

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

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

May 15, 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
Product Manufacturing Address:	3750 Ave. Julien Panchot, BP 424, 66004 Perpignan CEDEX, France

2. Product information

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

STN	New Product Name	Predicate Product Name
SE0015132	OCB Organic Hemp 1 ¼ Size	OCB Organic Hemp 1 ¼ Size
SE0015133	OCB Virgin 1-1/4	OCB Virgin 1-1/4
SE0015134	OCB Premium 1 1/4	OCB XPERT 1 1/4
SE0015135	OCB Organic Hemp 1-1/4 Size	OCB Organic Hemp 1-1/4 Size
SE0015136	OCB Virgin 1-1/4	Job Pristine 1-1/4

Product Identification

Product Category	Roll-Your-Own
Product Subcategory	Rolling Paper
Number of Products per Retail Unit and Product Package	300 rolling papers per booklet, 40 booklets per retail box, 12 retail boxes per shipping case

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for 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 the corresponding predicate products. 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 marketing orders. The Agency shall issue marketing orders, after considering the SE Reports, if the new products are found substantially equivalent to the corresponding predicate products. The predicate products were previously found substantially equivalent.

The new products differ from the predicate products due to changes in quantity of rolling papers (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.

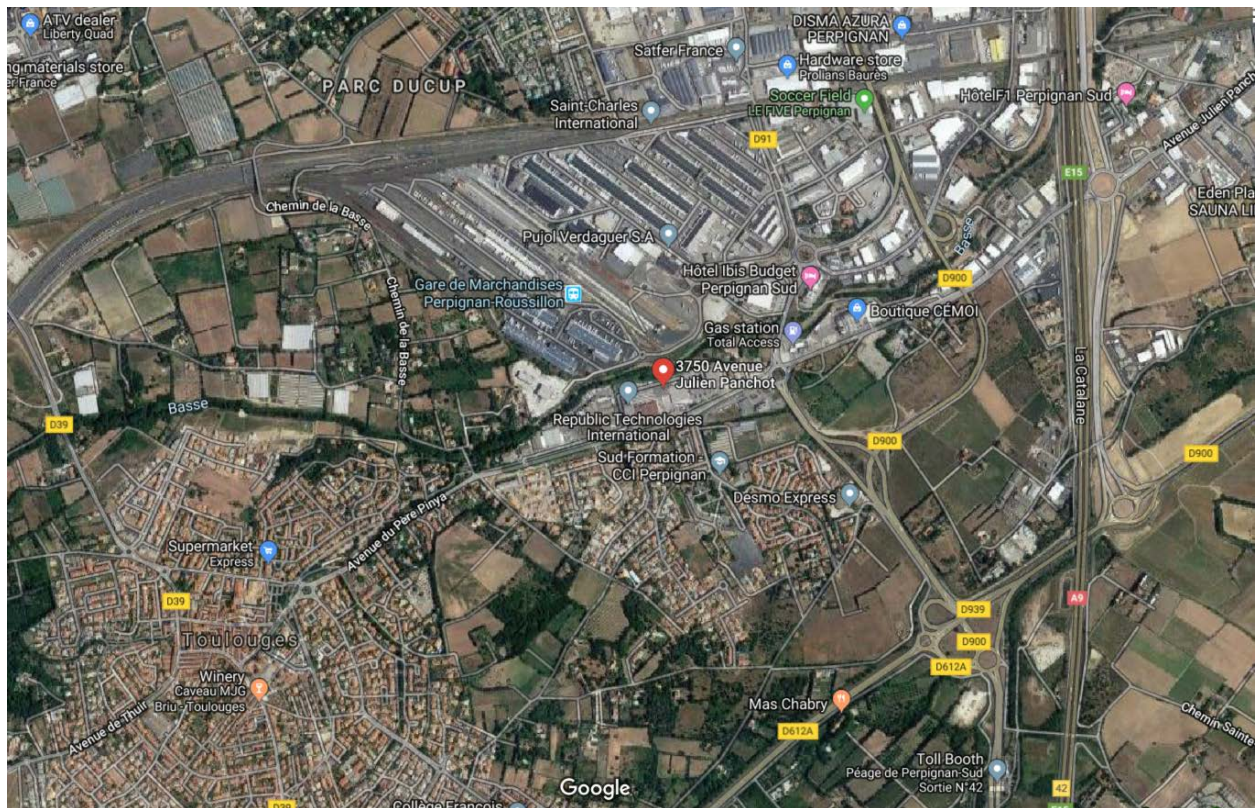
5. Potential Environmental Impacts of the Proposed Actions and the Alternatives – Manufacturing the New Products

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

5.1 Affected Environment

The new and predicate products are manufactured by Republic Technologies located at 3750 Ave. Julien Panchot, BP 424, 66004 Perpignan CEDEX, France (Figure 1). The manufacturing facility is located in a mixed industrial, commercial, and residential area consisting of stores and small industrial complexes. The facility is separated from housing by a two lane road to the south.

Figure 1. Location of the Manufacturing Facility¹



5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the new products based on information gathered by the Agency and the applicant's submitted information, including projected market volumes for the new and predicate products (Confidential Appendix 2).

¹ Land use surrounding manufacturing facility via Google Maps. Accessed April 5, 2019.

Environmental Resource	Analysis of Potential Impacts
Air quality	No air quality changes due to manufacturing would be expected because the new products differ only in package quantity compared to the predicate products. Similarly, the applicant stated that the new products are intended to compete with the predicate products and other similar products manufactured at the facility. Additionally, the applicant stated that production of the new products would occupy a small portion of the total production at the facility (Confidential Appendix 3). Lastly, the applicant stated that no new or revised air permits would be required due to manufacturing the new products.
Water resources and water quality	No impacts on water quality due to manufacturing would be expected because the new products differ only in package quantity compared to the predicate products. Similarly, the applicant stated that the new products are intended to compete with the predicate products and other similar products manufactured at the facility. Additionally, the applicant stated that production of the new products would occupy a small portion of the total production at the facility (Confidential Appendix 3). Lastly, the applicant stated that no new or revised water permits would be required due to manufacturing the new products.
Land use and zoning	No conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use is expected because the applicant stated that no facility expansion would occur as a result of manufacturing the new products. No zoning changes are anticipated because no construction that would require land use is projected.
Biological resources	The applicant stated that the suppliers for the RTC factory are certified by the Forest Stewardship Council (the FSC) and the Programme of Forest Certifications (the PEFC). 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 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, or on 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. 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 on 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 federal and regional regulations and requirements; this includes those related to emissions, solid waste and liquid waste.
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5.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the proposed actions from manufacturing the new products.

5.4 Impacts of the No-Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of manufacturing roll-your-own (RYO) tobacco products, as many similar RYO tobacco products would continue to be manufactured at the listed manufacturing facility.

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 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 information gathered by the Agency and the submitted SE Reports.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that no new compounds would be emitted from use of the new products. The ingredients in the new products are commonly used in other currently marketed RYO products. Therefore, 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 products or similar currently marketed products.
Environmental justice	No new emissions are expected due to 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, when considered with the proposed actions, would lead to cumulative impacts from use of the new products.

6.4. Impacts of the No-Action Alternative

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

7. Potential Environmental Impacts 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 includes human and natural environments in the United States because the marketing orders would allow for the applicant to distribute and sell the new tobacco products to consumers in the United States.

7.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from disposal of the new products based on information 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	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 would not significantly affect air quality.
Water resources and water quality	Proper disposal of used product and packaging material from the new products in the municipal solid waste stream would not affect water resources. Improper disposal could occur in or near surface water. However, 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).
Biological resources	Proper disposal of the used products and packaging material from the new products in MSW would not affect biological resources. Used product and packaging material 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 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 Agency's assessment and projected market volumes reported by the applicant. (Confidential Appendix 2)
Environmental justice	No significant environmental impacts associated with the disposal of the used product and packaging were identified, therefore no disproportionate impacts to environmental justice populations are anticipated.
Regulatory compliance	It is assumed that the portion of product and packaging waste that is disposed of by users as litter, despite littering ordinances, would be no greater than the current tobacco product littering rates.

7.3. Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the proposed actions from disposal of the new products.

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, as many other similar tobacco products would continue to be marketed.

8. List of Preparers

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

Preparer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
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 Experience: Four years in environmental science, three years in toxicology
 Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

Reviewer:

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 Education: B.S. and M.S. in Environmental Science
 Experience: Thirty-six years in regulatory environmental toxicology
 Expertise: Environmental risk assessment, ecotoxicology, NEPA analysis

9. List of Agencies and Persons Consulted

Not applicable.

CONFIDENTIAL APPENDIX 1

Modifications: The New Products Compared to the Predicate Products

STN	Number of Rolling Papers	
	New Product	Predicate Product
SE0015132	300	50
SE0015133	300	50
SE0015134	300	32
SE0015135	300	50
SE0015136	300	50

CONFIDENTIAL APPENDIX 2

Market Volume Projections for the New and Predicate Products

STN	Unit	First-Year Market Volume		Fifth-Year Market Volume	
		New Product	Predicate Product	New Product	Predicate Product
SE0015132	Rolling Papers	(b)(4)			
	Metric Tons	(b)(4)			
SE0015133	Rolling Papers	(b)(4)			
	Metric Tons	(b)(4)			
SE0015134	Rolling Papers	(b)(4)			
	Metric Tons	(b)(4)			
SE0015135	Rolling Papers	(b)(4)			
	Metric Tons	(b)(4)			
SE0015136	Rolling Papers	(b)(4)			
	Metric Tons	(b)(4)			

CONFIDENTIAL APPENDIX 3

New Products' Percentage of Total Facility Production

STN	Percent of Facility Production*
SE0015132	(b)(4)
SE0015133	(b)(4)
SE0015134	(b)(4)
SE0015135	(b)(4)
SE0015136	(b)(4)
Total	(b)(4)

*Percent of facility production based on first-year market volume projection and current production of (b) (4) at the Republic Technologies manufacturing facility