

**Programmatic Environmental Assessment for Marketing
Orders for New Roll-Your-Own Cigarette Papers by BBK
Tobacco & Foods LLP, Company D/B/A/ HBI International**

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

April 20, 2020

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1. Applicant and Manufacturer Information

Applicant Name:	BBK Tobacco & Foods, LLP Company d/b/a HBI International
Applicant Address:	3401 West Papago Street Phoenix, AZ 85009
Manufacturer Name:	BBK Tobacco & Foods, LLP Company d/b/a HBI International
Products Manufacturing Address:	See Confidential Appendix 1.

2. Products Information

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

STN	New Product Name	Predicate Product Name
SE0015745	Elements 1 ¼	Elements 1 ¼
SE0015746	Elements 1 ½	Elements 1 ½
SE0015747	Elements SW DF	Elements SW
SE0015748	Elements Three Hundred 20 CT Box	Elements 1 ¼
SE0015749	Elements 1 ¼ Perfect Fold	Elements 1 ¼

Product Identification

Product Category	Roll-Your-Own
Product Subcategory	Rolling Paper
Product Package	<p>SE0015745 – 50 papers (single feed of 50 papers) per booklet; 25 booklets per display box. The packaging materials consist of a paperboard booklet cover with a heavy cardboard paper between the cover and the booklet papers.</p> <p>SE0015746 – 33 papers (single feed of 33 papers) per booklet; 25 booklets per display box. The packaging materials consist of a paperboard booklet cover with a heavy cardboard paper between the cover and the booklet papers.</p> <p>SE0015747 – 100 papers (double feed of 50 papers) per booklet; 25 booklets per display box. The packaging materials consist of paperboard booklet cover with a heavy cardboard paper between the cover and the booklet papers.</p> <p>SE0015748 – 300 cigarette papers per tray; 20 trays per display box; The packaging materials consist of paperboard tray and a paperboard display box.</p>

	SE0015749 – 50 papers (single feed of 50 papers) per booklet; 25 booklets per display box. The packaging materials consist of paperboard booklet cover with a heavy cardboard paper between the cover and the booklet papers.
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3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for U.S. 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. The applicant wishes to introduce five new roll your own (RYO) products into interstate commerce and submitted to the Agency a substantial equivalence (SE) report. The Agency shall issue marketing orders if the new products are found substantially equivalent to the corresponding predicate products. The new and predicate products contain minor differences in the design of the watermark.

4. Alternatives to the Proposed Action

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 Action and Alternatives – Manufacturing the New Product

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

5.1 Affected Environment

The new and predicate products are manufactured in foreign facilities (Confidential Appendix 1). The manufacturing facilities are located in mixed-use industrial areas consisting of warehouses, and light manufacturing facilities.

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from manufacturing the new products based on information gathered by the Agency and the information in the SE Report, including projected market volumes for the new products (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products is not expected to result in changes to air emissions or require additional environmental controls for air emissions. According to the applicant, overall manufacturing at the facility is not expected to increase as result of manufacturing the new product.
Water resources	The Agency does not anticipate that manufacturing the new products would cause any new chemicals to be discharged into the water. The applicant stated that manufacturing the new products is not expected to result in changes to wastewater discharges or require any additional environmental controls.

Soil, land use, and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new products. 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 products 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 products 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 products would noticeably affect the current manufacturing waste generated from the production of all RYO product at this facility. The waste generated due to manufacturing the new products would be released to the environment and disposed of in landfills in the same manner as the waste generated from any other product 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 products 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

The Agency did not identify any actions that would lead to cumulative impacts due to the manufacturing of the new product.

5.4 Impacts from No-Action Alternative

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

6. Potential Environmental Impact 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 products and found no significant impacts.

6.1. Affected Environment

The affected environment is the entire United States because the marketing order would allow for the new tobacco products to be sold to consumers nationwide. The new RYO tobacco products are intended

to be rolled and filled with tobacco by users who may smoke them indoors or outdoors, 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 products based on information gathered by the Agency and the applicant-submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that the market volume predictions are a fraction of a percent of the total predicted cigarette sales in the United States. In addition, the new and predicate products differ only in the packaging. 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 corresponding predicate products or similar currently marketed products.
Environmental justice	The new products are expected to be used by the same consumers that use the predicate product. Therefore, no changes in impacts to environmental justice populations are anticipated.

6.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts due to the use of the new product.

6.4. Impacts from 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 and therefore used in the United States.

7. Potential Environmental Impacts of the Proposed Action and Alternatives – Disposal of the New Product

The Agency 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 is the entire United States because the marketing order would allow for the new tobacco products to be sold to consumers nationwide. The disposal would be via municipal solid waste (MSW) landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential impacts from disposal of the new products based on information submitted in the SE Report, including market volume projections for the new 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 product and packaging would not significantly affect air quality.
Biological resources	Proper disposal of the new products and the packaging materials in MSW would not affect biological resources. Used product and packaging materials may be littered in undeveloped areas and wildlife habitat. However, 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. Therefore, littering levels are not expected to change from the current levels due to existing tobacco products.
Environmental justice	No significant environmental impacts associated with the disposal of the new products and packaging materials were identified; therefore, no disproportionate impacts to environmental justice populations are anticipated.
Water resources and water quality	Proper disposal of used new products and packaging materials in the MSW stream would not affect water resources. Improper disposal could occur in or near surface water. However, 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). Therefore, littering levels are not expected to change from the current levels due to existing tobacco products.
Regulatory compliance	It is assumed that littering of the new products and packaging waste, despite state and local ordinances, would be no greater than the littering rate of the currently marketed RYO tobacco products.

7.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts due to the disposal of the new product.

7.4. Impacts from No-Action Alternative

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

8. List of Preparers

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

Preparer:

Thomas E. Creaven, Ph.D., Center for Tobacco Products
 Education: B.S. in Chemistry/Biology, Ph.D. in Biology/Neuroscience
 Experience: Ten years in science education and three years in NEPA Review
 Expertise: Physics, Chemistry, Biology education and NEPA Review

Reviewer:

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

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

Experience: Eleven years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1

Location of Manufacturing Facilities

The cigarette papers and packaging papers are milled in France by (b) (4), located at (b) (4).

(b) (4)

The cigarette papers are cut to size, gummed, converted to paper rolls after the watermark is applied to the paper, and packaged by (b) (4), located at (b) (4).

(b) (4)

CONFIDENTIAL APPENDIX 2.

Market Volume Information for the New Products

STN	Market Volume Information			
	Unit	Current Year (2019)	1 st Year	5 th Year
SE005745	Number of Booklets	(b) (4)		
	Weight (kg)			
SE005746	Number of Booklets			
	Weight (kg)			
SE005747	Number of Booklets			
	Weight (kg)			
SE005748	Number of Booklets			
	Weight (kg)			
SE005749	Number of Booklets			
	Weight (kg)			