

**Programmatic Environmental Assessment for Six
Loose Smokeless Tobacco Products by U.S. Smokeless
Tobacco Company LLC**

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

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1. Applicant and Manufacturer Information

Applicant Name:	U.S. Smokeless Tobacco Company LLC
Applicant Address:	2325 Bells Rd., Richmond, VA 23234
Manufacturer Name:	U.S. Smokeless Tobacco Company LLC.
Product Manufacturing Address:	800 Harrison St., Nashville, TN 37203

2. Product Information

New and Predicate Products

New Product Name	New Product STN	Predicate Product Name	Predicate Product STN
Husky Long Cut Natural	SE0015098	Husky Long Cut Natural	SE0014826
Copenhagen Snuff Fine Cut	SE0015099	PL Copenhagen Snuff Fine Cut	GF1906605
Copenhagen Long Cut Straight	SE0015101	Copenhagen Long Cut Straight	SE0014825
Copenhagen Snuff Fine Cut	SE0015102	Copenhagen Snuff Fine Cut	SE0014738
Copenhagen Long Cut	SE0015104	Copenhagen Long Cut	SE0014598
Copenhagen Long Cut	SE0015105	PL Copenhagen Long Cut	GF1906603

Product Identification

Product Category	Smokeless
Product Sub-Category	Loose Chewing Tobacco
Product Quantity Per Retail Unit	34.02grams/can
Product Package	SE0015098: Packaging materials consist of a polypropylene can and a metal lid. SE0015099: Packaging materials consist of a polypropylene can and a poly propylene lid SE0015101: Packaging materials consist of a polypropylene can and a metal lid. SE0015102: Packaging materials consist of a fiberboard can and a metal lid. SE0015104: Packaging materials consist of a fiberboard can and a metal lid. SE0015105: Packaging materials consist of a polypropylene can and a polypropylene lid.

3. The Need for the Proposed Action

The proposed actions, requested by the applicant, are for 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 after finding the new tobacco products substantially equivalent to the corresponding

predicate products. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The predicate products of SE0015099 and SE0015105 are grandfathered products. The predicate products for SE0015098 and SE0015101 were previously found to be substantially equivalent by the FDA on October 23, 2018. The agency found the predicate product of SE0015104 and SE0015102 to be substantially equivalent on November 1, 2018 and November 16, 2018, respectively.

The differences between the new and the corresponding predicate products are the replacement of ingredient and the addition of ingredients in the tobacco filler of the new products (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

The no-action alternative is the Agency does not issue marketing orders for the new tobacco products in the United States.

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

The Agency evaluated potential environmental impacts that may be caused by manufacturing the new products and found no significant impacts.

5.1. Affected Environment

The new products would be manufactured at the U.S. Smokeless Tobacco Company LLC facility at 800 Harrison St., Nashville, TN 37203 (Figure 1). The facility is within industrial park in downtown Nashville, with a railroad spur along its southern perimeter, an iron fabricator and Goodwill Industries headquarters to the west and north, offices and parking lots of the north, and a five-lane road to the east with the Nashville Farmers Market building on the other side of the road.

Figure 1. Location of the Manufacturing Facility



5.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing based on Agency-gathered information and the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products would have the same or similar air emissions as products currently manufactured at the facility and would not require a new or revised permit.
Water resources	The applicant stated that manufacturing the new products would have the same or similar wastewater discharges as products currently manufactured at the facility not require a new or revised permit.
Land use and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed actions.
Biological resources	The applicant stated that there would be no facility expansion due to the new products and manufacturing of the new products would not change emissions or discharges. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new products.
Soils	The applicant stated that there would be no facility expansion due to the new products. Therefore, no effects on soils would occur as a direct impact from manufacturing the new products.
Socioeconomic conditions	The applicant stated that there would be no facility expansion or increase in the net production volume at the facility. Therefore, no socioeconomic

	effects (beneficial or adverse) would occur as a direct impact from manufacturing the new products.
Solid waste and hazardous materials	The applicant stated that no changes to solid waste generation are expected to result from the manufacture of the new products and that waste generated by manufacturing of the new products would be disposed of in the same manner as any other tobacco products manufactured at the same facility.
Floodplains, wetlands, and coastal zones	The applicant stated that there would be no facility expansion due to manufacture of the new products. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impacts manufacturing the new products.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice population that near the manufacturing facility.
Regulatory compliance	The applicant stated that the manufacturing facility complies with the Clean Air Act, Clean Water Act, and Resource Conservation and Recovery Act; the applicant stated that manufacturing the new products would not change the facility's compliance with relevant federal, state, and local environmental regulations. The applicant provided detailed information for the following waste water discharge permit: Industrial User Waste Water Discharge Permit (CP-0286), issued in accordance with applicable Metropolitan Government of Nashville and Davidson County regulations, would be expired November 1, 2021. The Agency's search for the manufacturing facility in the U.S. Environmental Protection Agency's Enforcement and Compliance History Online database did not reveal any violations of environmental laws and regulations.

5.3. Cumulative Impacts

The Agency does not anticipate the proposed actions would incrementally increase or change the chemicals released to the environment from the facility's tobacco manufacturing. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2017, the U.S. Smokeless Tobacco's manufacturing facility in Nashville, Tennessee released 17,153 pounds of ammonia and 235 pounds of nicotine and nicotine salts to air (totaling 17,388 pounds) and transferred 40,409 pounds of ammonia and nicotine and nicotine salts to Central Wastewater Treatment Plant (Table 1),¹ constituting 14% of TRI releases in Davidson County.² No other hazardous air pollutants were reported. Ammonia adversely affects ocular and respiratory systems; nicotine and nicotine salts have known adverse developmental effects.³ The TRI database search did not show that the U.S.

¹ U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched March 11, 2019.

² U.S. EPA. <https://myrtk.epa.gov/info/report.jsp?IDT=TRI&ID=37203STBCC800HA>. The site allows for searching the industrial facilities that manage toxic waste chemicals. Accessed April 4, 2019.

³ Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

Smokeless Tobacco manufacturing facility disposed of, treated, or released into the environment any other toxicants associated with manufacturing tobacco products. In addition, EPA’s ECHO database⁴ did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at the U.S. Smokeless Tobacco Facility in 2017

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			17,970
Energy Recovery			0
Treated			102,420
<i>Subtotal Waste Managed</i>			<i>120,390</i>
On-site Release	Air	Ammonia	17,153
		Nicotine and Nicotine Salts	235
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-site Release			40,409
Subtotal Waste Released			57,793
Total Production-Related Waste			178,187

5.4. Impacts from No-Action Alternative

The no-actions alternative would not change the existing manufacturing of other smokeless tobacco at the U.S. Smokeless Tobacco Company facility, as many similar tobacco products would continue to be manufactured at the listed facility.

6. Potential Environmental Impacts of the Proposed Actions and the Alternatives - Use of the New Products

The Agency evaluated potential environmental impacts that may be caused 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.

⁴ EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed July 6, 2018.

6.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from use of the new products based on Agency-gathered information and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new products are likely to be used by the same consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, no change in impacts to environmental justice populations is expected.

6.3. Cumulative Impacts

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

6.4. Impacts from No-Action Alternative

The no-action alternative would not change the existing use of other smokeless tobacco products in the United States, as many similar tobacco products would continue to be marketed and therefore used.

7. Potential Environmental Impacts of the Proposed Actions and the Alternatives - Disposal of the New Products

The Agency evaluated potential environmental impacts that may be caused 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 the new tobacco products to be sold to consumers nationwide who would dispose of the used products and packaging as municipal solid waste, recycled material, or litter.

7.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from disposal of the new products based on Agency-gathered information and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Biological resources	Proper disposal of the used new products and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal (littering) of the used new products could lead to terrestrial wildlife having direct exposure to the used products and hazardous substances leaching to aquatic environments and soil. However, no net increase in littering is expected because the new products would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations from disposal of the used new products and packaging waste.
Water resources	Proper disposal of the used new products and packaging in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of the used new products could result in hazardous substances leaching into water systems. However, no net increase in littering is expected because the new products would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Regulatory compliance	The new products have no features that would lead to a different rate of used product littering compared to currently marketed smokeless tobacco products. Despite state and local ordinances, it is assumed that noncompliance (littering) would occur at the same rate for the new products as for currently marketed smokeless tobacco products. Therefore, these impacts are not considered significant.

7.3. Cumulative Impacts

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

7.4. Impacts from No-Action Alternative

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

8. List of Preparers

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

Preparer:

Thomas Creaven, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biology/Neuroscience

Experience: Three years in NEPA document review, Ten years in Chemistry/Physics education

Expertise: NEPA document review, Chemistry/Physics education

Reviewer:

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

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

Experience: Ten 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: Difference Between the New and Predicate Products

The differences between the new and corresponding predicate products would be limited to the replacement of a non-generally recognized as safe (GRAS)⁵ (b)(4) in the (b) (4) tobacco of the predicate products with an identical amount of a GRAS (b)(4). Additionally, a small amount of (b)(4) and (b)(4) would be added to the (b) (4) tobacco component of the new products.

⁵ GRAS designation does not apply to tobacco products

Confidential Appendix 2: Marketing Projections for the New Products

STN	Name	Unit	Projected Market Volume	
			First Year	Fifth Year
SE0014598	Husky Long Cut Natural	Cans	(b)(4)	(b)(4)
		Metric tons	(b)(4)	(b)(4)
SE0015099	Copenhagen Snuff Fine Cut	Cans	(b)(4)	(b)(4)
		Metric tons	(b)(4)	(b)(4)
SE0015101	Copenhagen Long Cut Straight	Cans	(b)(4)	(b)(4)
		Metric tons	(b)(4)	(b)(4)
SE0015102	Copenhagen Snuff Fine Cut	Cans	(b)(4)	(b)(4)
		Metric tons	(b)(4)	(b)(4)
SE0015104	Copenhagen Long Cut	Cans	(b)(4)	(b)(4)
		Metric tons	(b)(4)	(b)(4)
SE0015105	Copenhagen Long Cut	Cans	(b)(4)	(b)(4)
		Metric tons	(b)(4)	(b)(4)