

**Environmental Assessment for a Marketing Order for
Raw Organic 1/2**

By

**BBK Tobacco & Foods, LLP Company
dba HBI International**

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

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1. Applicant and Manufacturer Information

Applicant Name:	BBK Tobacco & Foods, LLP Company dba HBI International
Applicant Address:	3401 West Papago Street Phoenix, Arizona 85009
Manufacturer Name:¹	(b) (4)
Address Where Product is Manufactured²	(b) (4) (b) (4) (b) (4) Spain

2. Product Information

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

New Product Name	Raw Organic 1/2
STN	SE0014435
Predicate Product Name	ELEMENTS 1/2

Product Identification

Product Type	Roll-Your-Own
Product Subtype	Rolling Paper
Product Package	33 papers per booklet; 25 booklets per box. The packaging materials consist of paperboard booklet cover with a heavy cardboard paper between the cover and the booklet papers to provide support, and paperboard box.

3. The Need for the Proposed Action

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

The new product differs from the predicate product in design features and some ingredient changes (Confidential Appendix 2).

¹ The booklets are assembled in Spain.

² See Confidential Appendix 1 for the location of the paper manufacturer.

4. Alternative to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for the new tobacco product in the United States.

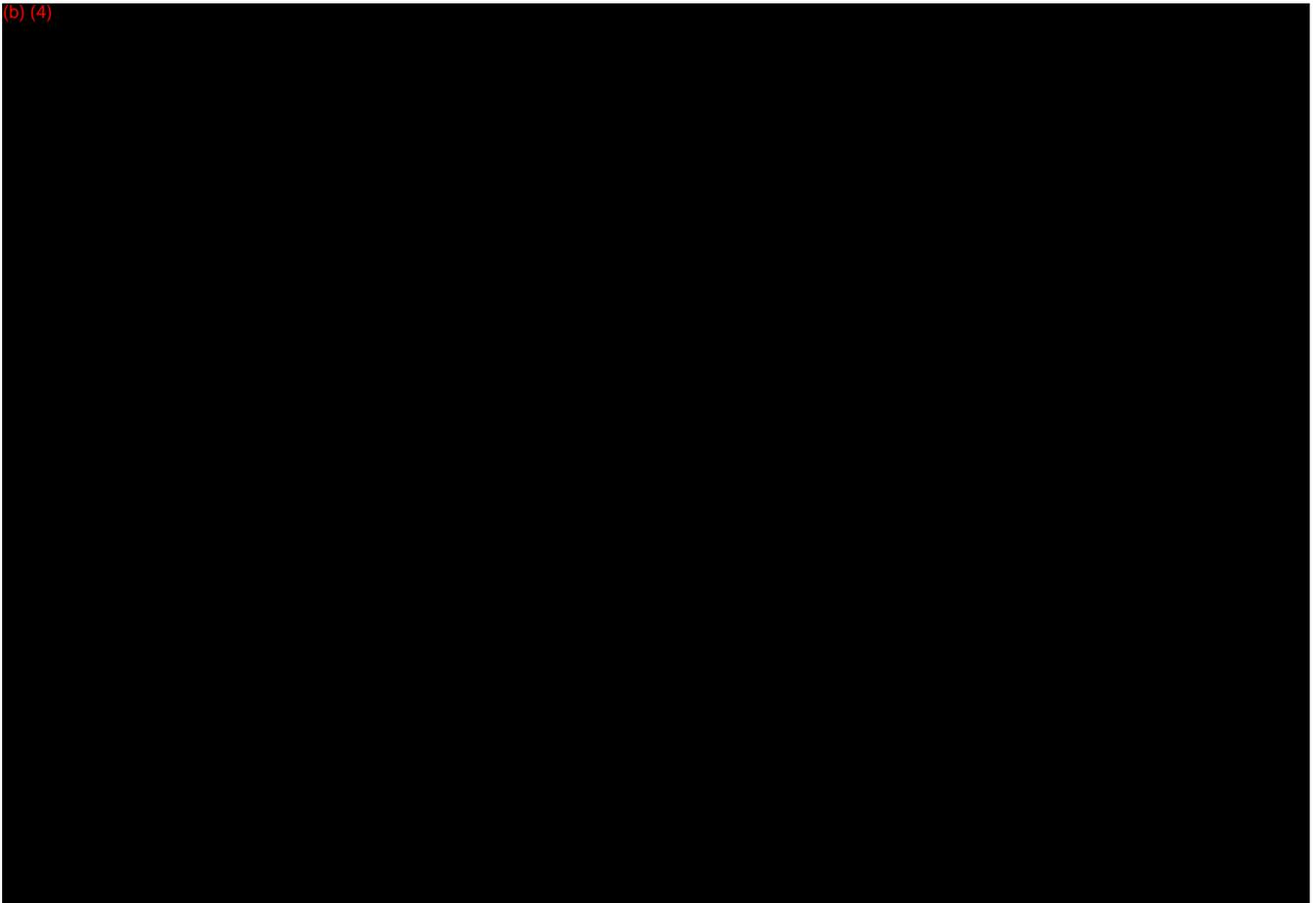
5. Potential Environmental Impacts of the Proposed Action and Alternative – Manufacturing the New Product

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 applicant’s information submitted in the SE Report.

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 manufacturer 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 predicate 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 to air emissions or require any additional environmental controls for air emissions because (1) the new product is expected to compete with the predicate product and potentially replace other rolling papers currently on the market; (2) the materials used in manufacturing the new product are currently used in the facility; and (3) any forecasted increase in the combined production of the new and predicate products rolling papers would add a fraction of a percent to the total paper and paperboard production in the country where the rolling papers are manufactured. (Confidential Appendix 3).
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, or land use and zoning. The applicant stated that there would be no 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) or identified under the Endangered Species Act (ESA).
Socioeconomic Conditions	There would be no expected impacts on employment, revenue, taxes, or community resources because the new product is intended to compete with and eventually replace similar tobacco products currently manufactured at the facility.
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 papers at this facility. The waste generated due to manufacturing the new product would be released to the environment, transferred to a publicly owned treatment works (POTW), and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other RYO papers manufactured in Spain and Europe. The manufacturer's compliance with applicable

	environmental laws, regulations, and local ordinances is assumed to indicate no significant impacts would occur.
Floodplains, Wetlands, and Coastal Zones	There would be no facility expansion due to manufacturing the new product and the applicant did not propose any land disturbance; therefore, there would 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 No Action Alternative

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

6. Potential Environmental Impacts of the Proposed Actions 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 because the marketing orders would allow for the new tobacco products to be sold to consumers nationwide. The new product is a RYO 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 use of the new product based on the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Air Quality	The applicant stated that no new compounds would 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 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 the 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. No Action Alternative

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

7. Potential Environmental Impacts of the Proposed Actions 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 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 new tobacco products to be sold to consumers nationwide. Consumers would 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 United States market is not expected to increase the nationwide use and eventually disposal of RYO tobacco products; (2) the new product is anticipated to compete with or replace currently marketed RYO 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 disposal of RYO tobacco products; therefore, it is not expected that the amount of littering would change from the current amount 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 would 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. No Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of 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 environmental assessment (EA):

Preparer:

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

Experience: 25 years in various scientific activities including 7 years in NEPA practice

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

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

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

Experience: 10 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) [REDACTED]
[REDACTED]

The booklets are assembled by (b) (4) [REDACTED] in Spain

Confidential Appendix 2:

Comparison Between the New Product and the Predicate Product

STN	Component	Change in the New Product as Compared to the Predicate Product
SE0014435	Rolling paper	Decreased paper porosity by █ CUs
		Decreased paper mass by 3.6%
		Decreased paper basis weight by 4%

CONFIDENTIAL APPENDIX 3

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

The applicant intends to continue marketing the predicate product after receiving a marketing order for the new product. The applicant used the 2016 statistical data of paper and paperboard production in Europe to conclude that the combined production of the new and predicate products rolling papers accounts for a minute fraction of total paper and paperboard production in France.³

STN	Unit	Market Volume					
		Current Year Production		First-Year Projection		Fifth-Year Projection	
		New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0014435	Number of Leaves	(b) (4)					
	Metric Tons	(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.