

**Programmatic Environmental Assessment for Modified Risk
Orders for Eight Snus Products Manufactured by Swedish
Match USA, Inc.**

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

October 3, 2019

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1. Applicant and Manufacturer Information

Applicant Name	Swedish Match USA, Inc.
Applicant Address	Two James Center 1021 East Cary Street, Suite 1600 Richmond, VA 23219
Manufacturer Name:	Swedish Match North Europe
Product Manufacturing Location:	Trollhättegatan 1, SE - 401 21 Göteborg, Sweden

2. Product Information

Product Names, Submission Tracking Numbers (STNs), and Package Size

STN	Product Name	Portion Size (g)	Number of Portions per can	Total Package Size (g)
MR0000020	General Loose	NA	NA	45
MR0000021	General Dry Mint Portion Original Mini	0.3	20	6
MR0000022	General Portion Original Large	1	24	24
MR0000024	General Classic Blend Portion White Large	0.9	12	10.8
MR0000025	General Mint Portion White Large	1	24	24
MR0000027	General Nordic Mint Portion White Large	0.9	12	10.8
MR0000028	General Portion White Large	1	24	24
MR0000029	General Wintergreen Portion White Large	1	24	24

3. The Need for the Proposed Actions

Swedish Match USA, Inc. (formerly Swedish Match North America, Inc.) submitted eight modified risk tobacco product applications (MRTPAs) [MR0000020- MR0000022, MR0000024, MR0000025, and MR0000027-MR0000029] for snus products to FDA seeking authorization under Section 911(g) of the FD&C Act on June 10, 2014 to change the statutory mandated health warnings on the package labels and advertisements.

On December 14, 2016, FDA completed its review of the MRTPAs and issued a partial decision on the applications. The request to remove one of the statutory claims was denied, while FDA deferred final action on the other requests. In deferring final action, FDA determined that the applications in their

current form did not provide sufficient evidence to meet the standards of 911(g)(1), but they could be amended in a way that would support the issuance of a modified risk order. Accordingly, FDA issued a Response Letter, which included three deficiencies.

On September 17, 2018, Swedish Match submitted an amendment to address the FDA Response Letter. The applicant amended their applications by proposing a revised modified risk claim. To communicate modified risk information to consumers, the applicant proposes to add the following claim to the advertising of the eight General Snus products that are the subject of these applications: “Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.”

4. Alternatives to the Proposed Actions

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

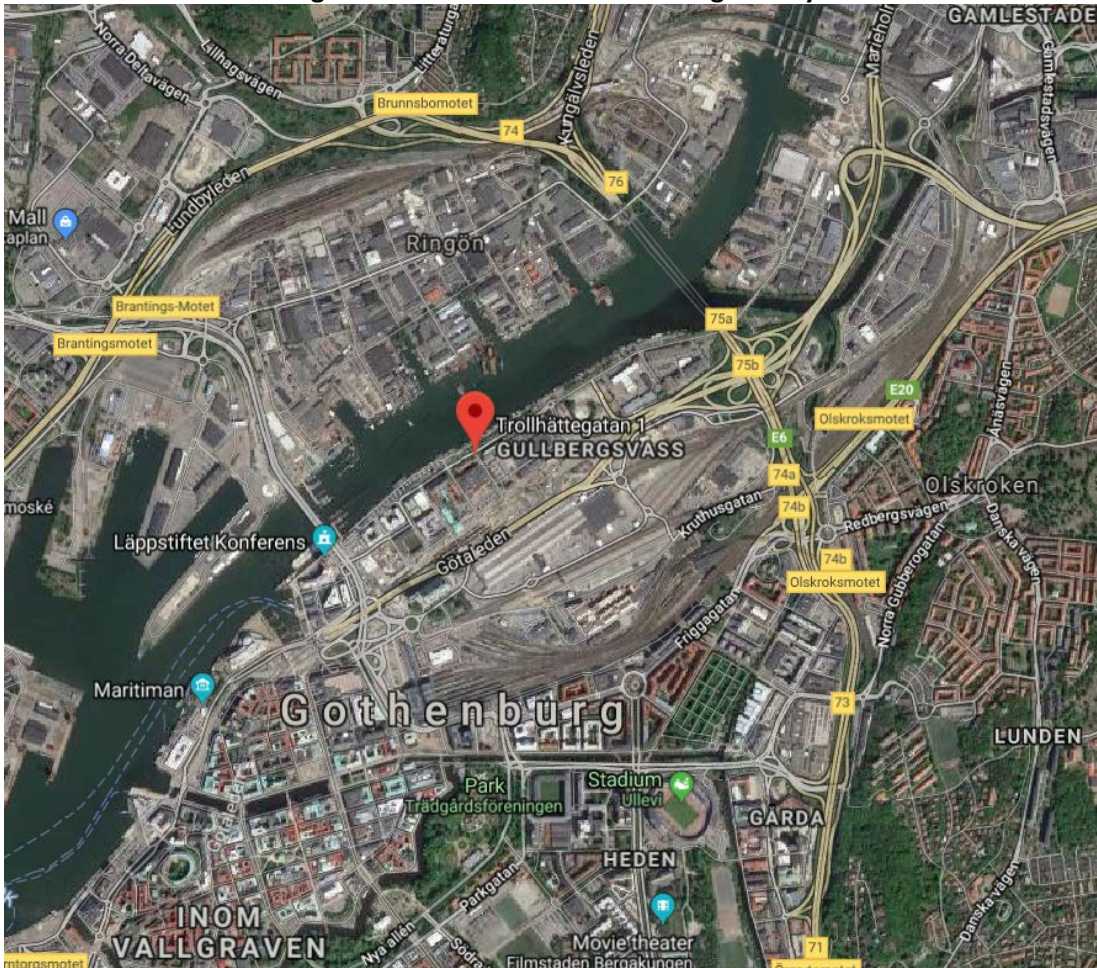
5. Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the Tobacco Products

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

5.1 Affected Environment

The tobacco products would be manufactured at Swedish Match North Europe located at Trollhättegatan 1, SE - 401 21 Göteborg, Sweden (Figure 1). The facility is surrounded by commercial and industrial buildings and a river to the north.

Figure 1. Location of Manufacturing Facility



5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the tobacco products based on information gathered by the Agency and the applicant’s submitted information, including projected market volumes for the tobacco products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that no changes to the products would be made, only the addition of modified risk claims to the products’ advertising. Additionally, the applicant stated that no expansion of the manufacturing facility would occur due to manufacturing the tobacco products. The applicant concluded that manufacturing the tobacco products would not lead to changes in air emissions.
Water resources	The applicant stated that no changes to the products would be made, only the addition of modified risk claims to the products’ advertising. Additionally, the applicant stated that no expansion of the manufacturing facility would occur due to manufacturing the tobacco products. The applicant concluded that manufacturing the tobacco products would not lead to changes in wastewater discharge.

Environmental Resource	Analysis of Potential Impacts
Land use and zoning	The applicant stated that no facility expansion would occur due to manufacturing the tobacco products. Therefore, no impacts on land use and zoning would occur.
Biological resources	The applicant stated that the tobacco products would replace the current products and does not anticipate an increase in manufacturing due to the tobacco products. Additionally, the applicant stated that manufacturing the tobacco products would not require additional resources. Therefore, the Agency does not expect any noticeable impacts on biological resources due to manufacturing the tobacco products.
Soils	The applicant stated that no facility expansion would occur due to manufacturing the tobacco products. Therefore, no effects on soils would occur from manufacturing the tobacco products.
Socioeconomic conditions	The applicant stated that no facility expansion would occur due to manufacturing the tobacco products. Therefore, no socioeconomic effects (beneficial or adverse) would occur from manufacturing the tobacco products.
Solid waste and hazardous materials	The applicant stated that there would be no increase of currently emitted compounds due to manufacturing the tobacco products. Additionally, the applicant stated that no changes to the products would be made, only the addition of modified risk claims to the products' advertising. Therefore, the Agency does not expect that manufacturing the tobacco products would change solid waste generation at the manufacturing facility and expects waste would be disposed of in the same manner as waste generated by other smokeless tobacco products manufactured at the same facility. So, no effects to solid waste or changes in disposal of hazardous materials would occur from manufacturing the tobacco products.
Floodplains, wetlands, and coastal zones	The applicant stated that no facility expansion would occur due to manufacturing the tobacco products. Therefore, no effects to floodplains, wetlands, or coastal zones would occur from manufacturing the tobacco 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 their facility is in full compliance with all environmental laws. The applicant stated that no adverse effects on any endangered species or critical habitat is expected due to manufacturing the tobacco products.

5.3 Cumulative Impacts

In addition to the MRTPAs, the applicant previously submitted substantial equivalence (SE) reports for the same eight snus products requesting market orders under section 910(a)(2) of FD&C Act and premarket tobacco product applications (PMTA) [PM0000010-PM0000017].

The agency has issued a finding of no significant impact (FONSI), dated August 20, 2015, for the PMTAs for “General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Portion White Large, and General Wintergreen Portion White Large” under section 910(a)(2) of FD&C Act. The FONSI is supported by a programmatic environmental assessment (PEA) issued on the same date.

Additionally, the Agency has issued a FONSI, dated October 8, 2015, for marketing orders for “General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Classic Blend Portion White Large – 12 CT, General Mint Portion White Large, General Nordic Mint Portion White Large – 12 CT, General Portion White Large, and General Wintergreen Portion White Large” under section 910(b) of FD&C Act. The FONSI is supported by a PEA issued also on the same date.

No significant environmental impacts were found from the actions above and the applicant stated that no changes to the tobacco products would be made, only the addition of modified risk claims to the products’ advertising, and that the tobacco products would replace the currently marketed products. Additionally, the Agency did not identify any actions that, when considered with the tobacco products’ manufacturing under the proposed actions, would lead to cumulative impacts. Therefore, the Agency does not expect any cumulative environmental impacts from the above actions and the proposed actions.

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 the current tobacco products would continue to be manufactured at the listed facility.

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

The Agency evaluated potential environmental impacts that may be caused by use of the 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 tobacco products to be marketed with the advertising claims nationwide.

6.2 Analysis of Potential Environmental Impacts

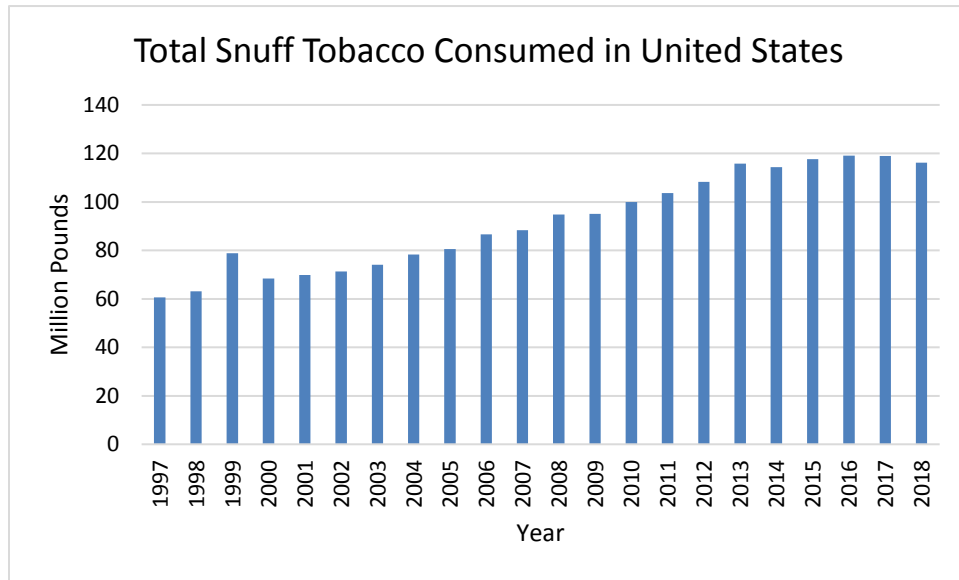
The Agency evaluated the proposed actions for potential environmental impacts from use of the tobacco products based on Agency-gathered information and the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	No changes in emissions from use of the products would occur because the applicant stated that no changes to the products would occur, only the addition of modified risk claims to the products’ advertising. Therefore, no change in impacts to environmental justice populations is expected.

6.3 Cumulative Impacts

Since 1997, snuff tobacco use (which includes snus tobacco use) in the United States has increased overall. However, in recent years snuff tobacco use has leveled off (Figure 2).¹ The Agency does not expect the tobacco products to significantly increase snus use in the United States.

Figure 2. Use of Snuff Tobacco in the U.S.



No significant environmental impacts were found from the past actions described in Section 5.3 of this PEA and the applicant stated that no changes to the tobacco products would be made, only the addition of modified risk claims to the products' advertising. The applicant also stated that the tobacco products would replace the currently marketed products. Additionally, the Agency did not identify any actions that, when considered with the tobacco products' use under the proposed actions, would lead to cumulative impacts. Therefore, the Agency does not expect any cumulative environmental impacts from the past actions and the proposed actions.

6.4 Impacts from No-Action Alternative

The no-action alternative would not change the existing use of the current products or other smokeless tobacco products in the United States, as the current tobacco products without the modified risk claim, as well as similar smokeless tobacco products, would continue to be marketed and therefore used.

¹ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 6, 2019.

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

The Agency evaluated potential environmental impacts that may be caused by disposal of the 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 the tobacco products to be sold to consumers nationwide who would dispose of the used tobacco 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 tobacco products based on Agency-gathered information and the applicant's submitted information, including market volume information for the tobacco products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Biological resources	Proper disposal of the used tobacco products and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal (littering) of the used tobacco products could lead to terrestrial wildlife having direct exposure to the used tobacco products and hazardous substances leaching to aquatic environments and soil. However, no net increase in littering is expected because the tobacco products would replace the current products and would compete for the same market share occupied by other currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Water resources	Proper disposal of the used tobacco products and packaging in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of the used tobacco products could result in hazardous substances leaching to water systems. However, littering levels are not expected to change from the current levels due to the existing tobacco products. Introducing the tobacco products into the U.S. market is not expected to increase the nationwide use of smokeless tobacco products based on the Agency's assessment and projected market volumes reported by the applicant (Confidential Appendices 1).
Regulatory compliance	The tobacco 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 tobacco products as for the current products and other currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.

7.3 Cumulative Impacts

No significant environmental impacts were found from the past actions described in Section 5.3 of this PEA. The applicant stated that no changes to the tobacco products would be made, only the addition of modified risk claims to the products' advertising, and that the tobacco products would replace the currently marketed products. Additionally, the Agency did not identify any actions that, when considered with the tobacco products' disposal under the proposed actions, would lead to cumulative impacts. Therefore, the Agency does not expect any cumulative environmental impacts from the past actions and the proposed actions.

7.4 Impacts from No-Action Alternative

The no-action alternative would not change the existing disposal of the current products or other smokeless tobacco products in the United States, as the current products without the modified risk claim and 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:

Shannon K. Hanna, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management

Experience: Four years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

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: Market Volume Projections for the Tobacco Products

STN	Projected Year of Marketing the Tobacco Products	Projected Market Volume (# of cans)	Weight of Product (gram/ can)	Projected Market Volume (grams)	Projected Market Volume (tons)
MR0000020	2019	(b) (4)	45	(b) (4)	(4)
	2024		45		
MR0000021	2019		6		
	2024		6		
MR0000022	2019		24		
	2024		24		
MR0000024	2019		10.8		
	2024		10.8		
MR0000025	2019		24		
	2024		24		
MR0000027	2019		10.8		
	2024		10.8		
MR0000028	2019		24		
	2024		24		
MR0000029	2019		24		
	2024		24		