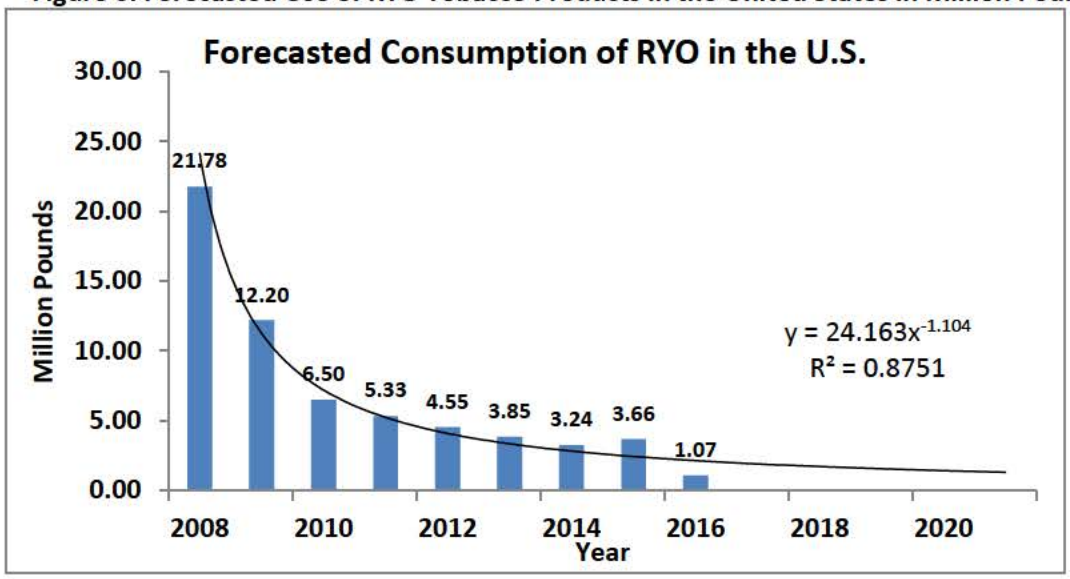
Figure 5. Use of RYO Tobacco Products in the United States in 2000-2016



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 0.8751.[4] Using this approach, the forecasted amount of RYO tobacco products to be used in the United States is estimated to be 1.90 million pounds in 2017 and 1.31 million pounds in 2021 (Figure 6).

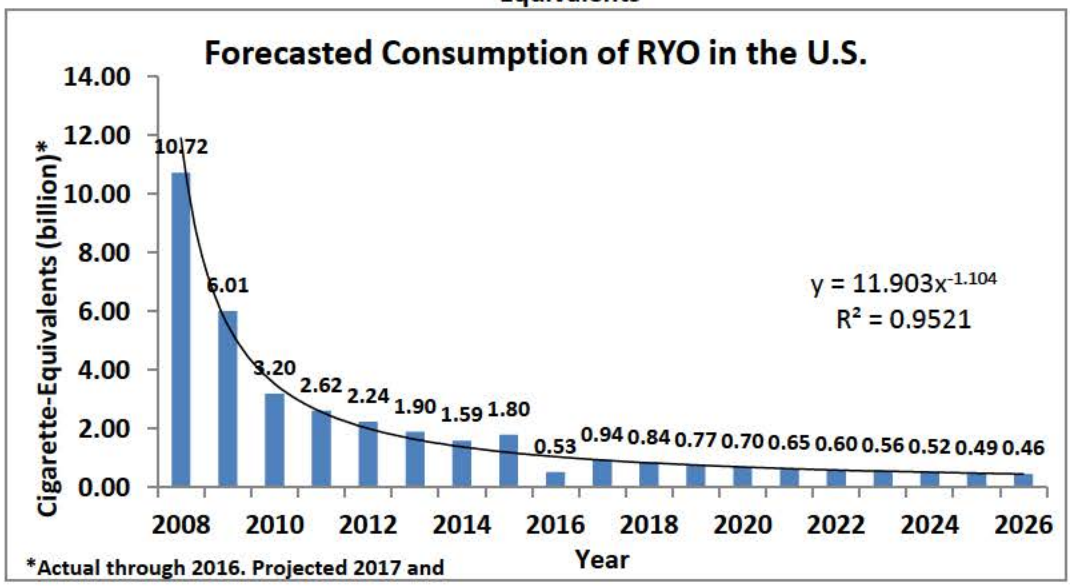
[4] Forecast trend lines extrapolated from TTB data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed March 15, 2017.

Figure 6. Forecasted Use of RYO Tobacco Products in the United States in Million Pounds



The results are also forecasted in units of cigarette-equivalents, based on the assumption that 0.0325 ounces of tobacco is used per cigarette (National Association of Attorneys General, 1998) (Figure 7).

Figure 7. Forecasted Use of RYO Tobacco Products in the United States in Cigarette-Equivalents



Year	RYO Tobacco Products (million pounds)[a]	RYO Tobacco Products (billion cigarette-equivalents)[b]
2016	1.07	0.5268
First Year (2017)	1.90	0.9354
Fifth Year (2021)	1.31	0.6449

[a] Projected first-year and fifth-year pounds of RYO tobacco products: $24.163\times(year-2007)^{-1.104}$

[b] Cigarette-equivalents = $RYO\ tobacco\ (pounds)\times\frac{16\ ounces}{pound}\times\frac{1\ cigarette}{0.0325\ ounches\ RYO\ tobacco}$

The applicant intends to [redacted] Because the new product is expected to compete with other RYO products on the market, the Agency anticipates minimal or no net increase in the use of all RYO products. Subsequently, the Agency does not anticipate new substances to be released into the environment from the use of the new RYO product, relative to the substances released by the predicate product already on the market.

During use, the new product is burned to ash, carbon dioxide (CO_2), and water vapor, as well as products of incomplete combustion such as carbon monoxide (CO). These combustion products from the new product are released in a similar manner to the predicate product. As noted, the only differences between the new and predicate products are in product quantity with the removal of the 60-leaf booklet of cigarette papers. Additionally, because 1) the new product will compete with other currently marketed RYO products; 2) the projected market volumes of the new product for the first and fifth years of marketing are comparatively less than that of the current market volume of the predicate product; and 3) the projected market volume of the new product is miniscule relative to the overall U.S. tobacco market, no net addition of GHG emissions is anticipated.

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

5.3.1 Disposal of Packaging Material

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the United States, and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 8 and 9). Paper and paperboard account for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), out of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW generated, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery. On average, 4.4 pounds per person of waste was generated, of which 2.1 pounds was recycled, composted, or combusted for energy recovery in the United States in 2014 (U.S. Environmental Protection Agency, 2016).

Figure 8. Municipal Solid Waste (MSW) Generation Rates in the United States, 1960-2014

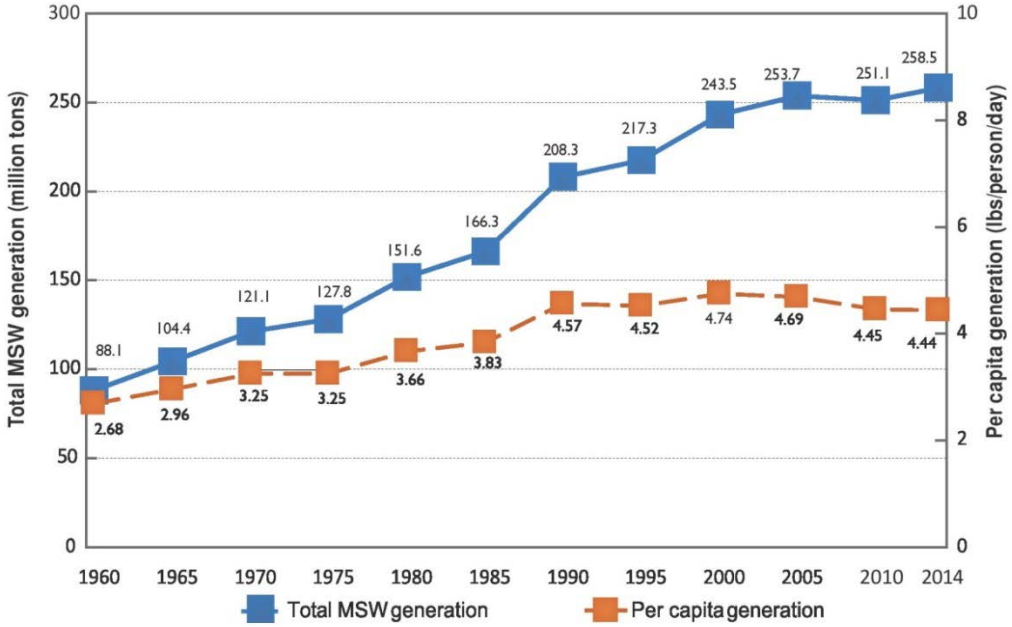


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 9. MSW Recycling Rates in the United States, 1960-2014

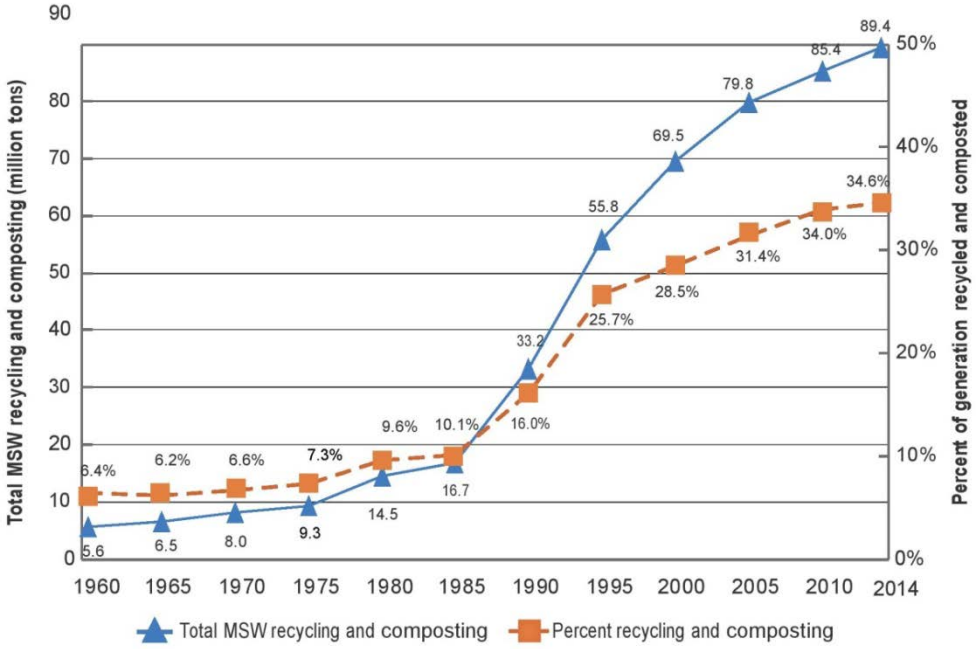


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency used the projected market volumes for the first and fifth years of marketing of the new product to estimate the waste from the disposal of packaging material, accounting for recycling of packaging waste and overall U.S. recycling of MSW, and used product material (cigarette butts), assuming all used product material is disposed of in MSW. As discussed, the estimated waste from packaging disposal and product material following product use would be miniscule compared to the total MSW forecasted to be disposed of in the United States (Confidential Appendix 4).

5.3.2 Disposal of Used RYO Tobacco Product Following Use

Used RYO tobacco products, consisting of cigarette butts[5], are usually disposed of in MSW landfills or as litter. The Agency utilized the historical data for use of RYO tobacco products in the United States to forecast the future use of RYO tobacco products and calculated the projected tobacco packaging waste accordingly (Figures 6 and 7 in Section 5.2.2). Assuming that the entire RYO cigarette is disposed of as MSW, the estimated waste from used RYO tobacco products is a miniscule fraction of a percent of the total 258.46 million tons (234.47 million metric tons; 516,920 million pounds) of projected MSW to be generated in the United States, as shown in the following table (U.S. Environmental Protection Agency, 2016).

Forecast of Waste of Used RYO Tobacco Products as Compared to Total MSW Forecast in the U.S.		
Year	Total U.S. RYO Tobacco (million pounds)[a]	Total U.S. RYO Tobacco Products as a Percent of Total MSW in the U.S.[b]
2016	1.07	0.00027%
First Year (2017)	1.90	0.00049%
Fifth Year (2021)	1.31	0.00034%

[a] Projected first-year and fifth-year pounds of RYO tobacco products: $24.163 \times (year - 2007)^{-1.104}$

[b] $\frac{Total\ RYO\ tobacco\ (million\ pounds)}{258.46\ million\ tons\ \text{(U.S.Environmental Protection Agency,2016)}} \times \frac{ton}{2000\ pounds} \times 100\%$

A related point to consider is the improper disposal of used product. Littered cigarette butts are a notable worldwide environmental concern. A 2009 study found that 65% of cigarettes disposed of in five types of non-residential public locations (recreation sites, bars/restaurants, retail stores, medical/hospital facilities, and a city center) were littered (Action Research, 2009). Adjusting this result for the proportion of time spent outside of the home compared to the time at home (not sleeping or bathing) (U.S. Environmental Protection Agency, 2011), a littering rate of 34% of total used cigarettes was estimated. The environmental effects of cigarette butt litter are summarized as follows (Novotny, et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide... The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes

[5] Cigarette butt is defined in this EA as remaining tobacco filler that is disposed of following use. The cigarette butt may or may not also include a filter, depending on whether the RYO cigarette had one.

> is the main component of cigarette butt waste... Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco; instead, they would compete for market share with existing products. Therefore, a marketing orderfor the new product is not expected to affect the overall level of cigarette butt litter in the United States, but it may displace the level of litter from other RYO products.

5.3.3 Air Emissions from Disposal

Landfill disposal or incineration of the used RYO tobacco products and packaging materials that are disposed of in MSW landfills or incinerated will produce GHGs. According to U.S. EPA, 64.7% of paper and paperboard waste generated in 2014 was recycled, leaving 28.4% disposed of in landfills and 6.9% combusted (U.S. Environmental Protection Agency, 2016).

Methane (CH_4) is a potent GHG that has a global warming potential of 28-36 times greater than CO_2, and has an atmospheric life of about 12 years. Landfills are the third largest source of human-related CH_4emissions in the United States, releasing an estimated 133.1 million metric tons of CO_2-equivalent, accounting for approximately 15.4% of these emissions in 2015 (U.S. Environment Protection Agency, July). The decomposition of landfill waste produces approximately 50% biogenic CO_2 and 50% CH_4, by volume, as well as trace amounts of non-CH_4organic compounds and volatile organic compounds. However, only CH_4generation and emissions are estimated and reported for landfills, a convention set forth by the 2006 Intergovernmental Panel on Climate Change (IPCC) Guidelines (Intergovernmental Panel On Climate change (IPCC), 2017). However, the Clean Air Act requires that all landfills constructed or modified after July 17, 2014 that have a waste capacity of 2.5 million metric tons or more to have landfill gas collection-and-control systems installed. Additionally, all landfills must report GHG emissions to the EPA under 40 CFR 98.

As discussed, the estimated waste from packaging disposal and product material following product use would be miniscule compared to the total MSW forecasted to be disposed of in the United States (Confidential Appendix 4). Therefore, the GHG emitted from the waste associated with the new product is negligible.

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

The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment because the new product is anticipated to be manufactured, used, and disposed of in the same way as other RYO tobacco products, including cigarette tobacco filler. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other tobacco products specifically including cigarette tobacco filler, manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use and disposal following use.

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

The applicant stated that the manufacturing facility is in compliance with all environmental laws applicable in the territory of the Netherlands and it holds any permits required. Therefore, cumulative introduction of materials released into the environment is not expected to exceed what can be introduced to the environment under relevant environmental laws.

As discussed above, the amount of materials anticipated to enter the environment due to the manufacturing and use of the new product are small fractions when compared to that of the projected RYO tobacco products imported from the Netherlands and used in the United States. The Agency does not expect the introduction of the new product to notably affect the current manufacturing waste generated from the production of all RYO tobacco products. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new product occupies a small fraction of the total forecasted MSWs in the United States. Consequently, no new substances or new type of emissions are expected to be released, and therefore no new environmental controls are needed. No new environmental effects are anticipated due to the new product.

8. Use of Resources and Energy

The new product will compete with other currently marketed RYO tobacco fillers that are similar to the new product, other than a change in product quantity with the removal of the 60-leaf booklet of cigarette papers. The applicant also stated that the proposed action will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total RYO market volumes in the United States, the Agency found that the projected market volume of the new product is a small fraction of the total forecasted RYO market volume in 2017 and 2021. The applicant stated that manufacturing the new product would use a miniscule fraction of a percent of the total energy usage at the manufacturing facility (Confidential Appendix 1). Therefore, no more than a negligible net increase of energy use will be expected from the proposed action. Additionally, the applicant stated they have a broad and comprehensive program to address environmental sustainability and are committed to effectively managing its environmental footprint, and the applicant stated that there are no anticipated adverse effects with respect to the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). The applicant also stated that the manufacturing facility complies with applicable Netherlands national legislation implementing CITES.

9. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for manufacturing, use, and disposal following 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 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

following use of tobacco products as the predicate product (Confidential Appendices 1 and 2) and many other similar RYO tobacco products will continue to be marketed.

Alternative B (Proposed actions): There is no substantial environmental effect due to the proposed actions of authorizing the new product (Confidential Appendix 1) and associated manufacture, use, and disposal following use of the new tobacco product.

11. List of Preparers

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment.

Preparers:

William E. Brenner, B.S., Center for Tobacco Products
- Education: B.S. in Biology
- Experience: 3 years in various scientific activities
- Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Gregory G. Gagliano, M.S., Center for Tobacco Products
- Education: M.S. in Environmental Science
- Experience: 34 years in Environmental Toxicology and Risk Assessment
- Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Plant Molecular Biology and Virology
- Experience: 23 years in various scientific activities
- Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA implementation

Reviewers:

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

12. List of Agencies and Persons Consulted

Not applicable.

13. Appendix List

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

14. Confidential Appendix List

Confidential Appendix 1: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products and Energy Usage

Confidential Appendix 2: Comparison of the Current-Year Market Volume for the Predicate Products with Total RYO Tobacco Products Used in the United States

Confidential Appendix 3: Comparison of the First- and Fifth-Year Market Volume Projections for the New Products with Total RYO Tobacco Products Used in the United States

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

15. References

Action Research. (2009). *Littering Behavior in America: Results of a National Study.* Retrieved from Keep America Beautiful: https://www.kab.org/sites/default/files/News%26Info_Research_LitteringBehaviorinAmerica_2009Report_Final.pdf

Intergovernmental Panel On Climate change (IPCC). (2017, January 23). *2006 IPCC Guidelines for National Greenhouse Gas Inventories*. Retrieved from http://www.ipcc-nggip.iges.or.jp/public/2006gl/

National Association of Attorneys General. (1998). *Master Settlement Agreement*. Retrieved from http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf

Novotny, T., Aguinaga Bialous, S., Burt, L., Curtix, C., da Costa, V., Usman Iqtidar, S., . . . d'Espaignet, E. (2015). The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. *Bull World Health Organ, 93*(12), 877-880.

U.S. Department of Health and Human Services. (2006a). *The health consequences of involuntary exposure to tobacco smoke: a report of the Surgeon General.* Atlanta, GA: Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

U.S. Department of Health and Human Services. (2006b). *The health consequences of involuntary exposure to tobacco smoke: a report of the Surgeon General - Secondhand smoke: what it means to you (Consumer Booklet).* Atlanta, GA: Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

U.S. Dept of Treasury Alcohol and Tobacco Tax and Trade Bureau. (2017, March 15). *Tobacco Statistics*. Retrieved from http://www.ttb.gov/tobacco/tobacco-stats.shtml

U.S. Environment Protection Agency. (July, 25 2017). *Landfille Methane Outreach Program (LMOP). Basic Information about Landfill Gas*. Retrieved from https://www.epa.gov/lmop/basic-information-about-landfill-gas

U.S. Environmental Protection Agency. (2011). *Exposure Factors Handbook.*

U.S. Environmental Protection Agency. (2016). *Advancing Sustainable Material Management: Facts and Figures*. Retrieved from https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf

APPENDIX 1

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

STN	Product Name	Product	Pouches per Retail Unit	Retail Units per Shipping Case	Amendments
SE0014067	Samson Halfzware	New	10	18	SE0014080, SE0014244
	Samson Halfzware	Predicate	5	20	

CONFIDENTIAL APPENDIX 1

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

STN	Unit	Current-Year (2016) Market Volume	First-Year Market Volume	Fifth-Year Market Volume
		Predicate Product	New Product	New Product
SE0014067	# of pouches	(b) (4)		
	Metric Tons			
	Cigarette-Equivalent			

The cigarette-equivalent for the new and predicate product is calculated using the following equation.

$$\text{\# of Cigarette-Equivalents} = \#of\ pouches \times \frac{40\ grams}{1\ pouch} \times \frac{0.0353\ oz.}{1\ gram} \times \frac{1\ cigarette}{0.0325\ oz.}$$

The applicant stated that the new RYO tobacco product is intended to comprise approximately (b) (4) % of the manufacturing facility's total energy use in 2016. The manufacturing facility's last reported total use of energy was (b) (4) gigajoules (GJ) in 2015, and first-year and fifth-year energy use forecasts were not included by the applicant. Therefore, an accurate energy use comsumption rate per cigarette-equivalent cannot be determined. The applicant also stated that no energy is generated on site.

CONFIDENTIAL APPENDIX 2

Comparison of the Current-Year Market Volume for the Predicate Product with Total RYO Tobacco Products Used in the United States

The current-year market volume of the predicate product occupying the U.S. market was compared to the use of total RYO tobacco in the United States (Figure 7, and Confidential Appendix 1). The percent of the total RYO tobacco market occupied in the current year of marketing of the predicate product was calculated using the equation below:

$$\text{2016 Market Occupation of Predicate Product (\%)} = \frac{\text{2016 Market Volume (cigarette–equivalent)}}{\text{Use of RYO in the U.S.for 2016 (cigarette–equivalent)}} \times 100\%$$

STN	Year	Use of Total RYO Tobacco in U.S. (Cigarette-Equivalent)[6]	Market Volume of Predicate Product (Cigarette-Equivalent)[7]	Market Occupation of Predicate Product in U.S. (%)
SE00014067	2016	(b) (4)		

[6] See Figure 7.

[7] See Confidential Appendix 1.

CONFIDENTIAL APPENDIX 3

Comparison of the First- and Fifth-Year Market Volume Projections for the New Product with Total RYO Tobacco Products Used in the United States

The first- and fifth-year market volumes of the new product to occupy the U.S. market were determined by comparing the projected market volume of the new product to the forecasted use of total RYO tobacco in the United States (Figure 7, and Confidential Appendix 1). The percent of the total RYO tobacco market occupied in the projected first and fifth year of marketing of the new product was calculated using the equations below:

First Year Market Occupation of New Product (%)

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

Fifth Year Market Occupation of New Product (%)

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

STN	Year	Forecasted Use of Total RYO Tobacco in the U.S. (Cigarette-Equivalent)[8]	Projected Market Volume of New Product (Cigarette-Equivalent)[9]	Projected Market Occupation of New Product in the U.S. (%)
SE0014067	First	(b) (4)		
	Fifth			

[8] See Figure 7.

[9] See Confidential Appendix 1.

CONFIDENTIAL APPENDIX 4

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

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

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

$$B_i = \frac{E_i}{F_i} \times G_i \times Z$$

$$C_i = \frac{E_i}{F_i \times H_i} \times I_i \times Z$$

$$D_i = E_i \times J_i \times Z$$

A_i: Projected paper and waste generation of the products (metric tons)
B_i: Projected retail plastic wrap waste generation of the products (metric tons)
C_i: Projected shipping case waste generation of the products (metric tons)
D_i: Projected pouch waste of the products (metric tons)
E_i: Projected market volume of the products (# individual pouches)
F_i: Number of pouches per retail wrap
G_i: Weight of empty retail wrap (grams)
H_i: Number of retail wraps per shipping case
I_i: Weight of empty shipping case (grams)
J_i: Weight of each pouch (grams)
Z: 1.0 x 10^{-6} metric tons/gram

	STN	Weight of Each Pouch K_i	Weight of Shipping Case I_i	# of Retail Wraps per Shipping case H_i	Weight of Retail Wrap G_i	Pouches Per Retail Wrap F_i	Market Volume (# of Pouches) E_i	Total Pouch Waste D_i	Total Shipping Case Waste C_i	Total Retail Wrap Waste B_i	Total Waste A_i
First Year	SE0014067	(b) (4)									
	First-Year Total Mixed Waste for New Product (metric tons)										(b) (4)

	STN	Weight	Weight	# of Retail	Weight	Pouches Per	Market Volume (#	Total	Total	Total	Total

		of Each Pouch K_i	of Shipping Case I_i	Wraps per Shipping case H_i	of Retail Wrap G_i	Retail Wrap F_i	of Pouches) E_i	Pouch Waste D_i	Shipping Case Waste C_i	Retail Wrap Waste B_i	Waste A_i
Fifth Year	SE0014067	(b) (4)									
	Fifth-Year Total Mixed Waste for New Product (metric tons)										(b) (4)

Paper and Waste. The shipping case is disposed of, recycled, or both, as paper waste; the remaining waste is disposed of as waste or litter. Estimation of generated total paper and waste for the new and predicate products is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper products at 64.7% in the United States, according to U.S. EPA (U.S. Environmental Protection Agency, 2016). Therefore, if 100% of the remaining waste and 35.3% of the shipping cases are disposed of as waste based on the 2014 waste generation data in the United States, the estimated cumulative paper and cardboard waste will be (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new product.[10]

If the entire packaging paper and remaining waste are disposed of as waste, which is a more conservative approach, the projected cumulative paper and remaining waste in the first and fifth years of marketing the new and predicate products is (b) (4) metric tons and (b) (4) metric tons, respectively. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.

(b) (4)