Programmatic Environmental Assessment for Market Authorizations for "HBI International RAW Organic SW Double and RAW SW SW"

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

September 29, 2017

Table of Contents

This programmatic environmental assessment (PEA) is for the marketing orders for two roll-your-own (RYO) cigarette paper products manufactured by HBI International. Information presented in the PEA is based on the submission referenced in Section 4.3.2, 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

HBI International

2. Address

3401 West Papago Street
Phoenix, AZ 85009

3. Manufacturer

Contract manufacturer (for HBI International)
(Confidential Appendix 1)

4. Description of Proposed Actions

These proposed actions are for the Food & Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of RYO cigarette paper products into interstate commercial distribution in the United States.

The marketing orders are based on the finding that these new products are substantially equivalent to a single predicate product that was on the market as of February 15, 2007. The applicant claimed that the new products differ from the predicate product in the rolling paper size, package quantity, material composition, and product names (Confidential Appendix 2).

The applicant intends to market the new and predicate products simultaneously after receiving marketing orders for the new products, and provided marketing projections for the new and predicate products for the current, first, and fifth years after marketing is authorized (Confidential Appendix 3).

4.1 Requested Action

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

4.2 Need for Action

HBI International wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the United States. The applicant claims that the new products and predicate product have different characteristics but that the new products do not raise different questions of public health (sec 910(a)(3)(A)(ii) of the FD&C Act). After considering the substantial equivalence (SE) reports (SE0002390 and 2393), the Agency shall issue orders 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 Products

RYO cigarette paper

4.3.2 Product Names and Their Original Submission Tracking Numbers

The names of the new products are listed below, along with the original submission tracking numbers (STNs), the name of the predicate product, and the STNS for additional submissions in support of these applications.

New Product		Predicate Product	Additional STNs	
STN	Name			
SE0002390	Raw Organic SW Double	RAW Classic 1¼	SE0006879 SE0014085	SE0008195 SE0010455 SE0010465 SE0010513 SE0012991 SE0013438 SE0013809 SE0013810 SE0013840 SE0014191
SE0002393	Raw SW SW		SE0006882 SE0010407	

4.3.3 Description of the Product Packages

The packaging details of the finished new products are different from those of the predicate product. In both cases, the new product packages contain a different amount of the product compared to 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
SE0002390	RAW Organic SW Double	100 plus 2*	25 booklets per box and 24 boxes per shipping case	RAW Classic 1¼	32 plus 2*	24 booklets per box and 42 boxes per shipping case
SE0002393	RAW SW SW	50 plus 2*	50 booklets per box and 24 boxes per shipping case			

*Each book also contains a starter leaf and a "warning" leaf that only a few papers remain.

Details of the product and package component materials and weights for the new and predicate products are described in Confidential Appendix 4.

4.3.4 Location of Manufacturing

The contract manufacturing location is outside of the United States and described in Confidential Appendix 1.

4.3.5 Location of Use

HBI International intends to distribute and sell the new tobacco products in the United States.

4.3.6 Location of Disposal

Once used, the new tobacco products 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 after use 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 the new products differ from the predicate product in the rolling paper size, package quantity, material composition, and product names (Confidential Appendix 2).

5. Potential Environmental Impacts Due to the Proposed Actions

5.1 Potential Environmental Impacts Due to Manufacturing the New Products

The Agency anticipates the environmental releases generated by manufacturing the new RYO tobacco products will be emitted to the air, discharged in wastewater to waterways or publicly owned treatment works, and disposed of in the solid waste stream. These releases would occur in the same manner as the releases and waste generated from the manufacture of any other RYO products.

The applicant stated that there would be no increase in manufacturing due to the new products. They also stated that manufacturing the new products would not result in changes in air emissions or wastewater discharges, no revised or new permits will be required, and no additional environmental controls will be required. The applicant statement that there would be no changes in air emissions also indicates there would be no significant impact on greenhouse gas (GHG) emissions. These conclusions are generally consistent with applicant-provided information that forecasts manufacturing the new products to add, cumulatively, only a few percent to the current production for one to five years after authorization, with much of that addition reflecting displacement of the predicate product's sales (Confidential Appendix 5). The small projected increase in product sales in the first and fifth years compared to the current year's sales is also consistent with a conclusion of no appreciable change in impacts from manufacturing the new products where these items are a fraction of the total production.

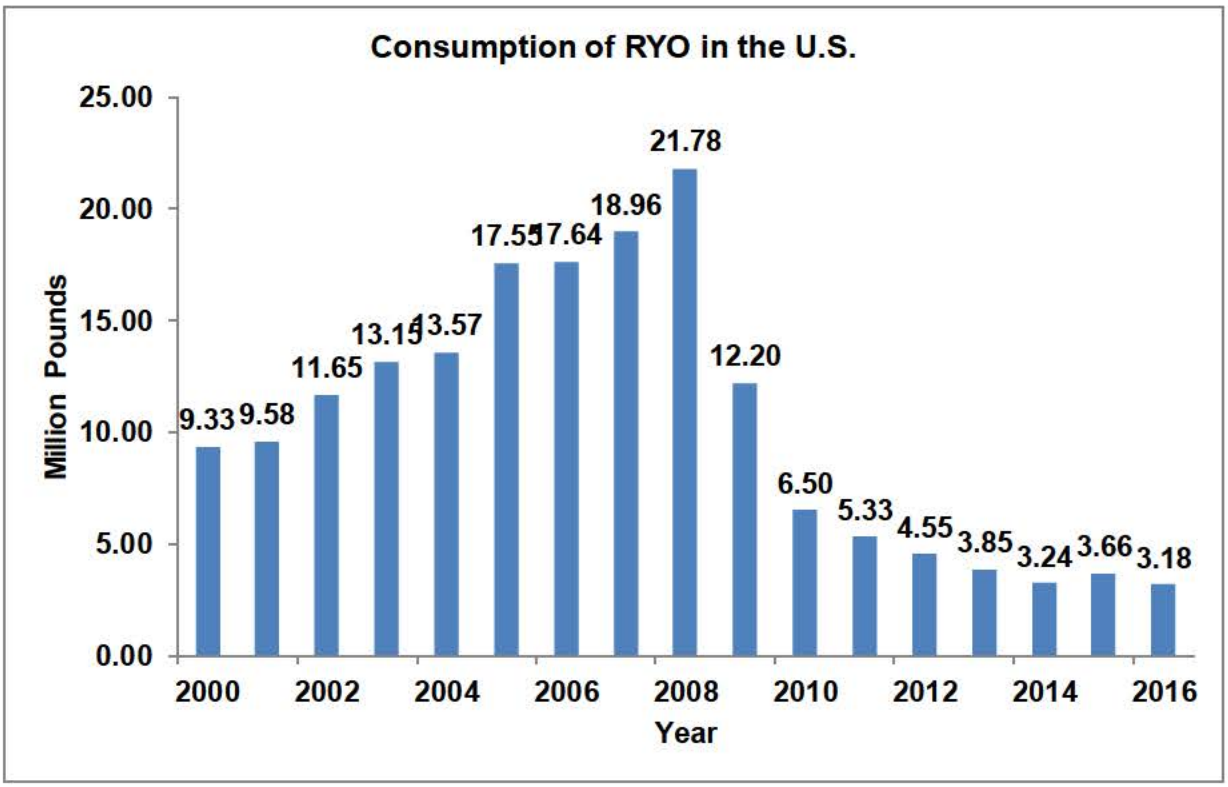
Based on information in the SE Reports, the product modifications include the rolling paper size, package quantity, material composition, and product names. While material composition has the highest potential for changing the chemical compounds emitted during manufacturing, the applicant stated that no new compounds would be emitted.

Because the new products will compete with other currently marketed RYO products, and the cumulative production volume of the new products is a small fraction of total production, no effects from increased GHG emissions are anticipated from the proposed actions.

5.2 Potential Environmental Impacts Due to Use of the New Products

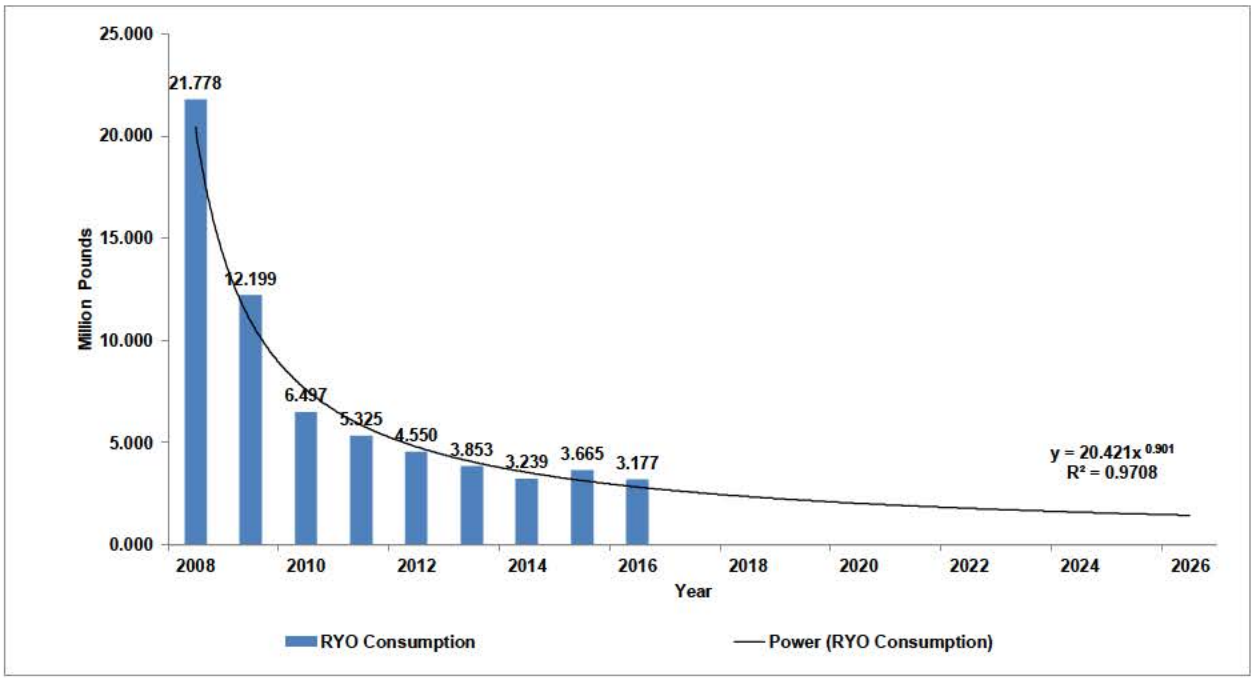
According to the U.S. Alcohol and Tobacco Tax and Trade Bureau's *Tobacco Statistical Release Reports*, the use of RYO tobacco products in the United States increased from 9.33 million pounds (4.23 million kilograms) in 2000 to 21.8 million pounds (9.89 million kilograms) in 2008. This was followed by 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 1) (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2017).

Figure 1. Use of RYO Tobacco Products in the United States, 2000–2016



To evaluate the environmental impact of the proposed actions due to use of the new products, 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 2.565 million pounds (1.163 million kilograms) in 2017 and 1.894 million pounds (0.8591 million kilograms) in 2021 (Figure 2). The Agency did not account for the historical data from 2000 to 2007 to forecast 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 2. Projected Use of RYO Tobacco Products in the United States, 2017–2021



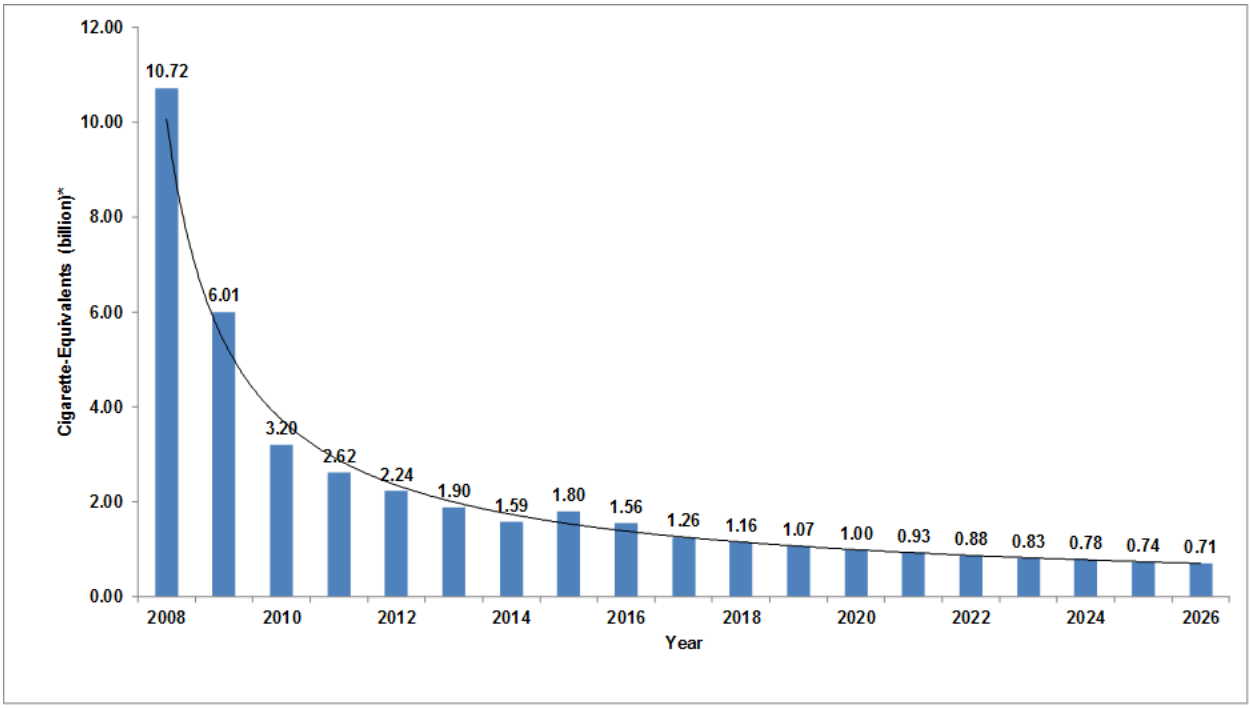
The results are also forecast in units of cigarette-equivalents, based on the assumption that 0.0325 ounces (0.921 grams) of tobacco is used per cigarette (National Association of Attorneys General, 1998) (Figure 3).

Year	RYO Tobacco Products (million pounds) [a]	RYO Tobacco Products (billion cigarette-equivalents) [b]
2016	3.177	1.564
First year (2017)	2.565	1.263
Fifth year (2021)	1.894	0.9325

[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 3. Projected Use of RYO Cigarette-Equivalents in the United States, 2017−2021



The applicant intends to market the new and predicate products after receiving marketing orders for the new products. Because the new products are expected to compete with other RYO products on the market, and represent a small fraction of the total RYO products market in the United States (Confidential Appendix 6), 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 products are 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 products would be similar to and released in a similar manner as the predicate product and other RYO cigarette paper products. The amount of carbon dioxide generated during combustion of RYO cigarettes that contributes to GHG emissions is miniscule (Confidential Appendix 7) and, because the new products 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 Products

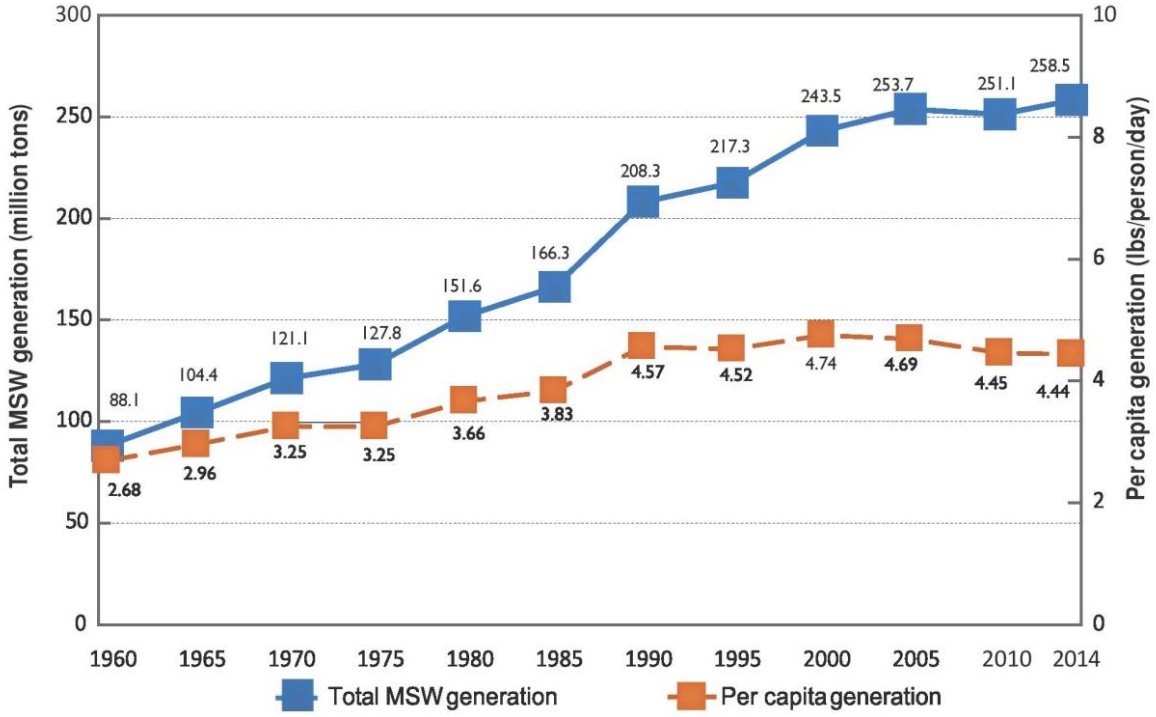
5.3.1 Disposal of Packaging Material

After using the new products, 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 (234.47 metric tons) of trash was generated in the United States, and approximately 89.4 million tons 81.1 million metric tons) of this material was

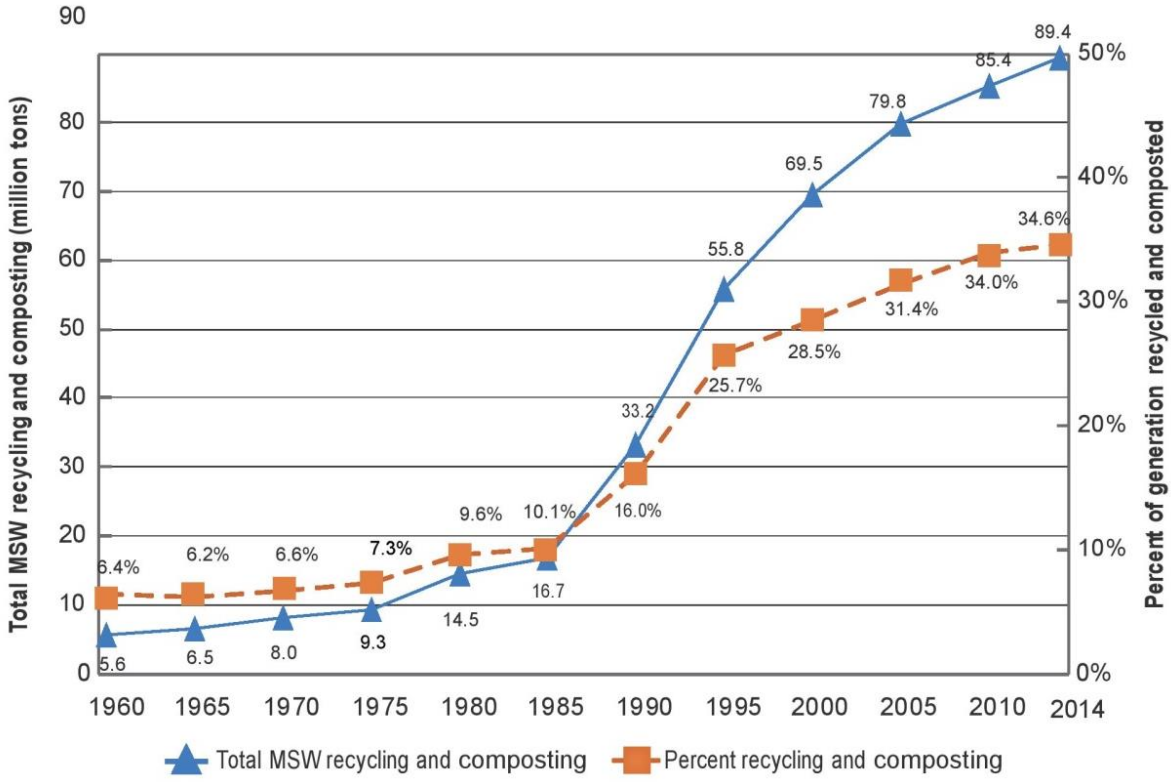
recycled and composted, equivalent to a 34.6% recycling rate (Figures 4 and 5). Paper and paperboard account for 68.61 million tons (62.24 million metric tons) (26.5%) of the total MSW generated in 2014. Plastics account for 33.25 million tons (30.16 metric tons) (12.9%) of total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (69.55 million metric tons) (29.7%), of which 39.13 million tons 35.50 million metric tons) was made of paper and paperboard. Of the total paper and paperboard MSW, 44.4 million tons (40.3 million metric tons) (64.7%) was recycled, 19.47 million tons (17.66 million metric tons) (28.4%) was disposed of in landfills, and 4.74 million tons (4.30 million metric tons) (6.9%) was combusted with energy recovery. On average, 4.4 pounds (2.0 kilograms) of waste was generated per person per day in the United States, of which 2.1 pounds (0.95 kilograms) was recycled, composted, or combusted for energy recovery (U.S. Environmental Protection Agency, 2016a).

Figure 4. MSW Generation Rates in the U.S, 1960 – 2014



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

Figure 5. 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 products 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 after use would be miniscule compared to the total MSW forecasted to be discarded in the United States (Confidential Appendix 8).

Because the new rolling paper products will compete with other similar rolling paper products on the market and the estimates described above and detailed in Confidential Appendix 8 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 actions.

5.3.2 Discarding 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 energy recovery (U.S. Environmental Protection Agency, 2016a). The Agency used the projected market

[1] "Cigarette butt" is defined in this PEA 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.

volumes for the first and fifth years of marketing the new products to estimate the waste from discarding used products (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 8). Because the new rolling paper products will compete with other similar rolling paper products on the market and the estimates described above and detailed in Confidential Appendix 8 indicate a negligible contribution to U.S. MSW, construction of new solid waste landfills or incinerators is not anticipated due to disposal of used products under the proposed actions.

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 products into the U.S. market is not expected to increase the nationwide use of cigarettes; instead, they would compete for market share with existing products. Thus, authorizing the new products 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.

5.3.3 Air Emissions from Disposal

Landfill disposal or incineration of the used products 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 the used products and packaging associated with the new and predicate products are miniscule (Confidential Appendix 7).

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

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment because the new products would be manufactured, used, and disposed of in the same way as other RYO tobacco products. Therefore, the fate of any materials released is anticipated to be the same as any materials from other RYO tobacco products manufactured in the same or similar facilities that are used and discarded in the same manner.

7. Environmental Effects of New Materials Released into the Environment due to the Proposed Actions

The applicant stated that the manufacturing of the new products is in full compliance with relevant environmental regulations.

As discussed in sections 5.1 through 5.3, the amount of materials anticipated to enter the environment due to the manufacturing, use, and disposal of the new products are small fractions when compared to that of all RYO tobacco products projected to be manufactured and used in the United States. No new substances or new types 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 products.

8. Use of Resources and Energy

In response to a request for information on compliance with the Endangered Species Act and the Convention in International Trade in Endangered Species, the applicant stated that the manufacturing of the new products is in full compliance with relevant environmental regulations.

The applicant provided quantitative information on energy used to manufacture the new products and the fraction of total production for the new products at the manufacturing facility. No significant impacts from emissions of GHGs were indicated based on these data (Confidential Appendix 7).

9. Mitigation

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

10. Alternatives to the Proposed Actions

Alternative A (No-action alternative). The no-action alternative is to not authorize the marketing of the new RYO cigarette papers 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 the predicate product and many other similar RYO tobacco products will continue to be marketed. The applicant forecasted a continued upward trend in manufacturing and sales of the predicate product. They stated that the new products' market volumes are predicted to largely consist of displacing future market volume of the predicate product (Confidential Appendix 5). Thus, an even greater future market volume of the predicate product could be expected if the new products are not authorized, indicating minimal, if any, difference between the environmental impacts of the no-action alternative and those from the proposed actions.

Alternative B (Proposed actions). There is no significant environmental effect due to the proposed actions of authorizing the new products and the associated manufacturing, use, and disposal following use of the products.

11. List of Preparers

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

Preparers:

Christine M. Modovsky, M.S., Center for Tobacco Products (product-specific analyses)
- Education: M.S. in Environmental Science
- Experience: 29 years in environmental compliance and analysis
- Expertise: NEPA analysis, regulatory compliance, evaluation of environmental health and ecological effects

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products (market trend analysis methodology)
- 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

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

12. List of Agencies and Persons Consulted

Not applicable.

13. Confidential Appendix List

Confidential Appendix 1: Manufacturer Information

Confidential Appendix 2: Modifications between New and Predicate Products

Confidential Appendix 3: The Current-, First-, and Fifth-Year Market Volume Projections of the New and Predicate Products

Confidential Appendix 4: Package Materials and Mass for New and Predicate Products

Confidential Appendix 5: New Product Sales as a Fraction of New and Predicate Product Sales

Confidential Appendix 6: Comparison of the U.S. Market Volumes for the New and Predicate Products with Rolling Papers for Total RYO Tobacco Products

Confidential Appendix 7: Greenhouse Gas Emissions from Manufacturing, Use, and Disposal of the Products

Confidential Appendix 8: Projected Product and Packaging Waste from Disposal after Use

14. References

Action Research. (2009). *Littering Behavior in America: Results of a National Study.* Keep America Beautiful. Retrieved from https://www.kab.org/sites/default/files/News%26Info_Research_LitteringBehaviorinAmerica_2009Report_Final.pdf

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.

National Association of Attorneys General. (1998). *Master Settlement Agreement.* Retrieved June 21, 2017, from http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf

Novotny, T. E., Aguinaga Bialous, S., Burt, L., Curtis, C., da Costa, V. L., Usman Iqtidar, S., . . . Tursan d'Espaignet, E. (2015). The environmental and health impacts of tobacco agriculture, cigarette manufacture and consumption. *Bull World Health Organ, 93*(12), 877-880.

U.S. Alcohol and Tobacco Tax and Trade Bureau. (2017). *Tobacco Statistics*. Retrieved March 15, 2017, from http://www.ttb.gov/tobacco/tobacco-stats.shtml

U.S. Environmental Protection Agency. (2011). *Exposure Factors Handbook.*

U.S. Environmental Protection Agency. (2016a). *Advancing Sustainable Materials Management: Facts and Figures.* Retrieved June 21, 2017, from U.S. Environmental Protection Agency web site: https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf

U.S. Environmental Protection Agency. (2016b). *Advancing Sustainable Materials Management: 2014 Fact Sheet.* Washington. Retrieved from https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf

U.S. Environmental Protection Agency. (2016c). Waste Reduction Model (WARM). (v. 14). Retrieved from www.epa.gov/warm

U.S. Environmental Protection Agency. (2017). *Basic Information about Landfill Gas*. Retrieved June 21, 2017, from Landfill Methane Outreach Program (LMOP): https://www.epa.gov/lmop/basic-information-about-landfill-gas

CONFIDENTIAL APPENDIX 1: Manufacturer Information

Contract manufacturer (for HBI International):

(b) (4)

The products are assembled outside of the United States at (b) (4)

(b) (4)

The facility is located in an industrial park, adjacent to similar facilities on all sides except to the southeast, which opens to an agricultural area.

The (b) (4) cigarette paper manufacturing facility in (b) (4) receives bobbins of unfinished paper from a paper mill at (b) (4) .

(b) (4)

The paper mill is bounded to the west and south by forest and to the north and east by a river (b) (4) , with a few residences within 100 meters along the road to the southeast and a village approximately 200 meters up the road to the northwest.

CONFIDENTIAL APPENDIX 2: Modifications between New and Predicate Products

The applicant claims that the new products and the predicate product are different in the rolling paper size, package quantity, material composition, and product names.

The applicant provided the product composition details for the new and predicate products as listed in the following table.

STN	Name	Components	Materials and Description	Source
SE0002390	RAW Organic SW Double	Paper	(b) (4)	SE0014191
				SE0013840
				SE0014191
			37 mm x 70 mm	SE0014191
		Adhesive	(b) (4)	SE0014191
		Packaging	100 leaves per booklet	SE0014191
			(plus starter and warning sheets)	SE0014191
			25 booklets per shrink-wrapped cardboard display box	SE0014191
			24 display boxes per cardboard shipping case	SE0014191
SE0002393	RAW SW SW	Paper	(b) (4)	SE0013438
				SE0013840
			37 mm x 70 mm	SE0013438
		Adhesive	(b) (4)	SE0013438
		Packaging	50 leaves per booklet	SE0013809
			(plus starter and warning sheets)	SE0014191
			25 booklets per shrink-wrapped cardboard display box	SE0014191
			24 display boxes per cardboard shipping case	SE0014191
Predicate	RAW Classic 1¼	Paper	(b) (4)	SE0013438
				SE0013840
			44 mm x 76 mm	SE0013438
		Adhesive	(b) (4)	SE0013438
		Packaging	32 leaves per booklet	SE0013840
			(plus starter and warning sheets)	SE0014191
			24 booklets per shrink-wrapped cardboard display box	SE0014191
			42 display boxes per cardboard shipping case	SE0014191

(b) (4) is an ingredient present in one of the new products but not in the predicate product. One of the new products lists (b) (4) as an ingredient that was not specified as an ingredient in the predicate product. Neither 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.

CONFIDENTIAL APPENDIX 3: 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
SE0002390	RAW Organic SW Double	Leaf	(b) (4)		
SE0002393	RAW SW SW	Leaf			
Predicate	RAW Classic 1¼	Leaf			

Source: Amendment SE0014191

CONFIDENTIAL APPENDIX 4: Package Materials and Mass for New and Predicate Products

STN	Name	Packaging	Material	Mass (g)
SE0002390	RAW Organic SW Double	Starter and warning papers	Paper	0.15
		Booklet cover	Cardboard	1.7
		Display box	Cardboard	9.8
		Shrink wrap	Plastic	0.8
		Shipping case	Cardboard	284
SE0002393	RAW SW SW	Starter and warning papers	Paper	0.15
		Booklet cover	Cardboard	2.75
		Display box	Cardboard	16
		Shrink wrap	Plastic	1.05
		Shipping case	Cardboard	268
Predicate	RAW Classic 1¼	Starter and warning papers	Paper	0.15
		Booklet cover	Cardboard	2.8
		Display box	Cardboard	14.9
		Shrink wrap	Plastic	1.05
		Shipping case	Cardboard	268

CONFIDENTIAL APPENDIX 5: New Product Sales Compared to Total New and Predicate Product Sales

STN	Name	Leaves Sold					Leaves Projected to be Sold	
		2012	2013	2014	2015	2016	2017	2021
SE0002390	RAW Organic SW Double	(b) (4)						
SE0002393	RAW SW SW							
Predicate	RAW Classic 1¼							
	Subtotal, new products only							
	Total, new and predicate products							
	New products as a percent of new and predicate products							
	Change in new product sales compared to 2016 sales of new + predicate products (leaves)						(b) (4)	
	Change in new product sales compared to 2016 sales of new + predicate products (%)							

The applicant stated that (b) (4) [redacted] ." Thus, it can be concluded that a similar, upward trending level of manufacturing at the same facilities would occur with or without authorization of the new products. There has been a clear overall downward trend in RYO tobacco use in the United State since 2008; see Figure 1 in section 5.2. Therefore, any actual increase in market volume over time for either the new or predicate products is expected to be offset by a corresponding decrease in sales of other similar RYO products on the market.

CONFIDENTIAL APPENDIX 6: Comparison of the U.S. Market Volumes for the New and Predicate Products with Rolling Papers for Total RYO Tobacco Products

The current-year, first-year, and fifth-year market volumes of the new and predicate products occupying the U.S. market were compared to the total current and projected number of rolling papers corresponding to the total RYO tobacco market (Figures 1 and 2 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]
SE0002390	RAW Organic SW Double	(b) (4)					
SE0002393	RAW SW SW						
Predicate for SE0002390 and 2393	RAW Classic 1¼						

[a] Current year RYO tobacco market in U.S.: (b) (4)
Projected first year (2017) RYO tobacco market in U.S.:
Projected fifth year (2021) RYO tobacco market in U.S.:

CONFIDENTIAL APPENDIX 7: Greenhouse Gas Emissions from Manufacturing, Use, and Disposal of the Products

GHG Emissions from Manufacturing of Products

The applicant stated that the parent company (BBK) voluntarily participates in a renewable energy program and annually purchases renewable energy certificates to offset any environmental impact from its overseas manufacturing activities. For the period beginning in June 2016, BBK "purchased (b) (4) of wind power certificates to save up to (b) (4) emissions. For the period beginning June 2017, BBK purchased (b) (4) " (Amendment SE0014191).

GHG Emissions from Use of Products

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 were estimated to be (b) (4) metric tons of CO_2-eq for the current, first, and fifth years, respectively. In each case, this is a negligible fraction (less than (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
SE0002390	RAW Organic SW Double	(b) (4)		
SE0002393	RAW SW SW			
Subtotal, new products:				
Predicate for SE0002390 and 2393	RAW Classic 1¼			
Total, new and predicate products:				
Total U.S. (2014):				
New and predicate products as a % of total U.S.:				

GHG Emissions from Disposal of Products

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 for the current, first, and fifth years, respectively. In each case, this is a negligible fraction (less than (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
SE0002390	RAW Organic SW Double	(b) (4)		
SE0002393	RAW SW SW			
Subtotal, new products:				
Predicate for SE0002390 and 2393	RAW Classic 1¼			
Total, new and predicate products:				
Total U.S. (2014):				
New and predicate products as a % of total U.S.:				

CONFIDENTIAL APPENDIX 8: Projected Product and Packaging Waste from Disposal after Use

To analyze the environmental effects from used product (cigarette butts) and packaging waste due to the proposed actions, the Agency estimated the weights of the waste that would be generated from disposal after use of the 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, cardboard, and plastic materials specific to the packaging for each product (Confidential Appendix 3), as follows:

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

$$B_i(\text{tons}) = E \times F_i\,(\text{leaves}) \times G_i\,(ounces) \times \frac{pound}{16\ ounces} \times \frac{ton}{2{,}000\ pounds}$$

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

$$D_i(\text{tons}) = \frac{S_i\,(grams)}{M_i \times K_i} \times T \times \frac{ton}{907{,}184.74\ grams}$$

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

$$Q_i(\text{grams}) = \frac{U_i\,(\text{grams})}{meter^2} \times P_i\,(millimeters) \times V_i\,(millimeters) \times \frac{meter^2}{1{,}000{,}000\ millimeter^2}$$

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

B_i = cigarette butts generated by the used products (tons)

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

D_i = plastic waste generated by the packaging for the new and predicate predicates (tons)

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

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

G_i = weight per cigarette butt (ounces)

H = 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)

I_i = "starter leaf" plus warning leaf that only a few leaves remain combined mass (grams)

J_i = booklet (grams)

K_i = leaves per booklet

L_i = display box (grams)

M_i = booklets per box

N_i = shipping case (grams)

O_i = boxes per case

P_i = cigarette rolling paper length (millimeters)

Q_i = cigarette rolling paper weight (grams)

R = fraction of cardboard paper waste not recycled = 1 - 0.647 = 0.353 (U.S. EPA 2016a)

S_i = plastic shrinkwrap per display box (grams)

T = fraction of plastic shrinkwrap not recycled = 1

U_i = paper basis weight (grams per square meter)

V_i = cigarette rolling paper width (millimeters)

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 (b) (4) tons (b) (4)) in the current, first, and fifth years, respectively. This is a negligible fraction (less than (b) (4) of the 192,080,000 tons (174,250,000 metric 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.

Current Year

STN	Name	V	U	(b) (4)	S	R	Q	P	O	N	M	K	L	K	J	I	H	G	F	E	D	C	B	A
SE0002390	RAW Organic SW Double	37	13.5		1.05		0.03497	37	24	268	13.5	70	68.75	100	2.75	0.15	27	0.0130						
SE00023931	RAW SW SW	37	14.0		1.05		0.03626	37	24	268	14.0	70	70.00	50	2.80	0.15	27	0.0130						
																		Subtotal, MSW						
Predicate for SE0002390	RAW Classic 1¼	44	14.0		0.80		0.04312	44	42	284	14.0	70	40.8	32	1.70	0.15	27	0.0131						
																			MSW from disposal of new and predicate products after use (tons)					(b) (4)
																			Total MSW disposed (not recycled) in U.S. (2014) (tons)					
																			MSW from product disposal as a % of total U.S.					

First Year

STN	Name	V	U	T	S	R	Q	P	O	N	M	K	L	K	J	I	H	G	F	E	D	C	B	A
SE0002390	RAW Organic SW Double	37	13.5	(b) (4)	1.05	(b) (4)	0.03497	37	24	268	13.5	70	69	100	3	0	27	0.0130	(b) (4)					
SE00023931	RAW SW SW	37	14.0		1.05		0.03626	37	24	268	14.0	70	70	50	3	0	27	0.0130						
																		Subtotal, MSW						
Predicate for SE0002390	RAW Classic 1¼	44	14.0		0.80		0.04312	44	42	284	14.0	70	41	32	2	0	27	0.0131						
																			MSW from disposal of new and predicate products after use (tons)					(b) (4)
																			Total MSW disposed (not recycled) in U.S. (2014) (tons)					
																			MSW from product disposal as a % of total U.S.					

Fifth Year

STN	Name	V	U	T	S	R	Q	P	O	N	M	K	L	K	J	I	H	G	F	E	D	C	B	A
SE0002390	RAW Organic SW Double	37	13.5	(b) (4)	1.05	(b) (4)	0.03497	37	24	268	13.5	70	69	100	3	0	27	0.0130	(b) (4)					
SE00023931	RAW SW SW	37	14.0		1.05		0.03626	37	24	268	14.0	70	70	50	3	0	27	0.0130						
																		Subtotal, MSW						
Predicate for SE0002390 and 2393	RAW Classic 1¼	44	14.0		0.80		0.04312	44	42	284	14.0	70	40.8	32	1.70	0.15	27	0.0131						
																			MSW from disposal of new and predicate products after use (tons)					(b) (4)
																			Total MSW disposed (not recycled) in U.S. (2014) (tons)					
																			MSW from product disposal as a % of total U.S.					