

**Programmatic Environmental Assessment for Marketing Orders for
Republic Tobacco, LP “Gambler Tubecut Regular King Size, Gambler
Regular King Size, and Zig-Zag Original King Size”**

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

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This programmatic environmental assessment (PEA) is for the marketing orders for roll-your-own (RYO) filtered cigarette tubes manufactured by Republic Tobacco, LP. 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 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)


4. Description of Proposed Actions

The proposed actions are for FDA to issue a marketing orders under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of multiple roll-your-own (RYO) filtered cigarette tubes into interstate commercial distribution in the United States. The authorization is based on the finding that the new products are 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 marketing orders for the new products.

4.1 Requested Actions

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

4.2 Need for Actions

Republic Tobacco, LP wishes to introduce three new tobacco products as described into interstate commerce for commercial distribution in the United States. The applicant claims that the new and predicate products differ in tipping paper length, tipping paper weight and tipping adhesive composition (sec 910(a)(3)(A)(ii) of the FD&C Act). In addition, the applicant claims that the new and predicate products have identical packaging composition. After considering the SE Reports, the Agency shall issue an order under the provisions of sections 910 and 905(j) of the FD&C Act when finding the new products to be substantially equivalent to the predicate product.

4.3 Identification of the New Tobacco Products that are the Subject of the Proposed Actions

4.3.1 Type of Tobacco Product

Roll-your-own (RYO) filtered cigarette tubes

4.3.2 Product Names and Submission Tracking Numbers

The names of the new products are listed below, along with the submission tracking number (STN) and the name of the predicate product. See Appendix 1 for additional STNs associated with the new and predicate products.

| STN | New Product | Predicate Product |
|-----------|-----------------------------------|---------------------------|
| SE0013338 | Gambler Tubecut Regular King Size | Gambler Regular King Size |
| SE0013339 | Gambler Regular King Size | Gambler Regular King Size |
| SE0013340 | Zig-Zag Original King Size | Gambler Regular King Size |

4.3.3 Description of the Product Package

The packaging materials of the new and predicate products are identical in composition format and weight. The new and predicate products each contain 200 RYO cigarette tubes which are packed in retail cardboard boxes. There are 50 retail boxes per shipping case. Details of the package components and weights of each packaging component for the new products are described in Confidential Appendix 3.

4.3.4 Location of Manufacturing

(b) (4)

(see Figure 1).

The facility is located in the (b) (4). This basin covers approximately 519,000 mi². Administratively, the facility is based in the sub-urban area of (b) (4) (Statistics Canada, 2011).

Figure 1. Location of the RYO Tobacco Product Manufacturing Facility in Canada

(b) (4)



4.3.5 Location of Use

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

4.3.6 Location of Disposal

Once used, the new tobacco products 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 products differ from the predicate product in tipping paper length, tipping paper weight and tipping adhesive composition.

5 Potential Environmental Impacts Due to the Proposed Actions

5.1 Potential Environmental Impacts Due to Manufacturing the New Products

The emission information associated with all tobacco products as reported in the Environment and Climate Change Canada's (ECC) National Pollutant Release Inventory (NPRI) database is publicly available (NPRI, 2017). In 2015, Canadian tobacco facilities released 2.56 tonnes of PM₁₀ (particulate matter <=10 microns) and 1.26 tonnes of PM_{2.5} (particulate matter <=2.5 microns) to the air¹. A search in the NPRI database indicates that the [REDACTED] is not listed in the database. The NPRI is Canada's legislated, publicly accessible inventory of pollutant releases (to air, water and land), disposals and transfers for recycling.

The applicant stated that they are in compliance with all Canadian federal, provincial and local environmental regulations and they provided information on the manufacturer's permits. The applicant also claimed that their paper and acetate tow ingredients are produced from renewable and sustainable resources in accordance with the Forest Stewardship Council, the program for the endorsement of forest certification scheme, and Canadian Sustainable Forest Management. Complying with the relevant environmental regulations and fulfilling sustainability measures do not appear to threaten any endangered species or critical habitat.

The applicant predicted that the manufacturing of the new products will encompass a slight fraction of the total production at the manufacturing facility (Confidential Appendix 2). Therefore, no expansion of the manufacturing facility is anticipated for manufacturing the new products.

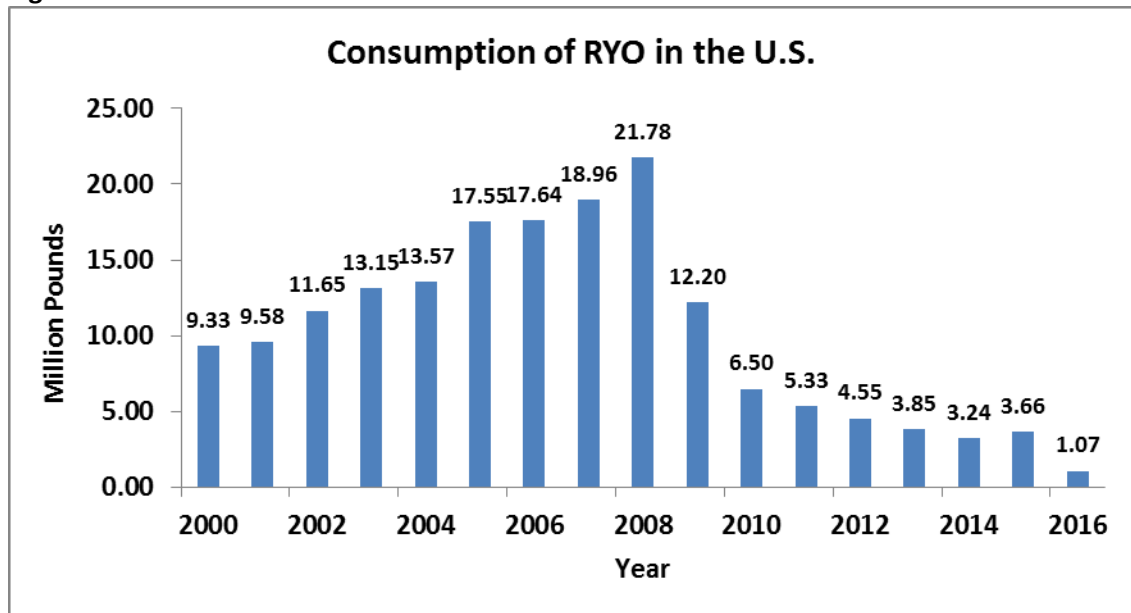
The applicant stated that the production processes for the new products are identical to those of all other productions at the manufacturing facility. Therefore, the Agency does not anticipate any new substances or new type of emissions to be released into the environment as a result of manufacturing the new products and no additional environmental control practices are needed.

¹ The data extraction is conducted from NPRI database (<https://www.ec.gc.ca/inrp-npri/>). Under the Canadian Environmental Protection Act, 1999, owners or operators of facilities that meet the NPRI [reporting requirements](#) are required to report to the NPRI. This database is managed by the Environment and Climate Change Canada and as of the 2015 year, it tracks 343 listed substances and groups of substances. Data associated with the tobacco facilities is extracted by using North American Industry Classification System (NAICS) codes of 3122. Not all pollutants release data of tobacco facilities are listed in the database.

5.2 Potential Environmental Impacts Due to Use of the New Products

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, the use of RYO tobacco products in the United States 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 2) (US TTB, 2017).

Figure 2. Use of RYO Tobacco Products in the United States in 2000-2016



Overall, the use of RYO tobacco products in the United States has noticeably decreased by 95% since 2008. Furthermore, the applicant claimed that the new products will compete with and replace other currently marketed RYO products. Therefore, the Agency does not anticipate more chemicals to be emitted into the environment from the use of the new products, compared to the chemicals released by the predicate product that is currently on the market.

As noted, the applicant claimed that the new products differ from the predicate product in the tipping paper characteristics (length, weight, and adhesive composition), which are not combusted or consumed by the users. Therefore, the Agency does not anticipate new chemicals to be emitted into the environment from the use of the new products, compared to the chemicals released by the predicate product that is currently on the market.

5.3 Potential Environmental Impacts Due to Disposal of the New Tobacco Product

To better understand the potential environmental impacts due to disposal of the new tobacco products, the Agency uses the environmental pathways of disposed packaging materials and the environmental pathways of discarded cigarette waste.

5.3.1 Disposal of Packaging Materials

Disposal of the packaging materials following use would either enter the recycling stream or be disposed of in MSW landfills or as litter. Information about trash generation in the United States, including details about disposal of materials comparable to those used in cigarette products, can be informative about the disposal of cigarette packing materials. Specifically, in 2014, approximately 258.46 million tons (234.47 million metric tons) of trash was generated in the United States, and roughly 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figure 3 and 4) (US EPA, 2014). 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 (US EPA, 2014).

To estimate the waste from the disposal of packaging material, the Agency utilized the projected market volumes for the first and fifth years of marketing the new and predicate products, assuming all used product material is disposed of in MSW. The estimated waste from packaging disposal and product material following product use would be diminutive compared to the total MSW forecasted to be disposed in the United States. (Confidential Appendix 3).

Figure 3. Municipal Solid Waste Generation Rates in the United States, 1960-2014

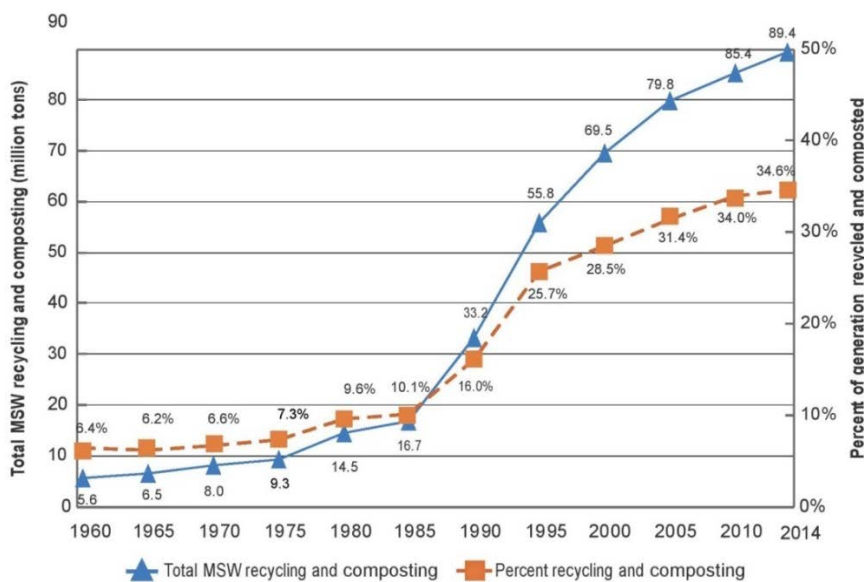


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

Figure 4. Municipal Solid Waste Recycling Rates in the United States, 1960-2014

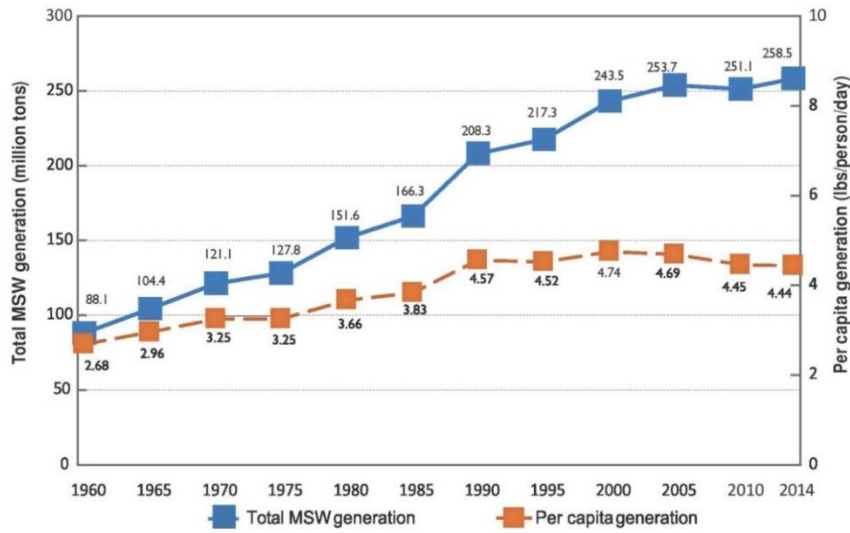


Figure excerpted from the U.S. EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet"

As previously discussed, because the applicant stated that the new products will compete with other similar products on the market and based on the above-mentioned information regarding waste, construction of new POTWs or landfills is not anticipated 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 due to manufacturing. Therefore, the fate of any materials emitted is anticipated to be the same as any materials from other cigarettes manufactured in the facility.

5.3.2 Disposal of RYO Waste

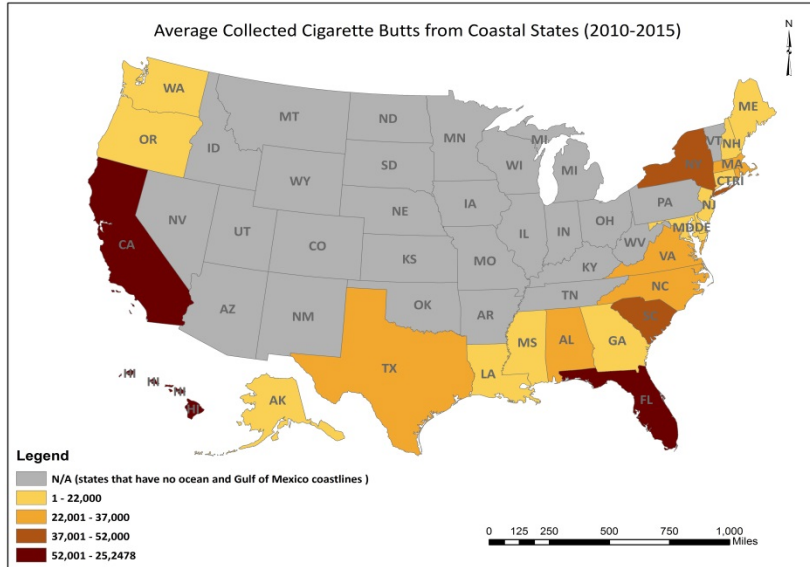
At the end of life, comparable to combusted cigarettes, RYO cigarette tubes usually undergo a series of scenarios for both managed and unmanaged waste. The managed waste is the waste that is handled by an organized solid waste collection. The unmanaged waste is the result of users littering cigarettes.

The managed waste for the cigarette waste is treated as MSW and more likely either incinerated with energy recovery or landfilled. According to a report published by "Keep America Beautiful", an observational study of 767 smokers conducted in 44 locations, showed 35% of used cigarettes were disposed of properly (with MSW) with a resulting 65% littering rate for cigarette butts (Schultz, 2009).

The majority of unmanaged cigarette waste ends up in oceans and beaches across the United States and worldwide. The annual Ocean Conservancy's International Coastal Cleanup (ICC) reports that cigarette waste has been the single most collected item since a day long collection

began (Novotny, Lum, & Smith, 2009). Using the data from ICC, the Agency produced a map displaying the average collected cigarette waste (2010-2015) from coastal states (excluding Great Lakes coast) on the international coastal cleanup day (Niazi & Forche, 2016) (Figure 5).

Figure 5. Collected Cigarette Waste from Coastal States (2010-2015)



A threat assessment study focusing on the most common types of litter that are found along the world's coastlines, based on data gathered during three decades of international coastal clean-up efforts, was conducted by Wilcox et al., 2016. The study was conducted based on elicited information from experts on the ecological threat of entanglement, ingestion and chemical contamination for three major marine taxa: seabirds, sea turtles and marine mammals (Wilcox & Mallos, 2016). The result of this study shows that cigarette butts are ranked seventh out of 20 marine debris items of interest for which information was elicited.

As previously discussed, the new RYO cigarette tubes will compete with other similar RYO tobacco products on the market. As such, introducing the new products into the U.S. market is not expected to increase the nationwide use of cigarettes. Thus, authorizing the new products is not expected to affect the overall level of cigarette butt litter in the United States. Based on this, and the above-mentioned information regarding waste, construction of new POTWs or landfills are not anticipated due to the proposed actions.

6 Use of Resources and Energy

The applicant stated that there will be no change in how the new products are manufactured compared to the predicate product. The same raw materials and energy will be used to manufacture the new products compared to the predicate product and the applicant does not anticipate any increased energy or resource needs to manufacture the new products. The applicant stated that the proposed actions will not require an expansion of the manufacturing facility. The applicant stated that the new products will compete with other similar RYO products as well as the predicate product. Therefore, no increase of market volume for RYO tobacco products and no net increase of energy use is expected from the proposed actions. The applicant stated that no adverse effects to endangered or threatened species or critical habitat are expected from manufacturing the new products.

7 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 products. Therefore, no mitigation measures are discussed.

8 Alternatives to the Proposed Actions

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 the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of new tobacco products as 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 products and associated manufacture, use, and disposal following use of the new tobacco products.

9 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:

Mehran Niazi, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Sciences

Experience: 12 years in environmental fate and transport and environmental modeling

Expertise: Water quality modeling, environmental fate and transport

Reviewers:

Hoshing W. Chang, PhD, Center for Tobacco Products

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

Experience: 9 years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

10 List of Agencies and Persons Consulted

Not applicable.

11 Appendix List

Appendix 1: Submission Tracking Numbers for the SE Reports and Package Sizes of the New and Predicate Products and Related Amendments Covered Under this Programmatic Environmental Assessment (PEA)

12 Confidential Appendix List

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

Confidential Appendix 2: Percentage of the Facility's Total Production Dedicated to the New Products

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

13 References

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- Wilcox, C., & Mallos, N. (2016). Using Expert Elicitation to Estimate the Impacts of Plastic Pollution on Marine Wildlife. *Marine Policy*, 107-114.

APPENDIX 1

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

| STN | Product Name | Tubes per Retail Box | Amendments |
|------------|-----------------------------------|-----------------------------|-------------------|
| SE0013338 | Gambler Tubecut Regular King Size | 200 | SE0014254 |
| SE0013339 | Gambler Regular King Size | 200 | SE0014254 |
| SE0013340 | Zig-Zag Original King Size | 200 | SE0014254 |

CONFIDENTIAL APPENDIX 1

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

| STN | Current-Year Market Volume (# RYO) | First-Year Market Volume (# RYO) | | Fifth-Year Market Volume (# RYO) | |
|-----------|---------------------------------------|-------------------------------------|-------------------|-------------------------------------|-------------------|
| | Predicate Product | New Product | Predicate Product | New Product | Predicate Product |
| SE0013338 | (b) (4) | | | | |
| SE0013339 | (b) (4) | | | | |
| SE0013340 | (b) (4) | | | | |

CONFIDENTIAL APPENDIX 2

Percentage of the Facility's Total Production Dedicated to the New Products

| STN | Percentage of the New Product to Facility's Total Production, 1 st Year | Percentage of the New Product to Facility's Total Production, 5 st Year |
|-----------|--|--|
| SE0013338 | (b) (4) | |
| SE0013339 | | |
| SE0013340 | | |

The applicant claimed that the new RYO tobacco products are intended to comprise approximately (b) (4)% to (b) (4)% of the facility's total production ((b) (4) RYO cigarette tubes).

CONFIDENTIAL APPENDIX 3

The First- and Fifth-Year Projections of Paper Waste of Packaging Materials and Product Materials Associated with Marketing the New and 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 materials waste (in metric tons) that would be generated from disposal after use of the new products in 2017 and 2021. Projected waste generation is the summation of the projected cardboard retail boxes and cartons.

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

$$B_i = \frac{D_i}{E_i} \times F \times I$$

$$C_i = \frac{E_i}{F_i \times G_i} \times H \times I$$

A_i: Projected paper 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 market volume of the products (# individual cigarette injector tubes)

E_i: Number of cigarette injector tubes per retail box

F: Weight of empty retail box (grams)

G_i: Number of retail boxes per shipping case

H: Weight of empty shipping case (grams)

I: 1.0 x 10⁻⁶ metric tons/gram

| | STN | H | G | F | E | D | C | B | A |
|------------|--------------------|-----|----|------|-----|---------|---|---------|---|
| First Year | SE0013338 | 532 | 50 | 26.4 | 200 | (b) (4) | | | |
| | SE0013339 | 532 | 50 | 26.4 | 200 | | | | |
| | SE0013340 | 532 | 50 | 26.4 | 200 | | | | |
| | Total New Products | | | | | | | (b) (4) | |
| | Predicate Product | 532 | 50 | 26.4 | 200 | (b) (4) | | | |
| Fifth Year | SE0013338 | 532 | 50 | 26.4 | 200 | (b) (4) | | | |
| | SE0013339 | 532 | 50 | 26.4 | 200 | | | | |
| | SE0013340 | 532 | 50 | 26.4 | 200 | | | | |
| | Total New Products | | | | | | | (b) (4) | |
| | Predicate Product | 532 | 50 | 26.4 | 200 | (b) (4) | | | |

If all the projected packaging waste generated from use of the products is disposed of in landfills, the projected cumulative cardboard waste generated in the first and fifth years of marketing the new products would be (b) (4) metric tons in 2017 and (b) (4) metric tons in 2021. This is a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014.

A portion of the generated cardboard waste is likely to be recycled, with an overall recycling rate for paper and paperboard products of 64.7% in the United States. If 64.7% of the cardboard boxes is recycled and the rest (35.3%) is disposed of as waste, the estimated cardboard waste disposed of in landfills would be decreased to (b) (4) metric tons (b) (4) metric tons) in the first year and (b) (4) metric tons (b) (4) metric tons) in the fifth year of marketing the new products.