

**Programmatic Environmental Assessment for Two
Market Authorizations of “GAMBLER® SINGLE WIDE”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

March 13, 2017

Table of Contents

| | | |
|--------|-------------------------------------------------------------------------------------------------------|----|
| 1. | Name of Applicant | 4 |
| 2. | Address | 4 |
| 3. | Manufacturer | 4 |
| 4. | Description of the Proposed Action..... | 4 |
| 4.1. | Requested Action..... | 4 |
| 4.2. | Need for Action..... | 4 |
| 4.3. | Identification of the New Tobacco Products that are Subjects of the Proposed Action.... | 5 |
| 4.3.1. | <i>Type of Tobacco Products.....</i> | 5 |
| 4.3.2. | <i>Product Names and Their Original STNs.....</i> | 5 |
| 4.3.3. | <i>Description of the Product Package.....</i> | 5 |
| 4.3.4. | <i>Location of Manufacturing.....</i> | 5 |
| 4.3.5. | <i>Location of Use.....</i> | 5 |
| 4.3.6. | <i>Location of Disposal.....</i> | 5 |
| 4.4. | Modification(s) Identified as Compared to the Predicate Product..... | 6 |
| 5. | Environmental Introduction Due to the Proposed Action..... | 6 |
| 5.1. | Introduction as a Result of Manufacturing the New Products..... | 6 |
| 5.1.1. | Tobacco Products Imported from France..... | 6 |
| 5.1.2. | Environmental introduction from manufacturing the new products..... | 7 |
| 5.2. | Environmental Introduction as a Result of Use of the New Products..... | 8 |
| 5.2.1. | <i>Use of RYO Rolling Papers.....</i> | 8 |
| 5.2.2. | <i>Environmental introduction from use of the new products.....</i> | 8 |
| 5.3. | Environmental Introduction as a Result of Disposal Following Use..... | 9 |
| 5.3.1. | <i>Disposal following use of RYO rolling papers.....</i> | 9 |
| 5.3.2. | <i>Environmental introduction of disposal following use of RYO rolling papers.....</i> | 11 |
| 5.3.3. | <i>Disposal of packaging material.....</i> | 11 |
| 6. | Fate of Materials Released into the Environment Due to the Proposed Action | 12 |
| 7. | Environmental Effects of New Materials Released into the Environment Due to the Proposed Action | 12 |
| 8. | Use of Resources and Energy | 12 |
| 9. | Mitigation..... | 13 |
| 10. | Alternatives to the Proposed Action..... | 13 |

| | | |
|-----|----------------------------------------------|----|
| 11. | List of Preparers | 13 |
| 12. | List of Agencies and Persons Consulted | 13 |
| 13. | Appendix List | 14 |
| 14. | Confidential Appendix List..... | 13 |

This programmatic environmental assessment (PEA) is for the market authorizations of two roll-your-own (RYO) rolling papers manufactured by Republic Tobacco, LP (Appendix 1). 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

Republic Tobacco, LP

2. Address

2301 Ravine Way
Glenview, Illinois 60025

3. Manufacturer

(b) (4)

4. Description of the Proposed Action

The proposed action is for FDA to issue market authorizations under section 910(a)(2) of the FD&C Act for the introduction of two new RYO rolling papers into interstate commerce. These authorizations are based on the finding that these new products are substantially equivalent to their corresponding predicate product that was on the market as of February 15, 2007. The applicant intends to continue marketing the predicate product after the new products are authorized.

4.1. Requested Action

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

4.2. Need for Action

Republic Tobacco, LP wishes to introduce the new tobacco products (as described) into interstate commerce for commercial distribution in the U.S. The applicant claims that the new products and corresponding predicate product differ only in product quantity and labeling and therefore the new products do not raise different public health questions (sec. 910(a)(3)(A)(ii)) as described in a FDA guidance to industry issued on March 4, 2015.¹ After considering the SE Reports, the Agency shall issue orders pursuant to section 910(a)(2) of the FD&C Act when finding the new products to be substantially equivalent to their corresponding predicate product.

¹ FDA Guidance for Industry. Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions. Issued March 4, 2015. Available at: <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf>. Accessed on July 14, 2016)

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

4.3.1. Type of Tobacco Products

Roll-your-own (RYO), rolling papers

4.3.2 Product Names and Their Original STNs

Names of the new products are listed below, along with the original submission tracking numbers (STNs) and the names of the corresponding predicate product. See Appendix 1 for additional STNs associated with the new and predicate products.

| STN | New Product | Predicate Product |
|-----------|----------------------|-------------------|
| SE0013713 | GAMBLER® SINGLE WIDE | TOP® STANDARD |
| SE0013715 | GAMBLER® SINGLE WIDE | TOP® STANDARD |

4.3.3 Description of the Product Package

The new products are RYO rolling papers enclosed in a cardboard booklet cover contained in a cardboard retail box.

4.3.4 Location of Manufacturing

(b) (4)



4.3.5 Location of Use

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

4.3.6 Location of Disposal

The used and unused rolling papers will be disposed of as municipal solid waste (MSW)

² Manufacturer address via aerial photo, Google Earth. Accessed 04/04/2016.

in the landfills or trashed as litter, in the same manner as any other marketed RYO cigarette. Disposal of the packaging materials following use will either enter the recycling stream or be deposited in MSW landfills or as litter. The distribution of waste from disposal after use should correspond to the pattern of product use.

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

The applicant stated that the differences between the new and predicate products would be in package quantity and labeling (see Confidential Appendix 1).

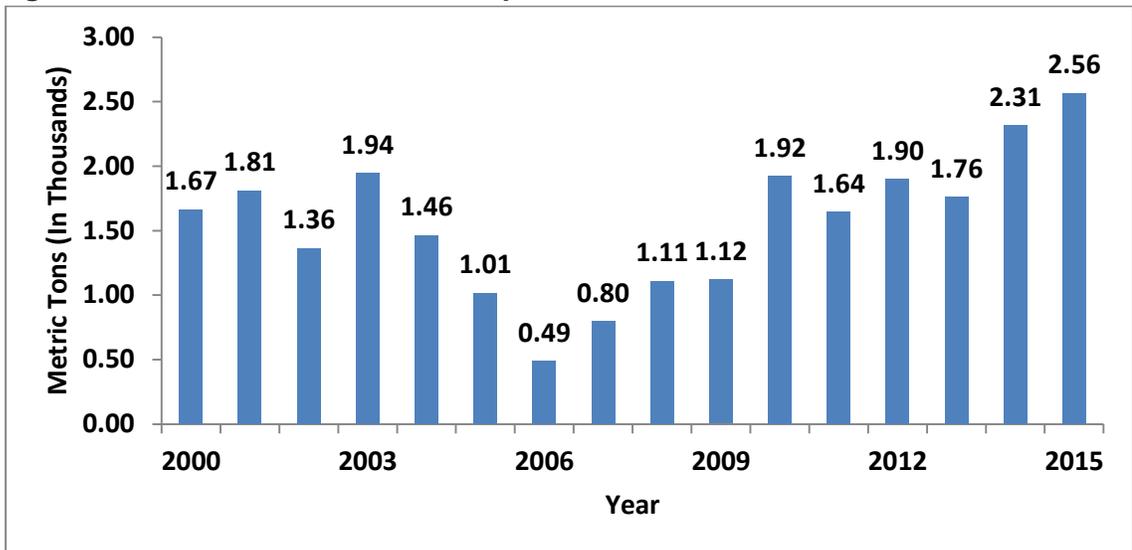
5. Environmental Introduction Due to the Proposed Action

5.1. Introduction as a Result of Manufacturing the New Products

5.1.1 Tobacco Products Imported from France

Based on information collected by the U.S. International Trade Commission (USITC), the import of total tobacco products to the U.S. from France has increased from 490 metric tons in 2006 to 2563 metric tons in 2015 (see Figure 2).³

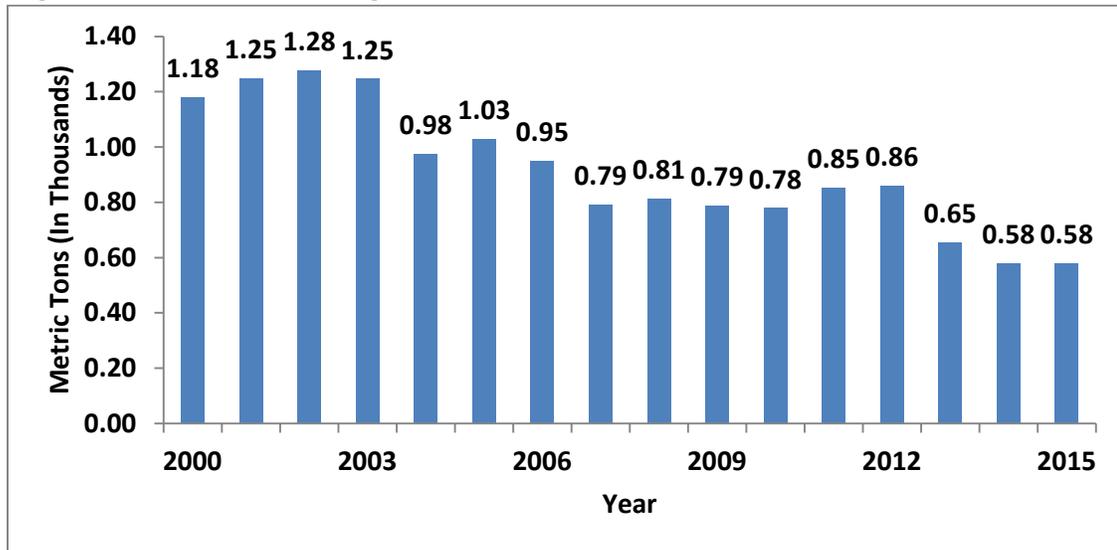
Figure 2. Total Tobacco Products Imported from France into the U.S. 2000 – 2015



When looking at the change in import specifically of cigarette papers to the U.S from France from 2002 to 2015, there was a decrease, from 1278 metric tons in 2002 to 579 metric tons in 2015, as shown in Figure 3.

³ Unit is defined by USITC, available at: http://dataweb.usitc.gov/scripts/tariff_current.asp?Phase=List_items&lookfor=481310. Accessed on March 23, 2016

Figure 3. U.S. Import of Cigarette Papers from France 2000 – 2015



The cigarette paper imported to the U.S. from France in 2015 (579 metric tons) represents 23% of the total amount of tobacco products imported from France in 2015 (2563 metric tons).

5.1.2 Environmental introduction from manufacturing the new products

Introduction from manufacturing new products in the proposed actions. The Agency anticipates the waste generated as a result of manufacturing the new products will be released to the environment, transferred to publicly owned treatment works (POTW), and disposed of in landfills in the same manner as any other products manufactured in the same facility and in a similar manner to other cigarette papers manufactured in France. The Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all RYO tobacco products in France because the new products will be marketed concurrently with the predicate product (Confidential Appendix 2) and compete with the predicate product and other currently marketed RYO cigarette paper products.

No particular market trend pattern is easily observed using data regarding cigarette paper importation to the U.S. from France from 2000 to 2015. Although there has been a decline of cigarette paper imports from France from 1180 metric tons in 2000 to 579 metric tons in 2015. The applicant stated that the manufacturing operation abides by all French regional and federal emissions, solid waste, and liquid waste regulations and requirements, which are applicable to their facility.

The new products are anticipated to compete with other cigarette papers and therefore, the Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all cigarette papers. Based on information in the SE Reports, the characteristics of the cigarette papers are

within the traditional range found throughout the industry.

The applicant stated that the differences between the new and corresponding predicate products would be in package quantity and labeling (see Confidential Appendix 1). 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.

The applicant provided the first- and fifth-year projected market volumes for the new products (Confidential Appendix 2). Comparing the projected market volume of the new products with the forecasted market volume of all tobacco products imported into the U.S. from France in 2016 and 2020, the cumulative projected market volumes of the new products are a small fraction of the total forecasted market volumes in 2016 and 2020 (Appendix 2 and Confidential Appendix 2). Therefore, no new control practices of air emission, water discharge, and solid waste disposal are needed when manufacturing the new products.

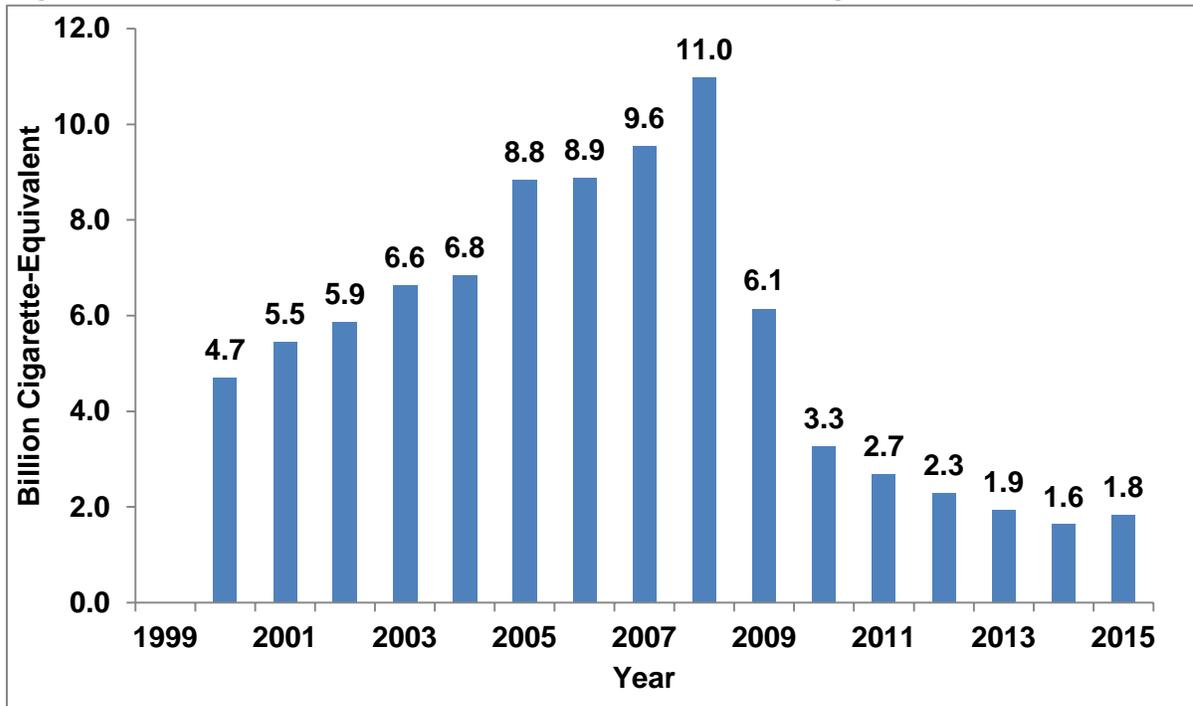
5.2. Environmental Introduction as a Result of Use of the New Products

5.2.1 Use of RYO Rolling Papers

Data from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistics reports showed a gradual linear increase in the use of RYO tobacco in the U.S. from 4.7 billion cigarette-equivalents to 11 billion cigarette-equivalents during the years 2000 to 2008, respectively (Figure 4).⁴ This was followed by a decline in its use to 3.3 billion cigarette-equivalents in 2010 and to 1.8 billion cigarette equivalents in 2015.

⁴ U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Tobacco Statistics. Available at: <http://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed February 7, 2017.

Figure 4. Use of RYO in the U.S. in 2000 – 2015 in Billion Cigarette-Equivalents



5.2.2 Environmental introduction from use of the new products

As noted, the primary differences between the new products and corresponding predicate product are the product quantity of rolling papers and the product label. During use, the new product is usually burned to ash, carbon dioxide, and water vapor, as well as products of incomplete combustion such as carbon monoxide. These combustion products from the new products are the same as those from the corresponding predicate product and are released in the same manner to those from the corresponding predicate product and other RYO, rolling paper products. The substances released during use of the new products are naturally occurring and no different from the predicate product.

To evaluate the environmental impact of the proposed action due to use of the new products, historical data regarding consumption of all RYO in the U.S. from 2005 to 2015 was also used. This was achieved by using one best-fit power trend line with the R^2 value of 0.9739 for the total RYO cigarette-equivalents used in the U.S. Accordingly, the forecasted amounts of all RYO cigarettes to be used in the U.S. are estimated to be 1.1 billion pieces and 0.9 billion pieces in 2017 and 2021, respectively (Appendix 2). These data indicate that the RYO market as a whole has decreased since 2008 and the introduction of the new product is not expected to change the decrease going forward.

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

5.3. Environmental Introduction as a Result of Disposal Following Use

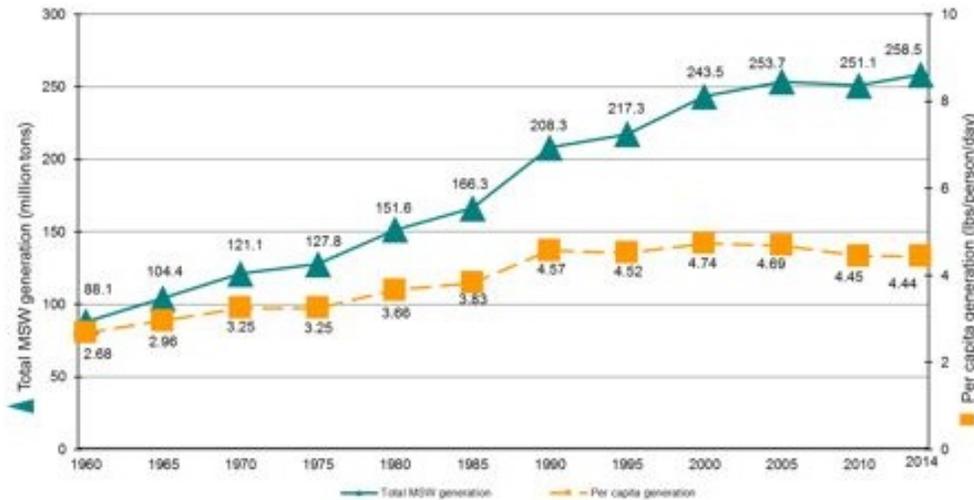
The waste that is generated following use of the new and corresponding predicate products consists of the disposed packaging materials along with the discarded ash and unused paper from RYO rolling papers. The unused RYO rolling paper along with the cardboard booklet cover and retail box material is biodegradable, and could also be recycled or thrown away as trash in MSW landfills or as litter.

5.3.1 Disposal following use of RYO rolling papers

a) Disposal of packaging material

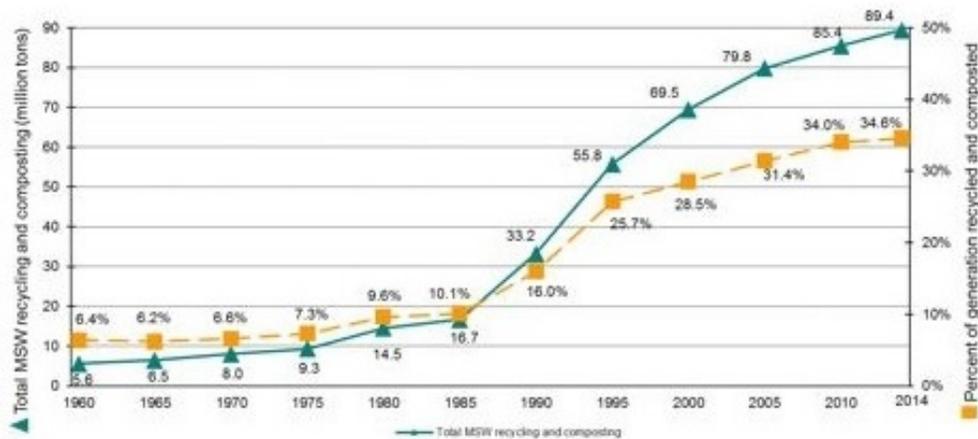
As noted above, the used RYO rolling papers will be disposed of in MSW landfills or as litter. Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. In 2014, the amount of waste generated in the U.S. was approximately 258 million tons and approximately 89 million tons of this material was recycled and composted, equivalent to a 34.5 percent recycling rate (Figure 5 and Figure 6). The recovery of newspaper/mechanical papers was about 68 percent (5.9 million tons). On average, 4.4 pounds per person per day of waste was generated, of which 1.5 pounds was recycled and composted in the U.S. in 2014.⁵

Figure 5. Municipal Solid Waste (MSW) Generation Rates in the U.S, 1960 – 2014



⁵ EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: <http://www.epa.gov/waste/nonhaz/municipal/>. Accessed February 7, 2017.

Figure 6. MSW Recycling Rates in the U.S., 1960-2014



5.3.2 Environmental introduction of disposal following use of RYO rolling papers

The Agency believes that the disposal of the new products will be similar to the disposal conditions of other RYO rolling paper products that are currently being marketed. After using the new product, the users may dispose of or recycle the cardboard packaging material. Users may also discard the unused RYO rolling paper and ashes as MSW or as litter.

5.3.3 Disposal of packaging material

The Agency assumes that all packaging material of the new products will be disposed of as MSW. However, paper products are more likely to be recycled than other types of MSW. According to the information presented in the SE Reports, the predicate product and the new products are packaged using the same cardboard material for the booklet cover and retail box. To determine the amount of waste from disposal of cardboard packaging material, the Agency used the first- and fifth-year projected volumes of marketing the new and predicate products (Confidential Appendix 3). The calculated cumulative waste of the cardboard packaging material is miniscule compared to all municipal solid waste generated and at least a portion of the waste is likely to be recycled. The Agency anticipates no new construction of MSW landfills as a result of disposal of cardboard packaging material.

Furthermore, the anticipated release of new substances into the environment as a result of disposal of the new products is miniscule compared to that of all tobacco products that are already on the market. The Agency anticipates no new construction of MSW landfills as a result of disposal of RYO rolling papers following use.

Global methane emissions from landfills are estimated between 30 and 70 million metric tons per year. MSW landfills are the third largest source of human-related methane emissions in the U.S., releasing an estimated 133.1 million metric tons of CO₂, accounting for approximately 18.2% of these emissions in 2014. Methane is a potent greenhouse gas (GHG) that has a global warming potential of 28-36 times greater than CO₂, and has an atmospheric life of about 12 years. EPA released a final rule stating an

expectation of methane emission reduction by an estimated 334,000 metric tons, the equivalent of reducing 8.2 million metric tons of CO₂ in 2025. Because the new products and predicate product will be marketed simultaneously and the new products are expected to compete with similar RYO products, the Agency anticipates no increase in GHG emissions as a result of use or disposal of the new products.

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 (RYO rolling papers with the same attributes and characteristics as the new products) have been sold and continue to be sold in the U.S. The new products are anticipated to be manufactured the same way as other products in the same facility. Therefore, the fate of additional materials emitted to the air, water and land is anticipated to be the same as other products manufactured in the facility. No new types of materials are anticipated to be emitted since the new products will be made using the same materials and processes as the predicate product.

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

The applicant stated that the manufacturing operation abides by all French regional and federal emissions, solid waste, and liquid waste regulations and requirements, which are applicable to their facility. Therefore, cumulative introduction is expected not to exceed what is allowed to be introduced to the environment under relevant environmental laws.

Consequently, the environmental effects of the materials released due to the manufacturing of the new products are anticipated to be no more than the potential maximum effects to the environment due to the manufacturing facility. Environmental protection laws generally are based on risk to sensitive populations and threshold limits are set using safety factors to address uncertainty. If the manufacturer remains in compliance with the existing laws, the environmental effects are expected to be below the level that would cause harm and no substantial effects are anticipated.

As outlined above, the amount of materials anticipated to enter the environment due to use and disposal following use of the new products is negligible. The environmental effects of the materials released due to the use and disposal following use of the new products are negligible. Consequently, no new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The applicant stated that the paper used to manufacture the RYO rolling papers is produced from sustainable resources in accordance with the Forest Stewardship Council and the Programme for the Endorsement of Forest Certification Schemes. These standards require that the applicant use raw materials that do not impact critical habitats or endangered species.

9. Mitigation

During our review of the available data and information, we did not identify adverse environmental effects for the new products and their use as RYO rolling papers. Therefore, no mitigation measures are discussed.

10. Alternatives to the Proposed Action

Alternative A (No-action alternative): The no-action alternative is to not allow the marketing of the new tobacco products in the U.S. 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 the predicate product, as well 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 action of authorizing the new products and the associated manufacture, use, and disposal from use of the new tobacco products.

Therefore, the difference between the environmental impacts of these two alternatives is not substantial.

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.

Preparer:

Shannon Hanna, PhD, Center for Tobacco Products

Education: PhD in Environmental Science and Management

Experience: Four years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

Reviewer:

Gregory Gagliano, MS, Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: 33 years in Environmental Toxicology and Risk Assessment

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

12. List of Agencies and Persons Consulted

Not Applicable

13. Appendix List

Appendix 1: List of SE Reports and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA).

Appendix 2: Forecasted Use of RYO Cigarette-Equivalents in the US

14. Confidential Appendix List

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

Confidential Appendix 2: Package Size for New and Predicate Products.

Confidential Appendix 3: The First- and Fifth-Year Projections of Cardboard Waste of Packaging Materials Associated with Marketing the Products

APPENDIX 1

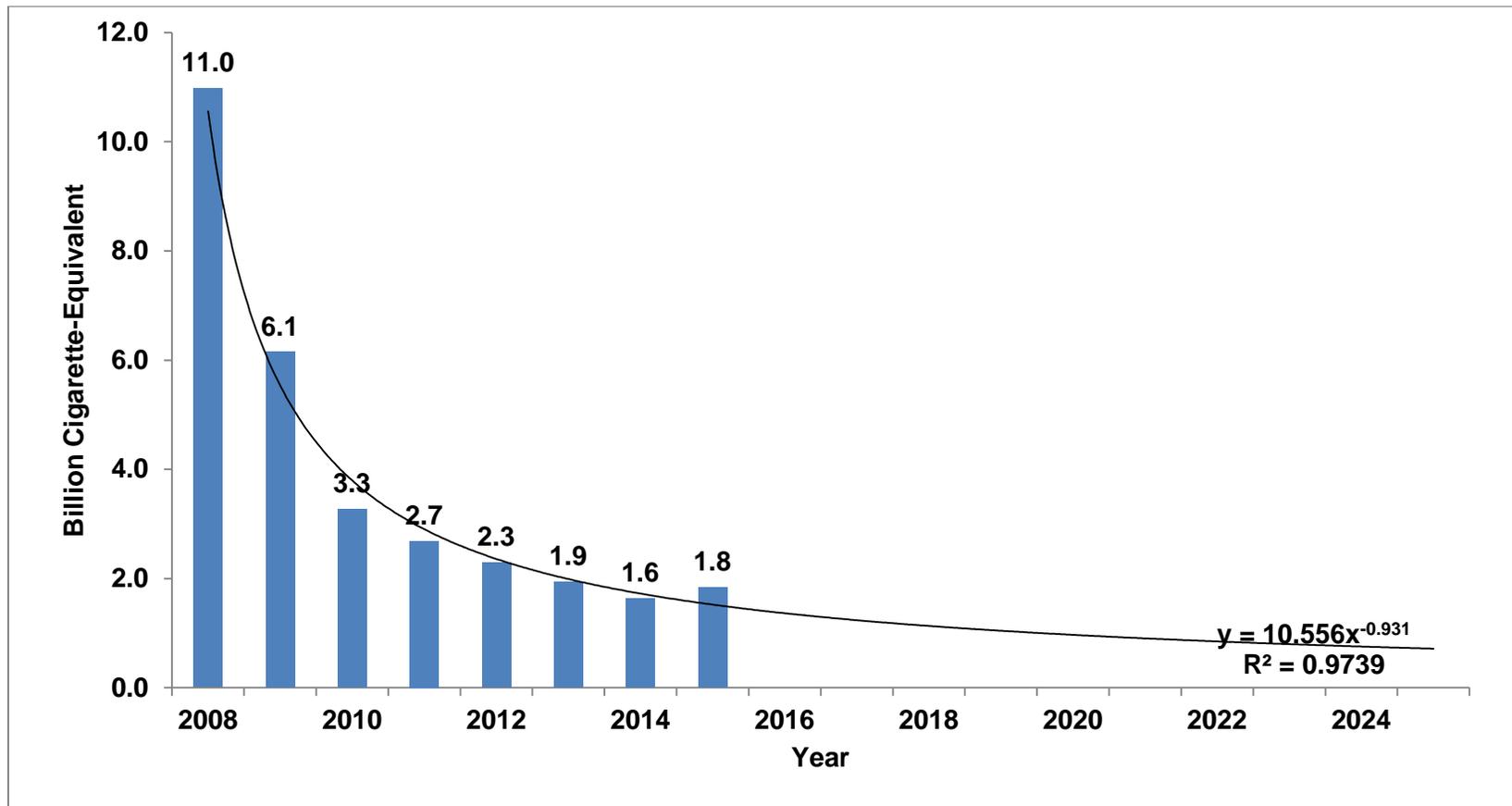
List of SE Report Submission Tracking Numbers with Names of the New and Predicate Products, and Related Amendments that are Covered Under this Programmatic Environmental Assessment (PEA)

| STN | New Product | Predicate Product | Amendments |
|------------|----------------------|--------------------------|-------------------|
| SE0013713 | GAMBLER® SINGLE WIDE | TOP® STANDARD | SE0013820 |
| SE0013715 | GAMBLER® SINGLE WIDE | TOP® STANDARD | |

APPENDIX 2

Forecasted Use of RYO Cigarette-Equivalents in the US

To evaluate the environmental impact of the proposed action due to use of the new products, historic data regarding use of RYO from 2008 to 2015 was used to forecast the use of RYO for the ten-year period from 2016 to 2025. This was achieved by using one best-fit power trend line with the R^2 value of 0.9739. Accordingly, the forecasted amounts of cigarette-equivalent use in the U.S. are estimated to be 1.4 billion cigarette-equivalents in 2016 and 0.9 billion cigarette-equivalents in 2021.



CONFIDENTIAL APPENDIX 1

Package Size for New and Predicate Products

| STN | Package Size (Papers/Booklet) | | Package Size (Booklets/Retail Box) | | New Product | Predicate Product |
|-----------|-------------------------------|-----------|------------------------------------|-----------|----------------------|-------------------|
| | New | Predicate | New | Predicate | | |
| SE0013713 | 24 | 100 | 160 | 24 | GAMBLER® SINGLE WIDE | TOP® STANDARD |
| SE0013715 | 50 | 100 | 90 | 24 | GAMBLER® SINGLE WIDE | TOP® STANDARD |

CONFIDENTIAL APPENDIX 2

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

| STN | | 1 st Year Market Volume | | 5 th Year Market Volume | |
|-------------------------------------------------------------|----------------|------------------------------------|-------------------|------------------------------------|-------------------|
| | | New Product | Predicate Product | New Product | Predicate Product |
| SE0013713 | Rolling Papers | (b) (4) | | | |
| | Metric Tons | | | | |
| SE0013715 | Rolling Papers | | | | |
| | Metric Tons | | | | |
| Total Projected Market Volume of New and Predicate Products | Metric Tons | | | | |

Compared to the forecasted manufactured RYO cigarette-equivalents in the U.S. in 2016 and 2021, 1.4 billion and 0.9 billion equivalents, the first- and fifth-year market volume for the new product projections occupy 0.6% and 0.9% of the forecasted market volume in the U.S., respectively.

CONFIDENTIAL APPENDIX 3

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

The Agency estimated the first- and fifth-year weights of the projected cardboard packaging material waste (in metric tons) that is generated from disposal after use of the new and predicate products as follows:

$$\sum_{i=1}^3 A_i = \sum_{i=1}^3 (B_i + C_i + D_i)$$

$$B_i = (E_i \times F_i \times K)$$

$$C_i = (G_i \times H_i \times K)$$

$$D_i = (I_i \times J_i \times K)$$

where,

A_i = Projected packaging material waste generation of a given product (metric tons)

B_i = Projected paper booklet cover waste generation for the product (metric tons)

C_i = Projected paper box waste generation for the product (metric tons)

D_i = Projected shipping case waste generation for the product (metric tons)

E_i = Weight of the booklet cover

F_i = Number of projected booklet covers (projected number of rolling papers divided by number of rolling papers per booklet cover)⁶

G_i = Weight of retail box

H_i = Number of projected retail boxes (projected number of rolling papers divided by the number of rolling papers per booklet cover divided by the number of booklet covers per retail box)⁷

I_i = Weight of shipping case

J_i = Number of projected shipping cases (projected number of rolling papers divided by the number of rolling papers per booklet cover divided by the number of booklet covers per retail box divided by the number of retail boxes per shipping case)

K = 10^{-6} (metric tons/gram)

⁶ Refer to Confidential Appendix 2 and 3 for data used for calculations.

⁷ Refer to Confidential Appendix 2 and 3 for data used for calculations.

| STN | Product Name | E g/cover | G g/box | I g/case | 1st Year (metric tons) | | | | 5th Year (metric tons) | | | |
|---------------------------------------------------------|-------------------------|--------------|------------|-------------|------------------------|---|---|---|------------------------|---|---|---|
| | | | | | B | C | D | A | B | C | D | A |
| SE0013713 | GAMBLER® SINGLE WIDE | (b) (4) | | | | | | | | | | |
| SE0013715 | GAMBLER® SINGLE WIDE | (b) (4) | | | | | | | | | | |
| Predicate | TOP® STANDARD | (b) (4) | | | | | | | | | | |
| Total Paper Waste for New and Predicate Products | | (b) (4) | | | | | | | | | | |

Paper Waste. Estimation for generated total cardboard is (b) (4) in the first year and (b) (4) in the fifth year. A portion of the generated cardboard waste is likely to be recycled with an overall recycling rate for paper products at 64% in the U.S. according to US EPA⁸. Therefore, if 36% of the box is disposed of as waste based on the 2014 waste generation data in the U.S., the estimated cumulative cardboard waste will be (b) (4) in the first year of marketing the products and the estimated cumulative cardboard waste will be (b) (4) in the fifth year of marketing the products.

If the entire packaging cardboard is disposed of as waste, in the worst case scenario, the projected cumulative cardboard waste in the first year of marketing the products is (b) (4) and (b) (4) of marketing the products. The worst case scenario for the projected cumulative cardboard waste is (b) (4) of total cardboard waste. This is a negligible fraction of the 258 million tons of total waste reported in the U.S. in 2014.

⁸ EPA. Wastes - Non-Hazardous Waste - Municipal Solid Waste. Available at: <http://www.epa.gov/waste/nonhaz/municipal/>. Accessed February 7, 2017