Environmental Assessment for Marketing Order for Republic Tobacco, LP "JOB 1.25 SLIM GOLD"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

March 13, 2018

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This environmental assessment (EA) is for the marketing order for one roll-your-own (RYO) rolling paper product manufactured by Republic Tobacco LP. Information presented in the EA is based on the submission referenced in Section 4.3.2, unless noted or referenced otherwise. This EA has been prepared in accordance with 21 CFR 25.40 as part of submissions under section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

1. Name of Applicant

Republic Tobacco LP

2. Address

2301 Ravine Way
Glenview, IL 60025

3. Manufacturer

(b) (4) [redacted]

4. Description of Proposed Action

This proposed action is for the Food & Drug Administration (FDA) to issue a marketing order under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of a RYO rolling paper product into interstate commercial distribution in the United States.

The marketing order is based on the finding that this new product is substantially equivalent to a predicate product that was previously found substantially equivalent and received a marketing order on October 9, 2013. The applicant claimed that there are minor ingredient differences between the new product and the predicate product (Confidential Appendix 1).

The applicant intends to market the new and predicate products after receiving a marketing order for the new product. The applicant provided marketing projections for the new and predicate products for the current, first, and fifth years after a marketing order is issued for the new product (Confidential Appendix 2).

4.1 Requested Action

Order finding the listed tobacco product is substantially equivalent to the predicate product.

4.2 Need for Action

Republic Tobacco wishes to introduce the new tobacco product as described into interstate commerce for commercial distribution in the United States. The applicant claims that the new product and predicate product have different characteristics but that the new product does not raise different questions of public health (sec 910(a)(3)(A)(ii) of the FD&C Act). After considering the substantial equivalence (SE) report (SE0014228), the Agency shall issue an order under the provisions of sections

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

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

4.3.1 Type of Tobacco Product

RYO rolling paper

4.3.2 Product Name and Submission Tracking Number

The name of the new product is listed below, along with the original submission tracking number (STN), the name of the predicate product, and the STN for an additional submission in support of this application.

New Product		Predicate Product		Additional STN
STN	Name	STN	Name	
SE0014228	JOB 1.25 SLIM GOLD	SE0003298	OCB ORGANIC HEMP KING SIZE SLIM	SE0014437

4.3.3 Description of the Product Packages

The packaging details of the finished new product are the same as those of the predicate product. The following table provides packaging information for the new and predicate products.

	New Product			Predicate Product		
STN	Name	Leaves per booklet	Packaging	Name	Leaves per booklet	Packaging
SE0014228	JOB 1.25 SLIM GOLD	32	24 booklets per box and 40 boxes per shipping case	OCB ORGANIC HEMP KING SIZE SLIM	32	24 booklets per box and 40 boxes per shipping case

Details of the materials and mass for the new and predicate products and the packaging are described in Confidential Appendix 3.

4.3.4 Location of Manufacturing

The new and predicate products are manufactured at (b) (4) , (b) (4) (Figure 1). The facility is in a mixed-use area, with a building materials showroom to the west, a marble works to the east, multifamily housing and a produce wholesaler shipping operation across a two-lane highway to the south, and the (b) (4) with a 50- to 100-foot vegetated buffer immediately to the north (Figure 2) (Google, 2018).

Figure 1. Location of the Rolling Paper Manufacturing Facility

(b) (4)

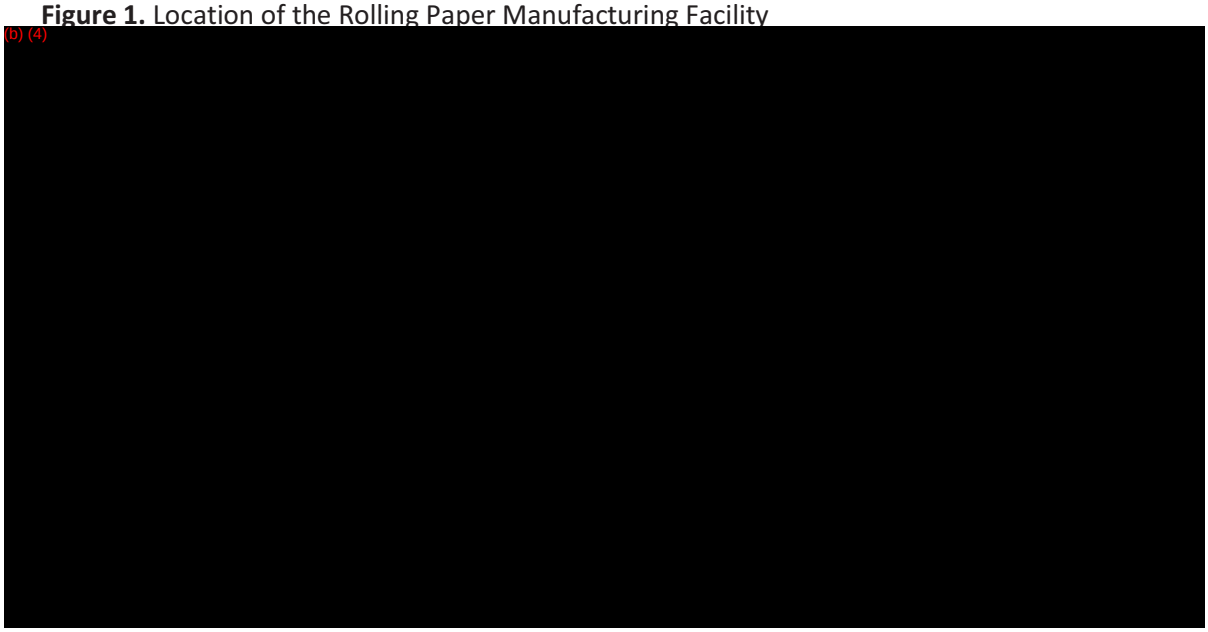
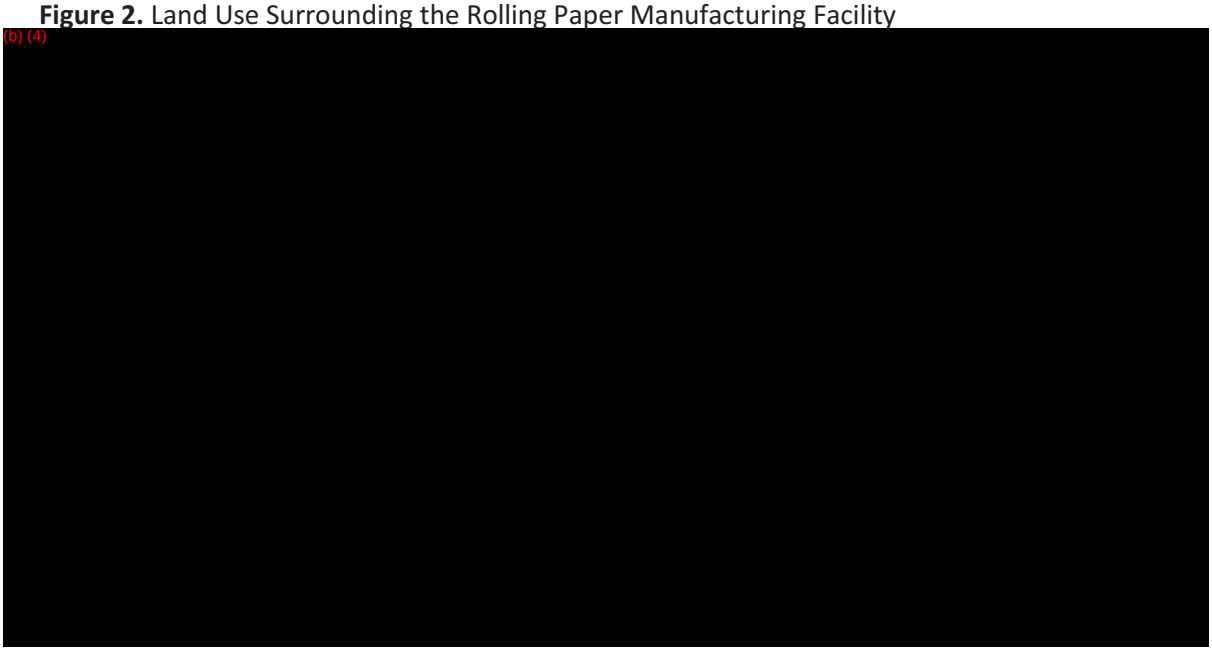


Figure 2. Land Use Surrounding the Rolling Paper Manufacturing Facility

(b) (4)



4.3.5 Location of Use

Republic Tobacco intends to distribute and sell the new product in the United States.

4.3.6 Location of Disposal

Once used, the new tobacco product will be disposed of as municipal solid waste (MSW) or litter, in the same manner as the predicate product and any other RYO products. Discarded packaging materials will enter the recycling stream, be transported to MSW landfills or incinerators, or discarded as litter. The

Agency anticipates the geographic distribution of waste from disposal of the new product and packaging will correspond to the geographic patterns of RYO product use.

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

The applicant claimed that there are minor ingredient differences between the new product and the predicate product (Confidential Appendix 1).

5. Potential Environmental Impacts Due to the Proposed Action

5.1 Potential Environmental Impacts Due to Manufacturing the New Product

The Agency anticipates that manufacturing the new RYO tobacco product will be associated with air emissions, wastewater discharges to waterways or publicly owned treatment works, and solid waste generation and disposal. These activities would occur in the same manner as those from manufacturing any other RYO products.

The applicant stated that there would be no increase in manufacturing or facility expansion due to the new product. They stated that manufacturing the new product results in no more than a negligible increase in MSW generation and that the air emissions and wastewater discharges from manufacturing the new product are the same types as from the predicate product and any increase in emissions or discharges would have a negligible environmental impact. The applicant also stated that manufacturing the new product would not require a revised or new air emissions or wastewater discharge permit and any changes to greenhouse gas (GHG) emissions would be negligible. These conclusions are consistent with applicant-provided information that forecasts manufacturing the new product to add only a fraction of a percent to the current production of the facility.

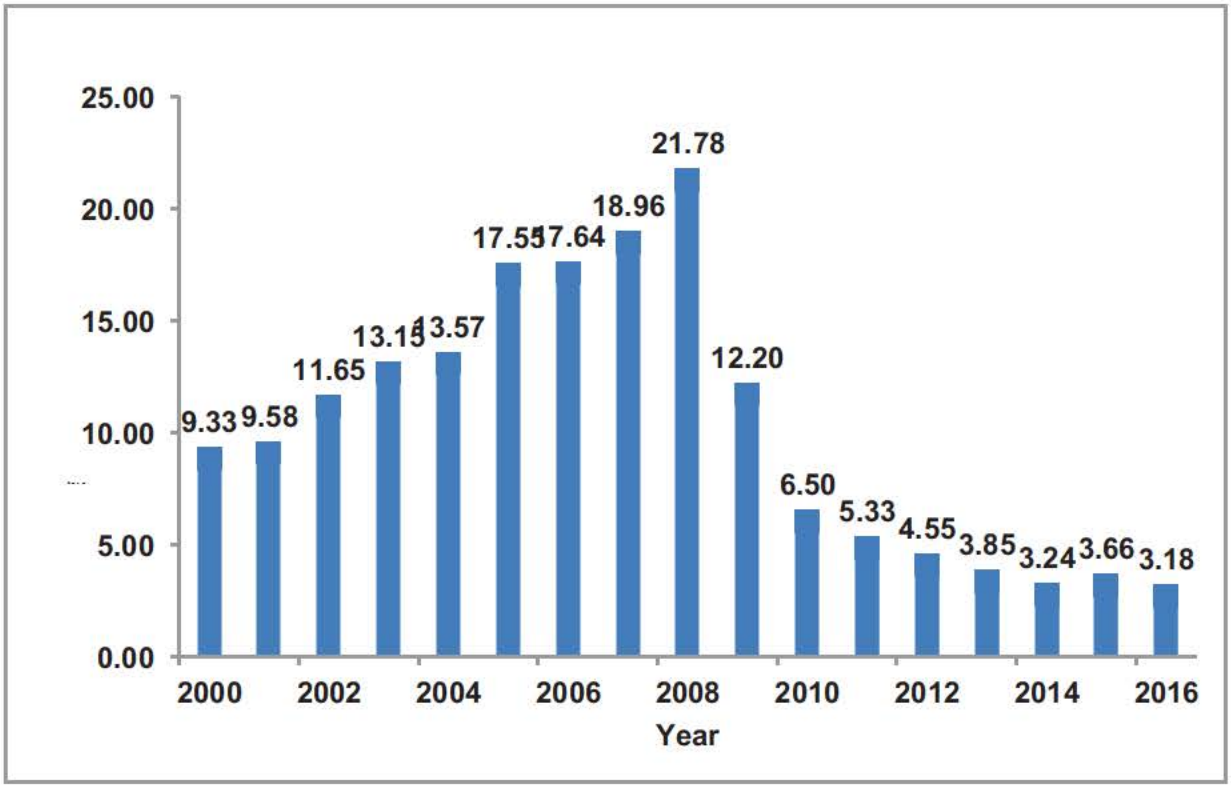
Based on information in the SE Report, the product modification consists of changes to material composition. While material composition has the highest potential for changing the chemical compounds emitted during manufacturing, the applicant stated that no new compounds would be emitted. Therefore, the Agency does not anticipate that manufacturing the new product will lead to the release of new chemicals into the environment.

Because the new product will compete with other currently marketed RYO products, and the applicant provided data demonstrating that the production volume of the new product is a small fraction of total production at the manufacturing facility, no effects from increased GHG emissions during manufacturing are anticipated from the proposed action.

5.2 Potential Environmental Impacts Due to Use of the New Product

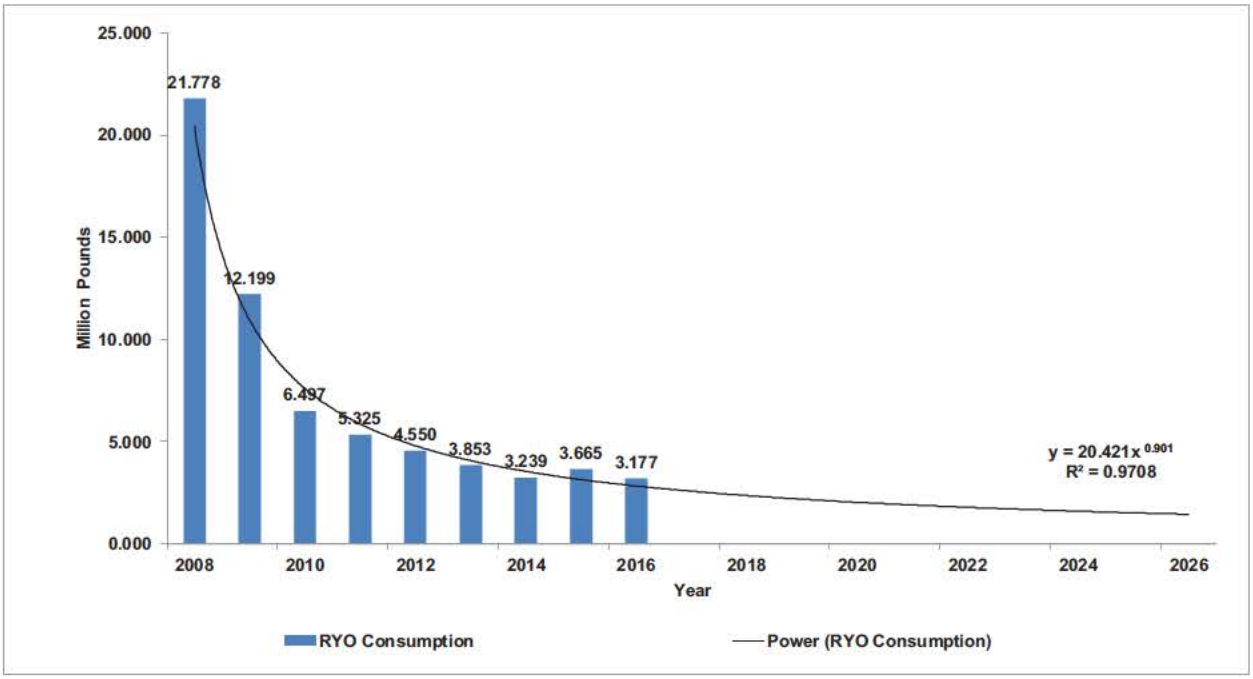
According to the U.S. Alcohol and Tobacco Tax and Trade Bureau's *Tobacco Statistical Release Reports*, the use of RYO tobacco products in the United States increased from 9.33 million pounds (4.23 million kilograms) in 2000 to 21.8 million pounds (9.89 million kilograms) in 2008. This was followed by a decrease from 12.2 million pounds (5.53 million kilograms) in 2009 to 1.07 million pounds (0.485 million kilograms) in 2016 (Figure 3) (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2017).

Figure 3. Use of RYO Tobacco Products in the United States, 2000 2016



To evaluate the environmental impact of the proposed action due to use of the new product, the Agency analyzed the historical use data for 2008 2016 to forecast the future use of RYO tobacco products in the United States. This was achieved by applying one best-fit power trend line with an R^2 value of 0.9708. Using this approach, the forecasted amount of RYO tobacco products to be used in the United States is estimated to be 2.354 million pounds (1.068 million kilograms) in 2018 and 1.780 million pounds (0.8074 million kilograms) in 2022 (Figure 4). The Agency did not factor in the historical data from 2000 to 2007 when forecasting the future use of RYO tobacco products because there has been a clear overall downward trend in RYO consumption since 2008, whereas the data preceding 2008 showed a trend of annual increases in RYO consumption that is no longer evident.

Figure 4. Projected Use of RYO Tobacco Products in the United States, 2018 2022



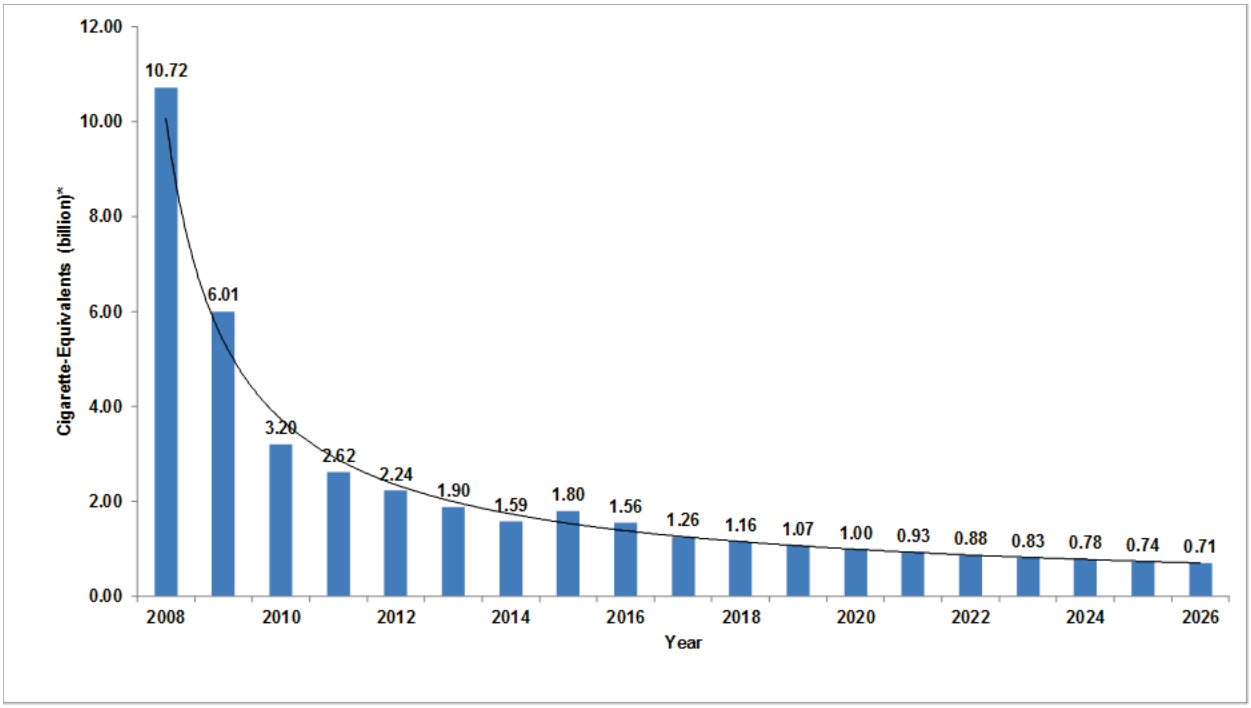
The results are also forecast in units of cigarette-equivalents, based on the assumption that 0.0325 ounces (0.921 grams) of tobacco is used per cigarette (National Association of Attorneys General, 1998) (Figure 5).

Year	RYO Tobacco Products (million pounds) [a]	RYO Tobacco Products (billion cigarette-equivalents) [b]
2016	3.177	1.564
First year (2018)	2.354	1.159
Fifth year (2022)	1.780	0.8763

[a] Projected first-year and fifth-year pounds RYO products: $20.421 (\text{year} - 2007)^{-0.901}$

[b] Cigarette-equivalents = RYO tobacco (pounds) x 16 ounces/pound x cigarette/0.0325 ounces RYO tobacco

Figure 5. Projected Use of RYO Cigarette-Equivalents in the United States, 2018 2022



Because the new product is expected to compete with other RYO products on the market, and represents a small fraction of the total RYO products marketed in the United States (Confidential Appendix 4), the Agency anticipates minimal or no net increase in the use of all RYO products. Thus, the Agency also does not anticipate more substances to be released into the environment from use of the new RYO products relative to the substances released by the predicate product and other RYO products already on the market.

During use, the new product is burned to ash, carbon dioxide, and water vapor, as well as products of incomplete combustion such as carbon monoxide. The combustion products from the new product would be similar to and released in a similar manner as the predicate product and other RYO rolling paper products. Therefore, the Agency does not anticipate use of the new product will lead to the release of new chemicals into the environment. The amount of carbon dioxide generated during combustion of RYO cigarettes that contributes to GHG emissions is miniscule (Confidential Appendix 5) and, because the new product will compete with other currently marketed RYO products, no net addition to GHG emissions is anticipated.

5.3 Potential Environmental Impacts Due to Disposal of the New Product

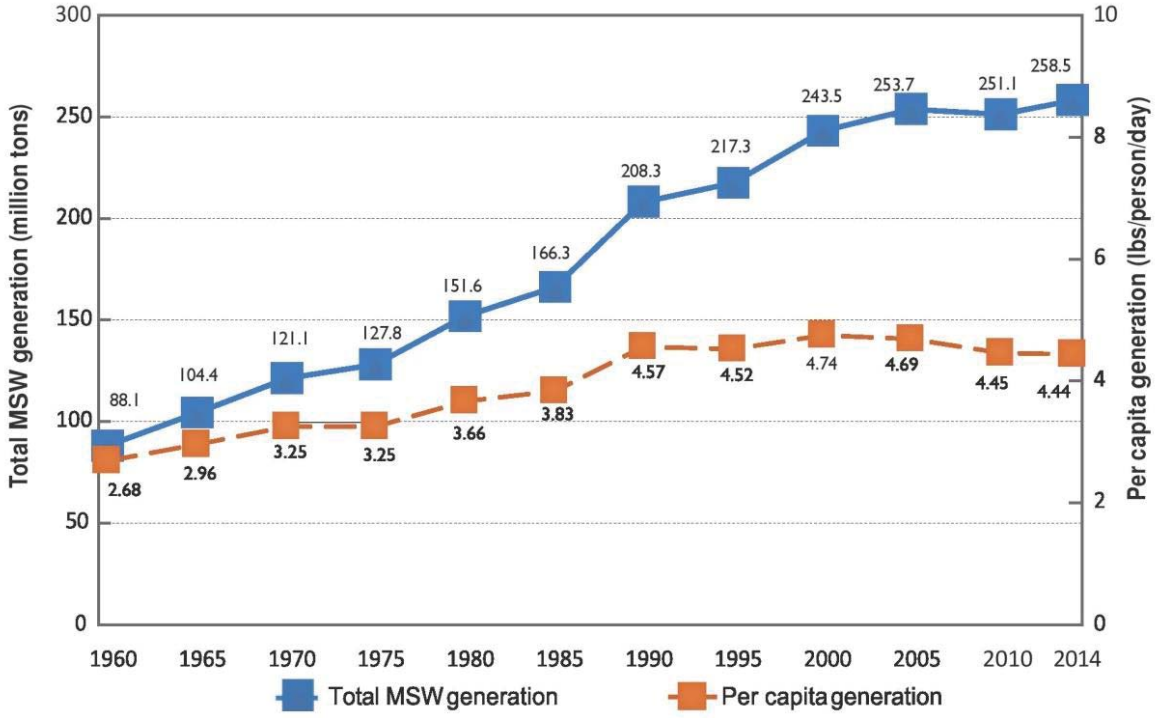
5.3.1 Disposal of Packaging Material

After using the new product, the users may recycle the packaging material or dispose of it as MSW or litter. Packaging disposal contributes to using landfill capacity.

Following use, the packaging materials either would enter the recycling stream or be disposed of as MSW or litter. In 2014, approximately 258.46 million tons of trash was generated in the United States,

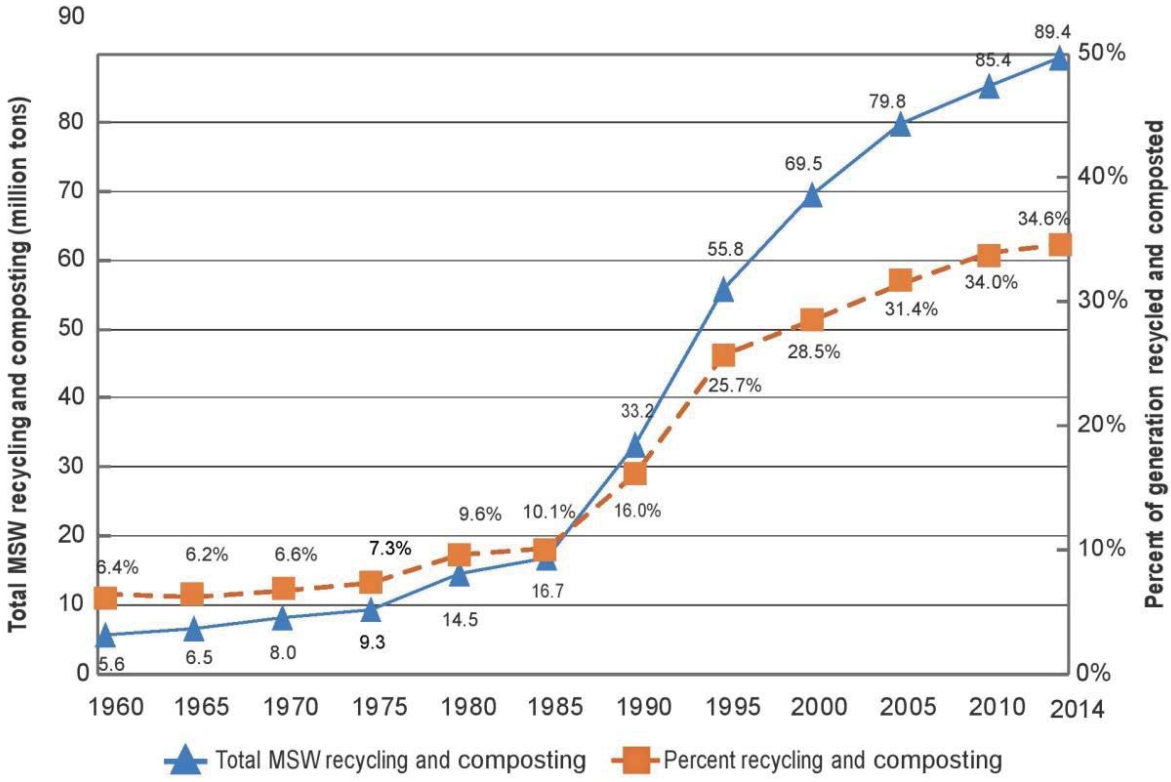
and approximately 89.4 million tons of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 6 and 7). Paper and paperboard accounted for 68.61 million tons (26.5%) of the total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (29.7%), of which 39.13 million tons was made of paper and paperboard. Of the total paper and paperboard MSW, 44.4 million tons (64.7%) was recycled, 19.47 million tons (28.4%) was disposed of in landfills, and 4.74 million tons (6.9%) was combusted with energy recovery. On average, 4.4 pounds of waste was generated per person per day in the United States, of which 2.1 pounds was recycled, composted, or combusted for energy recovery (U.S. Environmental Protection Agency, 2016a).

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



Source: (U.S. Environmental Protection Agency, 2016b)

Figure 7. MSW Recycling Rates in the United States, 1960 2014



Source: (U.S. Environmental Protection Agency, 2016b)

The Agency used the projected market volumes for the first and fifth years of marketing the new product to estimate the waste from disposal of packaging, accounting for recycling of packaging waste as part of overall U.S. recycling of MSW. The estimated waste from packaging disposal would be miniscule compared to the total MSW forecasted to be discarded in the United States (Confidential Appendix 6). The materials comprising the packaging elements (Confidential Appendix 3) are commonly found in U.S. MSW and, therefore, the Agency does not anticipate disposal of packaging from the new product will lead to the release of new chemicals into the environment.

Because the new rolling paper product will compete with other similar rolling paper products on the market and the estimates described above and detailed in Confidential Appendix 6 indicate a negligible contribution to U.S. MSW, construction of new solid waste landfills or incinerators is not anticipated due to disposal of packaging material under the proposed action.

5.3.2 Disposal of Used Products

Cigarette butt[1] waste may have an end-of-life-cycle scenario as either managed or unmanaged waste.

Managed waste is handled by an organized solid waste collection and management system. For the managed waste, 80.4% by weight enters landfills, and the remaining 19.6% by weight is incinerated for

[1] Cigarette butt is defined in this EA as the cigarette rolling paper containing remainder tobacco that is disposed of following use. The cigarette butt may or may not also include a filter, depending if the RYO cigarette had one.

energy recovery (U.S. Environmental Protection Agency, 2016a). The Agency used the projected market volumes for the first and fifth years of marketing the new product to estimate the waste from discarding used product items (RYO cigarette butts). The estimated waste from RYO cigarette butt disposal as MSW would be miniscule compared to the total MSW forecasted to be discarded in the United States (Confidential Appendix 6). Because the new rolling paper product will compete with other similar rolling paper products on the market and the estimates described above and detailed in Confidential Appendix 6 indicate a negligible contribution to U.S. MSW, construction of new solid waste landfills or incinerators is not anticipated due to disposal of used product items under the proposed action.

Unmanaged waste consists of littered cigarette butts. The environmental effects of cigarette butt litter were summarized as follows (Novotny, et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide… The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste... Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Introducing the new product into the U.S. market is not expected to increase the nationwide use of cigarettes; instead, it would compete for market share with existing products. Thus, issuing a marketing order for the new product is not expected to affect the overall level of cigarette butt litter in the United States, but may displace the level of litter from other cigarette products. Based on information in the SE Report, the product modification consists of changes to material composition and the new product will still be the cigarette paper element of a complete cigarette. Therefore, the Agency does not anticipate that disposal of the new product will lead to the release of new chemicals into the environment.

5.3.3 Air Emissions from Disposal

Landfill disposal or incineration of used product items and packaging materials will produce GHGs.

Methane is a potent GHG that has a global warming potential 28 36 times greater than carbon dioxide and persists in the atmosphere for about 12 years. Landfills are the third largest source of human-related methane emissions in the United States, accounting for approximately 15.4% of these emissions in 2015 (U.S. Environmental Protection Agency, 2017). Estimated GHG emissions from disposal of used product items and packaging associated with the new and predicate products are miniscule (Confidential Appendix 5).

6. Use of Resources and Energy

The SE Report stated that the manufacture, use, and disposal of the new and predicate products is not expected to jeopardize the continued existence of any endangered species, nor result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. Endangered Species Act. The applicant also confirmed that no plants used for the manufacture of the new and predicate products are listed as an endangered plant under the Convention on International Trade in Endangered Species of Wild Flora and Fauna.

The applicant provided quantitative information on energy used to manufacture the new product and the fraction of total production for the new product at the manufacturing facility. No significant impacts from emissions of GHGs were indicated based on these data (Confidential Appendix 5).

7. Mitigation

The Agency did not identify significant adverse environmental effects for the new product. Therefore, no mitigation measures were developed.

8. Alternatives to the Proposed Action

Alternative A (No-action alternative). The no-action alternative is to not authorize the marketing of the new RYO rolling paper product 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 RYO tobacco products, as many other similar RYO tobacco products will continue to be marketed.

Alternative B (Proposed action). The Agency did not identify any significant environmental effects due to the proposed action of issuing a marketing order for the new product and the associated manufacturing, use, and disposal following use of the product.

9. List of Preparers

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

Preparers:

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- Education: Ph.D. in Plant Molecular Biology and Virology
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- Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA implementation

Catherine W. McCollum, Ph.D., Center for Tobacco Products (impact analysis framework)
- Education: Ph.D. in Biochemistry and Cell Biology
- Experience: 10 years in various scientific activities
- Expertise: NEPA analysis, environmental impact analysis, ecotoxicity, developmental toxicology

Reviewer:

Hoshing W. Chang, Ph.D., 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. Confidential Appendix List

Confidential Appendix 1: Modifications Between the New and Predicate Product

Confidential Appendix 2: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products

Confidential Appendix 3: Materials and Mass for the New and Predicate Product Materials and Packaging

Confidential Appendix 4: Comparison of the U.S. Market Volumes for the New and Predicate Products with Rolling Papers for Total RYO Tobacco Products

Confidential Appendix 5: Greenhouse Gas Emissions from Manufacturing, Use, and Disposal of the New and Predicate Products

Confidential Appendix 6: Projected Product and Packaging Waste from Disposal

12. References

Geiss, O., & Dimitrios, K. (2007). *Tobacco, Cigarettes and Cigarette Smoke: An Overview.* European Commission, Directorate-General Joint Research Centre, Institute for Health and Consumer Protection.

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CONFIDENTIAL APPENDIX 1: Modifications between New and Predicate Products

The applicant claims that the new product and the predicate product are different in material composition.

The SE Report provided the product composition details for the new and predicate products as listed in the following table. The differences are highlighted.

STN	Name	Component	Materials and Description
SE0014228	JOB 1.25 SLIM GOLD	Paper	(b)(4)
			44 mm x 109 mm
		Adhesive	(b)(4)
			Width: 5 mm
		Packaging	32 leaves per booklet
			24 booklets per retail display box
			40 display boxes per shipping case
Predicate	OCB ORGANIC HEMP KING SIZE SLIM	Paper	(b)(4)
			44 mm x 109 mm
		Adhesive	(b)(4)
			Width: 5 mm
		Packaging	32 leaves per booklet
			24 booklets per retail display box
			40 display boxes per shipping case

Ingredients present in the new product but not in the predicate product ar (b)(4) None of these ingredients raises concerns related to Endangered Species Act-listed species or critical habitat, or species protected under the Convention on International Trade in Endangered Species of Wild Flora and Fauna.

CONFIDENTIAL APPENDIX 2: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products

STN	Name	Unit	Market Volume (units)		
			Current Year	First Year	Fifth Year
SE0014228	JOB 1.25 SLIM GOLD	Leaf	(b) (4) [redacted]		
Predicate	OCB ORGANIC HEMP KING SIZE SLIM	Leaf			

The applicant intends to market the new and predicate products after receiving a marketing order for the new product.

CONFIDENTIAL APPENDIX 3: Materials and Mass for New and Predicate Products and Packaging

STN	Name	Element	Material	Mass (g)
SE0014228	JOB 1.25 SLIM GOLD	Rolling paper leaf	Paper	0.08306
		Booklet cover	Cardboard	3.02
		Retail display box	Cardboard	16.7
		Shipping case	Cardboard	378
Predicate	OCB ORGANIC HEMP KING SIZE SLIM	Rolling paper leaf	Paper	0.07107
		Booklet cover	Cardboard	2.79
		Retail display box	Cardboard	17.24
		Shipping case	Cardboard	378

CONFIDENTIAL APPENDIX 4: Comparison of the U.S. Market Volumes for the New and Predicate Products with Rolling Papers for Total RYO Tobacco Products

The current-year market volumes for the predicate product and the first-year, and fifth-year market volume projections of the new and predicate products in the U.S. market were compared to the total current and projected number of rolling papers comprising the total market for RYO tobacco product use tobacco (Figures 3 and 4 in section 5.2) in the United States.

STN	Name	Market Volume					
		Current Year		First Year		Fifth Year	
		Rolling Papers (leaves)	% Rolling Papers for Total RYO Tobacco Market [a]	Rolling Papers (leaves)	% Rolling Papers for Total RYO Tobacco Market [a]	Rolling Papers (leaves)	% Rolling Papers for Total RYO Tobacco Market [a]
SE0014228	JOB 1.25 SLIM GOLD	(b) (4)					
Predicate	OCB ORGANIC HEMP KING SIZE SLIM						

[a] Current year RYO tobacco market in United States: 2,564,939 pounds 1,262,739,200 cigarette-equivalents
Projected first year (2018) RYO tobacco market in United States: 2,353,868 pounds 1,158,827,323 cigarette-equivalents
Projected fifth year (2022) RYO tobacco market in United States: 1,779,995 pounds 876,305,231 cigarette-equivalents

CONFIDENTIAL APPENDIX 5: Greenhouse Gas Emissions from Manufacturing, Use, and Disposal of the New and Predicate Products

GHG Emissions from Manufacturing the Product

The applicant stated that the energy that will be used to manufacture the new product is negligible compared to the total energy used by the facility. The SE Report provided the example that in year 5, energy for manufacturing the new product accounts for approximately 0.0002% of the total site's energy (19.95 kWh ÷ 10,900,764 kWh = 0.0002%). The applicant also stated that the new and predicate products are intended to compete with each other as well as other RYO papers that are on the market. Thus, they reasoned there will not be an increase in the overall market volume of RYO papers based on the marketing of the new product and, as Republic uses energy to manufacture the new product, less energy is expected to be needed to manufacture the predicate product. Because the change in energy use is minuscule, any change in resulting GHG emissions from manufacturing the new product would likewise be negligible.

GHG Emissions from Use of Product

The amount of CO_2-equivalent gases (CO_2-eq) emitted from the use of cigarettes has been estimated to be 45 65 mg per cigarette (Geiss & Dimitrios, 2007). As a conservative approach, the high end of this range was used to calculate the GHG emissions from use of each cigarette-equivalent containing 0.0325 ounces (90.921 grams) of RYO tobacco (National Association of Attorneys General, 1998) rolled with one rolling paper leaf from the new and predicate products. The total GHG emissions from the new product were estimated to be (b) (4) metric tons of CO_2-eq in each of the first and fifth years of marketing. Even when combined with GHG emissions from use of the predicate product, this is a negligible fraction (approximately (b) (4) of the 6.87 billion metric tons of CO_2-eq estimated to have been generated in the United States in 2014.

STN	Name	Metric Tons of CO_2-eq		
		Current Year	First Year	Fifth Year
SE0014228	JOB 1.25 SLIM GOLD	(b) (4)		
Predicate	OCB ORGANIC HEMP KING SIZE			
	Total, new and predicate products:			
	Total U.S. (2014):			
	New and predicate products as a % of total U.S.:			

GHG Emissions from Disposal of Product

GHG emissions from the product waste and packaging were calculated using the GHG emission rates from the Waste Reduction Model (WARM), v. 14 (U.S. Environmental Protection Agency, 2016c). WARM estimates GHG emissions across different material types commonly found in MSW. Taking into account the rates for recycling, landfill disposal, and combustion with energy recovery of the various material types in the new and predicate products, the total amount of GHG emissions from product waste and packaging disposal was estimated to be (b) (4) metric tons of CO_2-eq in each of the first and fifth years of marketing. Even when combined with GHG emissions from disposal of the predicate product, this is a negligible fraction (approximately (b) (4) of the 6.87 billion metric tons of CO_2-eq estimated to have been generated in the United States in 2014.

STN	Name	Metric Tons of CO_2-eq		
		Current Year	First Year	Fifth Year
SE0014228	JOB 1.25 SLIM GOLD	(b) (4)		
Predicate	OCB ORGANIC HEMP KING SIZE			
Total, new and predicate products:				
Total U.S. (2014):				
New and predicate products as a % of total U.S.:				

CONFIDENTIAL APPENDIX 6: Projected Product and Packaging Waste from Disposal

To analyze the environmental effects from used product (cigarette butts) and packaging waste due to the proposed action, the Agency estimated the weights of the waste that would be generated from disposal of the new and predicate products in the current, first, and fifth years of marketing. Projected used product and packaging waste is the sum of the cigarette butt and the paper and cardboard materials specific to the packaging for each product (Confidential Appendix 3), as follows:

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

$$B_i(\text{tons}) = E \times F_i\ (\text{leaves}) \times G_i\ (ounces) \times \frac{ton}{32{,}000\ ounces}$$

$$C_i(\text{tons}) = F_i\ (\text{leaves}) \times \left[\frac{J_i\ (grams)}{K_i} + \frac{L_i\ (grams)}{M_i \times K_i} + \frac{N_i\ (grams)}{O_i \times M_i \times K_i}\right] \times R \times \frac{ton}{907{,}184.74\ grams}$$

$$G_i\ (ounces) = \frac{H\ (millimeters)}{P_i\ (millimeters)} \times \left[\frac{0.0325\ ounces\ RYO\ tobacco}{leaf} + \left(\frac{Q_i\ (\text{grams})}{leaf} \times \frac{ounce}{28.35\ grams}\right)\right]$$

A_i = total cigarette butt and packaging MSW generated by the new and predicate products (tons)

B_i = cigarette butt MSW generated by the used products (tons)

C_i = cardboard and paper MSW generated by the packaging for the new and predicate predicates (tons)

D= fraction of cigarette butts disposed in MSW = 0.66 (34% littered)

E_i = leaves (cigarette-equivalents) for market projection of product

F_i = weight per cigarette butt (ounces)

G = cigarette butt length (millimeters). For filtered cigarettes: the greatest of 23 mm, length of filter + 8 mm, or length of overwrap + 3 mm, from draft 2015 revisions to ISO 3308 intense smoking regimen (Section 7.2.1). For unfiltered cigarettes: 27 mm, from ISO 15592-3:2008(E)

H_i = booklet (grams)

I_i = leaves per booklet

J_i = display box (grams)

K_i = booklets per box

L_i = shipping case (grams)

M_i = boxes per case

N_i = cigarette rolling paper length (millimeters)

O_i = leaf (grams)

P = fraction of cardboard paper waste not recycled = 1 - 0.647 = 0.353 (U.S. Environmental Protection Agency 2016a)

The product packaging elements are disposed of as MSW or recycled, and the cigarette butts are disposed of as MSW or litter. The Agency estimated the amount of MSW that would be disposed of in landfills or incinerated, after accounting for portions of the paper and cardboard packaging being recycled at a rate of 64.7% (U.S. Environmental Protection Agency, 2016a). The total estimated MSW generated from the new and predicate products is [redacted] tons in the current, first, and fifth years, respectively. This is a negligible fraction (less than [redacted] of the 192,080,000 tons of total MSW generated and not recycled in the United States in 2014, estimated as follows:

258,460,000 million tons generated 66,380,000 million tons recycled = 192,080,000 tons disposed of as MSW

The following tables detail the parameters used in the calculations for MSW generation from the new and predicate products in the current, first, and fifth years.

	STN	Name	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
Current Year	SE0014228	JOB 1.25 SLIM GOLD	0.353	0.08306	109	40	378	24	16.7	32	3.02	27	0.0088	[redacted]				
	Predicate	OCB ORGANIC HEMP KING SIZE	0.353	0.07107	109	40	378	24	17.2	32	2.79	27	0.0087					
	MSW from disposal of new and predicate products after use (tons)																	[redacted]
	Total MSW disposed (not recycled) in U.S. (2014) (tons)																	192,080,000
	MSW from product disposal as a % of total U.S.																	[redacted]

First Year

STN	Name	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
SE0014228	JOB 1.25 SLIM GOLD	0.353	0.08306	109	40	378	24	16.7	32	3.02	27	0.0088	(b) (4) [redacted]				
Predicate	OCB ORGANIC HEMP KING SIZE	0.353	0.07107	109	40	378	24	17.2	32	2.79	27	0.0087					
													MSW from disposal of new and predicate products after use (tons)				(b) (4) [redacted]
													Total MSW disposed (not recycled) in U.S. (2014) (tons)				192,080,000
													MSW from product disposal as a % of total U.S.				(b) (4) [redacted]

Fifth Year

STN	Name	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
SE0014228	JOB 1.25 SLIM GOLD	0.353	0.08306	109	40	378	24	16.7	32	3.02	27	0.0088	(b) (4) [redacted]				
Predicate	OCB ORGANIC HEMP KING SIZE SLIM	0.353	0.07107	109	40	378	24	17.2	32	2.79	27	0.0087					
													MSW from disposal of new and predicate products after use (tons)				(b) (4) [redacted]
													Total MSW disposed (not recycled) in U.S. (2014) (tons)				192,080,000
													MSW from product disposal as a % of total U.S.				(b) (4) [redacted]