

**Programmatic Environmental Assessment for Marketing  
Orders for Roll-Your-Own Tobacco Products By  
BBK Tobacco & Foods, LLP Company**

**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>	(b) (4)
<b>Address Where Products are Manufactured <sup>2</sup></b>	(b) (4)

**2. Product Information**

**New Product Names, Submission Tracking Numbers (STNs), and Predicate Product Name**

<b>New Product Name</b>	<b>STN</b>	<b>Predicate Product Name</b>
Elements Red Single Wide	SE0015036	Elements Single Wide Double Feed
Rawblack Single Wide	SE0015037	Elements Single Wide Double Feed

**Product Identification**

<b>Product Type</b>	Roll-Your-Own
<b>Product Subtype</b>	Rolling Paper
<b>Product Package</b>	100 papers (two feeds of 50 papers) per booklet; 50 booklets are packed in one display 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 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. The Agency shall issue marketing orders if the new products are 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 products differ from the predicate product in product design and packaging design (Confidential Appendix 2). The applicant provided first- and fifth-year marketing projections for the new products (Confidential Appendix 3).

<sup>1</sup> The booklets are assembled in (b) (4) .

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

#### **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 Products**

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

##### **5.1 Affected Environment**

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

**Figure 1. Location of the Manufacturer**

(b) (4)



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 actions 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 of air emissions or require any additional environmental controls for air emissions. This is supported by the applicant noting that (1) the new products are expected to compete with the predicate product, and (2) the materials used in manufacturing the new products are currently used in the facility.
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 the new products are intended to replace similar tobacco products currently manufactured at the facility and that manufacturing the new products would not require any additional environmental controls for water discharges.
Soil, Land Use, and Zoning	The Agency does not anticipate that manufacturing the new products would lead to changes in soil, land use, and zoning. The applicant stated that there would be no expected facility expansion or new construction 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 the raw materials are from sustainable and renewable resources. No facility expansion is expected; therefore, the Agency does not anticipate 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).
Socioeconomics and Environmental Justice	The Agency does not anticipate any impacts on employment, revenue, or taxes because the new products are 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 products 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 products 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 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 laws, regulations, and local ordinances.

### 5.3 Cumulative Impacts

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

### 5.4 Impacts of the No-Action Alternative

The environmental impact 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 Actions and Alternatives – Use of the New Products

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 includes human and natural environments in the United States. The marketing orders will allow for the distribution and sale of the new tobacco products to consumers in the United States. The new products are RYO tobacco products that are 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 actions for potential environmental impacts from the new products use based on the applicant’s submitted information:

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency anticipates that no new compounds would be emitted from use of the new products because (1) the new products are expected to compete with, or replace, similar currently marketed tobacco products; and (2) the ingredients in the new products are used in other currently marketed tobacco products.
Environmental justice	No new emissions are expected due to use of the new products. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

**6.3. Cumulative Impacts**

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

**6.4. Impacts of 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 Actions and Alternative – Disposal of the New Products**

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

**7.1. Affected Environment**

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

**7.2. Analysis of Potential Environmental Impacts**

The proposed actions were evaluated for potential environmental impacts from disposal:

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency does not anticipate disposal of the products or the packaging material would lead to the emission of new or increased chemicals into the air because (1) introducing the new products into the U. S. market is not expected to increase the nationwide use and eventual disposal of RYO tobacco products; (2) the new products are 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 actions are 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 products 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 would change due to disposal of the new products.
Environmental justice	The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. No new

	emissions are expected due to disposal of the new products. Therefore, there would be no new disproportionate impacts on the minority or low-income populations.
Water resources	Proper handling of waste generated due to disposal of the new products 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 products because (1) the chemicals in the new products are the same as in currently marketed RYO papers and (2) the new products would replace similar tobacco products currently on the market.

### 7.3. Cumulative Impacts

No actions were identified that, when considered with the proposed actions, 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 programmatic environmental assessment (PEA):

#### **Preparer:**

Mehran Niazi, PhD, Center for Tobacco Products

Education: PhD in Environmental Sciences

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

Expertise: Water quality modeling, environmental fate and transport modeling

#### **Reviewer:**

Gregory Gagliano, MS, Center for Tobacco Products

Education: BS and MS in Environmental Science

Experience: Thirty-six years in environmental toxicology

Expertise: Ecotoxicology, environmental risk assessment, NEPA analysis

## 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 (b) (4)

**CONFIDENTIAL APPENDIX 2:**

**Comparison of the New Products to the Predicate Product**

STN	Change
SE0015036	25% increase of paper mass
	9% less (b) (4) and addition of (b) (4)
SE0015037	11% decrease of paper mass

**CONFIDENTIAL APPENDIX 3**

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

To evaluate the environmental impacts of manufacturing due to the proposed actions, current production volumes and projected market volumes that include products marketed outside the United States were used. This is why there is current production information for the new products that are not currently on the U.S. market.

The applicant intends to continue marketing the predicate product after receiving marketing orders for the new products. The applicant used the 2016 statistical data of paper and paper board production in Europe to conclude that the combined production of the new and predicate products account for a minute fraction (0.24%) of total paper and paperboard production in (b) (4).<sup>3</sup>

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
SE0015036	# of leaves	(b) (4)					
SE0015037	# of leaves	(b) (4)					

<sup>3</sup> Confederation of European Paper Industries, Key Statistics 2016; [http://www.cepi.org/system/files/public/documents/publications/statistics/2017/KeyStatistics2016\\_Final.pdf](http://www.cepi.org/system/files/public/documents/publications/statistics/2017/KeyStatistics2016_Final.pdf). Accessed June 25, 2018.