

**Environmental Assessment for Marketing Order for
One Roll-Your-Own Tobacco Product by
BBK Tobacco & Foods, LLP Company**

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

March 25, 2019

Table of Contents

1.	Applicant and Manufacturer Information.....	3
2.	Product Information.....	3
3.	The Need for the Proposed Action.....	3
4.	Alternatives to the Proposed Action	4
5.	Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product	4
5.1	Affected Environment.....	4
5.2	Analysis of Potential Environmental Impacts	5
5.3	Cumulative Impacts	6
5.4	Impacts of the No-Action Alternative	6
6.	Potential Environmental Impacts of the Proposed Action and Alternatives – Use of the New product.....	6
6.1.	Affected Environment.....	6
6.2.	Analysis of Potential Environmental Impacts	6
6.3.	Cumulative Impacts	7
6.4.	Impacts of the No-Action Alternative	7
7.	Potential Environmental Impacts of the Proposed Action and Alternative – Disposal of the New product.....	7
7.1.	Affected Environment.....	7
7.2.	Analysis of Potential Environmental Impacts	7
7.3.	Cumulative Impacts	8
7.4.	Impacts of the No-Action Alternative	8
8.	List of Preparers	8
9.	A Listing of Agencies and Persons Consulted.....	8
	Confidential Appendix 1.....	9
	Location of the Manufacturing Facility	9
	Confidential Appendix 2:.....	10
	Modification to the to the Original Product to Create the New Product.....	10
	Confidential Appendix 3:.....	11
	Current Year Market Volume and First- and Fifth-Year Market Volume Projections for the New and Original Products.....	11

1. Applicant and Manufacturer Information

Applicant Name:	BBK Tobacco & Foods, LLP Company dba HBI International
Applicant Address:	3401 West Papago Street Phoenix, AZ 85009
Manufacturer Name: ¹	IBERPAPEL S.L.
Address Where Product is Manufactured ²	Polingono Industrial "La Creueta", s/n 03827 Benimarfull Alicante, Spain

2. Product Information

New Product Name, Submission Tracking Number (STN), and Original Product Name

New Product Name	New Product STN	Original Product Name
Raw Single Wide Cut Corners	EX0000424	Raw Single Wide Single Feed

Product Identification

Product Type	Roll-Your-Own
Product Subtype	Rolling Paper
Product Package	50 papers per booklet; 50 booklets per box. The packaging materials consist of paperboard booklet cover with a heavy cardboard paper between the cover and the booklet papers.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue an exemption from substantial equivalence reporting for a marketing order under the provisions of section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the introduction of a roll-your-own (RYO) rolling paper into interstate commerce for commercial distribution in the United States. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) a substantial equivalence report under section 905(j) of the FD&C Act is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the new tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant must obtain written notification that the Agency has granted the product an exemption from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated

¹ The booklets are assembled in (b)(4).

² This is the location where the booklets are assembled. See Confidential Appendix 1 for the location of the paper manufacturer.

report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new product for which the applicant has obtained an exemption from demonstrating substantial equivalence.

For this proposed action, the original product is a grandfathered product. The new product is made by modifying the original product by having the corner cutouts on the long side of the new product; the original product lacks the corner cutouts (Confidential Appendix 2).

4. Alternatives to the Proposed Action

The no-action alternative is FDA does not issue the Exemption Request for a marketing order for the new tobacco product.

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

The Agency considered potential impacts on resources in the environment that may be affected by manufacturing the new product and found no significant impacts based on the Agency-gathered information and the submitted information by the applicant.

5.1 Affected Environment

The new product would be manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturer



The manufacturing facility is located in a mixed-used industrial and residential area surrounded by forests.

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts due to manufacturing based on Agency-gathered information and the applicant's submitted information, including projected market volumes for the new and original products (Confidential Appendix 3).

Environmental Resource	Analysis of Potential Impacts
Air Quality	The applicant stated that manufacturing the new product is not expected to result in changes of air emissions or require any additional environmental controls for air emissions. This is supported by the applicant noting that (1) the new product is expected to compete with the original product, (2) the materials used in manufacturing the new product are currently used in the facility.
Water Resources	The Agency does not anticipate that manufacturing the new product would cause any new chemicals to be discharged into the water. The applicant stated that the new product is intended to replace similar tobacco products currently manufactured at the facility and that manufacturing the new product would not require any additional environmental controls for water discharges.
Soil, Land Use, and Zoning	The Agency does not anticipate that manufacturing the new product would lead to changes in soil, land use, or zoning. The applicant stated that there would be no expected facility expansion or new construction due to manufacturing the new product. Therefore, there would be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.
Biological Resources	The applicant stated that the raw materials are from sustainable and renewable resources. No facility expansion is expected; therefore, the Agency does not anticipate manufacturing the new product would jeopardize the continued existence of any listed species or result in adverse effects on species or habitats addressed under the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).
Socioeconomics and Environmental Justice	The Agency does not anticipate any impacts on employment, revenue, or taxes because the new product is intended to compete with and eventually replace similar tobacco products currently manufactured at the facility. Therefore, no disproportionate impacts to minority populations near the manufacturing facility is expected.
Solid Waste and Hazardous Materials	The Agency does not foresee that the introduction of the new product would notably affect the current manufacturing waste generated from the production of all RYO tobacco products at this facility. The waste generated due to manufacturing the new product would be released to the environment and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility. The manufacturer is in compliance with applicable environmental laws, regulations, and local ordinances; this is assumed to indicate no significant impacts will occur.
Floodplains, Wetlands, and	There would be no facility expansion due to manufacturing the new product and the applicant did not propose any land disturbance; therefore, there would

Coastal Zones	be no effects on floodplains, wetlands, or coastal zones.
Regulatory Compliance	The applicant stated that the manufacturing facility is in compliance with all applicable environmental laws, regulations, and local ordinances.

5.3 Cumulative Impacts

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

5.4 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing the RYO rolling papers, as many other similar tobacco products would continue to be manufactured at the listed facility.

6. Potential Environmental Impacts of the Proposed Action and Alternatives – Use of the New product

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

6.1. Affected Environment

The affected environment includes human and natural environments in the United States. The marketing order will allow for the distribution and sale of the new tobacco product to consumers in the United States. The new product is a RYO tobacco product that is intended to be filled with tobacco and smoked by users indoors or outside, as the law permits.

6.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from the new product use based on the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency anticipates that no new compounds will be emitted from use of the new product because (1) the new product is expected to compete with, or replace, similar currently marketed tobacco products and (2) the ingredients in the new product are used in other currently marketed tobacco products.
Environmental justice	No new emissions are expected due to use of the new product. 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 action, would lead to cumulative impacts.

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 the RYO rolling papers, as many other similar tobacco products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Action and Alternative – Disposal of the New product

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

7.1. Affected Environment

The affected environment includes human and natural environments in the United States. The market order will allow the applicant to distribute and sell the new tobacco product to consumers in the United States. Consumers will dispose of the used product and packaging via municipal solid waste landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from disposal.

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency does not anticipate disposal of the product or the packaging material would lead to the release of new or increased chemicals into the air because (1) introducing the new product into the U. S. market is not expected to increase the nationwide use and eventual disposal of RYO tobacco products; (2) the new product is anticipated to compete with or replace other currently marketed RYO tobacco products; (3) the paper components of the packages are more likely to be recycled, or at least a portion of the packaging waste is likely to be recycled; and (4) the packaging materials are commonly used and disposed of in the United States.
Biological resources	The proposed action is not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. Although improper handling of waste could occur in undeveloped areas and wildlife habitats, introducing the new product into the U. S. market is not expected to increase the nationwide use and eventually the disposal of RYO tobacco products. Therefore, it is not expected that the current amount of littering will change due to disposal of the new product.
Environmental justice	The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new product. No new

	emissions are expected due to disposal of the new product. Therefore, there would be no new disproportionate impacts on minority or low-income populations.
Water resources	Proper handling of waste generated due to disposal of the new product and packaging will not affect water resources. Although improper disposal could occur in or near surface water, there would be no expected changes of impacts on water quality due to disposal of the new product because (1) the chemicals in the new product are the same as in currently marketed RYO papers and (2) the new product would replace similar tobacco products currently on the market.

7.3. Cumulative Impacts

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

7.4. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of disposal of RYO tobacco products or packaging materials, 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 environmental assessment (EA):

Preparer:

Mehran Niazi, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Sciences

Experience: Twelve years in environmental fate and transport and environmental modeling

Expertise: Water quality modeling, environmental fate and transport modeling

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Ten years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1

Location of the Manufacturing Facility

The applicant stated that the papers are manufactured by (b) (4), located at the following address:

(b) (4)

The booklets are assembled by IBERPAPEL S.L. in Spain

Confidential Appendix 2:

Modification to the to the Original Product to Create the New Product

STN	Component	Modification
EX0000424	Rolling paper	Corner cutouts on the long side of the new product

Confidential Appendix 3:

Current Year Market Volume and First- and Fifth-Year Market Volume Projections for the New and Original Products

The applicant intends to continue marketing the original product after receiving a marketing order for the new product. The applicant used the 2016 statistical data for paper and paper board production in Europe and stated that the combined production of the new and original products account for a minute fraction (1.7×10^{-6} percent) of total paper and paperboard production in France.³

STN	Market Volume						
	Unit	Current Year Production		First-Year Projection		Fifth-Year Projection	
		New Product	Original Product	New Product	Original Product	New Product	Original Product
EX0000424	# of leaves	(b)(4)					

³ Confederation of European Paper Industries, Key Statistics 2016;
http://www.cepi.org/system/files/public/documents/publications/statistics/2017/KeyStatistics2016_Final.pdf. Accessed June 25, 2018.