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

May 26, 2020
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1. **Applicant and Manufacturer Information**

<table>
<thead>
<tr>
<th>Applicant Name</th>
<th>BBK Tobacco &amp; Foods, LLP Company dba HBI International</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicant Address</td>
<td>3401 West Papago Street Phoenix, AZ 85009</td>
</tr>
<tr>
<td>Manufacturer Name:</td>
<td>BBK Tobacco &amp; Foods, LLP Company dba HBI International</td>
</tr>
<tr>
<td>Product Manufacturing Address:</td>
<td>The product is manufactured in a foreign country (Confidential Appendix 1)</td>
</tr>
</tbody>
</table>

2. **Product Information**

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

<table>
<thead>
<tr>
<th>New Product Name</th>
<th>STN</th>
<th>Predicate Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELEMENTS RED 1¼</td>
<td>SE0015543</td>
<td>ELEMENTS 1¼</td>
</tr>
<tr>
<td>RAWBLACK 1¼</td>
<td>SE0015544</td>
<td></td>
</tr>
</tbody>
</table>

**Product Identification**

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Roll-Your-Own</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Sub-Category</td>
<td>Rolling Paper</td>
</tr>
<tr>
<td>Number of Products per Retail Unit</td>
<td>50 papers per booklet; 25 and 24 booklets per display box in SE0015543 and SE0015544, respectively.</td>
</tr>
<tr>
<td>Product Package</td>
<td>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.</td>
</tr>
</tbody>
</table>

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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1 The booklets are assembled in Spain.
2 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).

<table>
<thead>
<tr>
<th>Environmental Resource</th>
<th>Analysis of Potential Impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air quality</td>
<td>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.</td>
</tr>
<tr>
<td>Water resources and water quality</td>
<td>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.</td>
</tr>
<tr>
<td>Soil, land use and zoning</td>
<td>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.</td>
</tr>
<tr>
<td>Biological resources</td>
<td>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,</td>
</tr>
</tbody>
</table>
no impacts on endangered species due to manufacturing the new products are expected.

| Economic 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.


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.

<table>
<thead>
<tr>
<th>Environmental Resource</th>
<th>Analysis of Potential Impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air quality</td>
<td>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</td>
</tr>
</tbody>
</table>
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.


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).

<table>
<thead>
<tr>
<th>Environmental Resource</th>
<th>Analysis of Potential Impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air quality</td>
<td>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.</td>
</tr>
<tr>
<td>Biological resources</td>
<td>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.</td>
</tr>
</tbody>
</table>
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 (b)(4), a subsidiary located at (b)(4). The cigarette papers are cut to size, gummed, and packaged into booklets, after the watermark is applied (b)(4), located at (b)(4).
<table>
<thead>
<tr>
<th>STN</th>
<th>Change from the Predicate Product</th>
</tr>
</thead>
</table>
| SE0015543 | • Increase in cigarette paper basis weight.  
• Increase, with a tighter range, in  
• Deletion of [5](4) and [6](5)  
• Addition of [8](4)  
• Decrease in the level of [9](4)                                                                                           |
| SE0015544 | • Decrease in cigarette paper basis weight.  
• Decrease in the level of [10](4)                                                                                                            |
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.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Market Volumes (# of Leaves)</th>
<th>Current Market Volume</th>
<th>Projected Market Volumes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>First Year</td>
</tr>
<tr>
<td>ELEMENTS RED 1¼</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RAW BLACK 1¼</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ELEMENTS 1¼</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(b)(4)