

**Programmatic Environmental Assessment for Marketing
Orders for New Roll-Your-Own Rolling Papers
by Republic Tobacco, LP**

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

June 25, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	Republic Tobacco, LP
Applicant Address:	2301 Ravine Way Glenview, IL 60025
Manufacturer Name:	Republic Technologies France (RTF Factory)
Product Manufacturing Location:	3750 Avenue Julien Panchot, BP 424 66004 Perpignan CEDEX, France

2. Product information

New Product Submission Tracking Numbers (STN), Names, and Predicate Product Name

STN	New Product	Predicate Product
SE0015117	OCB Ultimate 1-1/2	Job Tribal King Size (Box)
SE0015118	OCB Ultimate 1-1/4	
SE0015119	OCB Ultimate Single Wide	
SE0015120	OCB Ultimate Slim	

Product Identification

Product Category	Roll-Your-Own	
Product Subcategory	Rolling Paper	
Product Quantity per Retail Unit	New Product	Leaves per Booklet
	OCB Ultimate 1-1/2	24
	OCB Ultimate 1-1/4	50
	OCB Ultimate Single Wide	50
	OCB Ultimate Slim	32
Product Package	Cardboard booklet cover and cardboard display box	

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco products substantially equivalent to a single predicate product. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency substantial equivalence (SE) reports to obtain the marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the single predicate product. The predicate product is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new products differ from the predicate product in product quantity (Appendix 1), ingredient levels and design features (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

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

5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

The Agency considered potential environmental impacts that may be caused by manufacturing the new products and found no significant impacts.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products are manufactured at 3750 Avenue Julien Panchot, BP 424, 66004 Perpignan CEDEX, France (Figure 1). The manufacturing facility is located in a mixed use industrial, commercial, and residential area 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. Location of the Manufacturing Facility¹



5.2 Analysis of Potential Environmental Impacts

The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new products based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for

¹ Land use surrounding manufacturing facility via Google Map. Accessed April 10, 2019.

the new and predicate products (Confidential Appendix 2) and the percentage of the facility's total production dedicated to manufacturing the new products (Confidential Appendix 3).

Environmental Resource	Analysis of Potential Impacts
Air quality	No air quality change surrounding the facility would be expected because the ingredients in the new products are used in similar products manufactured at the facility. Additionally, based on the SE Reports, production of the new products would occupy less than one percent of the total facility production (Confidential Appendix 3). The applicant stated that manufacturing the new products would not require a new or revised air emission permit.
Water resources	No impacts on water resources are expected because the liquid waste discharge is not anticipated to change at the manufacturing facility. The applicant stated that the manufacturing facility would not require a new or revised wastewater discharge permit.
Land use and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed actions.
Biological resources	The applicant stated that the manufacturing process is carried out under controls and standards that protect the environment, including species and habitats addressed under the Convention on International Trade in Endangered Species of Wild Fauna and Flora. No effects on listed species or their habitat and biological resources are anticipated because no facility expansion is expected.
Geological features and soils	No effects on geological features or soils are expected because no facility expansion is anticipated.
Socioeconomic conditions	No impacts would be expected on employment, state or municipal revenue and taxes, or on police force and fire department resources because there would be no facility expansion anticipated.
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 the new products would cumulatively occupy a small percentage of the facility's total production of roll-your-own (RYO) tobacco products (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	There would be no expected facility expansion due to manufacturing the new products. Therefore, no effects on floodplains, wetlands, or coastal zones are anticipated.
Regulatory compliance	The applicant stated that the manufacturing facility would comply with all applicable French regional and federal regulations and requirements, including those related to air emissions, solid waste, and liquid waste.

5.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts when considered with manufacturing the new products under the proposed actions.

5.4 Impacts of the No-Action Alternative

The no-action alternative would not change the existing conditions of manufacturing RYO rolling paper at the listed facility, as similar RYO tobacco products would continue to be manufactured.

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

The Agency evaluated potential environmental impacts that may be caused by use of the new products and found no significant impacts.

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

6.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from use of the new products based on Agency-gathered information and the applicant’s submitted SE Reports.

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency does not anticipate that using the new products would lead to the release of new chemicals into the air, as compared to the predicate product or other currently marketed RYO tobacco products. The applicant stated that although the new products contain new and additional ingredients, the combustion products of the new ingredients are similar to those from other currently marketed RYO tobacco products.
Environmental justice	No new emissions are expected due to the use of the new products. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.3. Cumulative Impacts

No actions were identified that would lead to cumulative impacts when considered with use of the new products under the proposed actions.

6.4. Impacts of the No-Action Alternative

The no-action alternative would not change the existing conditions of use of RYO tobacco products, as similar RYO tobacco products would continue to be used in the United States.

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

The Agency evaluated potential environmental impacts that may be caused by disposal of the new products and found no significant impacts.

7.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow the new tobacco products to be sold to consumers nationwide who would dispose of the used products and packaging as municipal solid waste (MSW), recycled material, or litter.

7.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from disposal of the new products based on information 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	Introducing the new products into the U.S. market is not expected to increase the nationwide use of RYO tobacco products; therefore, disposal of the used products and packaging would not significantly affect air quality.
Biological resources	Proper disposal of the used new products and packaging materials in the MSW stream would not affect biological resources. Although the used products and packaging materials may be littered in undeveloped areas and wildlife habitat, littering levels are not expected to change from the current levels due to existing tobacco products. Introducing the new products into the U.S. market is not expected to increase the nationwide use of RYO tobacco products based on the projected market volumes reported by the applicant (Confidential Appendix 2).
Water resources	Proper disposal of used new products and packaging materials in the MSW stream would not affect water resources. Improper disposal (littering) of used new products could result in hazardous substances leaching to water systems. However, no net increase in littering is expected; introducing the new products into the U.S. market is not expected to increase the nationwide use and disposal of RYO tobacco products, because the new products would compete for the same market share with other currently marketed RYO products.
Environmental justice	No significant environmental impacts associated with the disposal of the used new products and packaging were identified, therefore no change in impacts to environmental justice populations are anticipated.
Regulatory compliance	Despite state and local littering ordinances, it is assumed that noncompliance (littering) would occur at the same rate for the new products as for the currently marketed RYO tobacco products.

7.3. Cumulative Impacts

No actions were identified that would lead to cumulative impacts when considered with the new products disposal under the proposed actions.

7.4. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of the disposal of RYO tobacco products and packaging materials, as many other RYO tobacco products would continue to be disposed of in the United States.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

Preparer:

Susana Addo Ntim, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science

Experience: Seven years in various scientific activities

Expertise: NEPA Analysis; fate, transport and ecotoxicology of new and emerging contaminants; applications and environmental implications of nanotechnology

Reviewer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-two years in various scientific activities including eight years in NEPA practice

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

9. List of Agencies and Persons Consulted

Not applicable.

Appendix 1. Product Quantity: The New Products Compared to the Predicate Product

STN	Product Quantity					
	New Product			Predicate Product		
	Leaves per Booklet	Booklets per Retail Box	Retail Boxes per Shipping Case	Leaves per Booklet	Booklets per Retail Box	Retail Boxes per Shipping Case
SE0015117	24	24	40	32	50	50
SE0015118	50	100	10			
SE0015119	50	24	40			
SE0015120	32	50	50			

Confidential Appendix 1. Changes in the New Products as Compared to the Predicate Product

STN	Change in the New Products as Compared to the Predicate Product	
	Design Features	Ingredients
SE0015117	Decreased – paper length, base paper basis weight, and total rolling paper mass Increased – paper width, base paper porosity	Decreased – (b) (4) Increased – (b) (4)
SE0015118	Decreased – paper length, base paper basis weight, and total rolling paper mass Increased – base paper porosity	Removed – (b) (4) Added – (b) (4)
SE0015119	Decreased – paper length, paper width, base paper basis weight, and total rolling paper mass Increased – base paper porosity	
SE0015120	Decreased – base paper basis weight and total rolling paper mass Increased – base paper porosity	

(b) (4)

Confidential Appendix 2. Market Volume information for the New and Predicate Products

The predicate product is currently marketed in the United States. The applicant intends to commercially market the new and predicate products after marketing orders for the new products are issued.

STN	Unit	Market Volume				
		Current-Year (2018)	First - Year Projection		Fifth - Year Projection	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0015117	Leaves	14,160,000	92,160	14,301,600	115,200	14,444,616
	Metric Tons	0.9724	0.0051	0.9821	0.0064	0.9919
SE0015118	Leaves	Same as SE0015117	100,000	Same as SE0015117	250,000	Same as SE0015117
	Metric Tons		0.0036		0.0090	
SE0015119	Leaves		120,000		600,000	
	Metric Tons		0.0032		0.0160	
SE0015120	Leaves		80,000		400,000	
	Metric Tons		0.0041		0.0204	
Total	Leaves	14,160,000	392,160	14,301,600	1,365,200	14,444,616
	Metric Tons	0.9724	0.016	0.9821	0.0518	0.9919

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) for the new products were compared to the total 2018 rolling paper production at the RTF manufacturing facility to evaluate the percentage of overall production that would be used to manufacture the new products. The percentage of the total production at the manufacturing facility dedicated to the new products was estimated by the following equation:

Production Fraction of New Product (%)

$$= \frac{\text{Market Volume Projection (Leaves)}}{\text{Total Rolling Paper Production at RTF (2018)}^3} \times 100\%$$

STN	Percentage of Facility’s Total Production Dedicated to New Products (%)	
	First - Year	Fifth - Year
SE0015117	0.0002	0.0002
SE0015118	0.0002	0.0004
SE0015119	0.0002	0.0010
SE0015120	0.0001	0.0007
Total	0.0006	0.0022

The new RYO tobacco products cumulatively would account for 0.0006% and 0.0022% of the facility’s total production in the first- and fifth-year, respectively.

³ Total rolling paper production at RTF (2018) – 60,778,005,900 Leaves