

**Environmental Assessment for a Marketing Order for
a New Roll-Your-Own Rolling Paper by
BBK Tobacco & Foods, LLP Company
dba HBI International**

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

August 14, 2019

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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, AZ 85009		
Manufacturer Name: ¹	(b) (4)		
Address Where Product is Manufactured ²	(b) (4)	(b) (4)	

2. Product Information

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

New Product Name	STN	Original Product Name
Raw Organic Single Wide Cut Corners	EX0000629	Raw Organic Single Wide Single Window

Product Identification

Product Category	Roll-Your-Own
Product Subcategory	Rolling Paper
Product Quantity per Retail Unit	50 papers per booklet; 50 booklets per display box.
Product Package	The packaging materials consist of cardboard booklet cover with a starter paper and a warning paper between the cover and the booklet papers, and cardboard display box.

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 (SE) reporting for a marketing order under 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. 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) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

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

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

The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States. The applicant must obtain a written notification that FDA has granted the product an exemption from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated 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.

The new product is made by modifying the original product, which was previously found substantially equivalent by the FDA and received a marketing order on May 16, 2019. The new product differs from the original product in (b) (4), resulting in a reduction of an ingredient in the new product (Confidential Appendix 2).

4. Alternative to the Proposed Action

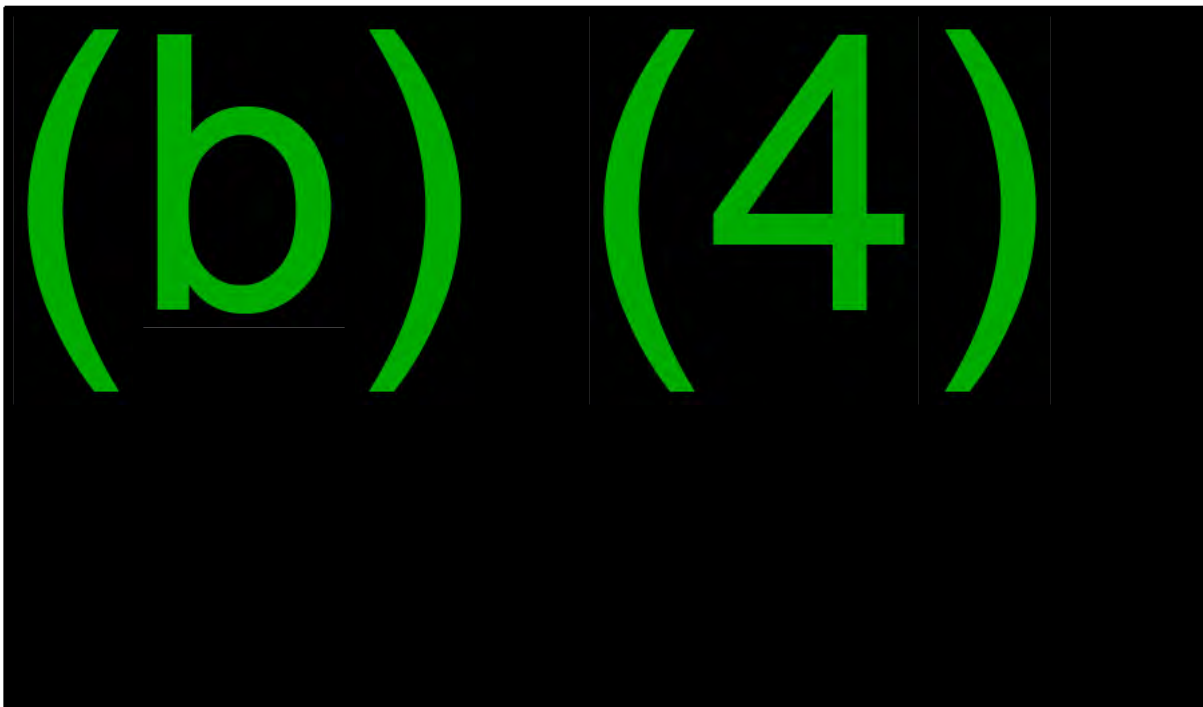
The no-action alternative is FDA does not issue a marketing order for the new tobacco product in the United States.

5. Potential Environmental Impacts of the Proposed Action and the 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 information submitted by the applicant.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new product would be manufactured at the address listed in section 1 of this document (Figure 1).



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 the new product 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 to air emissions or require any additional environmental controls for air emissions. The applicant also stated that any forecasted increase in the combined production of the new and original products would be offset by the decrease in other similar products manufactured at 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 applicant stated that there would be no facility expansion 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 there would be no facility expansion. Therefore, the Agency does not anticipate that 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).
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 and disposed of in landfills in the same manner as the waste generated from any other products manufactured in the same facility. The manufacturer's compliance with applicable environmental regulations 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 regulations, including CITES.

5.3 Cumulative Impacts

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

5.4 Impacts of the No Action Alternative

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

6. Potential Environmental Impacts of the Proposed Action and the Alternative – 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 order would allow for the new tobacco product to be sold to consumers in the United States. 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 Agency does not anticipate that using the new product would lead to the release of new chemicals to the air because the new product is expected to compete with, or replace, similar 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 use of the new product under the proposed action, would lead to cumulative impacts.

6.4. Impacts of the No Action Alternative

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

7. Potential Environmental Impacts of the Proposed Action and the 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 order would allow for the new tobacco product 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 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 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	Proper disposal of the used new product and packaging materials in the MSW stream would not affect biological resources. 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, based on the projected market volumes reported by the applicant (Confidential Appendix 3). Therefore, littering levels are not expected to change from the current levels.
Environmental Justice	No significant environmental impacts associated with the disposal of the used new product and packaging were identified. 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. Improper disposal could result in hazardous substances leaching to water systems. However, no net increase in littering would be expected because 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 new product disposal under the proposed action, would lead to cumulative impacts.

7.4. Impacts of the No Action Alternative

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

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this 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. 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], located at (b) (4) [REDACTED]

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

Confidential Appendix 2. Modification in the New Product as Compared to the Original Product

STN	Component	Modification in the New Product as Compared to the Original Product
EX0000629	Rolling paper	(b) (4) [REDACTED] [REDACTED]

Confidential Appendix 3. Current Year Market Volume for the Original Product 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 2017 statistical data of paper and paperboard production in Europe to conclude that the combined production of the new and original products rolling papers accounts for a minute fraction of total paper and paperboard production in (b) (4).³

STN	Unit	Market Volume				
		Current Year	First-Year Projection		Fifth-Year Projection	
		Original Product	New Product	Original Product	New Product	Original Product
EX0000629	Number of Leaves	(b) (4)	(4)			
	Metric Tons	(b) (4)	(4)			

³ Confederation of European Paper Industries, Key Statistics 2017; http://www.cepi.org/system/files/public/documents/publications/statistics/2018/210X140_CEPI_Brochure_KeyStatistics2017_WEB.pdf. Accessed June 25, 2019.