

**Programmatic Environmental Assessment for Marketing  
Orders for New Roll-Your-Own Rolling Papers 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

<b>Applicant Name:</b>	BBK Tobacco & Foods, LLP Company dba HBI International
<b>Applicant Address:</b>	3401 West Papago Street Phoenix, AZ 85009
<b>Manufacturer Name:<sup>1</sup></b>	BBK Tobacco & Foods, LLP Company dba HBI International
<b>Product Manufacturing Address:<sup>2</sup></b>	The product is manufactured in a foreign country (Confidential Appendix 1)

### 2. Product Information

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

New Product Name	STN	Predicate Product Name
ELEMENTS RED 1¼	SE0015543	ELEMENTS 1¼
RAWBLACK 1¼	SE0015544	

#### Product Identification

<b>Product Category</b>	Roll-Your-Own
<b>Product Sub-Category</b>	Rolling Paper
<b>Number of Products per Retail Unit</b>	50 papers per booklet; 25 and 24 booklets per display box in SE0015543 and SE0015544, respectively.
<b>Product Package</b>	The packaging materials consist of cardboard booklet cover with an additional piece of cardboard inserted in its back for additional stability, a starter and warning paper between the cover and the booklet papers, and cardboard display box.

### 3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the 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 two 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 for the new tobacco products. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the single predicate product. The predicate product is a grandfathered product (GF1200549) commercially marketed in the United States as of February 15, 2007.

The new products differ from the single predicate product due to changes in the design features and ingredients (Confidential Appendix 2). In addition, the predicate product paper has an "HBI" watermark,

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<sup>1</sup> The booklets are assembled in Spain.

<sup>2</sup> See Confidential Appendix 1 for the location of the paper manufacturer.

whereas the new product paper in SE0015543 and in SE0015543 has an “ELEMENTS” and “RAW” watermark, respectively.

**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 Alternatives – Manufacturing the New Tobacco Products**

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

**5.1 Affected Environment**

The affected environment includes human and natural environments surrounding the facility. The new tobacco products are manufactured outside of the United States (Confidential Appendix 1).

**5.2 Analysis of Potential Environmental Impacts**

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the new tobacco products based on information gathered by the Agency and the information in the SE Reports, including projected market volumes for the new products (Confidential Appendix 3).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products is not expected to result in changes in air emissions or require any additional environmental controls for air emissions. According to the applicant, overall production at the manufacturing facility is not expected to increase as result of manufacturing the new products because the new products are expected to replace other similar RYO papers manufactured at the facility.
Water resources and water quality	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 no facility expansion is anticipated. Therefore, no changes in zoning and no conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use are expected due to manufacturing the new products.
Biological resources	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). The applicant stated that there would be no facility expansion and, therefore,

	no impacts on endangered species due to manufacturing the new products are expected.
Socioeconomic conditions	No impacts on employment, revenue, taxes, or community resources, such as police force and fire department resources, are expected from manufacturing the new products because no facility expansion is anticipated.
Solid waste and hazardous materials	No impacts on solid waste or hazardous materials are expected. The applicant stated that the manufacturing facility already produces similar products compared to the new products and that the new products make up an extremely small portion of the total RYO production at the manufacturing facilities.
Floodplains, wetlands, and coastal zones	There would be no facility expansion 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 full compliance with all applicable environmental regulations and that the facility has ratified CITES.

### 5.3 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts when considered with manufacturing the new tobacco products under the proposed actions.

### 5.4 Impacts from No-Action Alternative

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

## 6. Potential Environmental Impact of the Proposed Actions and Alternatives – Use of the New Tobacco Products

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

### 6.1. Affected Environment

The affected environment is the entire United States because the marketing orders would allow for the new RYO tobacco products to be sold to consumers nationwide. The new RYO tobacco products are intended to be filled with tobacco and smoked by users indoors or outdoors, as the law permits.

### 6.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from use of the new tobacco products based on the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	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 product or

	similar currently marketed RYO products. The applicant stated that the market volume projections of the new products are a fraction of a percent of the total predicted cigarette sales in the United States
Environmental justice	The new products are expected to be used by the same consumers that use the predicate product. Therefore, no changes in impact to environmental justice populations are anticipated.

### 6.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts when considered with the use of the new products under the proposed actions.

### 6.4. Impacts from No-Action Alternative

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

## 7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Tobacco Products

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

### 7.1. Affected Environment

The affected environment is the entire United States because the marketing orders would allow for the new tobacco products to be sold to consumers nationwide. The disposal of the new products 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 actions for potential impacts from disposal of the new tobacco products based on information submitted in the SE Reports, including market volume projections for the new products (Confidential Appendix 3).

Environmental Resource	Analysis of Potential Impacts
Air quality	Introducing the new products into the United States market is not expected to increase the nationwide use of RYO tobacco products. Therefore, disposal of the used products and packaging would not significantly affect air quality.
Biological resources	Proper disposal of the new products and packaging materials in MSW would not affect biological resources. Used products and packaging materials may be littered in undeveloped areas and wildlife habitat. However, introducing the new products into the United States 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 United States market is not expected to increase the nationwide use of RYO tobacco products, based on the projected market volumes reported by the applicant. 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 when considered with the disposal of the new tobacco products under the proposed actions.

**7.4. Impacts from 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 programmatic environmental assessment:

***Preparer:***

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

***Reviewer:***

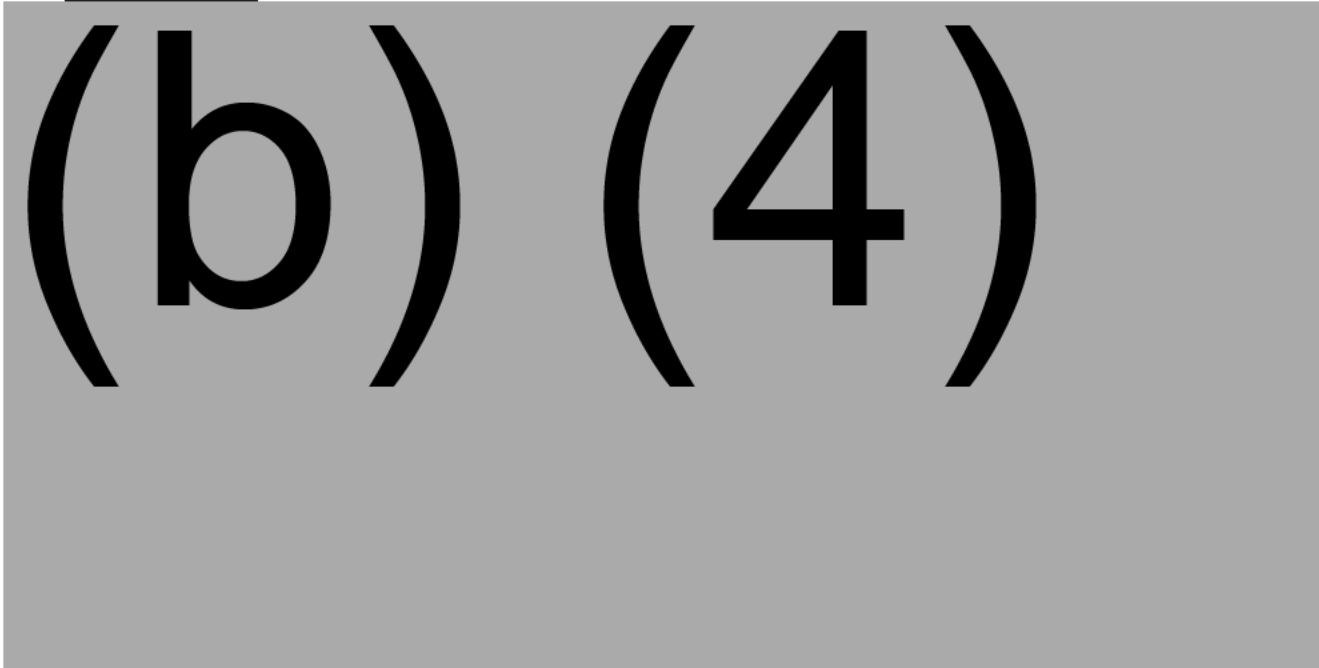
Gregory Gagliano, M.S., Center for Tobacco Products  
 Education: M.S. in Environmental Science  
 Experience: Thirty-seven years in environmental compliance and analysis  
 Expertise: Environmental toxicology, risk assessment, NEPA analysis, regulatory compliance

**9. List of Agencies and Persons Consulted**

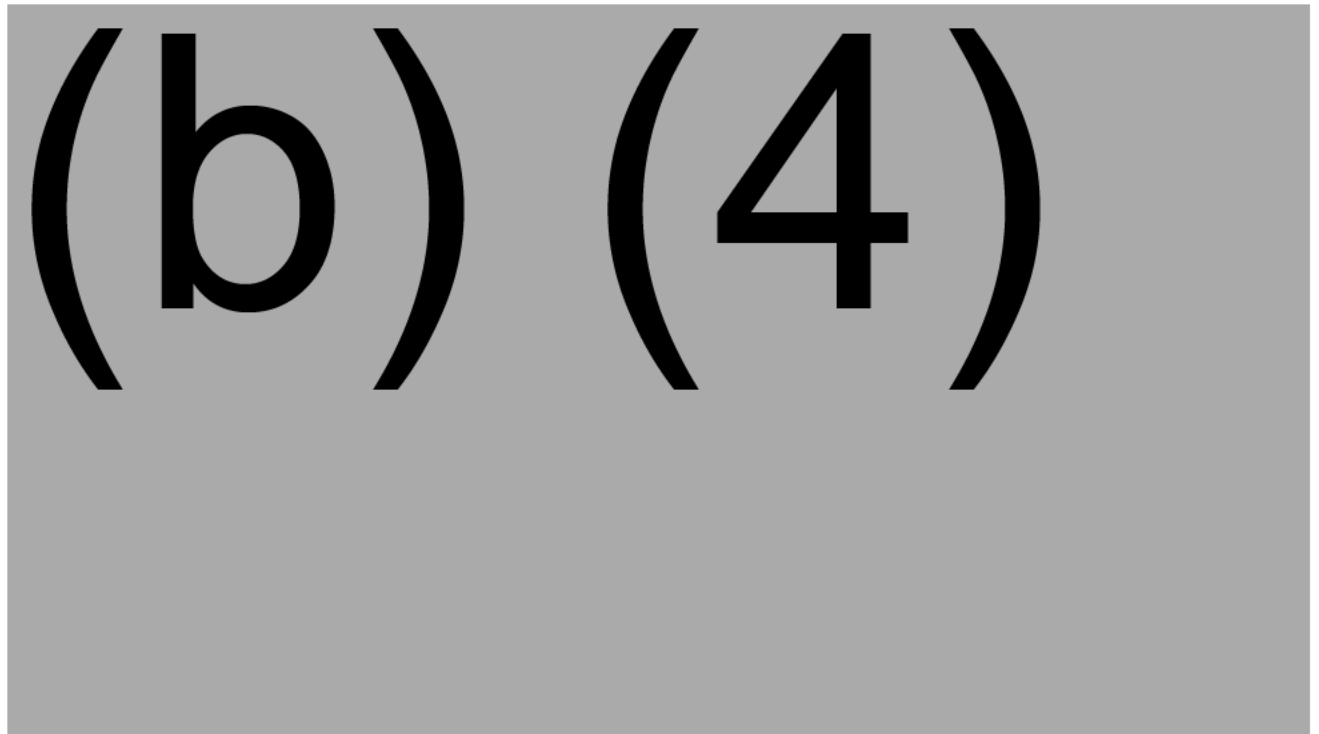
Not applicable.

**Confidential Appendix 1: Location of the Paper Manufacturing Facility**

The cigarette papers and packaging papers are milled in <sup>(b) (4)</sup> [REDACTED], a subsidiary of <sup>(b) (4)</sup> [REDACTED] located at <sup>(b) (4)</sup> [REDACTED].



The cigarette papers are cut to size, gummed, and packaged into booklets, after the watermark is applied is applied to the paper, by <sup>(b) (4)</sup> [REDACTED], located at <sup>(b) (4)</sup> [REDACTED] <sup>(b) (4)</sup> [REDACTED].





**Confidential Appendix 2: Changes in the New Products as Compared with the Predicate Product**

STN	Change from the Predicate Product
SE0015543	<ul style="list-style-type: none"> <li>• Increase in cigarette paper basis weight.</li> <li>• Increase, with a tighter range, in (b) (4)</li> <li>• Deletion of (b) (4) and (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Decrease in the level of (b) (4)</li> </ul>
SE0015544	<ul style="list-style-type: none"> <li>• Decrease in cigarette paper basis weight.</li> <li>• Decrease in the level of (b) (4)</li> </ul>

**Confidential Appendix 3: Current Market Volume and First- and Fifth-Year Market Volume Projections for the New and Predicate Products**

The applicants stated that the new products are being sold alongside the predicate product since 2016. The applicant intends to continue marketing the predicate product after receiving the marketing orders for the new products. The applicant used the 2017 Federal Trade Commission sales data for cigarettes in the United States to conclude that the combined production of the new and predicate products rolling papers accounts for a minute fraction of total cigarette use.

Product Name	Market Volumes (# of Leaves)		
	Current Market Volume	Projected Market Volumes	
		First Year	Fifth Year
ELEMENTS RED 1¼	<b>(b) (4)</b>		
RAW BLACK 1¼			
ELEMENTS 1¼			
<b>Total</b>			