

# **Environmental Assessment for Market Authorization for Republic Tobacco, LP “High Card Gold 100mm”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

September 13, 2017

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This environmental assessment (EA) is for the market authorization for a roll-your-own (RYO) cigarette injector tube manufactured by “Republic Tobacco, LP”. Information presented in the EA is based on the submission referenced in Appendix 1, unless noted or referenced otherwise. This EA has been prepared in accordance to 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act).

### **1. Name of Applicant**

Republic Tobacco, LP

### **2. Address**

2301 Ravine Way  
Glenview, IL 60025

### **3. Manufacturer**

(b) (4)

A large rectangular area of the document is redacted with a solid grey box. The redaction covers the manufacturer's name and address details.

### **4. Description of Proposed Action**

This proposed action is for FDA to issue a market authorization under the provisions of section 910 and 905(j) of the FD&C Act for the introduction of RYO cigarette injector tube into interstate commercial distribution in the U.S. The authorization is based on the finding that this new product is substantially equivalent to the predicate product that was on the market as of February 15, 2007. The applicant intends to market the new and predicate products simultaneously after receiving market authorization for the new product.

#### **4.1 Requested Action**

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

#### **4.2 Need for Action**

Republic Tobacco, LP wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the U.S. The applicant claimed that the new product differs from the predicate product in product quantity and package labeling (sec 910(a)(3)(A)(ii) of the FD&C Act). In addition, the applicant claimed that the new and predicate products have identical product and packaging composition. After considering the substantial equivalence (SE) report (SE0014064), the Agency shall issue an order pursuant to section 910(a)(2) of the FD&C Act when finding the new product to be substantially equivalent to the predicate product.

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

#### 4.3.1 Type of Tobacco Product

Roll-your-own (RYO) cigarette injector tube

#### 4.3.2 Product Name and Its Original STN

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

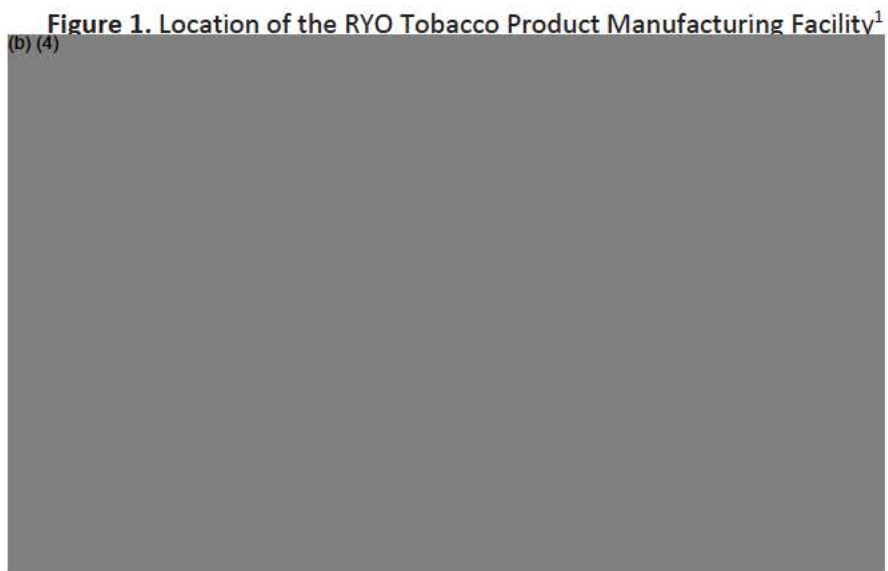
| STN       | New Product          | Predicate Product |
|-----------|----------------------|-------------------|
| SE0014064 | High Card Gold 100mm | Top Gold 100mm    |

#### 4.3.3 Description of the Product Package

The packaging materials of the finished new product are identical to those of its predicate product. Both product packaging components consist of a cardboard retail box in which the cigarette injector tubes are contained; however, the new product contains more cigarette injector tubes per box than the predicate product. Details of the package components and weights of each packaging component for the new product are described in [Confidential Appendix 4](#).

#### 4.3.4 Location of Manufacturing

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



<sup>1</sup> Manufacturer address via Google Map. Accessed July 10, 2017.

#### **4.3.5 Location of Use**

Republic Tobacco, LP intends to distribute and sell the new tobacco product to consumers in the U.S.

#### **4.3.6 Location of Disposal**

Once used, the new tobacco product will be disposed of in municipal solid waste (MSW) landfills or as litter, in the same manner as the predicate product and any other RYO products. Disposal of the packaging materials following use will either enter the recycling stream or be disposed of in MSW landfills or as litter. The Agency anticipates that the distribution of waste from disposal after use will correspond to the pattern of the product use.

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

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

### **5. Environmental Introduction Due to the Proposed Action**

#### **5.1 Introduction as a Result of Manufacturing the New Tobacco Product**

##### **5.1.1 Tobacco Products Imported from the Canada**

Tobacco Import and Tobacco Market Volumes. According to the U.S. International Trade Commission (USITC), the import of total tobacco products to the U.S. from Canada has increased from 10,725 metric tons in 2000 to 21,392 metric tons in 2016 (Figure 2).<sup>2</sup> When examining the change in import of cigarette paper in the form of tubes to the U.S. from Canada over the same period of time, there was a significant increase from 25 metric tons in 2000 to 2,983 metric tons in 2016 (Figure 3).<sup>2</sup>

Cigarette rolling paper in the form of tubes imported to the U.S. from the Canada in 2016 represented 13.9% by weight of the total amount of tobacco products imported from Canada in 2016.

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

Figure 2. Total Tobacco Products Imported from Canada into the U.S. 2000-2016<sup>2</sup>

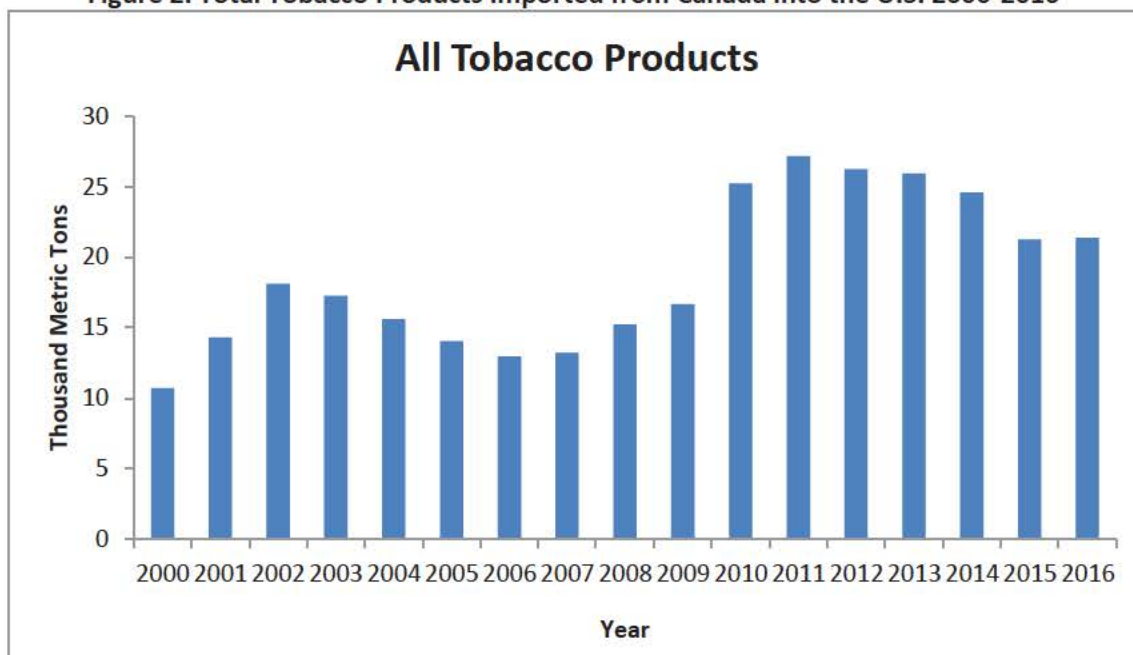
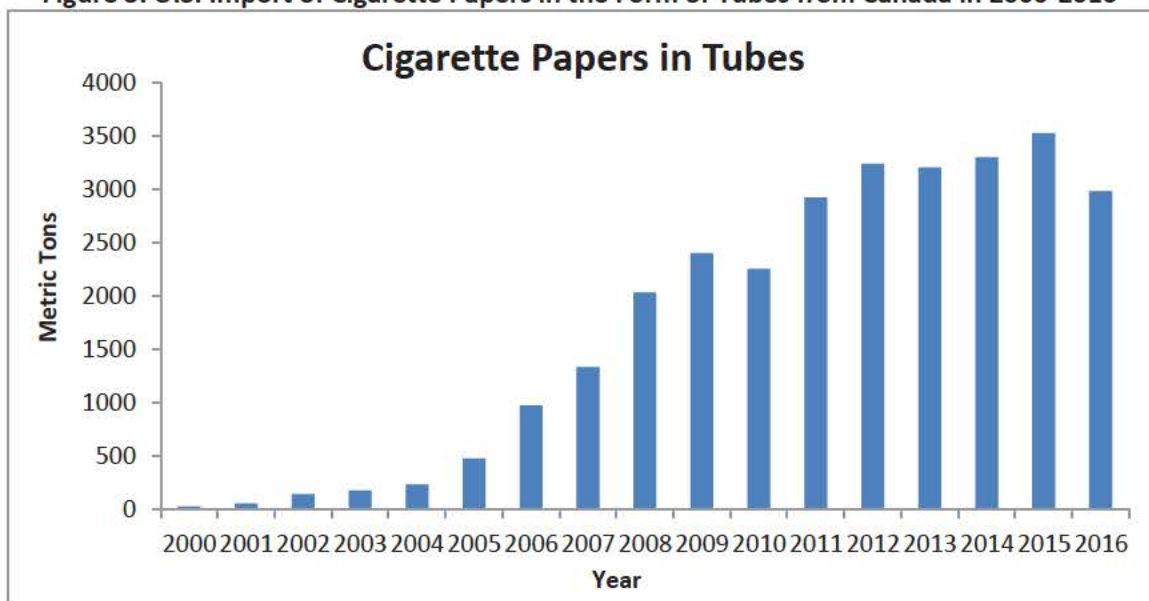


Figure 3. U.S. Import of Cigarette Papers in the Form of Tubes from Canada in 2000-2016<sup>2</sup>



### 5.1.2 Environmental Introduction from Manufacturing the New Tobacco Product

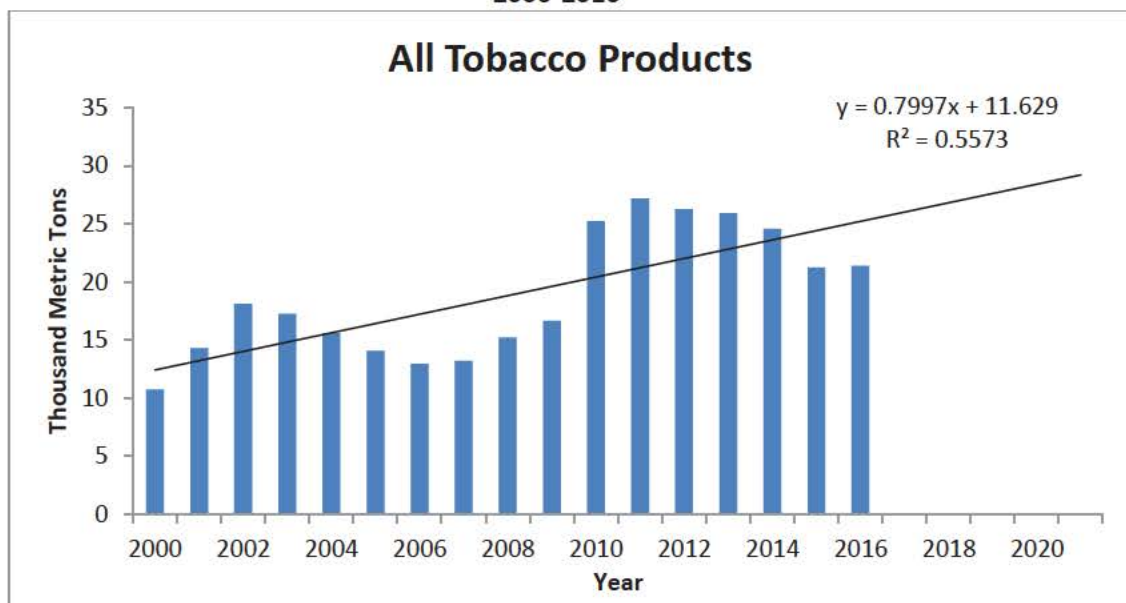
Introduction from Manufacturing the New Product in the Proposed Action. The Agency anticipates the waste generated as a result of manufacturing the new RYO tobacco product will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other RYO tobacco products manufactured in Canada. The new product will compete with other currently



marketed RYO cigarette injector tube products. The applicant provided the first- and fifth-year market volumes for the new product ([Confidential Appendix 1](#)).

To evaluate the environmental impact of the proposed action due to the import of the new product, historical data regarding the import of all tobacco products from Canada into the U.S. from 2000 to 2016 was used to forecast the manufacture of RYO tobacco products<sup>3</sup>. This was achieved by using a linear trend line with the  $R^2$  value of 0.9. Accordingly, the forecasted amount of all tobacco products to be imported from Canada into the U.S. is estimated to be about 19,909 metric tons in 2017 and 14,730 metric tons in 2021. The amount of all tobacco products imported from Canada into the U.S. is estimated at 21,392 metric tons in 2016 by USITC (Figure 4).

**Figure 4. Forecast of All Tobacco Products Imported into the U.S. from Canada into the U.S. 2000-2016<sup>3</sup>**



Comparing the projected market volume of the new product with the forecasted market volume of all tobacco products imported into the U.S. from Canada in 2017 and 2021, the cumulative projected market volumes of the new products are a small fraction of the total forecasted market volumes in 2017 and 2021 (Figure 4 and [Confidential Appendix 1](#)).

Additionally, the applicant forecasts that the manufacturing of the new product will comprise a small fraction (approximately (b) (4)) of the total production at the manufacturing facility. Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new product. The applicant stated that the manufacturing process for the new product is identical to that of all other production at the manufacturing facility. The applicant also stated that the manufacturing facility is already equipped to dispose of waste generated from manufacturing the new and predicate products in a manner that is compliant with applicable laws and regulations, and that the waste associated with manufacturing the new product is

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



negligible compared to the facility's total waste. Therefore, no additional resources will be required for waste disposal, and no new control practices of air emission, water discharge, and solid waste disposal are needed.

Based on information in the SE Report, the new product differs from the predicate product in product quantity and package labeling. All of the ingredients used to manufacture the new and predicate products and their physical characteristics are identical. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new product.

The manufacturing facility is located in Canada and the applicant stated that the facility is in compliance with applicable Canadian Regional and Federal emissions, solid waste, and liquid waste regulations and requirements. The applicant also stated that the RYO injector tube ingredients and packaging materials are produced from renewable and sustainable resources in accordance with the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification Schemes (PEFC), and the manufacture of the new product is carried out under controls and standards that do not appear to threaten any endangered species or critical habitat, as listed by the Endangered Species Act (ESA) or the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

Manufacturing cigarette injector tubes is an energy-intensive process that requires heat (in the form of steam) and electricity. The applicant claims that the manufacturing facility uses purchased electricity (99.3%) and gas (0.7%). The manufacturing facility's reported total use of energy was 3,786.7 megawatt hour (Mwh) in 2016. Because the new product comprises a miniscule fraction of the total manufacturing volume at the facility ([Confidential Appendix 1](#)), manufacturing the new products will not result in a significant net increase of energy use at the facility.

More than 99% of the electricity produced in (b) (4) is powered from water. Hydroelectricity is a source of clean, renewable electricity that generates very little greenhouse gas (GHG).<sup>4</sup> Additionally, the applicant stated that no different GHGs will be emitted because the new product and predicate product are identical in manufacturing and packaging components. Furthermore, because both new and predicate products will compete with other currently marketed RYO products, no increase in GHG emissions is anticipated from the proposed action. Additionally, the applicant stated that the manufacturing facility complies with all applicable Canadian Regional and Federal emissions regulations and requirements.

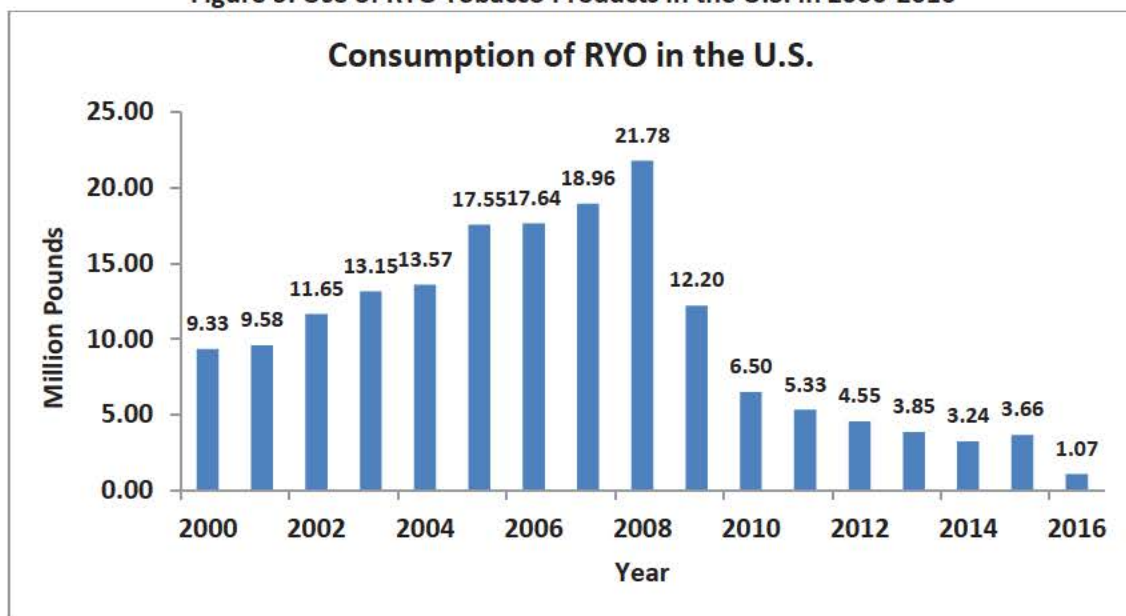
## **5.2 Environmental Introduction as a Result of Use of the New Tobacco Product**

### ***5.2.1 Use of the RYO Tobacco Products in the U.S.***

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

million pounds in 2009 to 1.07 million pounds in 2016 (Figure 5) (U.S. Dept of Treasury Alcohol and Tobacco Tax and Trade Bureau, 2017).

**Figure 5. Use of RYO Tobacco Products in the U.S. in 2000-2016**

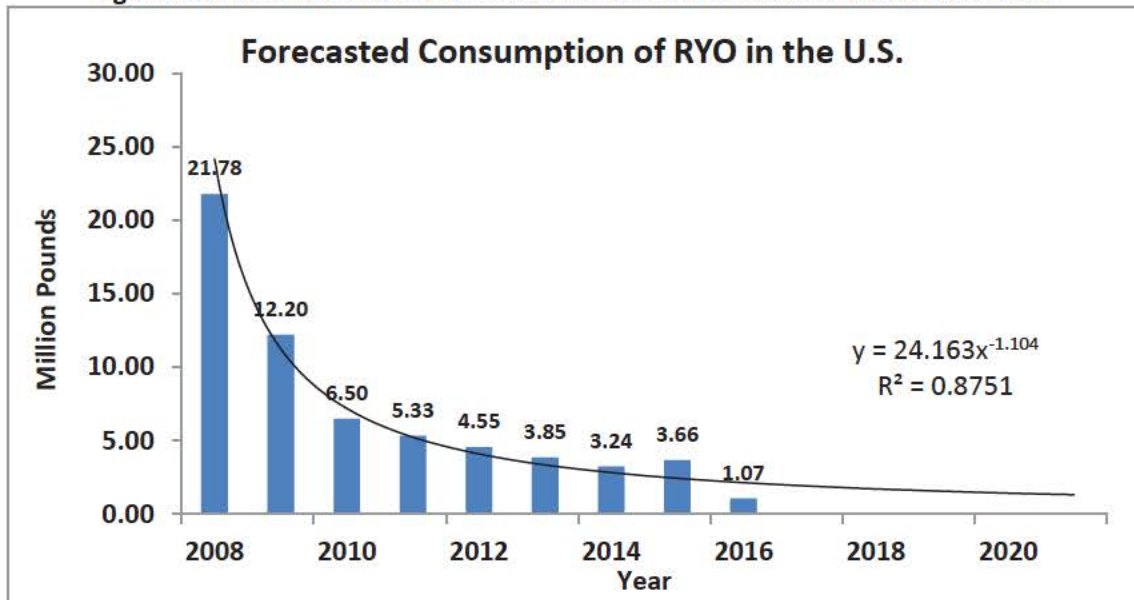


#### **5.2.2 Environmental Introduction from Use of the New Product**

To evaluate the environmental impact of the proposed action due to the use of the new product, the Agency analyzed historical use data for 2008-2016 to forecast the future use of RYO tobacco products in the U.S. This was achieved by using one best-fit power trend line with the  $R^2$  value of 0.8751.<sup>5</sup> Using this approach, the forecasted amount of RYO tobacco products to be used in the U.S. is estimated to be 1.90 million pounds in 2017 and 1.31 million pounds in 2021 (Figure 6).

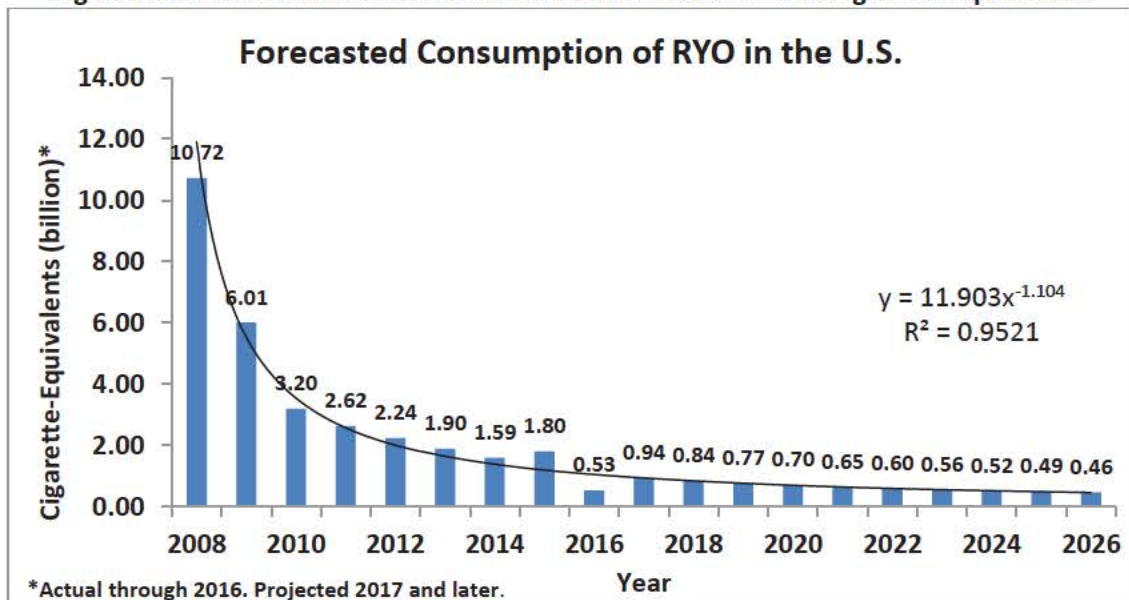
<sup>5</sup> Forecast trend lines extrapolated from TTB data. Available from <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 15, 2017.

Figure 6. Forecasted Use of RYO Tobacco Products in the U.S. in Million Pounds



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

Figure 7. Forecasted Use of RYO Tobacco Products in the U.S. in Cigarette-Equivalents



| Year              | RYO Tobacco Products (million pounds) <sup>a</sup> | RYO Tobacco Products (billion cigarette-equivalents) <sup>b</sup> |
|-------------------|----------------------------------------------------|-------------------------------------------------------------------|
| 2016              | 1.07                                               | 0.5268                                                            |
| First Year (2017) | 1.90                                               | 0.9354                                                            |
| Fifth Year (2021) | 1.31                                               | 0.6449                                                            |

<sup>a</sup> Projected first-year and fifth-year pounds of RYO tobacco products:  $24.163 \times (\text{year} - 2007)^{-1.104}$

<sup>b</sup> Cigarette-equivalents =  $\text{RYO tobacco (pounds)} \times \frac{16 \text{ ounces}}{\text{pound}} \times \frac{1 \text{ cigarette}}{0.0325 \text{ ounces RYO tobacco}}$

The applicant intends to market both new and predicate products after receiving market authorization 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 (CO<sub>2</sub>), and water vapor, as well as products of incomplete combustion such as carbon monoxide. These combustion products from the new product are released in a similar manner to its predicate product and other marketed RYO injector tubes. As noted, the only differences between the new and predicate products are in product quantity and package labeling. Additionally, because 1) the new product will compete with other currently marketed RYO products; 2) the projected market volumes of the new product and predicate product for the first and fifth years of marketing are, respectively, comparatively less than that of the current market volume of the predicate product; and 3) the projected market volume of the new product is miniscule relative to the overall U.S. tobacco market, no net addition of GHG emissions is anticipated.

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

The environmental consequences resulting from disposal following use of RYO cigarette injector tubes are a) disposal of packaging material, b) discarding of the used RYO tobacco product, and c) air emissions from disposal.

#### ***5.3.1 Disposal Following Use of RYO Cigarette Injector Tube***

##### **a) Disposal of Packaging Material**

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

**Figure 8. Municipal Solid Waste (MSW) Generation Rates in the U.S., 1960-2014**

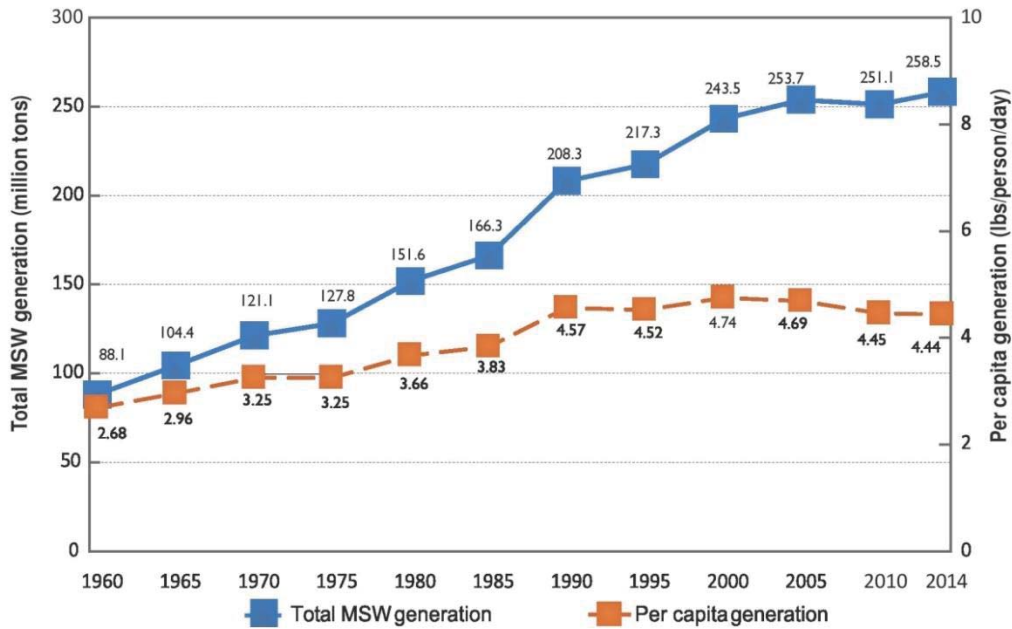


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

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

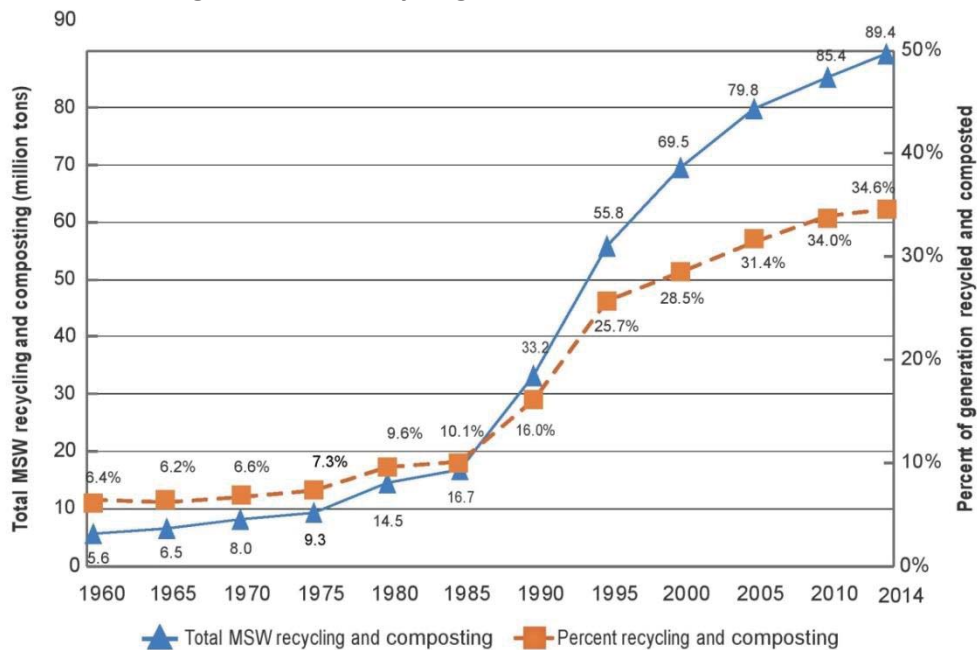


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

## b) Disposal of Used RYO Tobacco Product Following Use



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

| Forecast of Waste of Used RYO Tobacco Products as Compared to Total MSW Forecast in the U.S. |                                                      |                                                                      |                                                                                    |
|----------------------------------------------------------------------------------------------|------------------------------------------------------|----------------------------------------------------------------------|------------------------------------------------------------------------------------|
| Year                                                                                         | Total U.S. RYO Tobacco (million pounds) <sup>a</sup> | Total U.S. RYO Cigarette-Equivalents (million pounds) <sup>b,c</sup> | Total U.S. RYO Tobacco Products as a Percent of Total MSW in the U.S. <sup>d</sup> |
| 2016                                                                                         | 1.07                                                 | 1.42                                                                 | 0.00027%                                                                           |
| First Year (2017)                                                                            | 1.90                                                 | 2.52                                                                 | 0.00049%                                                                           |
| Fifth Year (2021)                                                                            | 1.31                                                 | 1.74                                                                 | 0.00034%                                                                           |

<sup>a</sup> Projected first-year and fifth-year pounds of RYO tobacco products:  $24.163 \times (\text{year} - 2007)^{-1.104}$

<sup>b</sup> 0.0325 ounces of RYO tobacco constitutes one cigarette (National Association of Attorneys General, 1998).

<sup>c</sup>  $\text{RYO tobacco (pounds)} + \left[ \left( \text{RYO tobacco (pounds)} \times \frac{16 \text{ ounces}}{\text{pound}} \times \frac{1 \text{ cigarette}}{0.0325 \text{ ounces tobacco}} \right) \times \left( \frac{1 \text{ injector tube}}{\text{cigarette}} \times \text{RYO injector tube (pounds)} \right)^7 \right]$

<sup>d</sup>  $\frac{\text{Total RYO cigarette-equivalents (million pounds)}}{258.46 \text{ million tons (U.S. Environmental Protection Agency, 2016)}} \times \frac{\text{ton}}{2000 \text{ pounds}} \times 100\%$

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

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

<sup>6</sup> "Cigarette butt" is defined in this EA as cigarette injector tube containing remainder tobacco that is disposed of following use. The cigarette butt may or may not also include a filter, depending on whether the RYO cigarette had one.

<sup>7</sup> See [Confidential Appendix 4](#).



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

### **c) Air Emissions from Disposal**

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

Methane is a potent GHG that has a global warming potential of 28-36 times greater than CO<sub>2</sub>, and has an atmospheric life of about 12 years. Landfills are the third largest source of human-related methane emissions in the U.S., releasing an estimated 133.1 million metric tons of CO<sub>2</sub>-equivalent, accounting for approximately 15.4% of these emissions in 2015 (U.S. Environment Protection Agency, July). The decomposition of landfill waste produces approximately 50% biogenic CO<sub>2</sub> and 50% methane (CH<sub>4</sub>), by volume, as well as trace amounts of non-methane organic compounds and volatile organic compounds. However, only methane 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 that have a waste capacity of 2.5 million metric tons or more to have landfill gas collection-and-control systems installed. Additionally, all landfills must report GHG emissions to the EPA under 40 CFR 98. Because 1) the new product will compete with other currently marketed RYO products; 2) the projected market volumes of the new product and predicate product for the first and fifth years of marketing are, respectively, comparatively less than that of the current market volume of the predicate product; and 3) the projected market volume of the new product is miniscule relative to the overall U.S. tobacco market, the GHG emitted from the waste associated with the new product is negligible.

### **5.3.2 Environmental Introduction from Disposal Following Use of the New Product**

The Agency believes that the disposal of the 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. Users may also discard what remains of the product after smoking, such as remaining combusted tobacco and cigarette injector tube, as discussed above, as MSW or litter.

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

As previously discussed, because the new RYO cigarette injector tube will compete with other similar RYO tobacco products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfills are not anticipated due to the proposed action.

The waste generated from using the new product is expected to make up a negligible fraction of the total MSW ([Confidential Appendix 4](#)); 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 new product is anticipated to be manufactured, used, and disposed of in the same way as other RYO tobacco products, including cigarette injector tubes. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other tobacco products specifically including cigarette injector tubes, manufactured in the facility. No new types of material are anticipated to be emitted to the environment at use and disposal following use.

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

The applicant stated that the manufacturing operation is in compliance with all Canadian regional and federal environmental regulations and requirements. Therefore, cumulative introduction of materials released into the environment is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws.

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

## **8. Use of Resources and Energy**

The new product will compete with currently marketed RYO tobacco products that are identical to the new product, other than a change in product quantity and package labeling. The applicant also stated that the proposed action will not require an expansion of the manufacturing facility. When comparing the market volume projections with the forecasted total RYO market volumes in the U.S., the Agency found that the projected market volume of the new product is a small fraction of the total forecasted market volume in 2017 and 2021. The applicant stated that manufacturing the new product would use a miniscule fraction of a percent of the total energy usage at the manufacturing facility ([Confidential Appendix 1](#)). Therefore, no more than a negligible net increase of energy use

will be expected from the proposed action. Additionally, the applicant stated that all ingredients used to manufacture the new product, as well as the predicate product, are from renewable and sustainable resources, in accordance with the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification Schemes (PEFC), and the manufacture of the new product is carried out under controls and standards that do not appear to threaten any endangered species or critical habitat, as listed by the Endangered Species Act (ESA) or the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

## 9. Mitigation

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

## 10. Alternatives to the Proposed Action

*Alternative A (No-action alternative):* The no-action alternative is to not authorize the marketing of the new tobacco product in the U.S. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of new tobacco product as the predicate product (Confidential Appendices [1](#) and [2](#)) and many other similar RYO tobacco products will continue to be marketed.

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

Therefore, the difference between the environmental impacts of these two alternatives is negligible, or non-existent.

## 11. List of Preparers

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

### Preparers:

Catherine W. McCollum, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biochemistry and Cell Biology  
Experience: 10 years in various scientific activities  
Expertise: NEPA analysis, environmental impact analysis, ecotoxicity, developmental toxicology

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

Education: M.S. in Environmental Science  
Experience: 34 years in Environmental Toxicology and Risk Assessment  
Expertise: NEPA analysis, environmental risk assessment, environmental toxicology, environmental fate and effects

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

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

Experience: 23 years in various scientific activities

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

Reviewers:

Hoshing W. Chang, PhD, Center for Tobacco Products

Education: M.S. in Environmental Science and PhD in Biochemistry

Experience: 8 years in FDA related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

## **12. List of Agencies and Persons Consulted**

Not applicable.

## **13. Appendix List**

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

## **14. Confidential Appendix List**

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

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

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

Confidential Appendix 4: The First- and Fifth-Year Projection of Paper and “Cigarette Butt” Waste of Packaging Materials and Product Materials Associated with Marketing the New and Predicate Products

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# APPENDIX 1

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

| STN       | Product Name         | Product   | Tubes per Retail Box | Retail Boxes per Shipping Case | Amendments |
|-----------|----------------------|-----------|----------------------|--------------------------------|------------|
| SE0014064 | High Card Gold 100mm | New       | 250                  | 40                             | SE0014190  |
|           | Top Gold 100mm       | Predicate | 200                  | 50                             |            |

# CONFIDENTIAL APPENDIX 1

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

| STN       | Unit             | Current-Year (2016) Market Volume | First-Year Market Volume |                   | Fifth-Year Market Volume |                   |
|-----------|------------------|-----------------------------------|--------------------------|-------------------|--------------------------|-------------------|
|           |                  | Predicate Product                 | New Product              | Predicate Product | New Product              | Predicate Product |
| SE0014064 | # Injector Tubes | (b) (4)                           |                          |                   |                          |                   |
|           | Metric Tons      |                                   |                          |                   |                          |                   |

The applicant stated that the new RYO tobacco product is intended to comprise approximately (b) (4) injector tubes) of the manufacturing facility's total production (b) (4) injector tubes).

The applicant stated that the manufacturing facility uses a total of 3,786.749 MWh of energy to produce (b) (4) injector tubes. The applicant also provided estimates of energy usage for producing the new and predicate products:

| Manufacturing Facility                              | New Product | Predicate Product |
|-----------------------------------------------------|-------------|-------------------|
| Energy per Injector Tube (kWh)                      | (b) (4)     |                   |
| Energy Usage for First Year (kWh) <sup>a</sup>      |             |                   |
| Energy Usage for Fifth Year (kWh) <sup>a</sup>      |             |                   |
|                                                     |             |                   |
| % of Total Energy Usage for First Year <sup>b</sup> |             |                   |
| % of Total Energy Usage for Fifth Year <sup>b</sup> |             |                   |

<sup>a</sup> Market Volume for First or Fifth Year × Energy per Injector Tube (kWh)

<sup>b</sup>  $\frac{\text{Energy Usage for First or Fifth Year (kWh)}}{\text{Total Energy Usage at Manufacturing Facility (kWh)}} \times 100\%$

## CONFIDENTIAL APPENDIX 2

### Comparison of the Current-Year Market Volume for the Predicate Product with Total RYO Tobacco Products Used in the U.S.

The current-year market volume of the predicate product occupying the U.S. market was compared to the use of total RYO tobacco in the U.S. (Figure 7, and [Confidential Appendix 1](#)). The percent of the total RYO tobacco market occupied in the current year of marketing of the predicate product was calculated using the equation below<sup>8</sup>:

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

| STN        | Year | Use of Total RYO Tobacco in the U.S. (Cigarette-Equivalent) <sup>9</sup> | Market Volume of Predicate Product (Cigarette-Equivalent) <sup>10</sup> | Market Occupation of Predicate Product in the U.S. (%) |
|------------|------|--------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------|
| SE00014064 | 2016 | (b) (4)                                                                  |                                                                         |                                                        |

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<sup>8</sup> Each individual injector tube is anticipated to be used in making a single cigarette unit. Therefore, one injector tube is equal to one cigarette-equivalent.

<sup>9</sup> See Figure 7.

<sup>10</sup> See Confidential Appendix 1.

### CONFIDENTIAL APPENDIX 3

#### Comparison of the First- and Fifth-Year Market Volume Projections for the New and Predicate Products with Total RYO Tobacco Products Used in the U.S.

The first- and fifth-year market volumes of the new and predicate products to occupy the U.S. market were determined by comparing the projected market volume of the new products to the forecasted use of total RYO tobacco in the U.S. (Figure 7, and [Confidential Appendix 1](#)). The percent of the total RYO tobacco market occupied in the projected first and fifth year of marketing of the new and predicate products was calculated using the equations below<sup>11</sup>:

First Year Market Occupation of New and Predicate Products (%)

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

Fifth Year Market Occupation of New and Predicate Products (%)

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

| STN       | Year  | Forecasted Use of Total RYO Tobacco in the U.S. (Cigarette-Equivalent) <sup>12</sup> | Projected Market Volume of New Product (Cigarette-Equivalent) <sup>13</sup> | Projected Market Occupation of New Product in the U.S. (%) |
|-----------|-------|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|------------------------------------------------------------|
| SE0014064 | First | (b) (4)                                                                              |                                                                             |                                                            |
|           | Fifth |                                                                                      |                                                                             |                                                            |
| Predicate | First |                                                                                      |                                                                             |                                                            |
|           | Fifth |                                                                                      |                                                                             |                                                            |

<sup>11</sup> Each individual injector tube is anticipated to be used in making a single cigarette unit. Therefore, one injector tube is equal to one cigarette-equivalent.

<sup>12</sup> See Figure 7.

<sup>13</sup> See Confidential Appendix 1.

#### CONFIDENTIAL APPENDIX 4

##### The First- and Fifth-Year Projection of Paper and “Cigarette Butt” Waste of Packaging Materials and Product Materials Associated with Marketing the New and Predicate Products

To analyze the environmental effects from paper and “cigarette butt”<sup>14</sup> waste due to the proposed action, the Agency estimated the first- and fifth-year weights of the projected packaging and product materials waste (in metric tons) that are generated from disposal after use of the products in 2017 and 2021. Projected paper and “cigarette butt” waste generation is the summation of the projected booklet cover, cardboard box, pouch (used to contain RYO tobacco), “cigarette butt”, and shipping case waste generation of the product:

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

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

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

$$D_i = E_i \times M_i \times Z$$

$A_i$ : Projected paper and “cigarette butt” waste generation of the products (metric tons)

$B_i$ : Projected retail cardboard box waste generation of the products (metric tons)

$C_i$ : Projected shipping case waste generation of the products (metric tons)

$D_i$ : Projected “cigarette butt” waste of the products (metric tons)

$E_i$ : Projected market volume of the products (# individual cigarette injector tubes)

$F_i$ : Number of cigarette injector tubes per retail box

$G$ : Weight of empty retail box (grams)

$H_i$ : Number of retail boxes per shipping case

$I$ : Weight of empty shipping case (grams)

$J_i$ : Length of cigarette injector tube (millimeters)

$K$ : Cigarette butt ratio (%)<sup>15</sup>

$L_i$ : Weight of empty cigarette injector tube (milligrams)

$M_i$ : Weight of cigarette butt ingredients (milligrams)<sup>16</sup>

$Z$ :  $1.0 \times 10^{-6}$  metric tons/gram

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<sup>14</sup> “Cigarette butt” in this EA is defined as cigarette rolling paper containing remainder tobacco that is disposed of following use.

<sup>15</sup> 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 as solid waste following use.

<sup>16</sup> As stated by the applicant, the cigarette butt ingredients include plugwrap, acetate tow, inner gluing, tipping paper, tipping adhesive, filter anchorage, and ink.



|            | STN                                                         | M       | L | K | J | I | H | G | F | E | D | C | B | A       |
|------------|-------------------------------------------------------------|---------|---|---|---|---|---|---|---|---|---|---|---|---------|
| First Year | SE0014064                                                   | (b) (4) |   |   |   |   |   |   |   |   |   |   |   |         |
|            | Predicate                                                   |         |   |   |   |   |   |   |   |   |   |   |   |         |
|            | First-Year Total Paper Waste for New and Predicate Products |         |   |   |   |   |   |   |   |   |   |   |   | (b) (4) |

|            | STN                                                         | M       | L | K | J | I | H | G | F | E | D | C | B | A       |
|------------|-------------------------------------------------------------|---------|---|---|---|---|---|---|---|---|---|---|---|---------|
| Fifth Year | SE0014064                                                   | (b) (4) |   |   |   |   |   |   |   |   |   |   |   |         |
|            | Predicate                                                   |         |   |   |   |   |   |   |   |   |   |   |   |         |
|            | Fifth-Year Total Paper Waste for New and Predicate Products |         |   |   |   |   |   |   |   |   |   |   |   | (b) (4) |

**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. Estimation of generated total paper and “cigarette butt” waste for the new and predicate products is (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year. A portion of the generated paper waste is likely to be recycled with an overall recycling rate for paper products at 64.7% in the U.S., according to U.S. EPA (U.S. Environmental Protection Agency, 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 U.S., 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.<sup>17</sup>

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 and fifth years of marketing the new and predicate products is (b) (4) metric tons and (b) (4) metric tons, respectively. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the U.S. in 2014.

<sup>17</sup> At 35.3% disposal rate as paper waste (on cardboard retail boxes and shipping cases) for the 1<sup>st</sup> Year, (b) (4)  
5<sup>th</sup> Year, (b) (4).