

**Environmental Assessment for a Marketing Order for Roll-Your-Own
Filtered Cigarette Tube “Hot Rod Regular King Size 100 Count”
Manufactured by Midwest Tobacco Tube, Inc.**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

October 10, 2017

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This environmental assessment (EA) is for the market authorization of a roll-your-own (RYO) filtered cigarette tube manufactured by Midwest Tobacco Tube, Inc. 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 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

Midwest Tobacco Tube, Inc.

2. Address of Applicant

10825 Medallion Road
Evendale, Ohio 45241

3. Manufacturer

10825 Medallion Drive
Cincinnati, Ohio 45241

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 new roll-your-own (RYO) tobacco filtered cigarette tubes into interstate commerce. This authorization is based on the finding that the new product is substantially equivalent to the predicate product that was commercially marketed in the United States as of February 15, 2007. The applicant intends to market the new and predicate products simultaneously after receiving a marketing order for the new product.

4.1. Requested Action

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

4.2. Need for Action

Midwest Tobacco Tube, Inc. submitted a substantial equivalence (SE) report, SE0013742, seeking a marketing order for the introduction of the new product (as described in Section 4.3 below) into interstate commerce for distribution in the United States. The applicant claims that the new product differs from the predicate product in product quantity, but the new product does not raise different questions of public health (sec. 910(a)(3)(A)(ii)). In addition, the applicant claims that the new and predicate products have identical product and packaging composition. After considering the SE Report, the Agency shall issue a marketing 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 Subject of the Proposed Action

4.3.1. Type of Tobacco Product

RYO filtered cigarette tubes

4.3.2. Product Name and I 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.

Table 1 Name of the New Product and the Predicate Product

STN	New Product	Predicate Product
SE0013742	Hot Rod Regular King Size 100 Count	Hot Rod Regular King Size 200 Count

4.3.3. Description of the Product Package

The packaging materials of the finished new product are identical to those of the predicate product. The product packaging components of both products consist of a cardboard retail box in which the filtered cigarette tubes are contained; however, the new product contains less filtered cigarette tubes per box than the predicate product and therefore, the dimensions of the products' package are different. Details of the package components and weights of each packaging component for the new product are described in Confidential Appendix 2.

4.3.4. Location of Manufacturing

The manufacturer, Midwest Tobacco Tubes, Inc. is located at 10825 Medallion Drive, Cincinnati, OH (Figure 1).

Figure 1. Location of the Manufacturer¹



¹ Manufacturer location via Google Map. Accessed September 14, 2017

4.3.5. Location of Use

Midwest Tobacco Tubes, Inc. intends to distribute and sell the new tobacco product to consumers in the United States.

4.3.6. Location of Disposal

The used and unused filtered cigarette tubes will be disposed of in municipal solid waste (MSW) landfills/incinerators or as litter, in the same manner as any other marketed filtered cigarette tubes. Following use, the packaging materials would either enter the recycling stream or be disposed of in MSW landfills or as litter. The geographic distribution of waste from disposal after use should correspond to the pattern of product use.

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

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

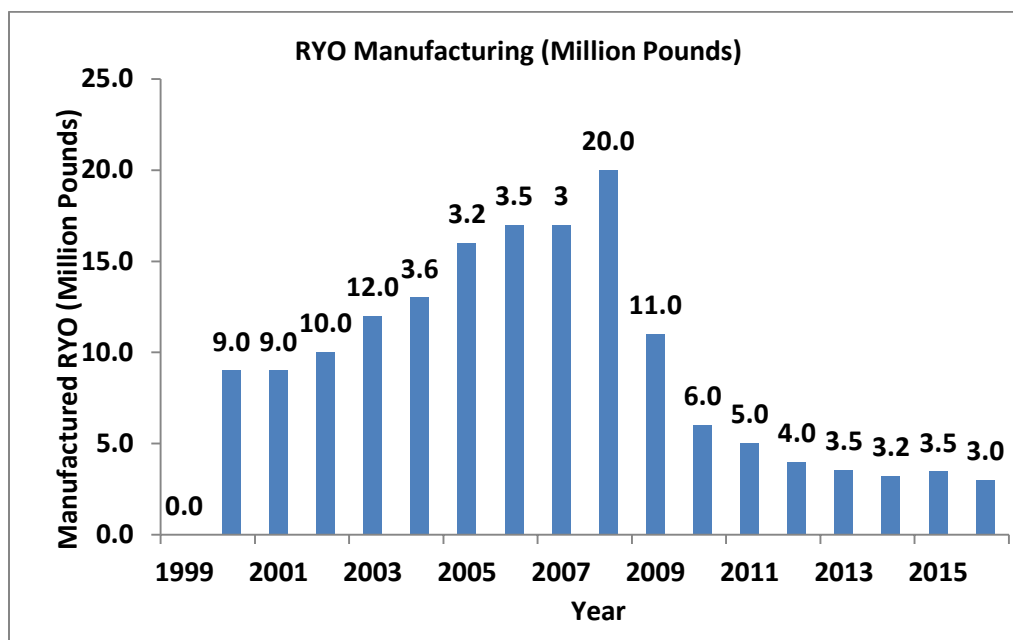
5. Potential Environmental Impacts Due to the Proposed Action

5.1. Potential Environmental Impacts Due to Manufacturing the New Product

There is limited information on the extent of manufacturing filtered cigarette tubes for RYO tobacco, or for other purposes, in the United States. However, statistical data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) shows a gradual linear increase in the manufacture of RYO tobacco in the United States from 2000 to 2008 from 9 million pounds (4.5 billion cigarette-equivalents) to 20 million pounds (10.1 billion cigarette-equivalents), respectively (Figure 2).² This was followed by a sharp decline in RYO tobacco use to 4 million pounds (2 billion cigarette-equivalents) in 2012 and to 3 million pounds (1.5 billion cigarette-equivalents) in 2016.

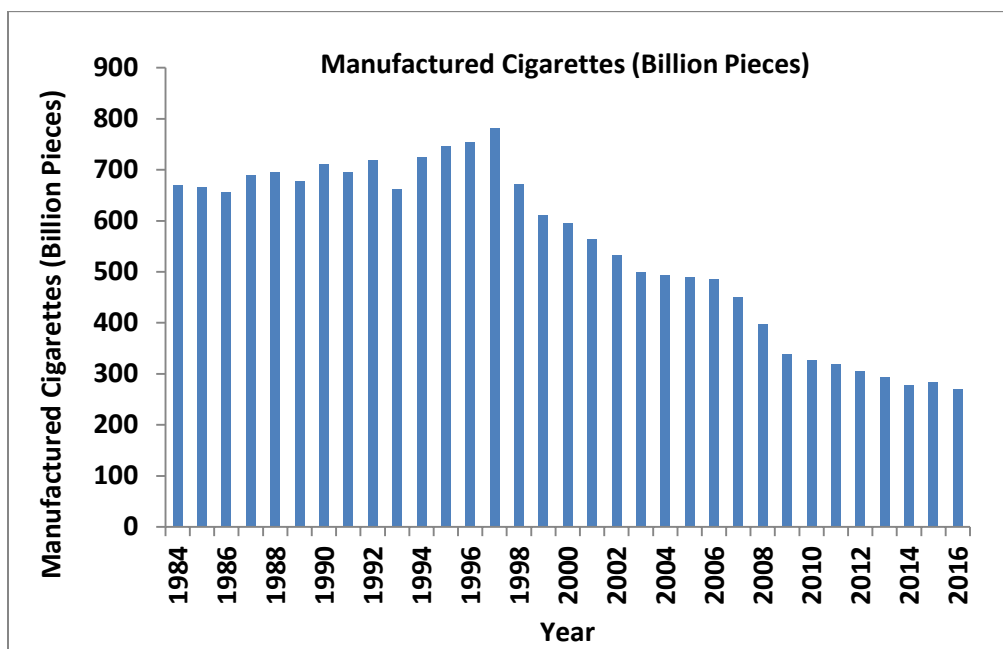
² Billion cigarette equivalents value is calculated based on the assumption that approximately 0.9 grams of tobacco is used per cigarette. Billion cigarette equivalents =
$$\frac{(X \text{ million pounds tobacco} \times 10^6) \times (\frac{453.59 \text{ g}}{0.9 \text{ g}})}{10^9}$$

Figure 2. Total RYO Manufactured in the United States, 1999-2016



Likewise, the TTB statistical data shows a continual decline in manufacturing cigarettes in the United States from 780.6 billion cigarettes (1,545.56 million pound) in 1997 to 270.2 billion cigarettes (535.08 million pound) in 2016 (Figure 3).³

Figure 3. Total Cigarettes Manufactured in the United States, 1984-2016



³ Million pound of cigarettes value is calculated based on the assumption that approximately 0.9 grams of tobacco

is used per cigarette. Million pound cigarettes =
$$\frac{(X \text{ billion cigarette pieces} \times 10^9) \times \left(\frac{0.9 \text{ g}}{453.59 \text{ g}}\right)}{10^6}$$

A search of EPA's Toxic Release Inventory (TRI) database showed a decrease in emissions associated with manufacturing of all tobacco products in 2016 as compared with emissions in 2015 (Table 2). However, the amount of nicotine and nicotine salts released to the land or transferred to publicly owned treatment works (POTW) or an off-site location increased in 2016 as compared with that in 2015. The search did not identify emissions associated with Midwest Tobacco manufacturing facility in Ohio.

Table 2 Emissions Associated with Manufacturing Cigarettes and RYO Tobacco Products in the United States⁴

Chemical Name	Air Release (Pound)		Land Release (Pound)		Water Release (Pound)		POTW Transfer (Pound)	
	2015	2016	2015	2016	2015	2016	2015	2016
Ammonia	474,614	406,454	0	1	220	186	19,550	18,056
Nicotine & Nicotine Salts	279,526	253,435	72,869	74,322	279	30	83,384	108,051

The Agency anticipates the waste generated as a result of manufacturing the new product will be released to the environment, transferred to 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 filtered cigarette tubes manufactured in the United States. The new product is anticipated to compete with other filtered cigarette tubes on the market. The Agency does not expect the introduction of the new product to notably affect the current manufacturing waste generated from the production of all filtered cigarette tubes in the United States.

The applicant claims that the manufacturing operation abides by all federal, state and local environmental laws which are applicable to their facility. The applicant claims that the new and predicate products are identical in the type and quantity of ingredients as well as product design. 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 products. In addition, the applicant notes that the manufacturing facility will not expand or relocate the current facility nor it will exceed previous production; therefore, the Agency does not anticipate the emissions from the manufacturing facility to be above what has been released in the past and no new control practices for air, water and solid waste disposal are needed.

Furthermore, there would be no additional resources with new control measures for air emissions, water discharge, or solid waste disposal are needed for manufacturing the new product. In addition, there would be no anticipated net increase in energy use or change in greenhouse gas emissions expected from manufacturing.

According to the SE Report, the raw materials used in the new and predicate products would be from renewable and sustainable resources that would not impact critical habitats or endangered

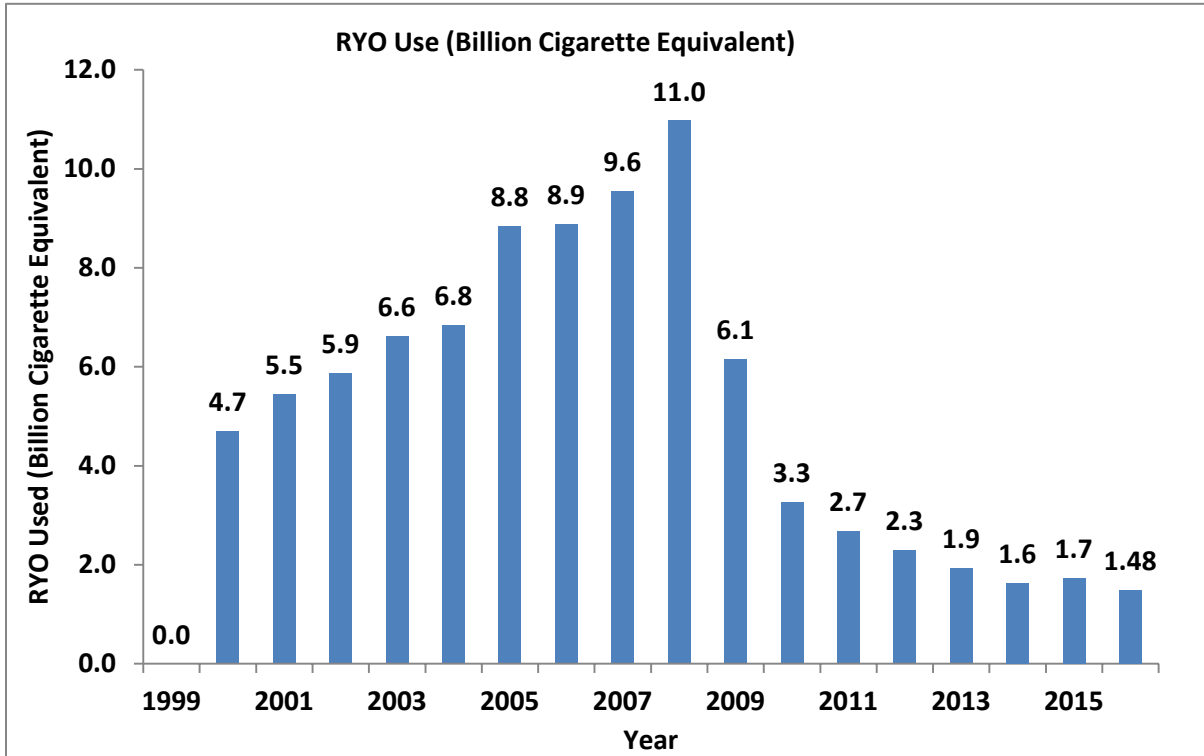
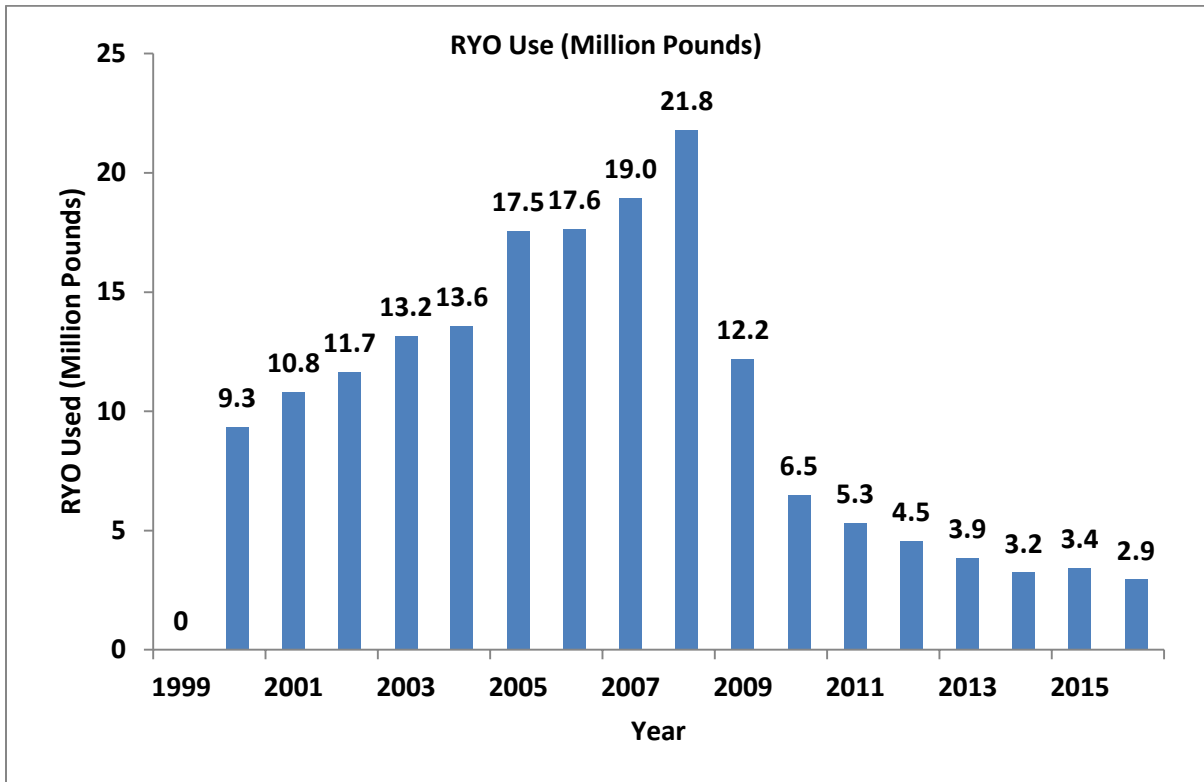
⁴ EPA TRI data available at: http://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Accessed September 18, 2017

species. The applicant purchases raw materials from companies that make their products from sustainable/renewable resources and are protected by the Brazilian Forestry Sector Association and other world organizations.

5.2. Potential Environmental Impacts Due to Use of the New Product

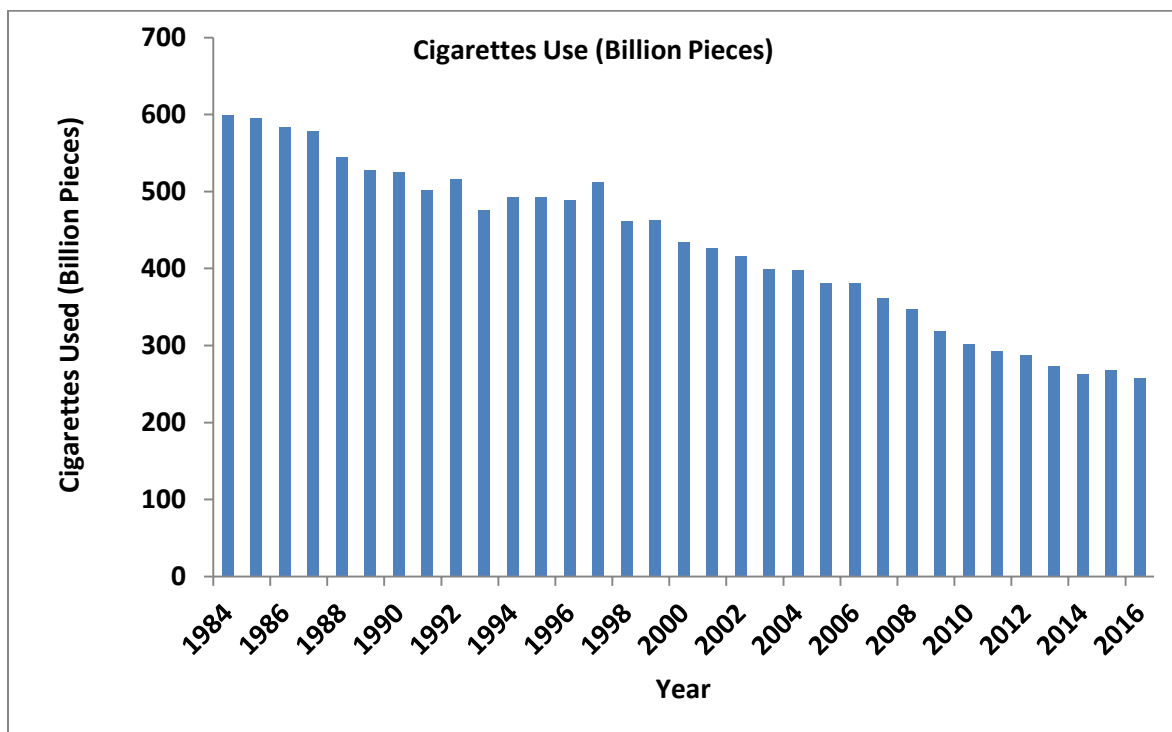
There is limited information on the extent of use of filtered cigarette tubes for RYO tobacco, or for other purposes, in the United States. However, statistical data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) shows a gradual linear increase in the use of RYO tobacco in the United States from 2000 to 2008 from 9.3 million pounds (4.7 billion cigarette-equivalents) to 21.8 million pounds (11 billion cigarette-equivalents), respectively (Figure 4). This was followed by a sharp decline in RYO tobacco use to 6.5 million pounds (3.3 billion cigarette-equivalents) in 2010 and to 2.9 million pounds (1.5 billion cigarette-equivalents) in 2016.

Figure 4. Use of RYO in the United States, 1999 – 2016



The TTB statistical data also shows a continual decrease in use of cigarettes in the United States from 1997 to 2016 from 512 billion cigarettes (1,1013.81 million pounds) to 257 billion cigarettes (509.83 million pounds), respectively (Figure 5).

Figure 5. Use of Cigarettes in the United States, 1984 – 2016

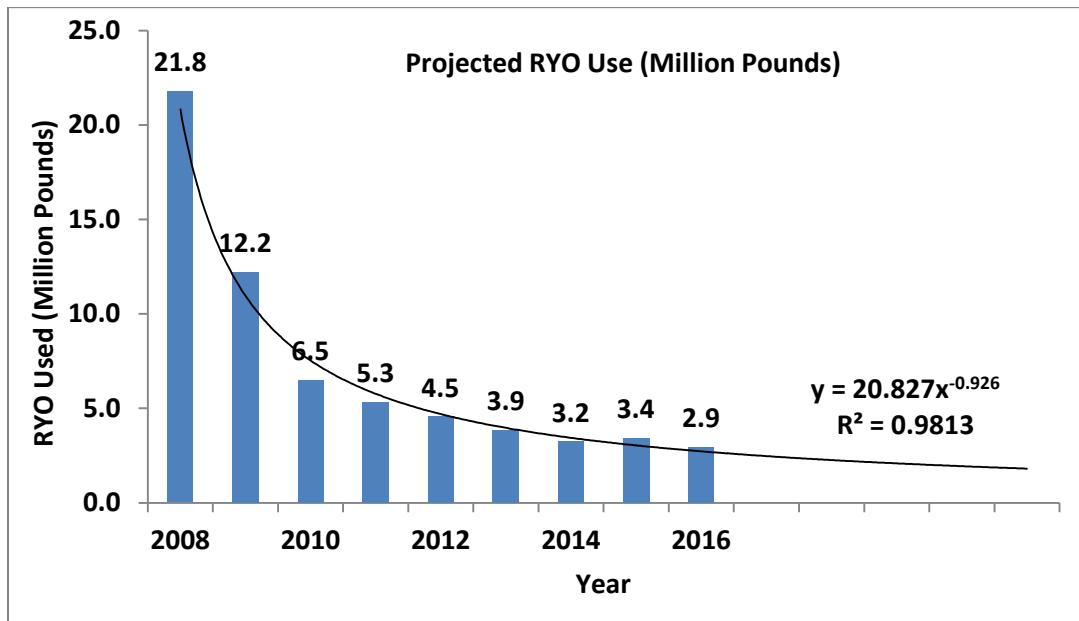


To evaluate the environmental impact of the proposed action due to use of the new product, historical data regarding total use of similar combustible products (i.e. RYO and cigarettes) from 2008 to 2016 was employed to mathematically estimate the forecast of the total used amount of these products in the United States.⁵ Using the one best-fit trend line with R^2 value of 0.9813, the forecasted number of RYO tobacco that will be used in the United States is estimated to be 2.47 million pounds (1.24 billion cigarette-equivalents) in 2017 and 2.26 million pounds (1.14 billion cigarette equivalents) and 1.7 million pounds (0.85 billion cigarette-equivalents) in the first year and fifth year, respectively, of issuance of marketing authorization (Figure 6 and Table 2).⁶

⁵ The forecast trend line is extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed September 15, 2017.

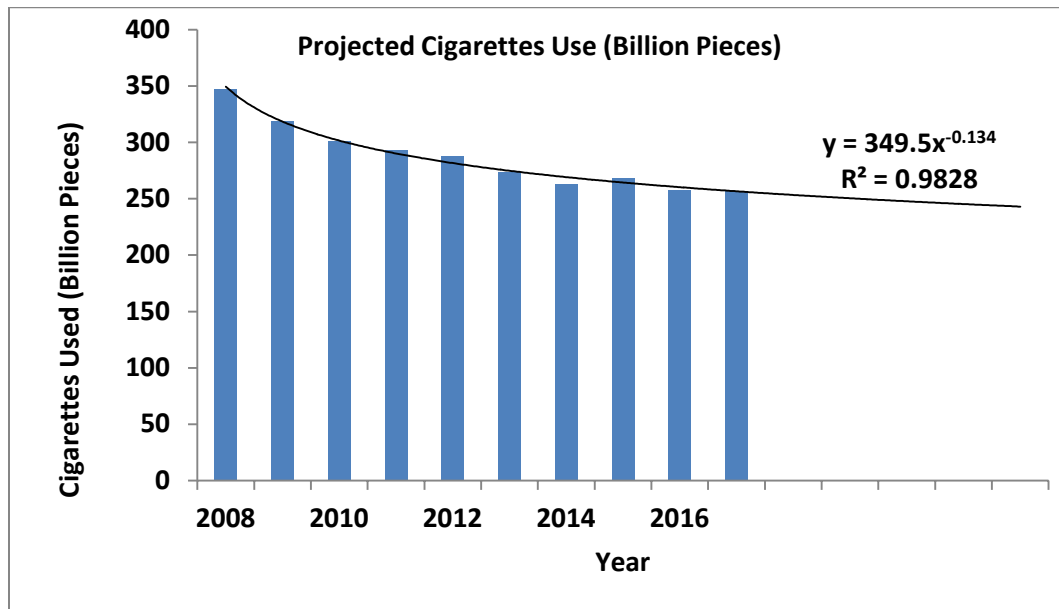
⁶ Projected first-year and fifth-year million pounds of RYO tobacco products: $20.827 \times (\text{year} - 2007)^{-0.926}$

Figure 6. Forecasted Use of RYO Tobacco Products in the United States, 2008-2016



Using same approach with the best-fit power trend line with R^2 value of 0.983, the forecasted number of cigarettes that will be used in the United States is estimated to be 256.73 billion cigarettes (508.31 million pounds) in 2017 and 253.47 billion cigarettes (501.88 million pounds) and 243.15 billion (281.45 million pounds) in the first year and fifth year, respectively, of marketing the new product (Figure 7 and Table 2).⁷

Figure 7. Forecasted Use of Cigarettes in the United States, 2008-2016



⁷ Projected first-year and fifth-year billion pieces of cigarettes = $349.5 \times (\text{year} - 2007)^{-0.134}$

Table 2. Summary of Projected use of Cigarettes and RYO in the United States in the First Year and Fifth Year of Marketing the New Product						
Year	RYO			Cigarettes		
	Billion Cigarette-Equivalents	Million Pounds	Metric Tons	Billion Pieces	Million Pounds	Metric Tons
Current Year (2017)	1.24	2.47	1,120	256.73	508.33	230,574
First Year (2018)	1.14	2.26	1,026	253.47	501.88	227,648
Fifth Year (2022)	0.85	1.7	770	243.15	281.45	218,380

The applicant intends to market both new and predicate products after receiving a marketing order for the new product. 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 (CO₂), 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 and other marketed RYO injector tubes. As noted, the only differences between the new and predicate products are in product quantity and weight of packaging material. Additionally, because (i) the new product will compete with other currently marketed RYO products; and (ii) the projected market volume of the new product is miniscule relative to the overall U.S. RYO and cigarette tobacco market (Confidential Appendix 1), no net addition of greenhouse gas (GHG) emissions is anticipated.

5.3. Potential Environmental Impacts Due to Disposal of the New 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. According to the U.S. Environmental Protection Agency (U.S. EPA), approximately 258.46 million tons of waste was generated in the United States in 2014, and approximately 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 8 and Figure 9). Paper and paperboard accounted 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%), of which

39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW, 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 of waste was generated per person in the United States, of which 2.1 pounds was recycled, composted, or combusted for energy recovery (U.S. EPA, 2016).

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

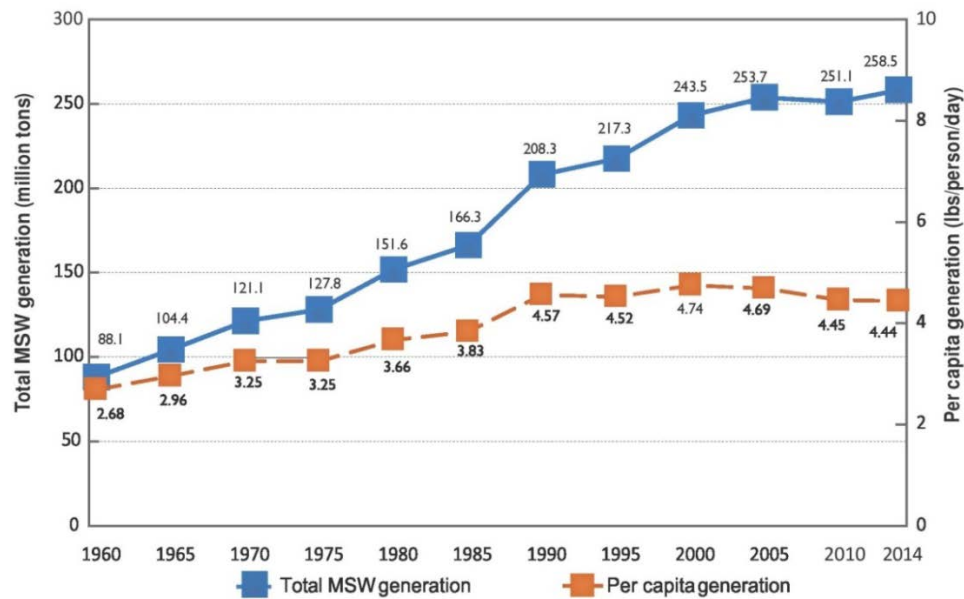


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

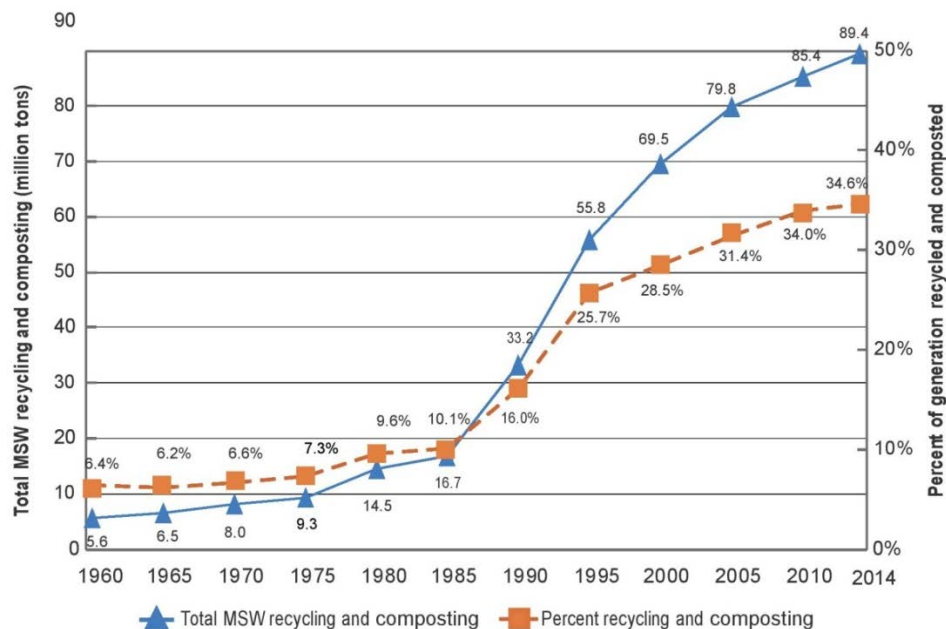


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

The Agency believes that the disposal of the packaging material new product will be similar to the disposal conditions of other RYO cigarette rolling paper, and any other RYO tobacco products that are currently being marketed. After using the new product, the users may dispose of or recycle the packaging material.

To calculate the amount of waste from disposal of paper packaging material, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products after issuance of the marketing order for the new product (Confidential Appendices 1 and 2). The calculated cumulative waste of the packaging material is a miniscule fraction of the forecasted MSW that would be generated in the United States. In addition, because paper components are more likely to be recycled, at least a portion of the packaging waste is likely to be recycled.

Because the new product will compete with other filtered tobacco products on the market and based on the above-mentioned information regarding waste, construction of new MSW management facilities is not anticipated due to the proposed action.

5.3.2 Discarding Used Products

Used RYO tobacco products, consisting of cigarette tube filters (cigarette butts)⁸, are usually disposed of in MSW landfills or as litter. The Agency utilized the historical data for use of RYO tobacco and cigarettes in the United States to forecast their future use and calculate the projected tobacco waste accordingly (Section 5.2). Assuming that the entire RYO tobacco and cigarette products are disposed of as MSW, the estimated waste from their use in 2018 and 2022 is a miniscule fraction of a percent of the total 258.46 million metric tons of projected MSW to be generated in the United States, as shown in the following table (U.S. EPA, 2016).

Table 3 Forecast of Waste of Used RYO Tobacco and Cigarette Products as Compared to Total MSW Forecast in the United States			
Year	Total RYO & Cigarettes (Billion Pieces) ^a	Total RYO & Cigarettes (Metric Tons) ^b	Waste of RYO & Cigarettes as a Percent of Total MSW in the U.S. ^c
Current Year (2017)	257.97	231,694	0.000896 %
First Year (2018)	254.61	228,674	0.000885 %
Fifth Year (2022)	244	219,150	0.000848 %
a = Projected RYO billion cigarette equivalents + projected billion cigarettes pieces (See Table 2) b = Projected RYO metric tons + Projected cigarette metric tons (See Table 2) $c = \text{Percentage} = \frac{\text{Total RYO and cigarette metric tons}}{\text{EPA, 2016 Waste metric tons: } (258.48 \times 10^6)} \times 100\%$			

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 in five types of non-residential public locations (recreation sites, bars/restaurants,

⁸ Cigarette butt is defined in this EA as the disposed filter and part of the injector tube that contains the remainder tobacco.

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. EPA, 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 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 and cigarette tobacco; instead, the new product would compete for market share with existing products. Therefore, a marketing order for the new product is not expected to affect the overall level of cigarette butt litter in the United States, but it may displace the litter from other RYO products.

To estimate the amount of waste from disposal of cigarette butts, the Agency used the total first- and fifth-year projected volumes of marketing the new and predicate products (Confidential Appendixes 1 and 2). Although the waste generated from cigarette filters remain as an environmental concern, the cumulative waste of the filters due to the proposed action is a miniscule fraction of the forecasted MSW that would be generated in the United States.

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 the 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. EPA, 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_4 emissions 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. EPA, July 2016). 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_4 organic compounds and volatile organic compounds. However, only CH_4 generation 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 to install landfill gas collection-and-control systems if they will have a waste capacity of 2.5 million metric tons or more. Additionally, all landfills must report GHG emissions to the EPA under 40 CFR 98.

Because 1) the new product will compete with other currently marketed RYO products; and 2) the projected market volumes of the new product and predicate product for the first- and fifth-year after issuance of the marketing order are, miniscule relative to the overall U. S. tobacco market, the GHG emitted from the waste associated with the new product is negligible.

The waste generated from using the new product is expected to make up a negligible fraction of the total MSW; no additional control of GHG emissions is anticipated in the landfills.

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

The Agency does not anticipate that the proposed action will lead to the release of new chemicals into the environment because the predicate product (filtered cigarette tubes with the same attributes and characteristics as the new product) has been sold and will continue to be sold in the United States. The new product is anticipated to be manufactured the same way as other products in the same facility and be used and disposed of the same way as other filtered cigarettes in the United States.

Therefore, the fate of any materials released to the environment is anticipated to be the same as the predicate product and other products manufactured in the facility. No new types of materials are anticipated to be released because the new product is substantially equivalent to the predicate product and 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 will comply with all applicable federal and local environmental laws and regulations. Therefore, cumulative introduction is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

Furthermore, as discussed above, the amount of materials anticipated to enter the environment due to manufacturing and use of the new product are small fractions when compared to that of the RYO and cigarettes used in the United States. 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 MSW in the United States. Consequently, no new environmental effects are anticipated due to the new product.

8. Use of Resources and Energy

In the SE Report, the applicant stated that the paper and acetate tow ingredients are produced from renewable and sustainable resources that do not impact critical habitats or endangered species. As to both resource and energy use, the new product will compete with other currently marketed tobacco products.

Furthermore, comparing the projected market volumes of the new and predicate products with the forecasted market volume of the total RYO and cigarette products in the United States, the projected

market volume of the new and predicate products combined is a small fraction of the total forecasted market volumes in 2018 and 2022. Accordingly, no additional use of resources and energy is anticipated.

9. Mitigation

During the review of the available data and information, the Agency did not identify adverse environmental effects for the new product and the proposed use as filtered cigarette tube. Therefore, no mitigation measures were developed.

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 this action would not change the existing condition of the manufacturing, use, and disposal following use of the tobacco products as many other RYO filtered cigarette tubes 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.

11. List of Preparers:

The following individuals were primarily responsible for preparing and reviewing this environmental assessment:

Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: 25 years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

Reviewer:

Hoshing Chang, PhD, Center for Tobacco Products

Education: PhD in Biochemistry and MS in Environmental Science

Experience: 9 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: Submission Tracking Numbers for the SE Report and Package Sizes of the New and Predicate Products, and Related Amendments that are Covered Under this Environmental Assessment (EA)

14. Confidential Appendix

Confidential Appendix 1: Projected Market Volumes in the First and Fifth Year of Marketing the New Product

Confidential Appendix 2: Projected Waste of Packaging Material and Cigarette Tube Filters in the First and Fifth Year of Marketing the New Product

15. References

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APPENDIX 1

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

STN	Product Name	Product	Tubes per Retail Box	Retail Box per Shipping Case	Amendments
SE0013742	Hot Rod Regular King Size 100 Count	New	100	100	SE0014288
	Hot Rod Regular King Size 200 Count	Predicate	200	50	

CONFIDENTIAL APPENDIX 1

Projected Market Volumes in the First and Fifth Year of Marketing the New Product

STN	Unit	First-Year Projected Volume		Fifth-Year Projected Volume	
		New	Predicate	New	Predicate
SE0013742	# of Cigarette Injector Tubes	(b) (4)			
	Metric Tons				
Cumulative volumes ⁹	# of Cigarette Injector Tubes	(b) (4)			
	Metric Tons				
Forecasted Total RYO & Cigarettes Use in U.S. ¹⁰	# of Cigarette Injector Tubes	254.61 billion		244 billion	
	Metric Tons	228,674		219,150	

The cumulative projected volumes of the products in the first and fifth year after issuance of a marketing order is negligible as compared with the estimated future use of RYO tobacco and cigarettes combined in the United States.

⁹ Summation of market volumes of new and predicate products

¹⁰ Data from Table 2

CONFIDENTIAL APPENDIX 2

Projected Waste of Packaging Material and Cigarette Tube Filters in the First and Fifth Year of 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 and product materials waste (in metric tons) that would be generated from disposal after use of the new and predicate products in 2018 and 2022. Projected waste generation is the summation of the projected cardboard retail boxes, plastic wrap of retail boxes, cigarette butts, and shipping cases of the new and predicate products:

$\sum_{i=1}^{10} A_i = \sum_{i=1}^{10} (B_i + C_i + D_i)$	A_i : Projected total paper and cigarette butts waste generation of the products (metric tons) B_i : Projected waste generation of retail paperboard boxes of the products (metric tons) C_i : Projected waste generation of cardboard shipping cases of the products (metric tons) D_i : Projected waste generation of cigarette butts of the products
$B_i = \frac{E_i}{F_i} \times G_i \times N$	E_i : Projected market volume of the products (# individual cigarette injector tubes) F_i : Number of cigarette injector tubes per retail box G_i : Weight of empty retail box (grams)
$C_i = \frac{E_i}{F_i \times H_i} \times I_i \times N$	H_i : Number of retail boxes per shipping case I_i : Weight of empty cardboard shipping case (grams)
$D_i = E_i \times J_i \times N$	J_i : Weight of cigarette butt (grams) N : 1.0×10^{-6} metric tons/gram

Projected Year	STN	Product	J	I	H	G	F	E	D	C	B	A
First Year	SE0013742	New	0.2	680.3	100	15.6	100	(b) (4)				
		Predicate	0.2	680.3	50	28.8	200					
	Projected Total Waste											
Fifth Year	SE0013742	New	0.2	680.3	100	15.6	100					
		Predicate	0.2	680.3	50	28.8	200					
	Projected Total Waste											

Paper and Cigarette Butt Waste. The retail cardboard box and shipping case are disposed of, recycled, or both, as paper waste; cigarette butt is disposed of as waste or litter. If the entire packaging paper and cigarette butt are disposed of as waste, which is a more conservative approach, the projected cumulative paper and cigarette butt waste in the first year and fifth year 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 258.5 million tons of total waste reported in the United States in 2014.

However, 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 EPA (U.S. EPA, 2016). Therefore, if 100% of the cigarette butts and 35.3% of the retail cardboard boxes and 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 and predicate products.¹¹

¹¹ At 35.3% disposal rate as paper waste (on cardboard retail boxes and shipping cases) for the (b) (4)