Programmatic Environmental Assessment for Marketing Orders for New Nicotine Pouch Products Marketed 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

On March 4, 2020, Swedish Match USA Inc. submitted premarket tobacco product applications (PMTAs) for ZYN Cool Mint, ZYN Peppermint, ZYN Spearmint, ZYN Wintergreen, ZYN Citrus, ZYN Coffee, ZYN Cinnamon, ZYN Smooth, ZYN Chill, and ZYN Menthol. In the PMTAs, Swedish Match USA Inc. requests the U.S. Food & Drug Administration issue marketing orders under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Public Law 111-31).

This document reviews the potential environmental effects from marketing the new products in the United States, and from the no-action alternative of the Agency not issuing marketing orders for the new products. The Agency did not identify any significant environmental impacts from the proposed actions.

1.2 Applicant and Manufacturers Information

Applicant Name:	Swedish Match USA Inc.
Applicant Address:	Two James Center 1021 East Cary Street, Suite 1600 Richmond, VA 23219
Manufacturers Names:	Swedish Match North America LLC
Product Manufacturing Locations:	1121 Industrial Drive, Owensboro, KY 42301 Swedish Match North Europe Rollsbovagen 45, SE-441 17 Kungälv, Sweden

2. Product Information

New Products Names and Submission Tracking Numbers (STNs)

New Product Name	STN New Product
ZYN Cool Mint 3 mg	PM00005593.PD1
ZYN Cool Mint 6 mg	PM00005594.PD1
ZYN Peppermint 3 mg	PM00005595.PD1
ZYN Peppermint 6 mg	PM00005596.PD1
ZYN Spearmint 3 mg	PM00005597.PD1
ZYN Spearmint 6 mg	PM00005598.PD1
ZYN Wintergreen 3 mg	PM00005599.PD1
ZYN Wintergreen 6 mg	PM00006600.PD1
ZYN Citrus 3 mg	PM00006601.PD1
ZYN Citrus 6 mg	PM00006602.PD1
ZYN Coffee 3 mg	PM00006603.PD1
ZYN Coffee 6 mg	PM00006604.PD1
ZYN Cinnamon 3 mg	PM00006605.PD1
ZYN Cinnamon 6 mg	PM00006606.PD1
ZYN Smooth 3 mg	PM00006607.PD1

ZYN Smooth 6 mg	PM00[redacted]608.PD1
ZYN Chill 3 mg	PM00[redacted]609.PD1
ZYN Chill 6 mg	PM00[redacted]610.PD1
ZYN Menthol 3 mg	PM00[redacted]611.PD1
ZYN Menthol 6 mg	PM00[redacted]612.PD1

Product Identification

Product Category	Other
Product Subcategory	Other
Product Number per Retail Unit	3 mg, 6 mg nicotine per pouch with 15 pouches per can.
Product Package	Polypropylene can with polyethylene film labels on the front, back, and sides. Cans are packaged in a paperboard carton and corrugated cardboard case.

3. The Need and Purpose for the Proposed Actions

Purpose: The applicant wishes to continue marketing the new products in interstate commerce for commercial distribution in the United States and submitted to the Agency PMTAs to obtain marketing orders. Upon receipt of a PMTA, FDA considers the submission, using criteria detailed in section 910(c) of the FD&C Act, to make a finding as to whether a marketing order for the product would be appropriate for the protection of public health.

Need: FDA's responsibility to review a PMTA, make a finding as described in the previous paragraph, and subsequently determine whether or not to issue a marketing order for the new product is a statutory requirement under section 910(c) of the FD&C Act.

4. Proposed Actions and Alternatives

The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of section 910 of the FD&C Act for introduction or delivery for introduction of tobacco products into interstate commerce in the United States after finding the new products would be appropriate for the protection of public health.

The no-action alternative is FDA does not issue marketing orders for the new products. The products will not be marketed in the United States and, for the purposes of the analysis in this programmatic environmental assessment, it is assumed that there will be no changes to the current nicotine pouch product market and no changes to the current or future use of nicotine pouch products.

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

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

- Short-term, construction related localized effects are anticipated due to the expansion of the manufacturing facility for production of the new products.
- The applicant has incorporated additional environmental controls for environmental compliance and to prevent environmental effects.
- Trends in energy use, emissions, and waste generated at the manufacturing facility are declining and further reductions after accounting for the increased net production due to the new products are anticipated.
- The increased net production would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity.

This analysis will focus on the manufacturing facility in Owensboro, KY. However, the applicant also states that the manufacturing facility located in Sweden is in compliance with all the applicable environmental regulations and does not require any new environmental permits due to manufacturing the new products.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facilities. The new products are manufactured at Swedish Match North America LLC facility, at 1121 Industrial Drive, Owensboro, KY 42301 (Figure 1). The facility is at the edge of a manufacturing district, with equipment fabricators and a beverage distributor to the north, a mechanical contractor and industrial equipment supplier to the west, a manufacturer and tire shop to the east, and residential housing to the south and southeast.

New products are also manufactured at Rollsbovagen 45, SE-441 17 in Kungälv, Sweden (Figure 2). Land use surrounding this facility constitutes industrial, residential, and natural areas.

Figure 1. Location of the Domestic Manufacturing Facility (Google, 2024a)

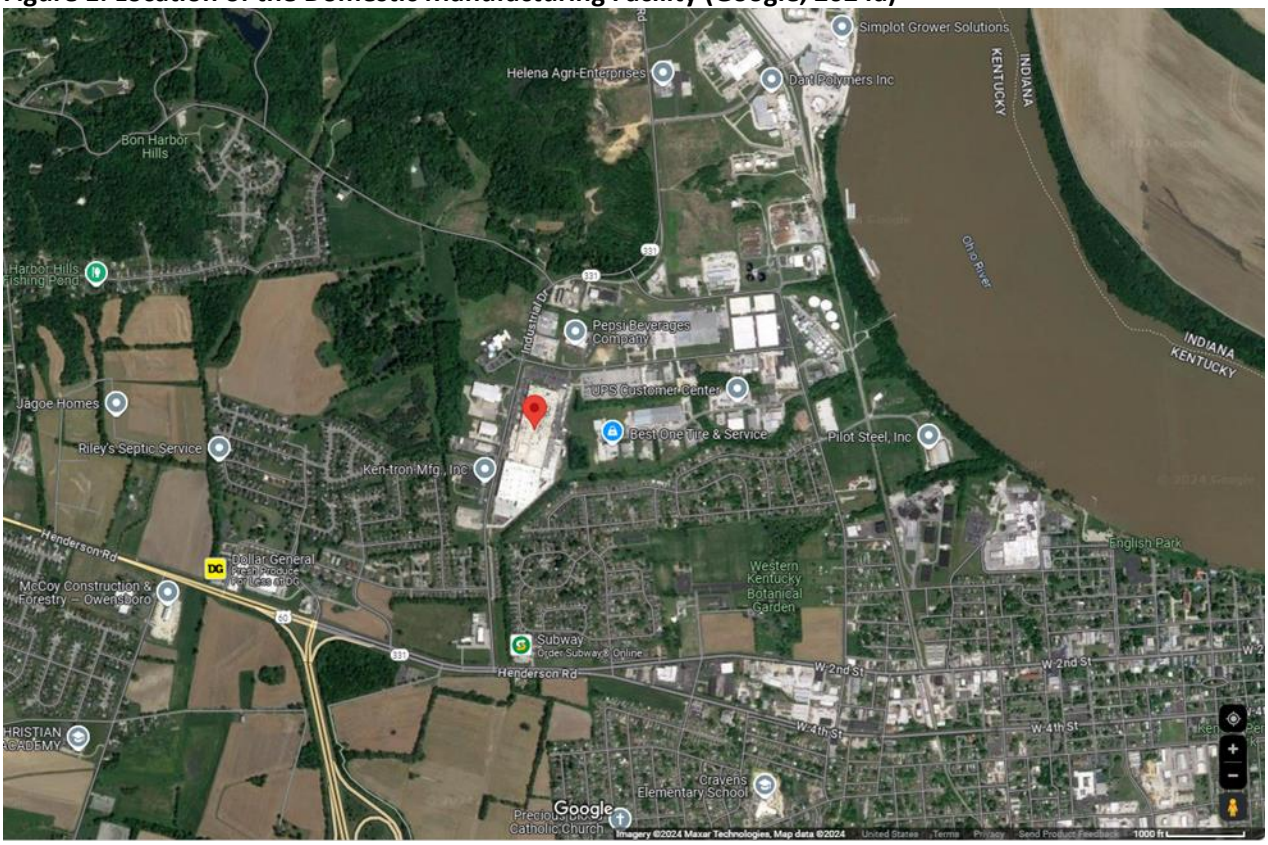


Figure 2. Location of the Foreign Manufacturing Facility (Google, 2024b)

5.2 Air Quality

Expansion of the facility for manufacturing the new products required a revised air emissions permit for the manufacturing facility. Additional environmental controls were required and implemented in the Owensboro manufacturing facility in relation to the expansion of the facility for manufacturing the new products. The revised air emissions permit from the Commonwealth of Kentucky allows the applicant to emit up to 90 tons of ethanol per year. In addition, the applicant implemented pollution controls to handle ethanol emissions.

Ethanol (190 Proof) is used in the new product manufacturing process as a carrier and is removed through volatilization. During processing, the ethanol volatilizes, leaving no measurable ethanol content in the finished product. To accommodate this production requirement, two above ground 8,000-gallon tanks were added in the ethanol storage building to store ethanol. Two 1,200-gallon tanks were added in the process expansion building to store an ethanol mixture. No underground storage tanks were installed. Ethanol waste is disposed of through Regenerative Thermal Oxidizers (RTOs), placed in the facility. The expected performance of the RTOs is 95- 99% destruction efficiency of ethanol.
The Agency does not anticipate that manufacturing the new products would lead to new or increased compounds being emitted at the Owensboro facility.

5.3 Water Resources

Manufacturing the new products resulted in an expansion of existing waste/sanitary water discharge. The applicant states that they obtained an additional water permit from the local Regional Water Resource Agency (Daviess Co, KY) for building expansion and are in compliance with all applicable regulations. The facility added additional sinks, floor drains, and toilets to accommodate increased facility discharges to the sewer system. This additional effluent flow is in compliance with all applicable regulations. The Agency does not anticipate that manufacturing the new products would cause any new chemicals to be discharged into the water and no significant impact on water resources are anticipated.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products will lead to changes in soil, land use, or zoning. The new products are manufactured at the Swedish Match North America LLC in Owensboro, KY, which currently manufactures other tobacco products. The Agency anticipates that the new construction due to manufacturing the new products resulted in localized, short-term construction related activities. Therefore, no zone changes or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use would be anticipated.

5.5 Biological resources

The Agency searched the U.S. Fish and Wildlife Service's Environmental Conservation Online System (ECOS) which shows that the manufacturing facility is not within or near critical habitat (U.S. Fish & Wildlife Service, 2024a) or endangered animal or plant species (U.S. Fish & Wildlife Service, 2024b).

ECOS (U.S. Fish & Wildlife Service, 2024b) identifies five mammal, 12 clam, one bird, and one insect species as endangered, proposed endangered, threatened, candidate, recovery, or under review in Daviess County, KY (Table 1). Critical habitat has not been designated for these species in Daviess County, KY (U.S. Fish & Wildlife Service, 2024a).

Table 1. Species Identified by USFWS in Daviess County, KY

Species	Status
tricolored bat (*Perimyotis subflavus*)	proposed endangered
Indiana bat (*Myotis sodalis*)	endangered
gray bat (*Myotis grisescens*)	endangered
little brown bat (*Myotis lucifugus*)	under review
northern long-eared bat (*Myotis septentrionalis*)	endangered
spectaclecase (mussel) (*Cumberlandia monodonta*)	endangered
sheepnose mussel (*Plethobasus cyphyus*)	endangered
pink mucket (pearlymussel) (*Lampsilis abrupta*)	endangered
rough pigtoe (pearlymussel) (*Pleurobema plenum*)	endangered
orangefoot pimpleback (pearlymussel) (*Plethobasus cooperianus*)	endangered
ring pink (mussel) (*Obovaria retusa*)	endangered
fat pocketbook (*Potamilus capax*)	endangered
clubshell (*Pleurobema clava*)	endangered
fanshell (*Cyprogenia stegaria*)	endangered
snuffbox mussel (*Epioblasma triquetra*)	endangered
rabbitsfoot (*Quadrula cylindrica cylindrica*)	threatened
longsolid (*Fusconaia subrotundra*)	threatened
least tern (*Sterno antillarum*)	recovery
monarch butterfly (*Danaus plexippus*)	candidate

The Agency does not anticipate that manufacturing the new products will jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the U.S. Endangered Species Act (ESA). The expansion to the Owensboro facility was conducted on the existing Swedish Match campus located in Daviess County, KY. The Owensboro facility is located in an area of significant industrial development and not within or near critical habitat for any endangered or threatened species. No rare or protected flora or fauna are used as materials or ingredients in the new product.

5.6 Regulatory Compliance

The applicant states that the manufacturing facility is in compliance with all applicable environmental regulations and provides details on relevant permits at the Owensboro plant for monitoring and controlling emissions as provided by state and local authorities. The Agency's search of the U.S. Environmental Protection Agency's (EPA) Enforcement and Compliance History Online (ECHO) database did not reveal any violations of environmental laws and regulations for the Swedish Match North America LLC manufacturing facility in Owensboro, KY (U.S. Environmental Protection Agency, 2024a). The applicant states that the Kungälv Facility in Sweden is in compliance with all applicable environmental laws. The applicant also states that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

5.7 Socioeconomics and Environmental Justice

No changes in socioeconomics are anticipated due to manufacturing the new products. The applicant states that the new products may result in additional employment. Therefore, the Agency does not anticipate any significant negative impacts on employment, revenue, or taxes.

No changes to effects on environmental justice are anticipated. The Agency's search of the U.S. Environmental Protection Agency's Enforcement and Compliance History Online (ECHO) database which summarizes demographic information for the community surrounding the Owensboro facility (in a 3-mile radius) based on 2020 U.S. Census and 2021 American Community Survey data indicates populations (or communities) of environmental justice concern comprise 20% of the population and the facility is not located on Native American lands Non-Hispanic white residents make up approximately 82% of the population (U.S. Environmental Protection Agency, 2024a).

5.8 Solid Waste and Hazardous Materials

The applicant submitted information about solid waste and hazardous materials management and environmental controls, specifically relating to nicotine. Production of the new products differs from the production of other products at the Owensboro facility. Therefore, the applicant states that new environmental controls were implemented at the Owensboro facility to accommodate new waste associated with the facility expansion and the new products, including nicotine. Unused bulk powder containing nicotine is handled as hazardous waste and disposed of by a third-party contractor using controlled methods. The applicant states that the handling of hazardous waste occurs using a laboratory style glove box and the waste does not come into direct contact with personnel. The applicant further describes waste streams associated with production of the new products, including, 1) a granulate waste stream (e.g., dry, non-metal materials, such as test cans, protective garments, and storage bags); 2) a finished waste stream (e.g., destruction of returned unsellable items, which are segregated from other returns and not run through unsaleable shredder); 3) a lab waste stream (e.g., residual materials from samples and the analysis of the new product); and 4) an ethanol waste stream (e.g., resulting from the rinsing of process equipment parts with ethanol). All waste streams are accumulated, then following EPA shipping compliance requirements, shipped to a certified incinerator for destruction.

The environmental controls aid in environmental compliance. There may be a net increase in manufacturing owing to new product manufacturing. The applicant states that new product manufacturing would not require additional resources for manufacturing waste disposal, such as onsite solid or hazardous waste accumulation capacity, new or expanded landfills, recycling centers, or other waste disposal or handling capacity. The applicant submitted data indicating declining trends in waste generation and declining forecasted waste generation for 2020-2024 (Confidential Appendix 1). The Agency's search of EPA's ECHO database did not reveal any Resource Conservation and Recovery Act (RCRA) violations at the manufacturing facility (U.S. Environmental Protection Agency, 2024b). Therefore, the Agency does not anticipate that manufacturing the new products would lead to new or increased solid waste and hazardous wastes.

5.9 Floodplains, Wetlands, and Coastal Zones

The Agency does not anticipate that manufacturing the new products would lead to changes in floodplains, wetlands, and coastal zones. The Agency anticipates that construction to accommodate manufacturing the new products is associated with localized, short-term land alterations within an existing industrial footprint.

5.10 Effects of the No Action Alternative

The environmental effect of the no-action alternative would not change the existing condition of manufacturing nicotine pouch products, as many similar tobacco products would continue to be manufactured in the United States.

6. Potential Environmental Effects of the Proposed Actions and Alternatives – Use of the New Products

The Agency considered potential effects to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes (Confidential Appendix 2) for the first-year and fifth-year of marketing of the new products.

6.1 Affected Environment

The affected environment includes human and natural environments in the United States; because the marketing orders will allow for the new products to be sold to consumers in the United States.

6.2 Environmental Justice

There are no available studies describing use of nicotine pouches among populations (or communities) with environmental justice concerns. The National Youth Tobacco Survey data from 2023 indicates that 1.5% of students reported current use of nicotine pouches, and non-Hispanic white students had the highest reported use (Birdsey et al., 2023). Among adults, the 2022 Tobacco Use Supplement to the Current Population Survey (TUS-CPS) indicates that 2.9% reported ever using nicotine pouches. The use of nicotine pouches was more prevalent among younger adults, males, and non-Hispanic White individuals, particularly those with a history of smoking (Dai et al., 2024).

Consumer research submitted by the applicant indicates that nicotine pouch users are more likely to have a higher income than consumers of moist snuff tobacco. The applicant also provided a Patterns of Use Study and a Likelihood of Use Study the participants of which included populations (or communities) with environmental justice concerns. The applicant states that neither of these studies indicate that never-smokers in populations (or communities) with environmental justice concerns would disproportionately adopt use of the new products. At this time, research studies and data suggesting disproportionate use prevalence of the new products by populations (or communities) with environmental justice concerns are not available and nonusers of tobacco have very little interest in ZYN (Plurphanswat et al., 2020). Therefore, the Agency does not expect that use of the new products will result in new disproportionate effects on populations (or communities) with environmental justice concerns.

6.3 Effects from the No-Action Alternative

The environmental effects of the no-action alternative will not change the existing condition of use of nicotine pouch products because similar tobacco products will continue to be used in the United States.

7. Potential Environmental Effects of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency evaluated potential effects 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 includes human and natural environments in the United States because the marketing orders will allow for the new products to be sold to consumers nationwide who will dispose of the used products and packaging as municipal solid waste (MSW), recycled material, or litter.

7.2 Air Quality

The Agency does not anticipate disposal of the new products, or the packaging material would lead to the release of new or increased chemicals into the air.

Currently, there are no studies available that describe the air quality effects resulting from the disposal of used nicotine pouches. The applicant provided information on the material composition of the pouches, which includes synthetic polymers and plastic materials. Some of these materials are known to be non-biodegradable or only slowly biodegradable.

No changes in air quality from disposal of the packaging materials in the new products would be expected because (1) the paper and cardboard components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste based on the projected market volume of the new products.

7.3 Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. Endangered Species Act. Proper disposal of the used new products and packaging into MSW would not affect biological resources. If improper disposal as litter occurs, the products are not expected to result in new or additional compounds emitted to the environment. Further, unlike combusted tobacco products, smoldering of used products is not a concern with disposal of the new nicotine pouches. Therefore, the risk of fires from smoldering tobacco products and associated effects to natural environments from littering are not a concern. The Agency does not anticipate disposal of the new products, or the packaging material would lead to significant impacts on biological resources.

7.4 Water Resources

Proper disposal of the used new products and packaging in the municipal solid waste stream will not affect water resources. Improper disposal (littering) of the used new products could result in hazardous substances leaching into 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 nicotine pouch products based on the Agency's assessment and projected market volumes reported by the applicant.

7.5 Solid Waste and Hazardous Materials

The distribution of waste generated due to disposal of the new products and packaging is anticipated to correspond to the pattern of the products' use in the United States. However, introducing the new products into the U.S. market is not expected to increase the nationwide use and disposal of tobacco products based on the Agency's assessment. Therefore, no net increase in littering is expected.

Users of the new products, which are intended as spit-free products, are not anticipated to expectorate the new product into the environment. The applicant examined the ecotoxicity potential according to Globally Harmonized System of Classification and Labelling of Chemicals (GHS) criteria and calculated an Expected Introduction Concentration (EIC) for seven substances among the ingredients. These substances, including nicotine, were classified as harmful or toxic to aquatic life with long-lasting effects according to GHS criteria. However, the applicant noted that each of these seven substances have an EIC less than 1% of the lowest respective No Observed Effect Concentration (NOEC). Therefore, considering that the waste predominantly will pass through local municipal waste systems, and as EICs are below concentrations with observable effects on aquatic life (including microorganisms in wastewater treatment), the Agency does not anticipate significant impacts on the Publicly Owned Treatment Works ("POTWs") or to the natural environment.

Applicant estimates of municipal solid waste loads for the new product packaging materials and the pouch were considered by the Agency (Confidential Appendices 2 and 3). The agency does not anticipate significant impacts from disposal of the packaging materials and pouch because packaging materials are similar to and will be similarly handled as other similar paper and plastic waste. Waste generated due to disposal of packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from tobacco products although a portion of those would be littered (U. S Environmental Protection Agency, 2018).

7.6 Socioeconomics and Environmental Justice

The Agency does not anticipate changes in effects on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products will be handled in the same manner as the waste generated from disposal of other tobacco products in the United States. No new emissions are expected due to disposal of the new products; therefore, there will be no disproportionate effects on populations (or communities) with environmental justice concerns.

7.7 Effects from the No-Action Alternative

The environmental effects of the no-action alternative will not change the existing condition of disposal of nicotine pouch products and their packaging, as many other similar tobacco products will continue to be disposed of in the United States.

8. List of Preparers

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

Preparer:

Christy Leppanen, M.S., Ph.D., Center for Tobacco Products

Education: B.S. in Chemistry and Biology, M.S. in Biology, Ph.D. in Biological Sciences
Experience: Thirty-one years in environmental management and compliance
Expertise: Environmental toxicology, risk assessment, population management, regulatory compliance

Reviewer:

Dilip Venugopal, Ph.D., Center for Tobacco Products

Education: M.S. in Ecology and Ph.D. in Entomology
Experience: Twenty-two years in various scientific activities
Expertise: NEPA analysis, environmental impact analysis, toxicology, ecological risk and benefit assessments, applied ecology, geo-statistics

9. A Listing of Agencies and Persons Consulted

None.

10. References

Birdsey J, Cornelius M, Jamal A, et al. Tobacco product use among U.S. middle and high school students - national youth tobacco survey, 2023. MMWR Morb Mortal Wkly Rep. 2023. 2023;72(44):1173-1182doi:10.15585/mmwr.mm7244a1. PMID: 37917558.

Dai HD, Leventhal AM. Prevalence of nicotine pouch use among U.S. adults. JAMA. 2024;332(9):755-757. https://doi.org/10.1001/jama.2024.10686.

Google. Map of 1121 Industrial Drive, Owensboro, KY 42301. Google Maps. Accessed October 18, 2024 (2024a) www.google.com/maps

Google. Map of Rollsbovagen 45, SE-441 17, Kungälv, Sweden. Google Maps. Accessed October 17, 2024 (2024b) www.google.com/maps

Plurphanswat N, Hughes JR, Fagerström K, Rodu B (2020). Initial information on a novel nicotine product. The American Journal on Addictions, 29(4), 279–286. https://doi.org/10.1111/ajad.13020

U.S. Environmental Protection Agency. Detailed facility report. Enforcement and Compliance History Online. Accessed October 17, 2024 (2024a) https://echo.epa.gov/detailed-facility-report?fid=110070626060

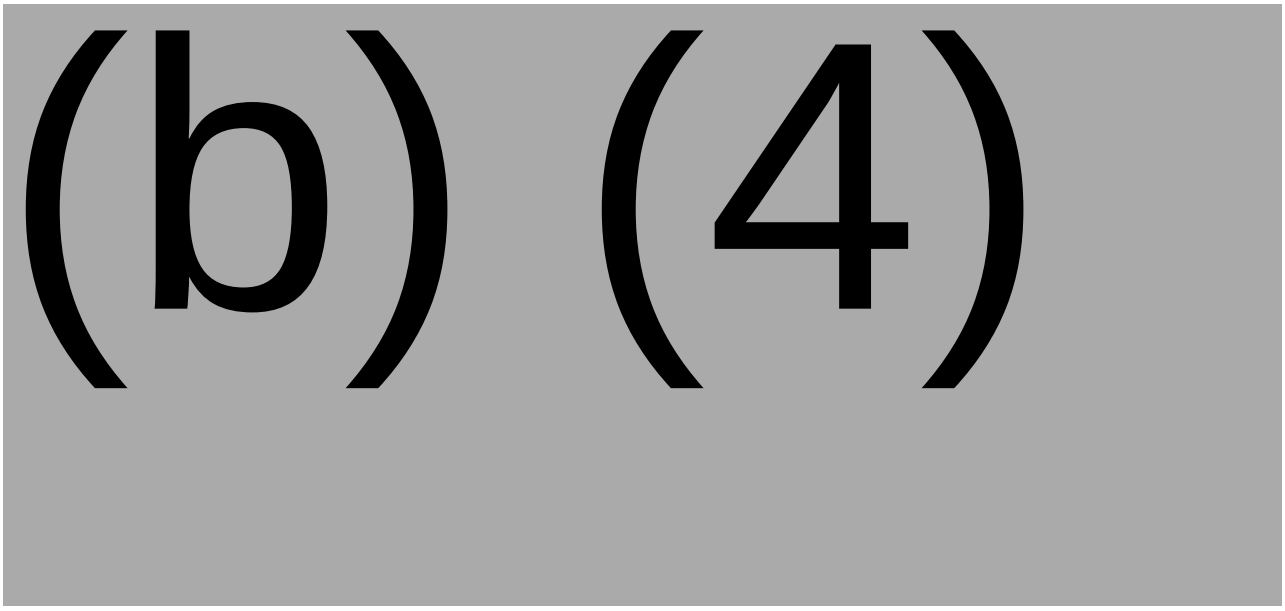
U.S. Environmental Protection Agency. Envirofacts RCRA Information. Accessed November 21, 2024 (2024b) https://enviro.epa.gov/envirofacts/rcrainfo/search

U.S. Environmental Protection Agency. Advancing Sustainable Material Management: Facts and Figures. Accessed November 8, 2024 (2018) https://www.epa.gov/sites/default/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

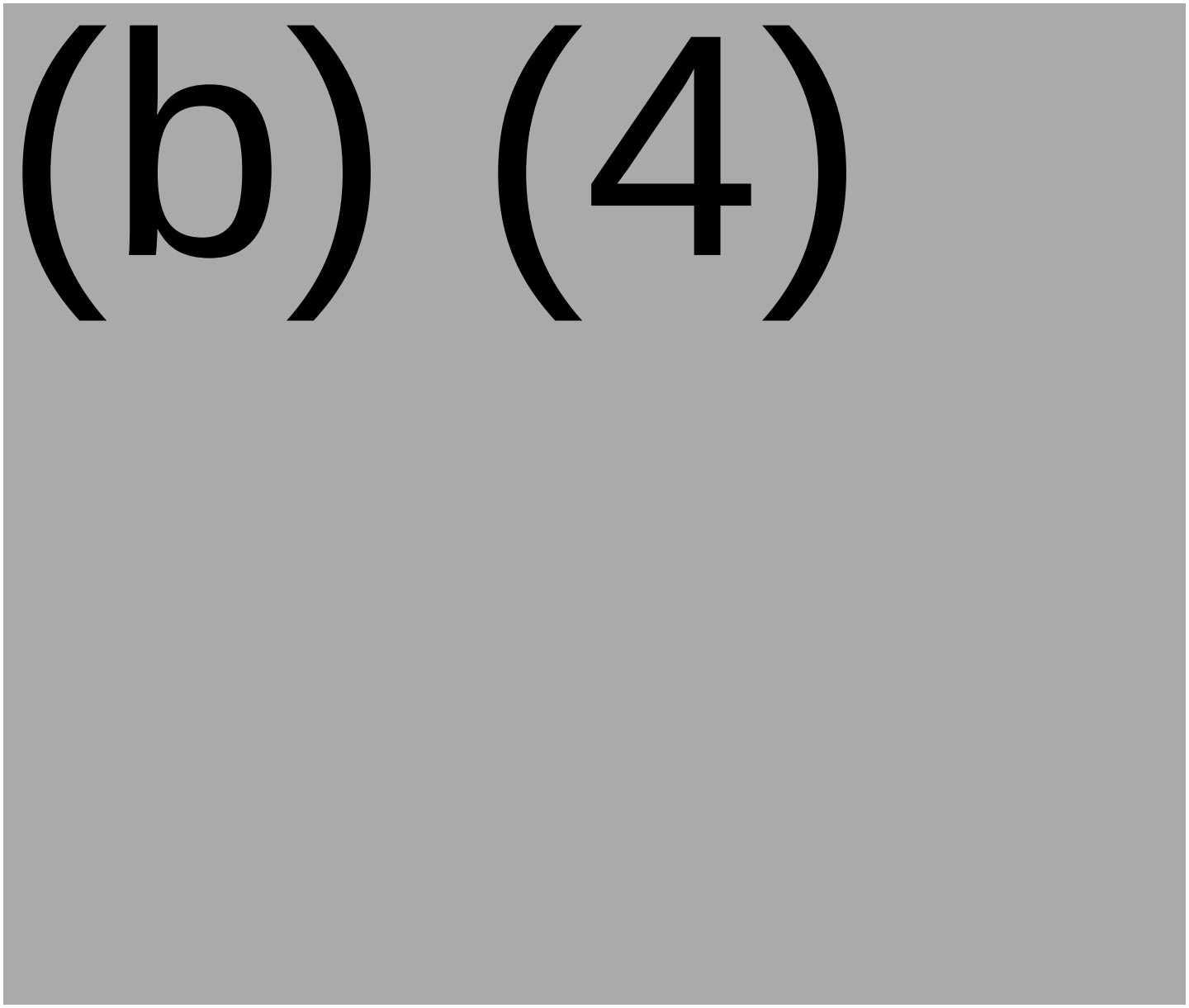
U.S. Fish & Wildlife Service. Listed species believed to or known to occur in Daviess, Kentucky. Accessed November 22, 2024 (2024a) https://ecos.fws.gov/ecp/report/species-listings-by-current-range-county?fips=21059

U.S. Fish & Wildlife Service. Critical habitat for threatened & endangered species. Accessed November 8, 2024 (2024b) https://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77

CONFIDENTIAL APPENDIX 1



CONFIDENTIAL APPENDIX 2



CONFIDENTIAL APPENDIX 3