

**Programmatic Environmental Assessment for Two Smokeless
Products Manufactured 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	Altria Client Services LLC
Applicant Address	2325 Bells Road Richmond, VA 23234
Manufacturer Name	U.S. Smokeless Tobacco Company LLC
Product Manufacturing Address	800 Harrison Street Nashville, TN 37203

2. Product Information

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

New Product	STN	Predicate Product
Copenhagen Pouches	SE0015100	PL Copenhagen Pouches
Copenhagen Pouches	SE0015103	Copenhagen Pouches

Product Identification

Product Category	Smokeless
Product Subcategory	Portioned moist snuff
Product Packages	SE0015100 has a plastic can and a plastic lid. SE0015103 has a fiberboard can and a metal lid. Both contain 15 1.55 gram portions of moist snuff in a 23.25 gram can size.

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 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 Agency shall issue marketing orders if, after considering the substantial equivalence reports and amendments submitted by the applicant, the new products are found substantially equivalent to the corresponding predicate products. The predicate products for SE0015100 and SE0015103 are not currently on the market.

The new products differ from the corresponding predicate products in the replacement of an ingredient with an identical amount of a similar ingredient used in the direct addition to the tobacco and in the (b) (4). The new products will also include two new ingredients in the (b) (4) (Confidential Appendix 1).

The applicant provided first- and fifth-year market volume projections for the new products (Confidential Appendix 2).

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.

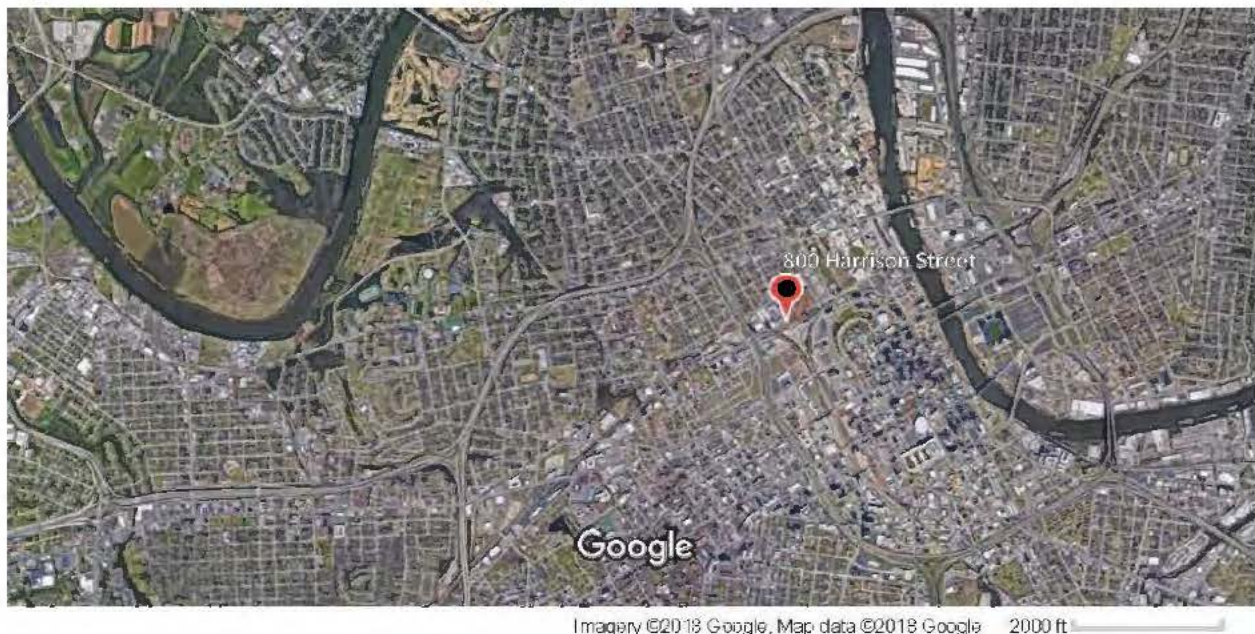
5. Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the New Products

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 U.S. Smokeless Tobacco Company LLC, 800 Harrison Street, Nashville, TN 37203 (Figure 1). The facility is within an 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 to 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 the new products based on information gathered by the Agency 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 those associated with 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 those associated with products currently manufactured at the facility and would not require a new or revised permit.
Land use and zoning	The applicant stated that there would be no facility expansion due to 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 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 due to the new products. 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 the new products would not change solid waste generation at the manufacturing facility and waste would be disposed of in the same manner as waste generated by other smokeless tobacco products manufactured at the same facility. Therefore, no effects to solid waste or change in disposal of hazardous materials would occur as a direct impact from manufacturing the new products.
Floodplains, wetlands, and coastal zones	The applicant stated that there would be no facility expansion due to the new products. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impact from manufacturing the new products.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations 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 Agency's search for the manufacturing facility in the U.S. Environmental Protection Agency's Enforcement and Compliance History Online database ¹ did not reveal any violations of environmental laws and regulations.

¹ U.S. Environmental Protection Agency. 2019. ECHO: Enforcement and Compliance History Online. <https://echo.epa.gov/>. Accessed April 4, 2019.

5.3 Cumulative Impacts

The Agency does not anticipate that 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),² constituting 14% of TRI releases in Davidson County.³ No other hazardous air pollutants were reported. Ammonia adversely affects ocular and respiratory systems; nicotine and nicotine salts have known adverse developmental effects.⁴ The TRI database search did not show that the U.S. 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 database 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.

² U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched April 4, 2019.

³ 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.

⁴ Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at 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
Subtotal Waste Managed			120,390
On-site Release	Air	Ammonia	17,153
		Nicotine and Nicotine Salts	235
	Water	Ammonia	0
		Nicotine and Nictotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-site Disposal/Release			40,409
Subtotal Waste Released			57,797
Total Production-Related Waste			178,187

5.4 Impacts from No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing conditions of manufacturing smokeless tobacco products, as many 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 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.

6.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions 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 smokeless tobacco products would continue to be marketed and therefore used.

7. Potential Environmental Impacts of the Proposed Actions and 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 new 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 product 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 to 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.

Environmental Resource	Analysis of Potential Impacts
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 smokeless 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 programmatic environmental assessment:

Preparers:

William E. Brenner, BS, Center for Tobacco Products

Education: BS in Biology

Experience: Five years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

Hoshing W. Chang, Center for Tobacco Products

Education: PhD in Biochemistry, MS 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: Differences Between New and Predicate Products

Both new products differ from the corresponding predicate products in (b) (4)
(b) (4)

The following table lists the differences between the new and corresponding predicate products.

New Product	STN	Predicate Product	Differences Between New Product and Corresponding Predicate Product
Copenhagen Pouches	SE0015100	PL Copenhagen Pouches	Replacement of non-GRAS (b) (4) (b) (4) used as a direct addition to tobacco and in the (b) (4), with an identical amount of (b) (4) that is GRAS ⁵ .
Copenhagen Pouches	SE0015103	Copenhagen Pouches	Inclusion of (b) (4) tobacco and (b) (4) to the (b) (4) (b) (4)

⁵ GRAS designation does not apply to tobacco products or ingredients used in tobacco products.

Confidential Appendix 2: Market Volume Projections for the New Products

STN	Name	Unit	Projected Market Volume	
			First Year	Fifth Year
SE0015100	Copenhagen Pouches	Can	(b) (4)	
		Metric ton		
SE0015103	Copenhagen Pouches	Can		
		Metric ton		

The predicate products for SE0015100 and SE0015103 are not currently on the market. The applicant stated that they do not intend to simultaneously manufacture any of the new products and the corresponding predicate products.