

**Environmental Assessment for a Marketing Order for “Bugler Cigarette
Rolling Papers, 50ct.”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

January 31, 2018

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

1. Name of Applicant

Scandinavian Tobacco Group, Lane Holding, Inc.

2. Address

2280 Mountain Industrial Blvd.
Tucker, GA 30084-8540

3. Manufacturer

Scandinavian Tobacco Group, Lane Holdings, Ltd.

4. Description of the Proposed Action

The 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 new roll-your-own (RYO) cigarette paper into interstate commerce. This authorization is based on the finding that this new product is substantially equivalent to the predicate product that was on the market as of February 15, 2007. The applicant intends to continue marketing the new and products simultaneously after the new product is authorized.

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 Holdings, Ltd. wishes to introduce the new tobacco product (as described in Section 4.3.2) into interstate commerce for commercial distribution in the United States. The applicant claims that the new and predicate products are identical except for changes in the product names. After considering the SE Report, the Agency shall issue an order under the provisions of section 905(j) and 910 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), filtered cigarette tubes

4.3.2 Product Name and Original STN

The name of the new product is listed below, along with the 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
SE0011198	Bugler Cigarette Rolling Papers, 50 ct.	Bugler Gummed Cigarette Papers, 115 ct.

4.3.3 Description of the Product Package

The new product is a RYO cigarette paper. There are 50 papers enclosed in a paperboard booklet cover and 25 boxes are contained in a box wrapped with polyolefin (50% polypropylene, 50% polyethylene).

4.3.4 Location of Manufacturing

2280 Mountain Industrial Blvd.
Tucker, GA 30084-8540

4.3.5 Location of Use

Scandinavian Tobacco Group, Lane Holdings, Ltd. intends to distribute and sell the new tobacco product to U.S. consumers nationwide.

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. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of 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 only differences between the new and predicate products are the number of papers per booklet and the product names.

5. Potential Environmental Impacts Due to the Proposed Action

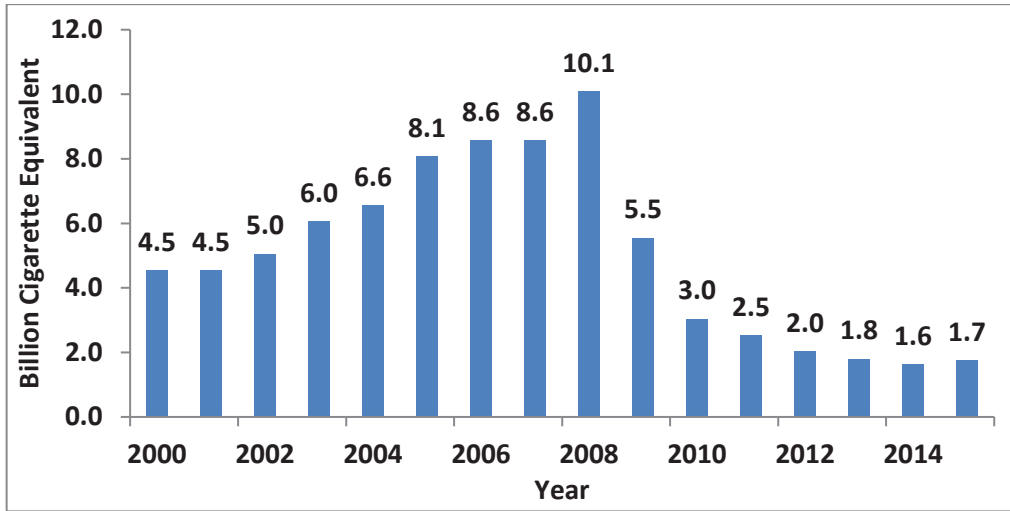
5.1. Potential Environmental Impacts Due to Manufacturing the New Product

Based on information collected by the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB)¹, there was a gradual linear increase in the manufacturing of RYO tobacco products in the United States from 4.5 billion cigarette equivalents² in 2000 to 10.1 billion cigarette equivalents in 2008 (see Figure 2). This was followed by a sharp decline in manufacturing to 1.7 billion cigarette equivalents in 2015.

¹ U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 30, 2016.

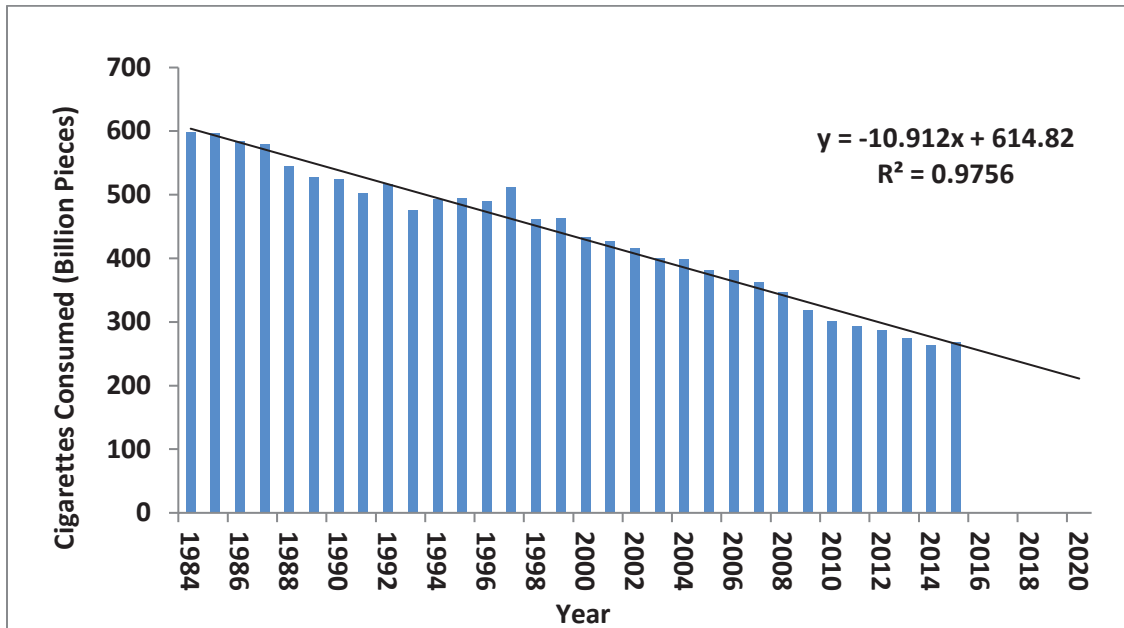
² The calculated cigarette equivalence data is based on the conversion rate in the Master Settlement Agreement (available at http://www.naag.org/naag/about_naag/naag-center-for-tobacco-and-public-health/master-settlement-agreement.php).

Figure 1. Manufactured RYO in the United States 2000 – 2015



To evaluate the environmental impact of the proposed action due to use of the new product, historical data³ regarding use of cigarettes from 1984 to 2015 was used to forecast the total number of cigarettes used for the period from 2017 to 2021 (Figure 2). This was achieved by using one best-fit linear trend line with the R^2 value of 0.9756. Accordingly, the forecasted number of cigarettes used in the United States are estimated to be 231.85 billion cigarettes in 2016 and 205.21 billion cigarettes in 2020.

Figure 2. Projected Use of Cigarette Tobacco Products in the United States



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, 2016.

Introduction from manufacturing the new product in the proposed action. The Agency anticipates the waste generated as a result of manufacturing the new product will be released to the environment, transferred to publicly owned treatment works (POTW), 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 cigarette rolling papers manufactured 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 cigarette rolling papers in the United States.

The applicant claims that the manufacturing operation abides by all federal, state and local environmental laws, regulations and requirements which are applicable to their facility. Therefore, cumulative introduction is expected not to exceed what is allowed to be introduced to the environment under relevant environmental laws. The applicant claims the only differences between the new and predicate products are the number of papers per booklet and the product names. They claim the composition and design 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.

Consequently, the environmental effects of the materials released due to the manufacturing of the new product 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 harm and no substantial effects are anticipated.

5.2. Potential Environmental Impacts Due to Use the New Product

Data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistics reports showed a gradual linear increase in the use of RYO tobacco in the United States from 4.7 billion cigarette equivalents to 11 billion cigarette equivalents during the years 2000 to 2008, respectively (Figure 1).⁴ 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.

As noted, the only differences between the new and predicate products are product names and product quantity, according to the SE Reports. During use, the combustion products from the new product will be released in the same manner as the combustion products from the predicate product and other RYO cigarette rolling papers.

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 March 30, 2016.

Also, to evaluate the environmental impact of the proposed action due to use of the new product, historical data regarding consumption of all cigarette products in the United States from 2005 to 2015 was used. This was achieved by using one best-fit power trend line with the R² value of 0.9756 for the total number of cigarettes used in the United States. Accordingly, the forecasted number of all cigarettes to be used in the United States are estimated to be 254,724 million pieces and 211,076 million pieces in 2016 and 2020, respectively (Appendix 2).

Essentially, the Agency anticipates no new substances to be released into the environment as a result of use of the new product, in comparison to the substances released by the predicate product already on the market and all other RYO filtered cigarette tubes.

5.3 Potential Environmental Impacts Due to Disposal of the New Product

The waste that is generated following use of the new and predicate products consists of the disposed packaging materials along with the discarded ash, the spent cigarette (cigarette butts and unused cigarette rolling papers). The butts and unused papers could be thrown away as trash in MSW landfills or as litter. The paper board retail box material could also be thrown away as trash in MSW landfills or as litter, but is biodegradable, and could also be recycled.⁵

5.3.1 Disposal of packaging material

As noted above, disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. According to EPA, in 2013 the amount of waste generated in the United States was approximately 254 million tons and approximately 87 million tons of this material was recycled and composted, equivalent to a 34.3 percent recycling rate (Figure 2 and Figure 3). Additional EPA information indicated a recovery rate for newspaper/mechanical papers of 67 percent that represents 5.7 million tons. On average, 4.40 pounds per person per day of waste was generated, of which 1.51 pounds was recycled and composted in the United States in 2013.⁶

Projected packaging materials waste (cardboard, plastic and booklet covers) for the new and predicate products is discussed in Confidential Appendix 3. The estimated waste (metric tons) for the first and fifth years after marketing authorization of the new product is presented for the predicate product using data from 2006 and 2011. The amount of waste due to disposal of the new product is projected to be less than that for the predicate product.

⁵ Novotny TE and Zhao F. Consumption and production waste: Another externality of tobacco use. *Tobacco Control* 1999; 8:75-80.

⁶ EPA. Sustainable Materials Management: Facts and Figures. Available at: <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures> (accessed August 11, 2016).

Figure 2. MSW Generation Rates in the United States, 1960 – 2013

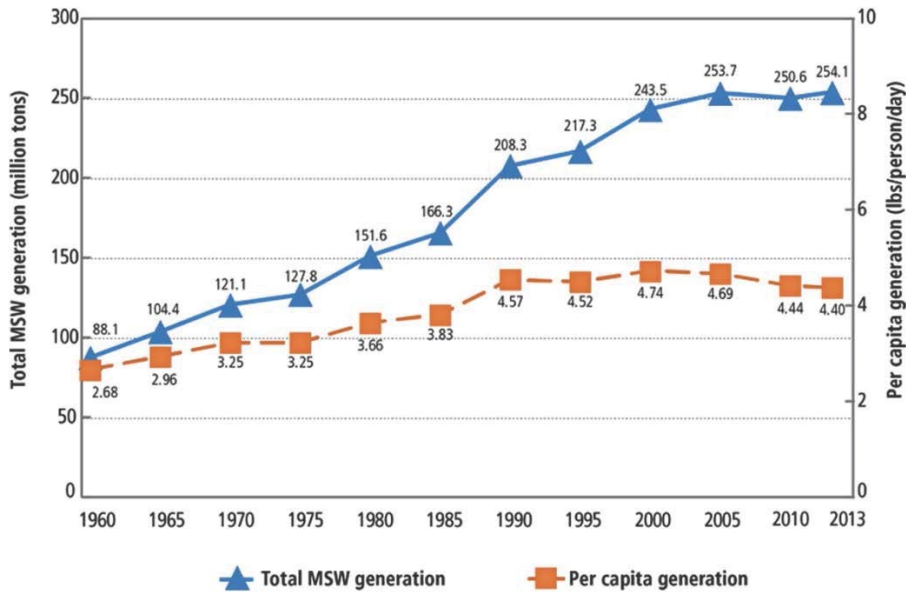


Figure reproduced from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 3. MSW Recycling Rates in the United States, 1960 – 2013

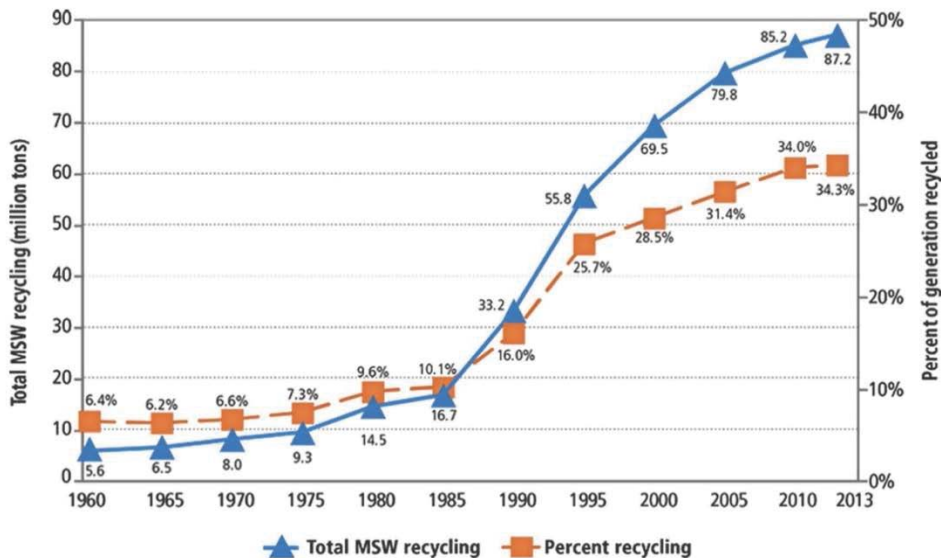


Figure reproduced from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency assumes that all packaging material of the new product will be disposed of as MSW. However, paper products used in the packaging are more likely to be recycled than other types of

MSW. According to the information presented in the SE Report, the new and predicate products are packaged using the same cardboard material for the booklet cover and retail box. To determine the amount of waste from disposal of cardboard packaging material, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products (Confidential Appendix 1). The calculated cumulative waste of the cardboard packaging material is miniscule compared to all MSW generated and at least a portion of the packaging material waste is likely to be recycled. Furthermore, the anticipated release of new substances into the environment as a result of disposal of the new product's packaging is miniscule compared to that of all tobacco products already on the market. The Agency anticipates no new construction of MSW landfills as a result of disposal of the new product's cardboard packaging material.

5.3.2 Disposal of cigarette rolling papers following use

Data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistics reports showed a gradual linear decrease in the total cigarettes used in the United States from 599 billion cigarette-equivalents to 267 billion cigarette-equivalents during the years 1984 to 2015, respectively (see Appendix 2). The Agency believes that the disposal of the new product will be the same as the disposal conditions of other RYO filtered cigarette rolling paper products that are currently being marketed. After using the new product, users may discard the remaining unused paper and ashes or cigarette butts as MSW or as litter.

To determine the amount of waste from disposal of used paper, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products (Confidential Appendix 3). The calculated waste for the first and fifth year, based on projections, shows that the waste from the cardboard packaging is miniscule compared to all MSW generated in the United States in 2013. The Agency anticipates no new construction of MSW landfills as a result of disposal of this packaging.

Furthermore, the anticipated release of substances into the environment as a result of disposal of the new product is miniscule compared to that of all tobacco products that are already on the market. The Agency anticipates no new substances will be released into the environment as a result of disposal of the new product following use because, as the applicant states, the only differences between the new and predicate products are the number of papers per booklet and the product names.

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 only differences between the new and predicate products are the number of papers per booklet and the product names. The new product is anticipated to be manufactured the same way as other products in the same facility. Therefore, no new types of materials are anticipated to be emitted since the new product will be made using the same materials and processes as the predicate product.

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

The applicant stated that the manufacturing operation abides by all federal, state, and local environmental regulations and requirements that are applicable to their facility. 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 product 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 harm and no substantial effects are anticipated.

8. Use of Resources and Energy

The applicant stated that the paper used to manufacture the new product is produced from sustainable and renewable resources in accordance with the Portuguese, Spanish, and EU standards. These standards require that the applicant use raw materials from sustainable and renewable sources that do not impact critical habitats or endangered species.

9. Environmental Compliance

The Applicant has provided certification that they comply with ISO 9001:2008 and ISO 14001:2004. These are certifications of compliance with general systems management and environmental systems management; respectively⁷.

10. Mitigation

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

11. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not allow the marketing of the new tobacco product in the United States. The environmental impact of this action would not change the existing condition of the manufacturing, use, and disposal following use of tobacco products as the predicate product, as well as many other RYO cigarette rolling 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 product and the associated manufacture, use, and disposal from use of the new tobacco product.

⁷ ISO 14001:2004 was revised in 2015.

12. List of Preparers:

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:

James F. Hobson, Ph.D., DABT

Education: M.S. Toxicology, Ph.D. Biology and Environmental Toxicology

Experience: 38 years in Toxicology and Environmental Toxicology Risk Assessment

Expertise: Regulatory toxicology, environmental toxicology, NEPA and risk assessment

Reviewers:

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

Education: M.S. in Environmental Science

Experience: 33 years in environmental toxicology and risk assessment

Expertise: Environmental risk assessment, regulatory environmental toxicology

Hoshing Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: 8 years in NEPA practice

Expertise: Waste water treatment, environmental impact analysis

12. List of Agencies and Persons Consulted

Not Applicable

13. Appendix List

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 Environmental Assessment (EA)

14. Confidential Appendix List

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

Confidential Appendix 2: The First- and Fifth-Year Projections of Cardboard Waste of Packaging Materials Associated with Marketing the New and Predicate Products

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

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 Environmental Assessment (EA)

STN	New Product	Predicate Product	Amendments
SE0011198	Bugler Cigarette Rolling Papers, 50 ct.	Bugler Gummed Cigarette Papers, 115 ct.	SE0013416

Confidential Appendix 1

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

	Product Name	Projected Market Volume First Year (# booklets)	Projected Market Volume Fifth Year (# booklets)	Projected Market Volume First Year (metric tons)	Projected Market Volume Fifth Year (metric tons)
SE0011198	Bugler Cigarette Rolling Papers, 50 ct.	(b) (4)			
GF1300846	Bugler Gummed Cigarette Papers, 115 ct.				

Confidential Appendix 2

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

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 and product materials waste (in metric tons) that would be generated from disposal after use of the new and predicate products in 2016 and 2020. Projected waste generation for each new product is the summation of the projected cardboard retail boxes, cardboard of the cartons, foil inner liner, plastic wrap of retail boxes, and cigarette butts of that new product.

Estimation of the Total waste of Packing Materials (e.g. Cardboard, Booklet Covers) based on First and Fifth Year of Production

$\sum_{i=1}^2 A_i = \sum_{i=1}^2 (B_i + C_i + D_i + E_i + F_i)$ $B_i = \frac{G_i}{H_i} \times I \times Z$ $C_i = \frac{G_i}{H_i \times J_i} \times K \times Z$ $D_i = \frac{G_i}{H_i \times J_i \times L_i} \times M \times Z$ $E_i = G_i \times N_i \times Z$ $F_i = \frac{G_i \times P_i \times Q_i}{100} \times Z$ $P_i = \frac{27}{O_i} \times 100$	<p>A_i: Projected paper waste generation of the new and predicate products (metric tons)</p> <p>B_i: Projected booklet cover waste generation of the new and predicate products (metric tons)</p> <p>C_i: Projected retail cardboard box waste generation of the new and predicate products (metric tons)</p> <p>D_i: Projected shipping case waste generation of the new and predicate products (metric tons)</p> <p>E_i: Projected used tip waste generation of the new and predicate products (metric tons)</p> <p>F_i: Projected cigarette butt⁸ waste of the new and predicate products (metric tons)</p> <p>G_i: Projected market volume of the new and predicate products (# individual leaves of rolling paper)</p> <p>H_i: Number of individual leaves of rolling papers per booklet</p> <p>I: Weight of booklet cover (grams)</p> <p>J_i: Number of booklets per retail cardboard box</p> <p>K: Weight of empty retail cardboard box (grams)</p> <p>L_i: Number of retail cardboard boxes per shipping case</p> <p>M: Weight of empty shipping case (grams)</p> <p>N_i: Weight of tip (grams)</p> <p>O_i: Length of rolling paper (millimeters)</p> <p>P_i: Cigarette Butt Ratio (%)⁹</p> <p>Q_i: Weight of rolling paper (milligrams per leaf)</p>
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⁸ Cigarette butt in this EA is defined as cigarette rolling paper containing remainder tobacco that is disposed of following use.

⁹ ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed of as solid waste following use.

	Z: 1.0×10^{-6} metric tons/gram
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SE0011198	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
First Year	38	0.00	0.00	0.000	0.00	25	11.80	25	1.4	50	(b) (4)						
Fifth Year	38	0.00	0.00	0.000	0.00	25	11.80	25	1.4	50							
GF1300846																	
First Year	38	0.00	0.00	0.00	0.00		15.28	24	2.4	115							
Fifth Year	38	0.00	0.00	0.00	0.00		15.28	24	2.4	115							

Paper and Packaging Waste. Estimation for generated cumulative paper waste is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new product. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper products at 67% in the United States according to US EPA¹⁰. Therefore, if 33% of the cumulative paper waste is disposed of in MSW, based on the 2013 waste generation data for the United States, the estimated cumulative paper waste will be (b) (4) metric tons in the first year and the (b) (4) metric tons in the fifth year of marketing the products. The estimated cumulative paper waste that would be disposed of in MSW for the predicate product is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new product. These values are negligible fractions of the 254 million tons (230 million metric tons) of total waste reported in the United States in 2013.

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 percent of the market volumes of the new product projected to occupy the U.S. RYO cigarette market in the first and fifth years of marketing were determined by comparing the projected market volume of the new product to the forecasted use of total RYO tobacco in the United States. The percent of the total RYO cigarette market projected to be occupied in the first and fifth year of marketing of the new product was calculated using the equations below¹¹:

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

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

Percentage of the Projected Total Cigarette Market in the United States Occupied by the New and Predicate Products in the First- and Fifth-Year of Marketing the New Product

SE0011198	Forecasted RYO Used in the U.S. (Metric Tons)	Projected Market Volume for New and Predicate Products (Metric Tons)	Percent of Total RYO Use in the U.S.
First Year	1,334	(b) (4)	
Fifth Year	1,120		

The projected market volume for the new product is (b) (4) and (b) (4) metric tons in the first year and fifth year of marketing the new product, respectively. Compared to the volume for the total number of RYO cigarette products projected to be used in the United States the first- and fifth-year market volumes of the new product may occupy (b) (4) and (b) (4) of the total RYO cigarette market in the United States in the first and fifth years of marketing the new product, respectively (see section 5.1.1).

¹¹ Each individual leaf of rolling paper is anticipated to be used in making a single cigarette unit. Therefore, one leaf of rolling paper is equal to one cigarette-equivalent.