

**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**

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## 1. Introduction

### 1.1 Background

Swedish Match USA, Inc. (formerly Swedish Match North America, Inc.) submitted eight modified risk tobacco product applications (MRTPAs) [MR0000256.PD1-MR0000256.PD5, MR0000256.PD7-MR0000256.PD9] for snus products to FDA seeking reauthorization under Section 911(g) of the FD&C Act on July 17, 2023 to continue marketing the products with a modified risk claim. The agency had previously issued a finding of no significant impact (FONSI), dated October 3, 2019, for these products under section Section 911(g) of the FD&C Act.

The agency has also issued a FONSI, dated August 20, 2015, for the Pre Market Tobacco Applications for some of these products (“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 these products under section 910(b) of FD&C Act. The FONSI is supported by a PEA issued also on the same date.

FDA prepared this PEA to evaluate the potential environmental impacts from continued marketing of the new products in the United States and from the no-action alternative of not issuing marketing orders for the products. This PEA is prepared in accordance with the Council on Environmental Quality’s (CEQ’s) regulations (40 CFR 1500 - 1508) implementing the National Environmental Policy Act (NEPA) and FDA’s NEPA regulations (21 CFR Part 25.40).

### 1.2 Applicant and Manufacturer Information

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

### 1.3 Product Information

#### Submission Tracking Numbers (STN) and Names of the New Product

New Product STN	New Product Name
MR0000256.PD1	General Loose
MR0000256.PD2	General Dry Mint Portion Original Mini
MR0000256.PD3	General Portion Original Large
MR0000256.PD4	General Classic Blend Portion White Large
MR0000256.PD5	General Mint Portion White Large
MR0000256.PD7	General Nordic Mint Portion White Large
MR0000256.PD8	General Portion White Large
MR0000256.PD9	General Wintergreen Portion White Large

## 1.4 Product Identification

<b>Product Category</b>	Smokeless
<b>Product Subcategory</b>	Loose Snus Portioned Snus
<b>Product Quantity per Retail Unit</b>	45 grams of loose moist snuff per can (MR0000256.PD1), 20 pouches containing 6 grams of portioned snus (MR0000256.PD2), 20 pouches containing 24 grams of portioned snus (MR0000256.PD3, MR0000256.PD5, MR0000256.PD8, MR0000256.PD9), 12 pouches containing 10.8 grams of portioned snus (MR0000256.PD4, MR0000256.PD7)
<b>Product Package</b>	The packaging materials consist of cardboard can with plastic lid. The top and side labels consist metalized silver paper, with shrink film packaging overall.

## 2. The Purpose and Need for the Proposed Action

**Purpose:** Swedish Match USA, Inc. (formerly Swedish Match North America, Inc.) submitted eight modified risk tobacco product applications (MRTPAs) [MR0000256.PD1-MR0000256.PD5, MR0000256.PD7-MR0000256.PD9] for snus products to FDA seeking reauthorization under Section 911(g) of the FD&C Act on July 17, 2023 to continue marketing the products with a modified risk claim. To communicate modified risk information to consumers, the applicant proposes to continue marketing with 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.”

Upon receipt of an MRTPA, FDA considers the submission, using criteria detailed in section 911(g) of the FD&C Act, and issues a risk modification order that either allows or denies the proposed risk modification claim for a commercially marketed tobacco product. The purpose of FDA’s MRTPA review is to determine whether an applicant has shown that the tobacco product sold or distributed with the proposed modified risk information will (A) significantly reduce harm and the risk of tobacco related disease to individual tobacco users and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

**Need:** FDA is responsible for reviewing an MRTPA, making a finding as described in the previous paragraph, and subsequently determining whether or not to issue a marketing order for the proposed new product.

## 3. Proposed Action and the Alternative

**Proposed action:** The proposed action is for the FDA to issue modified risk granted orders under the provisions of 911(g)(1) reauthorizing the marketing of the MRTPA products with the modified risk claim as identified in Section 2.

**Alternative:** The no-action alternative is the FDA does not issue a modified risk order for marketing the new products in the United States.

#### 4. Potential Environmental Impacts of the Proposed Action and Alternative – Manufacturing the New Products

The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new product and found no significant impacts based on Agency-gathered information and the following applicant-submitted information:

- No changes to ingredients in the new products for continued marketing.
- Ingredients in the new products are commonly used in other smokeless tobacco products.
- The new products would not require additional resources or equipment to produce.
- No facility expansion or new construction is expected due to manufacture of the new products.
- Declining trends in sales of the currently marketed products.

##### 4.1 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**



#### 4.2 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.
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.

#### **4.3 Impacts from the 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.

#### **5. Potential Environmental Impacts of the Proposed Action and Alternative – Use of the New Products**

The Agency evaluated potential environmental impacts that may be caused by use of the new product with the modified risk claim and found no significant impacts.

##### **5.1 Affected Environment**

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new modified risk product to be sold to consumers in the United States with the advertising claim nationwide.

##### **5.2 Analysis of Potential Environmental Impacts**

The proposed action was evaluated for potential environmental impacts from use of the new product based on Agency-gathered information and the applicant’s submitted information. Included in the information the Agency considered were the projected market volumes for the new products as proxy for use (Confidential Appendix 1).

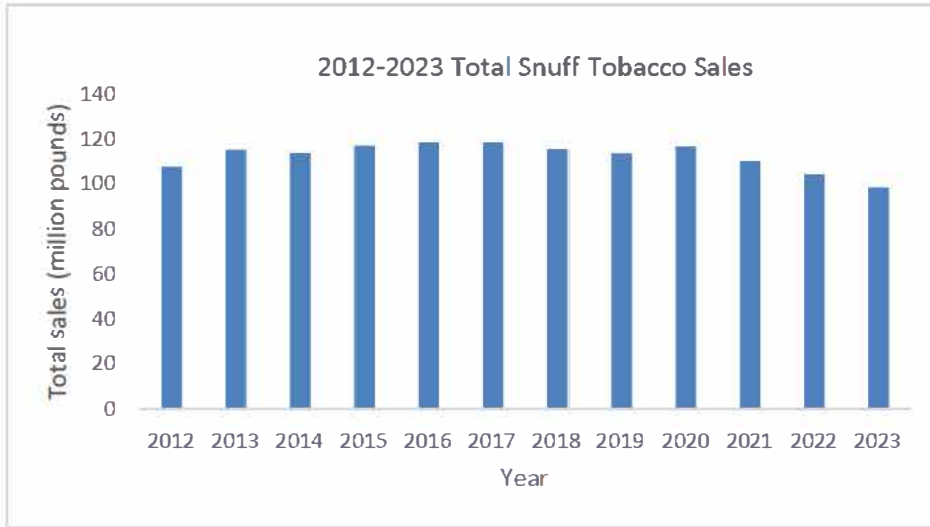
Data from the tobacco products monthly statistical release reports from U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) show that since 2012, snuff tobacco sale as a proxy for consumption in the United States increased slightly till 2020 but has since then reduced through 2023. (Figure 2; U.S. TTB, 2024).<sup>1</sup>

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<sup>1</sup> Sales data reported by TTB are used as a proxy for consumption.



**Figure 2. Use of Smokeless Tobacco in the United States, 2012 – 2023**



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	<p>No changes in emissions from use of the products are anticipated as the products are not modified.</p> <p>Additionally applicant provided data indicates that the participants in the General Snus Patterns of Use Study were predominantly White, in their late 30s, male, had some college or, an Associate or Bachelor’s degree, had a household income of \$50,000-\$99,999 per year, and resided in the South and Midwest regions of the United States (Appendix 1). The demographic attributes of Camel Snus study participants do not directly equate to use prevalence data by specific race/ethnicity and socio-economic status in the U.S. However, these applicant-provided data indicate that racial/ethnic minority and low-income populations may not be disproportionately affected by use of the new products.</p>

**5.3 Impacts from the No-Action Alternative**

- 6 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.



**6. Potential Environmental Impacts of the Proposed Action and Alternative – Disposal of the New Products**

The Agency evaluated potential environmental impacts that may be caused by disposal of the new product and found no significant impacts based on Agency-gathered information and the applicant’s submitted information.

**6.1 Affected Environment**

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new product to be sold to consumers nationwide who would dispose of used new product and packaging as municipal solid waste (MSW), recycled material, or litter.

**6.2 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 2).

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.

### **6.3 Impacts from the No-Action Alternative**

The no-action alternative would not change existing smokeless tobacco product and packaging material disposal because disposal of similar products would continue in the United States.

### **7. List of Preparers**

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

#### **Preparers:**

Dilip Venugopal, PhD, Center for Tobacco Products

Education: MS in Ecology and PhD in Entomology

Experience: Twenty-two years in various scientific activities

Expertise: NEPA analysis, environmental impact analysis, toxicology and risk assessments, applied ecology, spatial analysis

#### **Reviewer:**

Alex Lowe, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biology

Experience: Twelve years in environmental science

Expertise: Ecosystem science, human impacts, and water quality

### **8. List of Agencies and Persons Consulted**

None.

### **9. References**

U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB). (2024). Tobacco statistics. U.S. Department of the Treasury. statistical data Available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed April 22, 2024.

**Appendix 1: Demographics and Tobacco Use by People who Used General Snus at Baseline and Wave 4, Based on FDA Analysis of Applicant Data**

		Total baseline participants (n=1,655)		Baseline values for participants who completed Wave 4 (n=451)
	n	mean (std) or % (95% CI)	n	mean (std) or % (95% CI)
<b>Mean age (years)</b>	1,655	36.1 (10.4)	451	37.5 (10.5)
<b>Gender</b>				
Male	1,517	91.7 (90.2, 92.9)	423	93.8 (91.2, 95.8)
Female	138	8.3 (7.1, 9.8)	28	6.2 (4.2, 8.8)
<b>Race/ethnicity</b>				
Non-Hispanic White	1,471	88.9 (87.3, 90.4)	406	90.0 (86.9, 92.6)
Black/African American	24	1.5 (0.9, 2.2)	5	1.1 (0.4, 2.6)
Hispanic	42	2.5 (1.8, 3.4)	11	2.4 (1.2, 4.3)
Non-Hispanic Other	100	6.0 (4.9, 7.3)	27	6.0 (4.0, 8.6)
Don't know/Decline to answer	18	1.1 (0.6, 1.7)	2	0.4 (0.1, 1.6)
<b>Geographic region</b>				
West	199	12.0 (10.5, 13.7)	60	13.3 (10.3, 16.8)
South	467	28.2 (26.1, 30.5)	138	30.6 (26.4, 35.1)
Midwest	567	34.3 (32.0, 36.6)	157	34.8 (30.4, 39.4)
Northwest	422	25.5 (23.4, 27.7)	96	21.3 (17.6, 25.4)
<b>Education attainment</b>				
<High school/High school/GED	261	15.8 (14.0, 17.6)	54	12.0 (9.1, 15.3)
Some college/Associate degree	621	37.5 (35.2, 39.9)	170	37.7 (33.2, 42.3)
Bachelor's	571	34.5 (32.2, 36.8)	167	37.0 (32.6, 41.7)
Post-graduate	195	11.8 (10.3, 13.4)	59	13.1 (10.1, 16.5)
Missing	7	0.4 (0.2, 0.9)	1	0.2 (0.0, 1.2)
<b>Household income</b>				
<\$50,000	508	30.7 (28.5, 33.0)	116	25.7 (21.7, 30.0)
\$50,000 - \$99,999	621	37.5 (35.2, 39.9)	166	36.8 (32.3, 41.4)
\$100,000+	463	28.0 (25.8, 30.2)	152	33.7 (29.3, 38.3)

**Confidential Appendix 1: First- and Fifth-Year Market Volume Projections for the New Products**

