Programmatic Environmental Assessment for Marketing Orders for Roll-Your-Own Rolling Papers, "Smoking Master Double Cigarette Paper, Smoking Red Double Cigarette Paper (120 Ct.), Smoking Orange Double Cigarette Paper (120 Ct.)" Manufactured by Miquel Y Costas & Miquel, S.A.

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

October 30, 2017

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This programmatic environmental assessment (PEA) is for market orders for roll-your-own (RYO) tobacco rolling papers manufactured by Miquel Y Costas & Miquel, S.A. Information presented in the PEA is based on the submissions referenced in Appendix 1, unless noted or referenced otherwise. This PEA has been prepared in accordance with 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

1. Name of Applicant

Miquel y Costas & Miquel, S.A.

2. Address of Applicant

1300 Pennsylvania Avenue, NW, Suite 700
Washington, D.C. 2000

3. Manufacturer

Miquel y Costas & Miquel, S.A. (MCM)

4. Description of the Proposed Action

The proposed action is for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of new roll-your-own (RYO) tobacco rolling papers into interstate commerce for commercial distribution in the United States. These authorizations are based on the finding that the new products are substantially equivalent to the corresponding predicate products that were commercially marketed in the United States as of February 15, 2007. The applicant stated that the new products are "intended to compete with the predicate products and the existing roller paper products that are already on the market for many years." The applicant also stated that "the manufacture of the new products will be accompanied by (b) (4) of the predicate products and other products produced at MCM's manufacturing facility."

4.1. Requested Action

Orders finding the new tobacco products are substantially equivalent to the corresponding predicate products.

4.2. Need for Action

Miquel y Costas & Miquel, S.A. submitted SE Reports SE0011190-SE0011191 and SE0011196 seeking marketing orders for the introduction of the new products (as described in Section 4.3 below) into interstate commerce for commercial distribution in the United States. The applicant claims that the new products and the corresponding predicate products are identical except for changes in the package pertaining to quantity of the products, but the new products do not raise different questions of public health (sec. 910(a)(3)(A)(ii)) as described in FDA guidance to industry issued on March 4, 2015. After considering the SE Reports, the Agency shall issue market orders pursuant to

sections 910 and 905(j) of the FD&C Act when finding the new products to be substantially equivalent to the corresponding predicate products.

4.3. Identification of the New Tobacco Products that are Subjects of the Proposed Action

4.3.1. Type of Tobacco Products

RYO rolling papers

4.3.2. Products Names and the Submission Tracking Numbers (STN)

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

STN	New Product	Predicate Product
SE0011190	Smoking Master Double Cigarette Papers	Smoking Blue Cigarette Papers
SE0011191	Smoking Red Double Cigarette Papers (120 Ct.)	Smoking Red Cigarette Papers (60 Ct.)
SE0011196	Smoking Orange Double Cigarette Papers (120 Ct.)	Smoking Orange Cigarette Papers (60 Ct.)

4.3.3. Description of the Products Package

Each of the retail booklets of the new products and the corresponding predicate products contains a paperboard stiffener leaf, warranty leaf, and a warning leaf (inserted five leaves before the end of the booklet). The booklets are packaged in a cardboard carton that is wrapped in (b) (4) wrap. Details of the package components and weights of each packaging component for the new products are described in Confidential Appendix 2.

4.3.4. Location of Manufacturing

The manufacturer, Miquel y Costas & Miquel, S.A. (MCM), is located outside the United States. at Carrer Torrent de la Bleda, Capellades, 08786 Barcelona, Spain (Figure 1). The facility is situated in a small industrial area bounded to the east by the Anoia River and hilly woodlands, to the north by mixed-use land (residential, commercial and agricultural) and to the west by residential areas and woodlands, and to the south by industrial and residential areas.

Figure 1. Location of the Manufacturer[1]

4.3.5. Location of Use

MCM intends to distribute and sell the new tobacco products to consumers in the United States.

4.3.6. Location of Disposal

The used and unused rolling papers will be disposed of in municipal solid waste (MSW) landfills or incinerators, or as litter, in the same manner as any other marketed RYO tobacco rolling papers. 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 products use.

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

The applicant claims that the new products differ from the corresponding predicate products in the products' quantity.

[1] Manufacturer location via Google Map. Accessed July 14, 2017

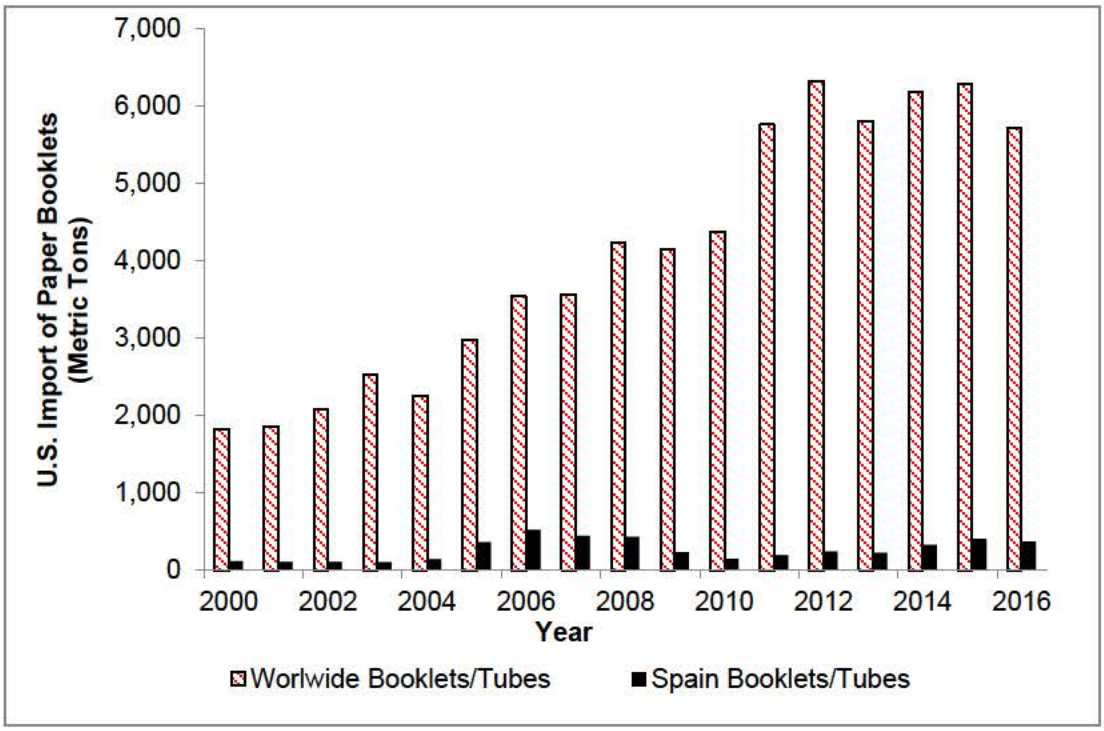
5. Potential Environmental Impacts Due to the Proposed Action

5.1. Potential Environmental Impacts Due to Manufacturing the New Products

Based on information collected by the U.S. International Trade Commission (U.S. ITC), the worldwide U.S. import of cigarette paper booklets or tubes decreased from 6,291 metric tons in 2015 to 5,724 metric tons in 2016 (Figure 2).[2] This comprised 2.3% and 2.1% of the worldwide U.S. import of tobacco products in 2015 and 2016, respectively. Likewise, U.S. import of cigarette paper booklets or tubes from Spain decreased from 406 metric tons in 2015 to 372 metric tons in 2016. This comprised 6.45% and 6.5% of the worldwide U.S. import of cigarette paper booklets in 2015 and 2016, respectively (Figure 2).

It is worth noting that the U.S. import of cigarette paper booklets from Spain comprised 17.86% and 15.28% of U.S. import of all tobacco products from Spain in 2015 and 2016, respectively.

Figure 2. U.S. Import of Cigarette Paper Booklets or Tubes, 2000-2016



The Agency anticipates the waste generated due to manufacturing the new RYO products to 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 RYO products manufactured in Spain. The new products are anticipated to compete with other currently marketed RYO cigarette paper products and to (b) (4)

[2] Unit is defined by the United States International Trade Commission, available at: http://dataweb.usitc.gov/. Accessed on July 14, 2017.

(b) (4) . The SE Reports note that the manufacturing facility has the necessary equipment to handle waste disposal from manufacturing the new products in a manner compliant with applicable laws and regulation.

The manufacturing facility is in Spain and the applicant stated that the facility is compliant with federal and provincial regulations for air emissions, solid waste, and liquid waste. In addition, the new products and the corresponding predicate products are manufactured in a similar manner using identical ingredients and the only difference is in the quantity of the product. Consequently, 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.

Furthermore, the new products would compete with the predicate products; manufacturing the new products would be accompanied by (b) (4) the predicate products and other products at the facility. Therefore, there would be no anticipated expansion of the manufacturing facility, which was confirmed by the applicant, and no additional resources with new control measures for air emission, water discharge, or solid waste disposal are needed for manufacturing the new products. In addition, there would be no anticipated net increase in energy use or change in greenhouse gas (GHG) emissions expected from manufacturing since the new products would (b) (4) and compete with other currently marketed RYO products.

The European Environmental Agency (EEA) reported a decrease of GHG emissions in 2009 in Spain and the European Union (EU) member states, as compared to GHG in 2005, due to the global financial and economic crisis and the subsequent decrease in the industrial activity. However, emissions increased in 2010 and decreased again from 2011 and beyond. Although it continued to decrease, there was a 19% overall increase in GHG emissions in Spain in 2015 as compared with the 1990 GHG emissions indicator.[3]

The applicant stated that MCM complies with the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES), which deals directly with the international trade of specimens of listed wild animals and plants. According to the SE Reports, none of the plants used for manufacturing the new products are listed as an endangered plant on the CITES list and the requested actions will neither jeopardize the continued existence of any endangered species, nor result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act ESA or CITES.

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

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

[3] https://ec.europa.eu/eurostat/statistics-explained/images/1/6/2017-GHG_statistics_tables_and_figures-update.xlsx. Accessed July 27, 2017

pounds (11 billion cigarette-equivalents), respectively (Figures 3 and 4).[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 3. Use of RYO (Million Pounds) in the United States, 1999 – 2016

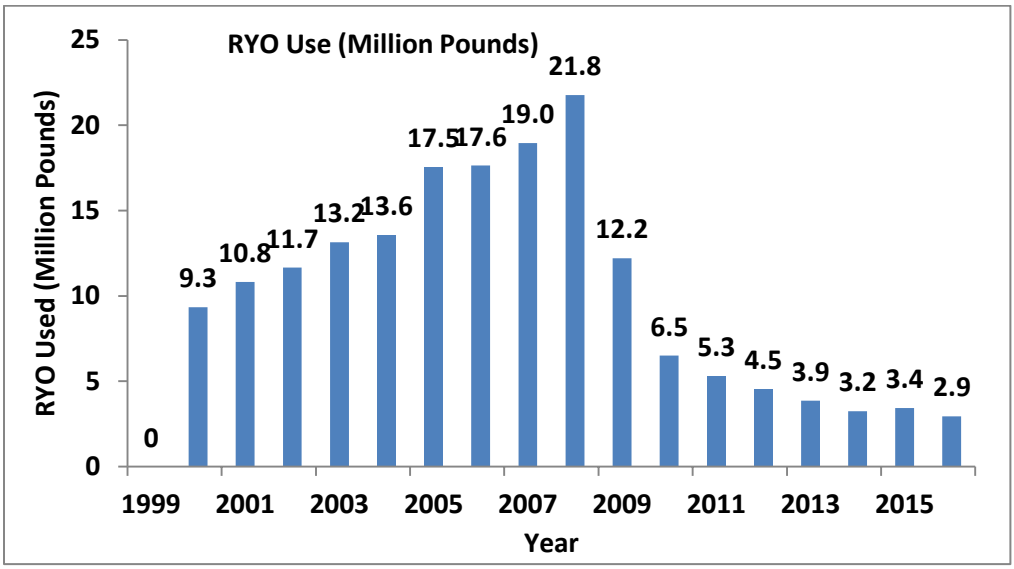
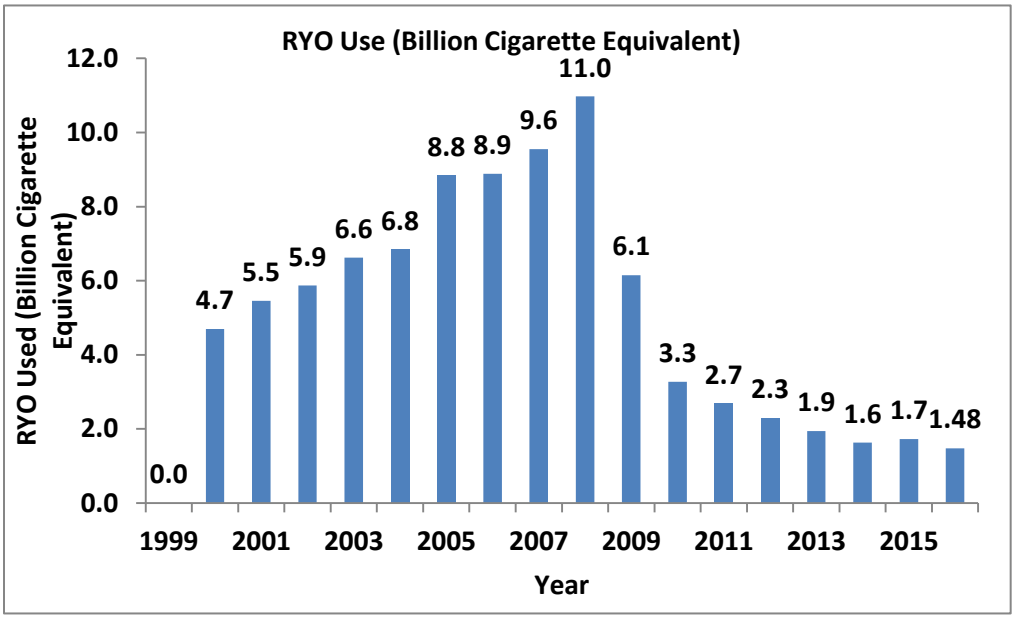


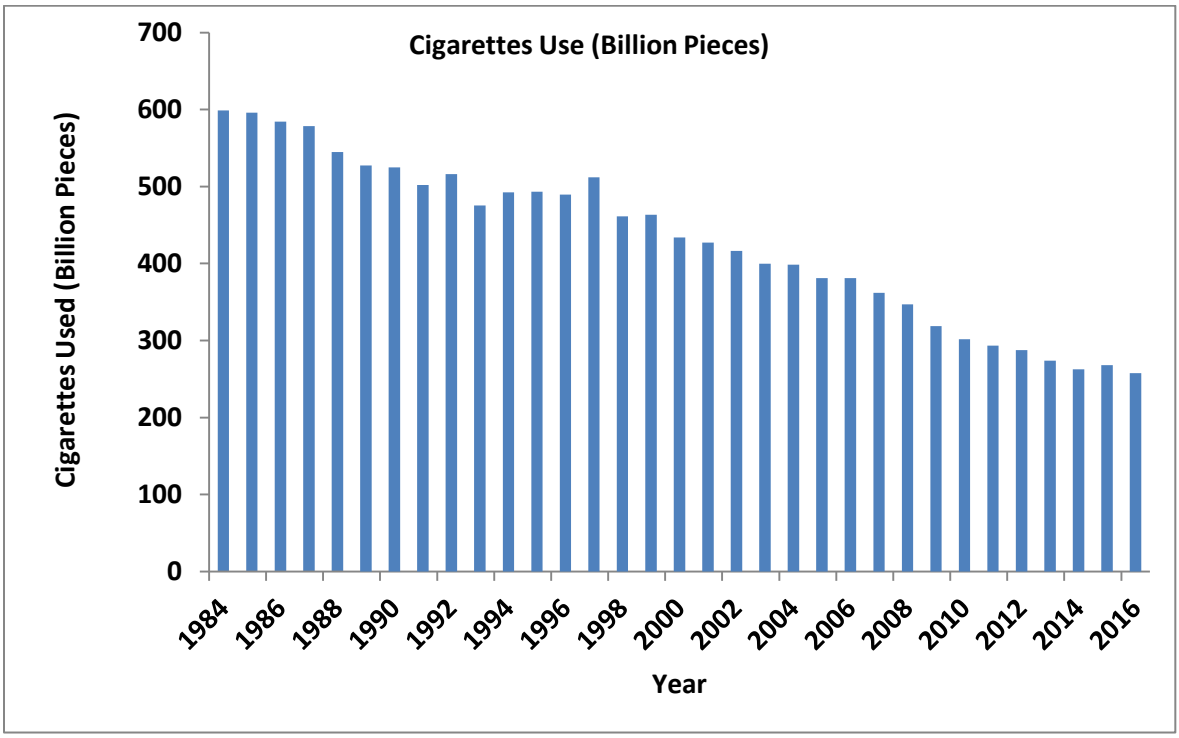
Figure 4. Use of RYO (Billion Cigarette-Equivalents) in the United States, 1999 – 2016



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

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

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



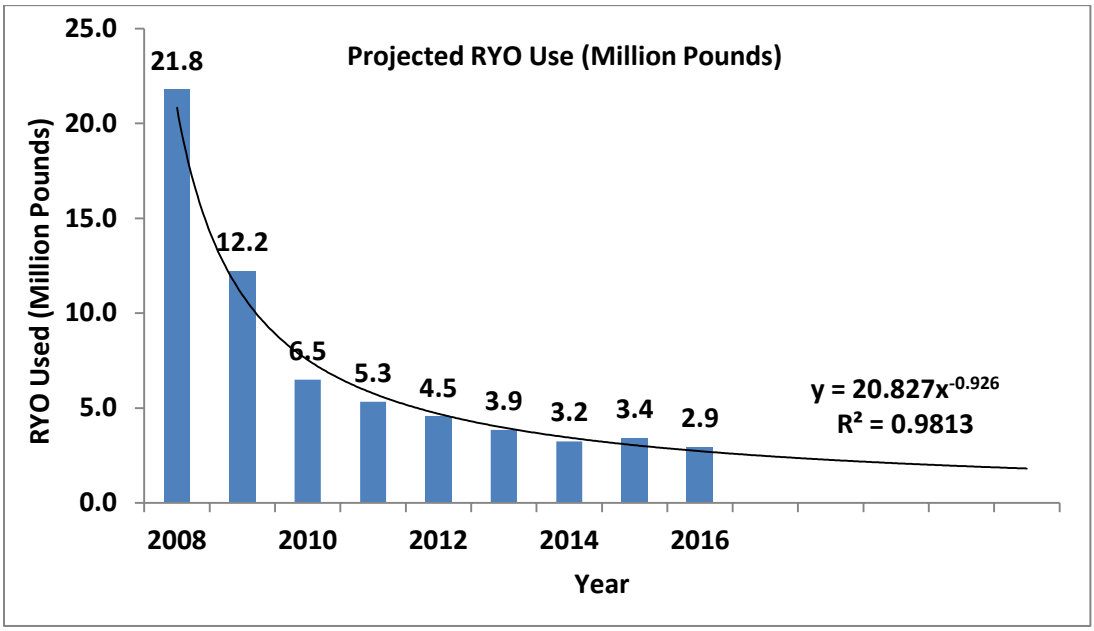
To evaluate the environmental impact of the proposed actions due to use of the new products, historical data regarding total use of similar combusted products (i.e. RYO and cigarettes) from 2008 to 2016 was employed to mathematically estimate the forecast of the total amount of these products used in the United States.[6] Using the one best-fit trend line with an R^2 value of 0.9813, the forecasted amount 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 of marketing the new products, respectively (Figure 6 and Table 1).[7]

[5] 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 = $\frac{(X \text{ billion cigarette pieces} \times 10^9)\times(\frac{0.9\text{ g}}{453.59\text{ g}})}{10^6}$

[6] The forecast trend line is extrapolated from TTB data. Available from http://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed July 15, 2017.

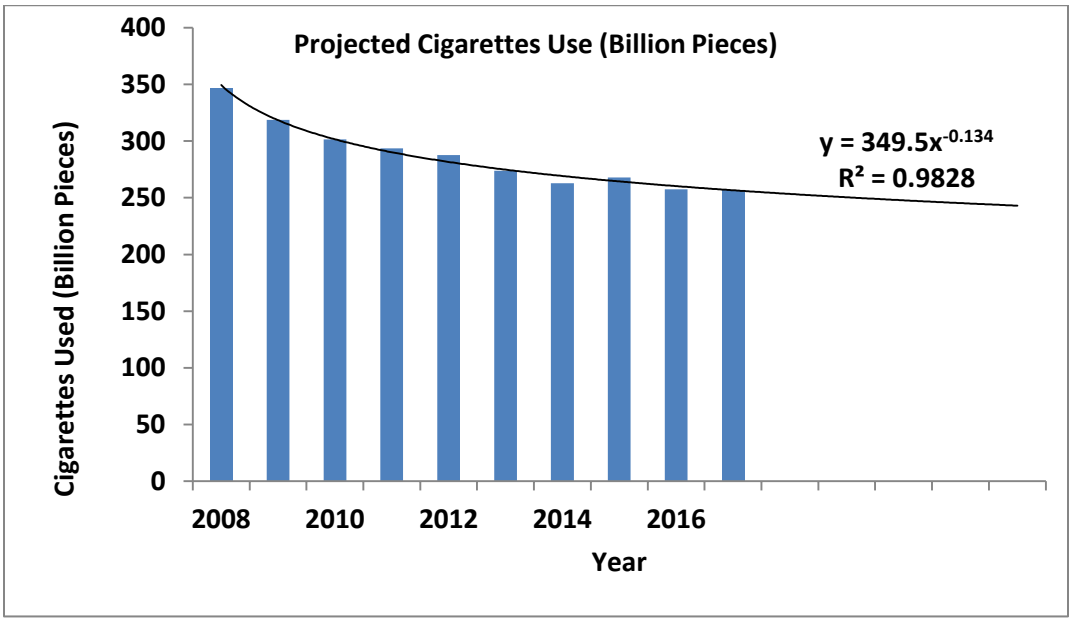
[7] Projected first-year and fifth-year million pounds of RYO tobacco products: $20.827 \times (\text{year} - 2007)^{-0.926}$

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; 253.47 billion cigarettes (501.88 million pounds) and 243.15 billion cigarettes (281.45 million pounds) are forecasted to be used in the first year and fifth year, respectively, of marketing the new products (Figure 7 and Table 1).[8]

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



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

Table 1. Summary of Projected use of Cigarettes and RYO in the United States in the First Year and Fifth Year of Marketing the New Products						
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

During use, the new products are burned to ash, carbon dioxide (CO_2), and water vapor, as well as products of incomplete combustion such as carbon monoxide. These combustion products from the new products are released in a similar manner to the combustion products of the corresponding predicate products and other marketed RYO injector tubes. As noted, the only differences between the new products and the corresponding predicate products are in product quantity and weight of packaging material. Additionally, because (1) the new products will compete with the predicate products and other currently marketed RYO products; and (2) the projected market volume of the new products and the corresponding predicate products in the first and fifth year of marketing the new products occupy a negligible fraction of the total projected estimate of use of cigarette and RYO products in the United States (Confidential Appendix 1), no net addition of GHG emissions is anticipated

5.3. Potential Environmental Impacts Due to Disposal of the New Products

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 (Figures 8 and 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. Environmental Protection Agency, 2016).

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

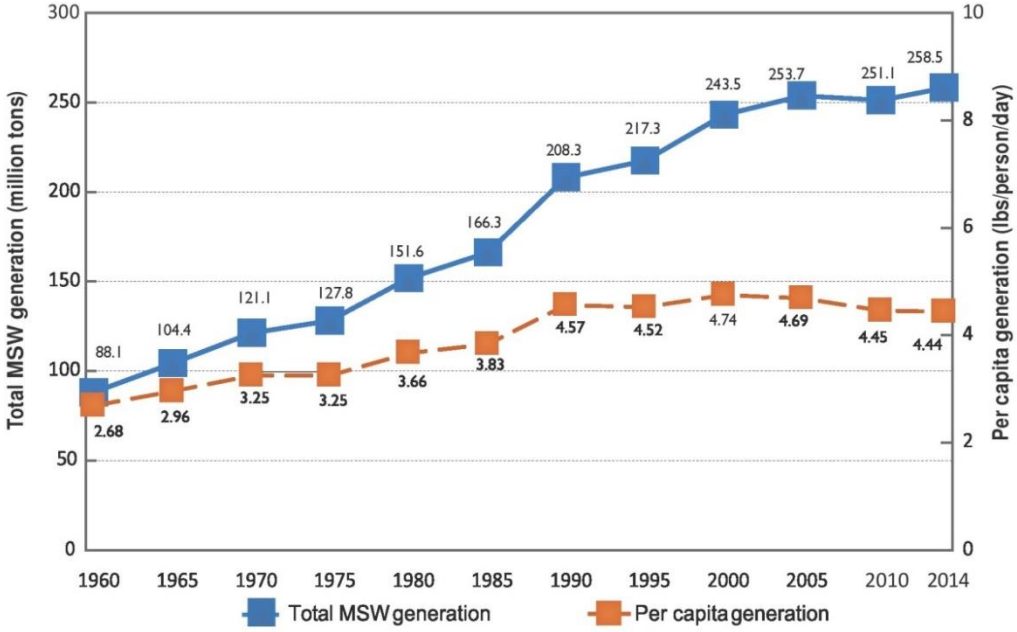


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 9. MSW Recycling Rates in the U.S., 1960 – 2014

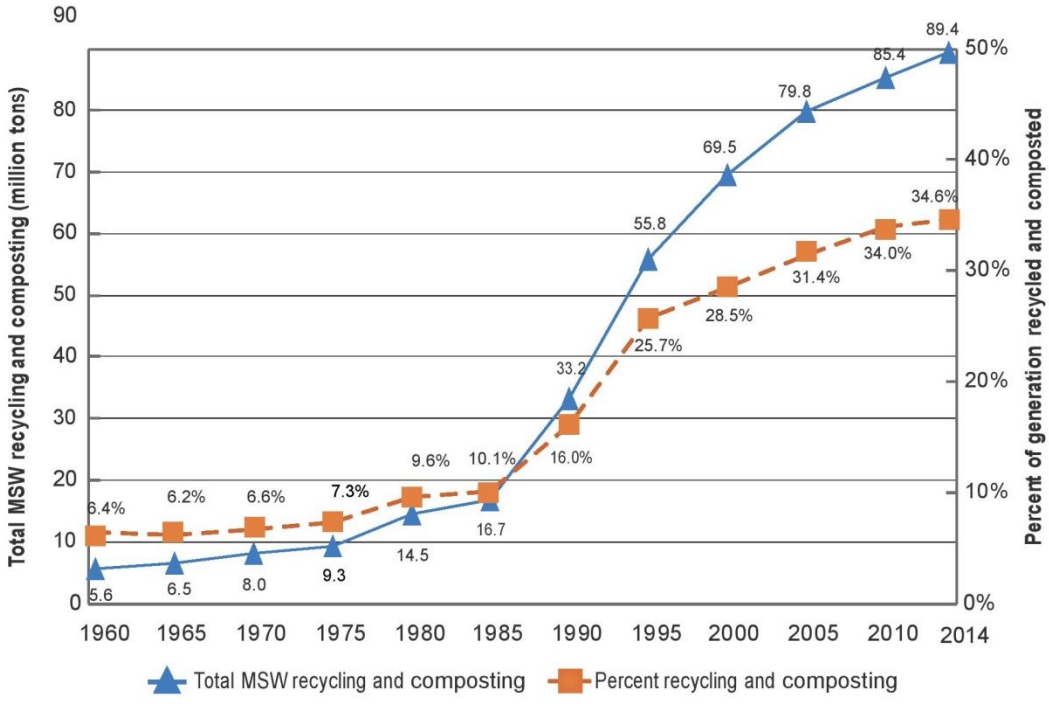


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

To calculate the amount of waste from disposal of paper packaging material and plastic wrap, the Agency used the first- and fifth-year projected volumes of marketing the new and corresponding predicate products after issuance of the marketing orders for the new products (Confidential Appendix 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 and plastic wrap are more likely to be recycled, at least a portion of the packaging waste is likely to be recycled.

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

5.3.2 Air Emissions

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. 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_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. Environment Protection Agency, 2017). 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 U.S. EPA under 40 CFR 98.

Because (1) the new products will compete with other currently marketed RYO products; and (2) the projected market volumes of the new and corresponding predicate products for the first and fifth year after issuance of the marketing orders are miniscule relative to the overall United States tobacco market, the GHG emitted from the waste associated with the new products is negligible. Therefore, no additional control of GHG emissions is anticipated in the landfills.

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

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment because the predicate products and similar RYO tobacco products are sold in the United States. The new products are 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 RYO tobacco products in the United States.

Therefore, the fate of any materials released to the environment is anticipated to be the same as other products manufactured in the facility. No new types of materials are anticipated to be released because the new products are substantially equivalent to the corresponding predicate products and will be made using the same materials and processes as the predicate products.

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

The applicant stated that the manufacturing operation will comply with all provincial and federal environmental laws in Spain. 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 products are small fractions when compared to that of similar products imported in the United States. In addition, the amount of materials anticipated to enter the environment due to disposal following use of the new products occupies a small fraction of the total forecasted MSW in the United States. Consequently, no new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

In the SE Reports, the applicant stated that none of the plants used for the manufacture of the new products are listed as an endangered plant on the CITES list and that the requested actions will neither jeopardize the continued existence of any endangered species, nor result in the destruction or adverse modification of the habitat of any such species identified under the ESA or CITES. As to both resource and energy use, the new products will compete with other currently marketed tobacco products. Accordingly, no additional use of resources and energy is anticipated.

9. Mitigation

During review of the available data and information, the Agency did not identify adverse environmental effects for the new products and the proposed use as rolling papers. 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 products in the United States. The environmental impact of these actions would not change the existing condition of the manufacturing, use, and disposal following use of the tobacco products as many other RYO cigarette paper products will continue to be marketed.

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

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:

Gregory G. Gagliano, MS, Center for Tobacco Products

Education: MS in Environmental Science
Experience: 34 years in environmental toxicology and risk assessment
Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

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 of the SE Reports and Package Sizes of the New and Corresponding Predicate Products and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

14. Confidential Appendix

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

Confidential Appendix 2: Projected Waste of Packaging Material in the First and Fifth Year of Marketing the New and Corresponding Predicate Products

15. References

EPA. Advancing Sustainable Materials Management: Facts and Figures Report. Available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report. Accessed April 4, 2017.

Environmental Production Agency (EPA). *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2015.* 2017(EPA 430-P-17-001). Issued February 15, 2017. Available at https://www.epa.gov/sites/production/files/2017-02/documents/2017_complete_report.pdf. Accessed July 25, 2017.

Intergovernmental Panel on Climate Change (IPCC) *2006 IPCC Guidelines for National Greenhouse Gas Inventories.* 2006; Available from: http://www.ipcc-nggip.iges.or.jp/public/2006gl/. Accessed July 25, 2017.

APPENDIX 1

Submission Tracking Numbers of the SE Reports and Package Sizes of the New and Corresponding Predicate Products and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

STN	New Product	Package Size		Predicate Product	Package Size		Amendments
		Sheet/ Booklet	Booklets/ Carton		Sheet/ Booklet	Booklets/ Carton	
SE0011190	Smoking Master Double Cigarette Paper	120	25	Smoking Blue Cigarette Paper	60	50	SE0011890 SE0013938 SE0014122 SE0014125
SE0011191	Smoking Red Double Cigarette Paper (120 Ct.)	120	25	Smoking Red Cigarette Paper (60 Ct.)	60	50	SE0011890 SE0013938 SE0014122 SE0014125
SE0011196	Smoking Orange Double Cigarette Paper (120 Ct.)	120	25	Smoking Orange Cigarette Paper (60 Ct.)	60	50	SE0011890 SE0013938 SE0014122 SE0014125

CONFIDENTIAL APPENDIX 1

Projected Market Volumes in the First and Fifth Year of Marketing the New and Corresponding Predicate Products

STN	First-Year Projected Volume (metric tons)		Fifth-Year Projected Volume (metric tons)		First-Year Projected Volume (# of pieces)		Fifth-Year Projected Volume (# of pieces)	
	New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0011190	(b) (4)							
SE0011191								
SE0011196								
Total								
Cumulative volumes[9]								
Projected RYO Use in United States[10]	1,026		770		1.14 billion		0.85 billion	
Projected Use of RYO and Cigarettes in United States.[11]	228,674		219,150		254.61 billion		244 billion	

The cumulative projected market volumes of the products in the first and fifth year of marketing the new products comprise a fraction of the estimated future use of combusted products in the United States.

[9] Summation of market volumes of new and predicate products

[10] See section 5.2, Table 1

[11] See section 5.2, Table 1

CONFIDENTIAL APPENDIX 2

Projected Waste of Packaging Material in the First and Fifth Year of Marketing the New and Corresponding Predicate Products

To analyze the environmental effects from total waste due to the proposed actions, 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 2017 and 2021. Projected waste generation is the summation of the projected cardboard and paper material of retail booklets and shipping cartons in addition to the plastic wrap of shipping cartons of the new and predicate products:

$$\sum_{i=1}^{4} A_i = \sum_{i=1}^{4} (B_i + C_i + D_i)$$	A_i: Projected total waste generation of the product (metric tons) B_i: Projected waste generation of cardboard/paper booklet cover of the product (metric tons) C_i: Projected waste generation of cardboard shipping carton of the product (metric tons) D_i: Projected waste generation of carton plastic wrap of the product (metric tons) E_i: Projected market volume of the product (total number of rolling papers)
$$B_i = \frac{E_i}{F_i} \times G \times K$$	F_i: Projected market volume of the product (number of rolling papers per booklet) *G*: Weight of booklet cardboard/paper cover (grams)[12]
$$C_i = \frac{E_i}{F_i \times H_i} \times I \times K$$	H_i: Number of booklets per cardboard shipping carton I: Weight of empty cardboard shipping carton (grams)
$$D_i = \frac{E_i}{F_i \times H_i} \times J \times K$$	J: Weight of plastic wrap per shipping carton (grams) K: 1.0 x 10^{-6} metric tons/gram

[12] This includes the weight of the cardboard stiffener leaf and the paper warranty leaf and the warning leaf in the booklet

Projected Waste of Packaging Material of the Products												
Projected Year	**STN**	***Product***	E_i	F_i	G	H_i	I	J	D_i	C_i	B_i	A_i
First-Year Projected Volume	**SE0011190**	New	(b) (4)									
		Predicate										
		Total										
	SE0011191	New										
		Predicate										
		Total										
	SE0011196	New										
		Predicate										
		Total										
	Cumulative											
Fifth-Year Projected Volume	**SE0011190**	New										
		Predicate										
		Total										
	SE0011191	New										
		Predicate										
		Total										
	SE0011196	New										
		Predicate										
		Total										
	Cumulative											

If all the projected packaging waste generated from use of the products is disposed of in MSW, which is the most conservative approach, the projected cumulative packaging waste generated in the first and fifth years of marketing the new products would be (b) (4) metric ton (equivalent to (b) (4) tons) in 2018 and (b) (4) metric ton (equivalent to (b) (4) tons) in 2022. This is a negligible fraction of the 258.5 million tons of total waste reported in the United States in 2014.[13] However, a portion of the generated paper and plastic 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).

[13] EPA. Advancing Sustainable Materials Management: Facts and Figures Report. Available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-

facts-and-figures-report (accessed April 4, 2017).