

**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**

August 6, 2020

Table of Contents

- 1. Applicant and Manufacturer Information 3**
- 2. Products Information 3**
- 3. The Need for the Proposed Actions..... 3**
- 4. Alternatives to the Proposed Actions 4**
- 5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Tobacco Products 4**
 - 5.1 Affected Environment 4
 - 5.2 Analysis of Potential Environmental Impacts 5
 - 5.3 Cumulative Impacts 5
 - 5.4 Impacts from No-Action Alternative 6
- 6. Potential Environmental Impact of the Proposed Actions and Alternatives – Use of the New Tobacco Products..... 6**
 - 6.1. Affected Environment 6
 - 6.2. Analysis of Potential Environmental Impacts 6
 - 6.3. Cumulative Impacts 6
 - 6.4. Impacts from No-Action Alternative 6
- 7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Tobacco Products 6**
 - 7.1. Affected Environment 7
 - 7.2. Analysis of Potential Environmental Impacts 7
 - 7.3. Cumulative Impacts 7
 - 7.4. Impacts from No-Action Alternative 7
- 8. List of Preparers 8**
- Confidential Appendix 1: Locations of Paper Manufacturing Facilities..... 9**
- Confidential Appendix 2: Current Market Volume and First- and Fifth-Year Market Volume Projections for the New Products10**

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:	IBERPAPEL S.L.
Products Manufacturing Address:	Polingono Industrial “La Creueta”, s/n 03827 Benimarfull Alicante, Spain

2. Products Information

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

STN	New Product Name	Predicate Product Name
SE0015819	Elements Rolls Ultra Thin SW	Elements Rolls Ultra Thin SW
SE0015820	Elements Rolls Ultra Thin 1 ¼	Elements Ultra Thin Rice Slim (1 ¼)
SE0015821	Elements Rolls Ultra Thin 1 ½ KS	Elements Rolls Ultra Thin 1 ½ KS
SE0015822	Elements Refills SW	Elements Rolls Ultra Thin SW
SE0015823	Elements Refills 1 ¼	Elements Ultra Thin Rice Slim (1 ¼)
SE0015824	Elements King Size	Elements KS

Product Identification

Product Category	Roll-Your-Own
Product Subcategory	Rolling Papers
Product Number per Retail Unit	SE0015819 – 5 m roll (37 mm), 10 rolls per display case SE0015820 – 5 m roll (44 mm), 10 rolls per display case SE0015821 – 5 m roll (54 mm), 10 rolls per display case SE0015822 – 5 m roll (37 mm), 20 rolls per display case SE0015723 – 5 m roll (44 mm), 20 rolls per display case SE0015824 – 33 papers per booklet, 50 booklets per display case
Product Package	SE0015819, SE0015820 and SE0015821 – The packaging materials consist of a plastic dispenser, cardboard tube, and (b) (4) cardboard display case. SE0015822 and SE0015823 – The packaging materials consist of a cardboard tube and (b) (4) cardboard display case. SE0015824 – The packaging materials of a (b) (4) cardboard booklet with an additional piece of (b) (4) inserted in its back for additional stability.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are 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 six new roll your own (RYO) products into interstate commerce and submitted to the Agency substantial equivalence (SE) reports to obtain marketing orders for the new tobacco products. The Agency shall issue marketing orders if the new products are found

substantially equivalent to the corresponding predicate products . The agency determined that all of the predicate products are grandfathered products on April 4, 2020.

The new products differ from the corresponding predicate products due to changes in the design of the watermark. The predicate products have the ‘HBI’ watermark, whereas the new products have the ‘ELEMENTS’ water mark.

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.

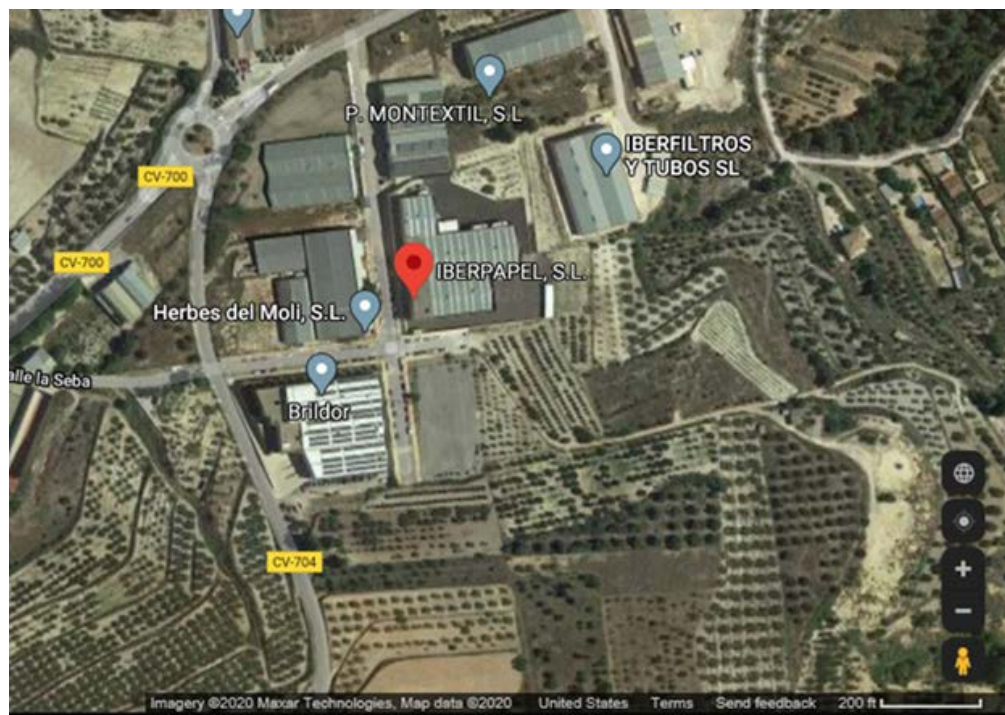
5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Tobacco Products

The Agency evaluated 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 affected environment includes human and natural environments surrounding the manufacturing facility. The new products would be manufactured at Polingono Industrial “La Creueta”, s/n, 03827 Benimarfull, Alicante, Spain.¹

Figure 1: Location of the manufacturing facility



¹ Google. 2020. Map of Polingono Industrial “La Creueta”, s/n 03827 Benimarfull Alicante, Spain. Retrieved from Google Maps: www.google.com/maps. July 10, 2020

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the new 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 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products are not expected to result in changes in air emissions. The applicant also stated that manufacturing the new products would not require any additional environmental controls for air emissions.
Water resources	No impacts on water resources are expected due to manufacturing the new products because the liquid waste discharge is not anticipated to change at the manufacturing facility. The applicant stated that manufacturing the new products would not require additional environmental controls for wastewater discharge.
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 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	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 total production at the manufacturing facility.
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 compliance with all applicable environmental regulations and that the facility's country had re ratified CITES.

5.3 Cumulative Impacts

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

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 tobacco products would continue to be manufactured at the same facility.

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 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 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 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 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 products or similar currently marketed products.
Environmental justice	The new products are expected to be used by the same consumers that use the predicate products. 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 products under the proposed actions.

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 used in the United States.

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 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 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 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 products 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 products 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	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 products under the proposed actions.

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 disposed of in the United States.

8. List of Preparers

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

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products
Education: Ph.D. in Plant Molecular Biology and Virology
Experience: Forty-three years in various scientific activities including nine years in NEPA practice
Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1: Locations of Paper Manufacturing Facilities

The cigarette papers and packaging papers are milled in (b) (4), located at (b) (4)².

(b) (4)

² Google. 2020. Map of (b) (4). Retrieved from Google Maps: [w.google.com/maps](https://www.google.com/maps). July 10, 2020.

Confidential Appendix 2: Current Market Volume and First- and Fifth-Year Market Volume Projections for the New Products

STN	Units	Market Volumes		
		Current Market Volume	Projected Market Volume	
			First Year	Fifth Year
SE0015819	Number of Rolls	(b) (4)		
	Weight (kg)			
SE0015820	Number of Rolls			
	Weight (kg)			
SE0015821	Number of Rolls			
	Weight (kg)			
SE0015822	Number of Rolls			
	Weight (kg)			
SE0015823	Number of Rolls			
	Weight (kg)			
SE0015824	Number of Rolls			
	Weight (kg)			

The applicant stated that the new products were marketed as of August 8, 2016.