

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

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

May 17, 2019

Table of Contents

1. Applicant and Manufacturer Information..... 3

2. Product Information 3

3. The Need for the Proposed Actions 4

4. Alternatives to the Proposed Actions 4

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

5.1. Affected Environment..... 5

5.2 Analysis of Potential Environmental Impacts 5

5.3 Regulatory Compliance 7

5.4 Impacts from No-Action Alternative..... 7

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

6.1 Affected Environment..... 8

6.2 Analysis of Potential Environmental Impacts 8

6.3 Cumulative Impacts..... 8

6.4 Impacts from No-Action Alternative..... 8

7 Potential Environmental Impacts of the Proposed Actions and the Alternative - Disposal of the New Products 8

7.1 Affected Environment..... 8

7.2 Analysis of Potential Environmental Impacts 8

7.3 Cumulative Impacts..... 9

7.4 Impacts from No-Action Alternative..... 9

8 List of Preparers..... 9

9 List of Agencies and Persons Consulted10

Confidential Appendix 1: Difference between the New and Predicate Products.....11

Confidential Appendix 2: Marketing Projections for the New Products.....12

1. Applicant and Manufacturer Information

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

2. Product Information

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

New Product Name	STN	Predicate Product Name
Copenhagen Long Cut Black	SE0015157	Copenhagen Long Cut Black
Husky Fine Cut Wintergreen	SE0015160	Husky Fine Cut Wintergreen
Husky Long Cut Natural	SE0015161	Husky Long Cut Natural
Husky Long Cut Straight	SE0015162	Husky Long Cut Straight
Skoal Fine Cut Original WG	SE0015169	Skoal Fine Cut WG
Skoal Long Cut Classic Mint	SE0015170	Skoal Long Cut Mint
Skoal Long Cut Classic Straight	SE0015171	Skoal Long Cut Straight
Skoal Long Cut Classic Wintergreen	SE0015176	Skoal Long Cut Wintergreen

Product Identification

Product Category	Smokeless		
Product Sub-Category	Loose and Portioned Moist Snuff		
Product Name	Characterizing Flavor	Packaging Materials	Weight/Can (grams)
Copenhagen Long Cut Black	None	Plastic Can/Metal Lid	34.2
Husky Fine Cut Wintergreen	None	Plastic Can/Plastic Lid	34.2
Husky Long Cut Natural	None	Plastic Can/Plastic Lid	34.2
Husky Long Cut Straight	None	Plastic Can/Plastic Lid	34.2
Skoal Fine Cut Original WG	Wintergreen	Plastic Can/Metal Lid	34.2
Skoal Long Cut Classic Mint	Mint	Plastic Can/Metal Lid	34.2
Skoal Long Cut Classic Straight	None	Plastic Can/Metal Lid	34.2
Skoal Long Cut Classic Wintergreen	Wintergreen	Plastic Can/Metal Lid	34.2

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 predicate products are grandfathered products that were on the market as of February 15, 2007.

The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) reports and amendments submitted by the applicant, the new products are found substantially equivalent to the corresponding predicate products.

The new products differ from the corresponding predicate products in the composition of the fermented tobacco (Confidential Appendix 1).

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.

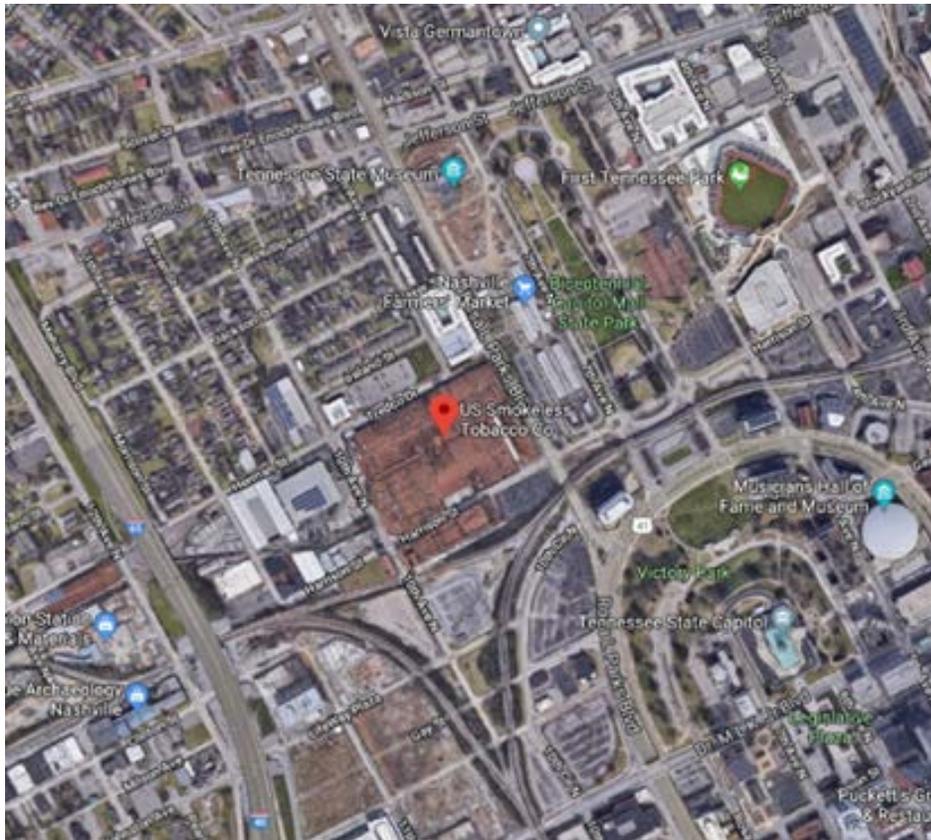
5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

The Agency 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 are manufactured at the U.S. Smokeless Tobacco Company LLC facility at 800 Harrison St., Nashville, TN 37203 (Figure 1). The facility is in 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 of 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 that may be caused by manufacturing the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated the new products would be manufactured at the same facility as the corresponding predicate products. USSTC anticipates the same or similar substances and types of air emissions to be generated from manufacturing the new products as those associated with current smokeless tobacco production at the facility. Manufacturing the new products would not require any additional environmental controls. New air permits would not be necessary.
Water resources	The applicant stated the new products would be manufactured at the same facility as the corresponding predicate products. No water quality changes are expected. USSTC anticipates the same or similar substances and types of water discharges to be generated from manufacturing the new products as those associated with current smokeless tobacco production at the facility. Manufacturing the new products would not require any additional environmental controls. New wastewater permits would not be necessary.
Land use and zoning	The applicant stated that an expansion of the USSTC facility would not be necessary due to manufacturing the new products. Therefore, no changes in land use or zoning would result from the proposed actions.
Biological resources	The applicant stated that the USSTC Nashville facility, where the new products would be manufactured, complies with the Clean Air Act (CAA), Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA). Manufacturing the new products would not result in changes in compliance with relevant federal, state, and local environmental regulations.
Soils	According to the applicant no facility expansion would be required due to manufacturing the new products and consequently no impact to soils are expected.
Socioeconomic conditions	No impacts on employment, revenue, or taxes are expected due to the new products. The new products are intended to replace similar tobacco products currently manufactured at the facility. No socioeconomic effects (beneficial or adverse) would occur as a direct impact from manufacturing the new products.
Solid waste and hazardous materials	Manufacturing the new products would result in minimal or no impacts on total manufacturing waste. The manufacturer stated that the hazardous waste resulting from production at the USSTC facility is managed according to federal environmental regulations.
Floodplains, wetlands, and coastal zones	No facility expansion due to manufacturing the new products is expected. The applicant did not describe potential land disturbances; or other impacts to floodplains, wetlands, or coastal zones as a direct result from production of the new products.
Environmental justice	Future projections of production at the facility, including the new products, are within the existing permitted manufacturing capacity and facility expansion is not required. No changes in impacts on environmental justice populations are anticipated.

5.3 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations.

5.4 Cumulative Impacts

The Agency does not anticipate the proposed actions to incrementally increase or change the chemicals released to the environment from the facility's tobacco. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2017 the USSTC facility in Nashville, TN (1) recycled 17,970 pounds of ammonia and nicotine and nicotine salts, (2) treated 102,420 pounds both chemicals, and (3) released 57,367 pounds of both chemicals to the air and to Metro Central Wastewater Treatment Plant. Out of the amount released, 1,395 pounds of both chemicals transferred to the wastewater treatment plant (Table 1).¹ No other hazardous air pollutants were reported. Nicotine and nicotine salts have known adverse developmental effects and ammonia has been proven to adversely affect the respiratory system. 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 reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database² 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	Chemical Mass (Pounds)
Recycled	17,970
Treated	102,420
Released	57,367

5.4 Impacts from No-Action Alternative

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

¹ U.S. Environmental Protection Agency (EPA). TRI Available at: <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Facility/37203ST&CC800HA>
Searched January 14, 2019.

² EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000370820>. Accessed January 14, 2018.

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 proposed actions were evaluated for potential environmental impacts from use 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

No actions were identified that would lead to cumulative impacts due to the use of the new products.

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 Alternative - Disposal of the New Products

The Agency evaluated 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 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 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 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 products 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 existing smokeless tobacco products; therefore, these impacts are not considered significant.

7.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the disposal of the new tobacco products.

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 programmatic 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: Nine 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 difference between the new and corresponding predicate products would be limited to the replacement of a non-GRAS³ type (b) (4) in the predicate products with an equivalent amount of (b) (4) that is GRAS in the new products. In addition, miniscule amounts of (b) (4), (b) (4) and GRAS type (b) (4) would be added to the (b) (4) in the new products.

³ Generally recognized as safe (GRAS) is a designation for food additives and not applicable to tobacco products.

Confidential Appendix 2: Marketing Projections for the New Products

New Products STN	New Products Name	Unit	First-Year Projected Market Volume	Fifth-Year Projected Market Volume
SE0015157	Copenhagen Long Cut Black	Cans	(b) (4)	
		Metric Tons		
SE0015160	Husky Fine Cut Wintergreen	Cans		
		Metric Tons		
SE0015161	Husky Long Cut Natural	Cans		
		Metric Tons		
SE0015162	Husky Long Cut Straight	Cans		
		Metric Tons		
SE0015169	Skoal Fine Cut Original Wintergreen	Cans		
		Metric Tons		
SE0015170	Skoal Long Cut Classic Mint	Cans		
		Metric Tons		
SE0015171	Skoal Long Cut Classic Straight	Cans		
		Metric Tons		
SE0015176	Skoal Long Cut Classic Wintergreen	Cans		
		Metric Tons		