

**Programmatic Environmental Assessment for Marketing
Orders for Eight New Roll-Your-Own Rolling Paper
Manufactured by Republic LP**

**Prepared by Center for Tobacco Products
U.S. Food and Drug Administration**

June 22, 2018

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1. Applicant and Manufacturer Information

Applicant Name:	Republic Tobacco LP.
Applicant Address:	2301 Ravine Way Glenview, IL 60025
Manufacturer Name:	(b) (4)
Product Manufacturing Address:	(b) (4)

2. Product information

New and Predicate Products

New Product Name	New Product STN	Predicate Product Name
Job Pristine 1-1/4	SE0014410	Job Tribal King Size (Box)
Job Pristine Single Wide	SE0014411	Job Tribal King Size (Box)
Job Pristine Single Wide	SE0014412	Job Tribal King Size
Job Pristine Slim	SE0014413	Job Tribal King Size
Job Pristine 1-1/2	SE0014414	Job Tribal King Size (Box)
Job Pristine 1-1/2	SE0014415	Job Tribal King Size
Job Pristine Slim	SE0014416	Job Tribal King Size
Job Pristine 1-1/4	SE0014417	Job Tribal King Size

Product Identification

Product Type	Roll-Your-Own	
Product Sub-Category	Rolling Paper	
Product Package	New Product	Leaves per Booklet
	Job Pristine 1-1/4	50
	Job Pristine Single Wide	50
	Job Pristine Single Wide	50
	Job Pristine Slim	32
	Job Pristine 1-1/2	24
	Job Pristine 1-1/2	24
	Job Pristine Slim	32
	Job Pristine 1-1/4	50

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders finding the new tobacco products substantially equivalent to the corresponding predicate products under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States.

The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) reports and amendments submitted by the applicant, the new products are found substantially equivalent to the corresponding predicate products. The predicate product for SE0014410-SE0014411 and SE0014414 is a grandfathered tobacco product and the predicate product for SE0014412-SE0014413 and SE0014415-SE0014417 was previously found substantially equivalent and received a marketing order on June 30, 2017.

The new products differ from the corresponding predicate products based on changes in ingredients, ingredient levels, paper dimensions, paper porosity, and total rolling paper mass. (Confidential Appendix 1).

4. Alternatives to the Proposed Action

The no-action alternative is FDA does not issue marketing orders for the new tobacco products in the United States.

5. Potential Environmental Impact of the Proposed Action and the Alternatives – Manufacturing the New Product

The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts.

5.1 Affected Environment

The new and predicate products are manufactured at (b) (4) [REDACTED]. The manufacturing facility is located on the southernmost border of an industrial area that is bounded to the south by a residential area. The industrial area is a mixed-use area. The manufacturing facility has 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 La Bassa river with a 50- to 100-foot vegetated buffer immediately to the north (Figure 1).

Figure 1. Location of the Manufacturing Facility¹

(b) (4)



5.2 Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from manufacturing based on information gathered by the Agency and submitted in the SE Reports, including market volume information for the new and predicate products (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	No air quality change surrounding the facility is anticipated because the ingredients in the new products are the same or similar to those already used in the facility. Additionally, based on the SE Reports, production of the new products will occupy less than a percent of the total production at the facility (Confidential Appendices 2 and 3).
Water resources	No impacts on water quality is anticipated because the liquid waste discharge is not anticipated to change at the manufacturing facility due to little to no change in the ingredients being used in the facility. No impacts on water resources are anticipated; the applicant stated that no expansion of the manufacturing facility is anticipated.

¹ Land use surrounding manufacturing facility via Google Map. Accessed May 8, 2018.

Land use and zoning	No conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use is expected because no facility expansion is anticipated. No zoning changes are anticipated because no construction would occur that would require land use.
Biological resources	The applicant stated that the rolling paper suppliers for the new products are certified by the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification (PEFC). Manufacture of the new and predicate products are carried out under controls and standards that protect the environment, including species and habitats addressed under the Endangered Species Act (ESA) and Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). No effects on listed species or their habitat and biological resources are anticipated because no facility expansion is anticipated.
Geological features and soils	No effects on geological features or soils are expected because no facility expansion is anticipated.
Socioeconomic conditions	No facility expansion is anticipated; therefore, no impacts are expected on: employment; state or municipal revenue and taxes; additional demand on community services; and state and municipal resources, such as police force and fire department resources.
Solid waste and hazardous materials	The applicant stated that no additional capacity for disposal of manufacturing waste or any additional environmental controls would be required because production of the new products will occupy less than one percent of the total production at the facility (Confidential Appendices 2 and 3). Additionally, proper disposal of any waste related to manufacturing the new products would be handled in compliance with applicable laws and regulations.
Floodplains, wetlands, and coastal zones	No effects to floodplains, wetlands, or coastal zones are expected because no facility expansion is anticipated.
Regulatory compliance	The applicant stated that the manufacturing facility would comply with all applicable French regional and federal emissions, solid waste, and liquid waste regulations and requirements.

5.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the proposed actions.

5.4 Impacts from No-Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of manufacturing RYO tobacco products, as many other similar RYO tobacco products will continue to be manufactured and marketed.

6. Potential Environmental Impact of the Proposed Actions and the Alternatives – Use of the New Products

The Agency considered potential impacts to resources in the environment that may be affected by use of the new products and found no significant impacts.

6.1. Affected Environment

The affected environment is the entire United States because the marketing orders will allow for the new tobacco products to be sold to consumers nationwide. The new products are RYO products that are intended to be filled with tobacco and smoked. Users may smoke RYO cigarettes indoors or outside, as the laws permit.

6.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from use.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that no new compounds would be emitted from use of the new products. Therefore, the Agency does not anticipate that using the new products will lead to the release of new chemicals into the air, as compared to the predicate product.
Environmental justice	The new products are expected to be used by the same consumers that use the predicate products. Therefore, no change in impacts to environmental justice populations are expected.

6.3. Cumulative Impacts

No actions were identified that, when considered with the proposed actions, would lead to cumulative impacts.

6.4. Impacts from No-Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of the use of RYO tobacco products, as many other similar RYO tobacco products will continue to be marketed and therefore used.

7. Potential Environmental Impact of the Proposed Actions and the Alternatives – Disposal of the New Products

The Agency has considered potential impacts to resources in the environment that may be affected by disposal of the new products and found no significant impacts.

7.1. Affected Environment

The affected environment is the entire United States because the marketing orders will allow for the new tobacco products to be sold to consumers nationwide who will dispose of the used products and packaging via MSW landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from disposal.

Environmental Resource	Analysis of Potential Impacts
Air quality	Introducing the new products into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, thus, disposal of the used products and packaging will not significantly affect air quality.
Biological resources	Proper disposal of the used products and packaging materials from the new products in MSW would not affect biological resources. Used product and packaging materials from the new products may be littered in undeveloped areas and wildlife habitat. However, littering levels are not expected to change from the current levels due to existing products. Introducing the new products into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, per the Agency's experience.
Environmental justice	No significant environmental impacts associated with the disposal of the used products and product packaging were identified, therefore no disproportionate impacts to environmental justice populations are anticipated.
Water resources	Proper disposal of used product and packaging materials from the new products disposed of in the municipal solid waste stream would not affect water resources. Used product and packaging materials from the new products may be littered in or near surface water. However, littering levels are not expected to change from the current levels due to existing products. Introducing the new products into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, per the projected market volumes reported by the applicant (Confidential Appendices 2 and 3).
Regulatory compliance	It is assumed that the portion of product and packaging waste that is disposed of by users, despite littering ordinances, will be no greater than the current tobacco product littering rates.

7.3. Cumulative Impacts

No actions were identified that will lead to cumulative impacts due to the proposed actions.

7.4. Impacts from No Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of the disposal of RYO tobacco products, as many other similar RYO tobacco products will continue to be marketed.

8. 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 programmatic environmental assessment.

Preparer:

Susana Addo Ntim, PhD, Center for Tobacco Products
 Education: PhD in Environmental Science
 Experience: 6 years in various scientific activities

Expertise: Fate, transport and ecotoxicology of new and emerging contaminants, applications and environmental implications of nanotechnology

Reviewer:

Hoshing W. Chang, PhD, Center for Tobacco Products

Education: MS in Environmental Science and PhD in Biochemistry

Experience: 9 years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1: Modifications between New and Predicate Products

The new and corresponding predicate products differ in certain additives and design features. There are differences in ingredients and ingredient levels, paper dimensions, paper porosity, and total rolling paper mass.

The applicant provided the product material details for the new and corresponding predicate products in the SE Reports and amendments; this information is presented in the following table.

STN	Ingredient Changes	Paper Dimensions	Paper Porosity	Total Rolling Paper Mass	Changes in Packaging Materials	
					Retail Box Weight	Shipping Case Weight
SE0014410	(b) (4)	Decreased length	Increased in new product	Decreased in new product	Decreased in new product	Decreased in new product
SE0014411						
SE0014412						
SE0014413		Unchanged				
SE0014414		Decreased length				
SE0014415						
SE0014416	Same as SE0014413	Unchanged				
SE0014417	Same as SE0014410	Decreased length				

(b) (4)

Confidential Appendix 2: Current Market Volumes for the Predicate Products and Market Volume Projections of the New and Predicate Products

STN	Unit	Current-Year (2016) Market Volume	First - Year Market Volume		Fifth - Year Market Volume	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0014410	Leaves	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
	Metric Tons			(b) (4)		(b) (4)
SE0014411	Leaves	Same as SE0014410		Same as SE0014410		Same as SE0014410
	Metric Tons					
SE0014412	Leaves	(b) (4)		(b) (4)		(b) (4)
	Metric Tons	(b) (4)		(b) (4)		(b) (4)
SE0014413	Leaves	Same as SE0014412		Same as SE0014412		Same as SE0014412
	Metric Tons					
SE0014414	Leaves	Same as SE0014410		Same as SE0014410		Same as SE0014410
	Metric Tons					
SE0014415	Leaves	Same as SE0014412		Same as SE0014412		Same as SE0014412
	Metric Tons					
SE0014416	Leaves					
	Metric Tons					
SE0014417	Leaves					
	Metric Tons					

Confidential Appendix 3: Percentage of the Facility's Total Production Dedicated to the New Products

The projected first- and fifth-year market volumes (Confidential Appendix 2) of the new products were compared to the total 2016 cigarette paper production at the RTF manufacturing facility to evaluate the percentage of the manufacturing facility's overall production that would be used to manufacture the new products. The percentage of the facility's total production dedicated to each of the new products was estimated by the following equation:

Production Fraction of New Product (%)

$$= \frac{\text{Market Volume Projection (metric tons)}}{\text{Total Cigarette Paper Production at RTF (2016)}^3} \times 100\%$$

STN	Percentage of the New Products to Facility's Total Production (%)	
	First - Year	Fifth – Year
SE0014410	(b) (4)	
SE0014411		
SE0014412		
SE0014413		
SE0014414		
SE0014415		
SE0014416		
SE0014417		
Total		

The new RYO tobacco products are intended to account cummulatively for (b) (4) and (b) (4) of the facility's total production in the first- and fifth-year, respectively.