

**Programmatic Environmental Assessment for  
Marketing Orders for  
Multiple ENDS Tobacco Products  
by  
NJOY LLC**

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

June 14, 2024

**Table of Contents**

- 1. Introduction ..... 3
  - 1.1 Background ..... 3
  - 1.2 Applicant and Manufacturer Information ..... 3
  - 1.3 Product Information ..... 3
- 2. The Need and Purpose for the Proposed Actions..... 4
- 3. Proposed Actions and Alternatives..... 4
- 4. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products..... 4
- 5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products ..... 4
  - 5.1. Affected Environment..... 4
  - 5.2. Air Quality ..... 4
  - 5.3. Environmental Justice ..... 6
  - 5.4. Impacts from the No-Action Alternative ..... 6
- 6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products ..... 7
  - 6.1. Affected Environment..... 7
  - 6.2. Air Quality ..... 7
  - 6.3. Biological Resources ..... 7
  - 6.4. Water Resources and Water Quality ..... 8
  - 6.5. Solid Waste and Hazardous Materials ..... 8
  - 6.6. Socioeconomics and Environmental Justice ..... 9
  - 6.7. Impacts from the No-Action Alternative ..... 9
- 7. List of Preparers ..... 9
- 8. A Listing of Agencies and Persons Consulted ..... 10
- 9. References ..... 10
  
- CONFIDENTIAL APPENDIX 1: Market Volume Projections for the New Products ..... 14**

## 1. Introduction

### 1.1 Background

On March 10, 2020, NJOY LLC submitted premarket tobacco product applications (PMTAs) for two closed e-liquids (NJOY ACE POD MENTHOL 2.4% and NJOY ACE POD MENTHOL 5%). In the PMTAs, NJOY LLC 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 impacts 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 Manufacturer Information

<b>Applicant Name:</b>	NJOY LLC
<b>Applicant Address:</b>	155 6th Ave., 2nd Floor, New York, NY 10013
<b>Manufacturer Name:</b>	(b) (4)
<b>Product Manufacturing Location:</b>	(b) (4)

### 1.3 Product Information

#### New Product Names and Submission Tracking Numbers (STNs)

New Product Name	STN New Product
NJOY ACE POD MENTHOL 2.4%	PM0000616
NJOY ACE POD MENTHOL 5%	PM0000617

#### Product Identification

<b>Product Category</b>	Electronic Nicotine Delivery System (ENDS)
<b>Product Subcategory</b>	ENDS Component, Closed E-Liquid
<b>Product Number per Retail Unit</b>	PM0000616: Two NJOY ACE PODS MENTHOL 2.4%, 1.9mL of e-liquid with 2.4% weight by weight nicotine in each pre-filled POD, sealed, non-refillable, single use.  PM0000617: Two NJOY ACE PODS MENTHOL 5%, 1.9mL of e-liquid with 5% weight by weight nicotine in each pre-filled POD, sealed, non-refillable, single use.
<b>Product Package</b>	Silicone mouthpiece plug, silicone bottom (silicone air inlet plug), a polyvinyl chloride tray sealed on the back by foil, and a printed paper insert.

## **2. 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 tobacco product is a statutory requirement under section 910(c) of the FD&C Act.

## **3. 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 would not be marketed in the United States and, for the purposes of the analysis in this programmatic environmental assessment, it is assumed that there would be no changes to the current ENDS market and no changes to the current or future use of tobacco products.

## **4. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products**

The applicant stated that the manufacturing facility is in compliance with all the applicable environmental regulations. However, because this facility is located outside the United States, environmental impacts associated with manufacturing the new products will not be discussed.

## **5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products**

The Agency considered potential impacts 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 1) for the first- and fifth-year of marketing of the new products.

### **5.1. Affected Environment**

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

### **5.2. Air Quality**

The impacts from use of ENDS products include exposure to second and thirdhand aerosol. Secondhand aerosol is created when an ENDS user exhales mainstream aerosol into the environment (Czogala et al.,

2014). Thirdhand aerosol is created when an ENDS is inhaled and the chemicals in the aerosol, exhaled by the user, deposit on surrounding surfaces (Goniewicz et al., 2015) and clothing (Nath et al., 2020). Studies have shown that secondhand ENDS aerosol contains chemicals such as propylene glycol, glycerol, volatile organic compounds (VOCs), nicotine, particulate matter, and other tobacco-specific nitrosamines (TSNAs) (Tan et al., 2017; Visser et al., 2019). Other studies suggest that for every 70 mL puff, 0.019% of the e-liquid byproduct can deposit on metal, floors, wood, windows, and walls (Davis et al., 2017; Li et al., 2020).

Exposure to secondhand and thirdhand ENDS aerosol may have short- and long-term, adverse effects on human and environmental health. Exposure to nicotine from secondhand aerosol may cause an increase in blood pressure and palpitations (Visser et al., 2019). Heavy metals found in secondhand aerosol from ENDS include chromium, iron, aluminum, lead, copper, nickel, cadmium (Li et al., 2020), and silver (Hess et al., 2016). These metals may cause irritation to the respiratory system and respiratory damage. The aromatic VOCs found in exhaled aerosol include benzene and toluene, listed by the International Agency for Research on Cancer (IARC) as a human carcinogen and a potential neurotoxin, respectively. The carbonyls include formaldehyde (a known carcinogen), acetaldehyde (a potential carcinogen), acetone, acrolein, and propanal. These are considered cytotoxic aldehydes that cause damage to the respiratory system (Li et al., 2020). Exposure to propylene glycol (PG) and glycerol from secondhand aerosol may cause respiratory irritation (Visser et al., 2019). Over time, as PG levels build up in the body, it can cause hemolysis, hypoglycemia, lactic acidosis, seizures, coma, and central nervous system depression (Nath et al., 2020). Tobacco-specific nitrosamines found in secondhand aerosol, such as nicotine-derived nitrosamine ketone (NNK) and N-nitrosornicotine (NNN), are known to cause increased risk of tumor development and cancer (Visser et al., 2019). The levels of nicotine and other chemicals released to the air differ depending on a number of factors including type of device, composition of the e-liquid used, temperature of the heating coil, and power voltage of the device (Li et al., 2020).

Secondhand ENDS aerosol impacts indoor air quality and is not risk-free to bystanders (Palmisani et al., 2019). Although room size, temperature, air exchange rate, and relative humidity have an effect on aerosol dilution, these aerosols do not dilute in the air of enclosed locations (i.e. cars, homes, workplaces) as compared to outdoors (Li et al., 2020). Independent of the e-liquid chosen by the user, the concentration of ultrafine particles found in ENDS aerosol exhaled from the user can be up to 3800 times more concentrated than secondhand smoke from a combusted cigarette (Palmisani et al., 2019). Higher concentrations of smaller particles may place bystanders at increased risk due to the particles' high penetration capacity of the respiratory system (Davis et al., 2017; Palmisani et al., 2019). This may pose a greater risk to other populations such as pregnant women, children, and adolescents (Hess et al., 2016; Palmisani et al., 2019). Short-term exposure to secondhand aerosol may cause respiratory and cardiovascular disease and may adversely affect susceptible populations with respiratory complications such as asthma (Li et al., 2020).

Route of exposure to thirdhand aerosol is achieved through ingestion, (Goniewicz et al., 2015) inhalation, and touch (Goniewicz et al., 2015; Nath et al., 2020). Nicotine exposure from thirdhand aerosol may place children and infants at higher risk of adverse health effects (Goniewicz et al., 2015). Studies show thirdhand aerosol from ENDS including those from e-liquids that do not contain nicotine may compromise immune response, brain, and spleen development (Chen et al., 2020), placing infants at increased risk of disrupting brain development (Nath et al., 2020).

More research is required in order to determine the full health implications that secondhand and thirdhand exposure from ENDS aerosol has on public and environmental health.

As of July 2023, 28 states and the District of Columbia had implemented state-level bans on the use of electronic nicotine delivery systems (ENDS) in many public spaces (American Nonsmokers' Rights Foundation, 2024; Public Health Law Center, 2022). Twenty-five states had state-level regulations on the use of ENDS while at least 40 states had city or county level restrictions on ENDS. Such laws are also expected to reduce the levels of non-users' exposure to secondhand and thirdhand aerosol.

The Agency does not anticipate new chemicals would be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other ENDS products already on the market because (1) the new products are expected to compete with other currently marketed ENDS products, and (2) the ingredients in the new products are used in other currently marketed tobacco products.

### **5.3. Environmental Justice**

Recent studies suggest that ENDS use prevalence is lower among minorities compared to non-Hispanic whites (NHW) (Bello et al., 2019; Centers for Disease Control and Prevention, 2019; Du et al., 2019; Gilbert et al., 2021; McCabe et al., 2020; Roberts et al., 2022). Data from the 2014 and 2018 National Health Interview Survey showed an increase in ENDS ever use among adults in the United States for all races, with the highest prevalence rates observed among NHW adults for both years (Centers for Disease Control and Prevention, 2019). Prevalence rates among minority youth also appear to be lower compared to NHW youth (Bello et al., 2019; Gilbert et al., 2021; McCabe et al., 2020). Data from national surveys show significantly higher use prevalence among NHW adolescents and at schools with higher proportions of NHW students (Gilbert et al., 2021; McCabe et al., 2020). Two studies analyzing data from local and regional surveys reported higher prevalence of ENDS ever use among Hispanics compared to NHW (Barrington-Trimis et al., 2019; Springer et al., 2018). One nationally representative survey reporting higher odds of ENDS use among Hispanics also reported lower odds of use among non-Hispanic Blacks and Asians compared to NHW (Yu et al., 2017).

Studies describing ENDS use by socioeconomic status (SES) reveal inconclusive results. While some studies analyzing nationally representative survey data report inverse associations with household income and educational attainment (Assari et al., 2020; Stallings-Smith et al., 2019), other studies analyzing data from regional and product-specific surveys report positive association with high SES (Du et al., 2019; Roberts et al., 2022; Vallone et al., 2020). Among adolescents, lower parental education and school subjective societal status have been reported to be associated with increased odds of past or current use of ENDS (Bello et al., 2019). Also, ENDS retail landscape poses environmental health risks to youth (Bostean et al., 2016; Giovenco et al., 2016; Venugopal et al., 2020). A recent national analysis reported that specialty vape shops are more densely distributed, and are in closer proximity to schools, in school districts with higher proportions of Asian and Black or African American populations, raising environmental justice and health equity concerns. However, vape shops were further away from schools in school districts with higher proportions of the population in poverty (Venugopal et al., 2020).

At this time, these data do not show disproportionately high ENDS use prevalence among minorities and low-income groups. Therefore, the agency does not anticipate potential disproportionate environmental impacts on Environmental Justice populations from using the new products.

### **5.4. Impacts from the No-Action Alternative**

The environmental impacts of the no-action alternative would not change the existing condition of use of ENDS tobacco products because many similar tobacco products would continue to be used in the United States.

## **6. Potential Environmental Impacts of the Proposed Actions and Alternatives – 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 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 1) for the first- 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 would allow for the new products to be sold to consumers nationwide who would dispose of the used products and packaging as municipal solid waste (MSW), recycled material, or litter.

### **6.2. 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.

No changes in air quality are anticipated from disposal of the new products. The chemicals in the ENDS pods are not likely to be emitted to the air in any distinguishable amount because these are closed systems. Although littering of the e-liquid pods may cause some of the e-liquid to leach into the environment, the majority of e-liquid will be consumed by the user, leaving only trace amounts remaining in the pod that may leach out and be emitted to the air.

No changes in air quality from disposal of the packaging materials in the new products would be expected because (1) the paper and plastic 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 MSW based on the projected market volume of the new products.

### **6.3. Biological Resources**

Proper disposal of the used new products and packaging in the MSW 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 products and hazardous substances leaching to aquatic environments and soils. E-liquid is composed of several chemicals that may leach into the environment if not properly disposed. In general, e-liquids are composed of a base, which is typically PG and vegetable glycerin, as well as nicotine and flavorants (Dai et al., 2018; DeVito et al., 2018), vanillin, ethyl maltol, and ethyl butyrate being the most common flavoring ingredients (Krüseemann et al., 2021). Leaching of chemical constituents in e-liquids from the disposal or littering of used cartridges is of environmental concern (Baran et al., 2020; Chang, 2014; Panitz et al., 2015). Further, transfer of metals from the cartridge or device into the e-liquid also raises potential environmental concerns (Hess et al., 2017; Zervas et al., 2020). At the time of writing this environmental assessment, studies identifying and characterizing environmental impacts of ENDS leachate are not available. While other flavorants and chemicals may be present in e-liquids, their concentration is typically low. Furthermore, although users may dispose of used cartridges improperly as litter, the majority of e-liquid will be consumed, leaving only trace amounts to potentially leach into the environment. Therefore, to the best of our knowledge, no significant environmental impacts are expected due to disposal of the new products.

#### **6.4. Water Resources and Water Quality**

Proper disposal of the used new products and packaging in the MSW 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 would be expected because the new products will continue to compete for the same market share occupied by other currently marketed ENDS products. Additionally, although littering of the e-liquid pods may cause some of the e-liquid to leach into the environment, the majority of e-liquid will be consumed by the user, leaving only trace amounts left in the pod. Nicotine is especially concerning because it is considered hazardous waste, (U.S. Environmental Protection Agency, 2023) however, little is expected to remain in littered pods and nicotine has a very short half-life on the order of hours to days, (Seckar et al., 2008) depending on the media it is in. Therefore, these impacts are not considered significant.

#### **6.5. Solid Waste and Hazardous Materials**

Requirements for disposal of e-liquid cartridges containing nicotine vary by state and collecting entity responsible for disposal. EPA has the authority to control hazardous waste from “cradle-to-grave” under the Resource Conservation and Recovery Act (RCRA) in 40 CFR Parts 260 through 273 (U.S. Environmental Protection Agency, 2021c). Under Subtitle C of RCRA, nicotine (including nicotine salts) is regulated as an acute hazardous waste (U.S. Environmental Protection Agency, 2023). Cartridges containing nicotine must be handled according to applicable federal, state, and local regulations. Additional laws may apply, including 40 CFR Part 266 Subpart P, where ENDS products containing nicotine must be managed as hazardous waste pharmaceuticals (U.S. Environmental Protection Agency, 2023).

Non-residential disposal of e-liquid cartridges containing nicotine is the responsibility of the collecting entity (e.g. schools, airports, etc.), which EPA considers “generators” of hazardous waste by accumulating RCRA-listed chemicals (U.S. Environmental Protection Agency, 2022a). Due to nicotine being considered an acute hazardous waste, generators are registered as either a very small quantity generator or large quantity generator based on a threshold of one kilogram generated per month (U.S. Environmental Protection Agency, 2022a). Following collection by state or local authorities, hazardous waste is recycled, treated, stored, or disposed (U.S. Environmental Protection Agency, 2021b).

Residential disposal (household hazardous waste) of e-liquids containing nicotine is excluded from Subtitle C of RCRA. Residential disposal is regulated under Subtitle D of RCRA as non-hazardous solid waste, 40 CFR parts 239 through 259 (U.S. Environmental Protection Agency, 2021a). Additional state and local laws may apply for disposal.

Improper disposal of e-liquids can pose a threat to the environment; therefore, cartridges containing nicotine or nicotine residue should not be rinsed (U.S. Environmental Protection Agency, 2024). Additionally, cartridges should be stored in a cool, temperature controlled environment (U.S. Environmental Protection Agency, 2024) and separated from the ENDS device prior to disposal, as nicotine is combustible when exposed to heat (National Institute for Occupational Safety and Health, 2011) and lithium-ion batteries have been linked to explosions during MSW transportation (U.S. Environmental Protection Agency, 2024). As of May 2021, the Agency did not find any data reporting the amount of ENDS products containing nicotine collected or littered in the United States; however, the *Marine Debris Tracker* mobile application allows individuals to track debris in the United States (National Oceanic and Atmospheric Administration, 2023). At this time, the Agency does not anticipate any significant impacts due to cartridge disposal.

Non-residential entities that accumulate or transport universal waste and specialized universal waste destination facilities are considered by EPA as universal waste “handlers” (U.S. Environmental Protection Agency, 2022b). Handling and disposal requirements depend on how much universal waste a handler accumulates at any one time; handlers are classified as either small quantity handlers or large quantity handlers based on a threshold of 5,000 or more kg of accumulated universal waste. Once it reaches a universal waste destination facility, universal waste is recycled, treated, or disposed (U.S. Environmental Protection Agency, 2022b).

The Agency does not foresee that the introduction of the new products into the U.S. market would notably affect the nationwide waste generated from the use of ENDS products. The distribution of waste generated due to disposal of the new products and packaging is anticipated to correspond to the pattern of the product use in the United States. Therefore, no net increase in littering would be expected.

#### **6.6. Socioeconomics and Environmental Justice**

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products would be handled in the same manner as the waste generated from disposal of other ENDS products in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations.

#### **6.7. Impacts from the No-Action Alternative**

The environmental impacts of the no-action alternative would not change the existing condition of disposal of ENDS products and their packaging, as many other similar ENDS products would continue to be disposed of in the United States.

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

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

#### ***Preparer:***

Ronald L. Edwards Jr., MS, Center for Tobacco Products

Education: MS in Biology

Experience: Twenty-eight years in environmental regulation and six years in laboratory toxicology

Expertise: NEPA analysis, heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

#### ***Reviewer:***

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-eight years in various scientific activities including twelve years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

## 8. A Listing of Agencies and Persons Consulted

Not applicable.

## 9. References

- American Nonsmokers' Rights Foundation. States and municipalities with laws regulating use of electronic cigarettes. Accessed March 28, 2024. <https://no-smoke.org/wp-content/uploads/pdf/ecigslaws.pdf>
- Assari S, Mistry R, Bazargan M. Race, educational attainment, and e-cigarette use. *J. Med. Res. Innov.* 2020;4(1):e000185.
- Baran W, Madej-Knysak D, Sobczak A, Adamek E. The influence of waste from electronic cigarettes, conventional cigarettes and heat-not-burn tobacco products on microorganisms. *J. Hazard. Mater.* 2020;385:121591.
- Barrington-Trimis JL, Bello MS, Liu F, Leventhal AM, Kong G, Mayer M, Cruz TB, Krishnan-Sarin S, McConnell R. Ethnic differences in patterns of cigarette and e-cigarette use over time among adolescents. *J. Adolesc. Health.* 2019;65:359-365.
- Bello MS, Khoddam R, Stone MD, Cho J, Yoon Y, Lee JO, Leventhal AM. Poly-product drug use disparities in adolescents of lower socioeconomic status: emerging trends in nicotine products, marijuana products, and prescription drugs. *Behav. Res. Ther.* 2019;115:103-110.
- Bostean G, Crespi CM, Vorapharuek P, McCarthy WJ. E-cigarette use among students and e-cigarette specialty retailer presence near schools. *Health Place.* 2016;42:129-136.
- Centers for Disease Control and Prevention. QuickStats: age-adjusted percentage of adults who had ever used an e-cigarette, by race and ethnicity — National Health Interview Survey, United States, 2014 and 2018. *Morb. Mortal. Wkly. Rep.* 2019;68:1102.
- Chang H. Research gaps related to the environmental impacts of electronic cigarettes. *Tob. Control.* 2014;23(Suppl 2):ii54-ii58.
- Chen H, Li G, Allam VSRR, Wang B, Chan YL, Scarfo C, Ueland M, Shimmon R, Fu S, Foster P, Oliver BG. Evidence from a mouse model on the dangers of thirdhand electronic cigarette exposure during early life. *ERJ Open Res.* 2020;6(2):00022-2020.
- Czogala J, Goniewicz M, Fidelus B, Zielinska-Danch W, Travers M, Sobczak A. Secondhand exposure to vapors from electronic cigarettes. *Nicotine Tob. Res.* 2014;16(6):655-662.
- Dai J, Kim KH, Szulejko JE, Jo SH, Kwon K, Choi DW. Quantification of nicotine and major solvents in retail electronic cigarette fluids and vaped aerosols. *Microchem. J.* 2018;140:262-268.
- Davis ES, Sassano MF, Goodell H, Tarran R. E-liquid autofluorescence can be used as a marker of vaping deposition and third-hand vape exposure. *Sci. Rep.* 2017;7(1):7459.
- DeVito EE, Krishnan-Sarin S. E-cigarettes: impact of e-liquid components and device characteristics on nicotine exposure. *Curr. Neuropharmacol.* 2018;16(4):438-459.

Du Y, Shih M, Shah MD, Weber MD, Lightstone AS. Prevalence and sociodemographic disparities in ever e-cigarette use among adults in Los Angeles County. *Prev. Med. Rep.* 2019;15:100904.

Gilbert PA, Kava CM, Afifi R. High-school students rarely use e-cigarettes alone: A sociodemographic analysis of polysubstance use among adolescents in the United States. *Nicotine Tob. Res.* 2021;23(3):505-510.

Giovenco DP, Casseus M, Duncan DT, Coups EJ, Lewis MJ, Delnevo CD. Association between electronic cigarette marketing near schools and e-cigarette use among youth. *J. Adolesc. Health.* 2016;59(6):627-634.

Goniewicz M, Lee L. Electronic cigarettes are a source of thirdhand exposure to nicotine. *Nicotine Tob. Res.* 2015;17(2):256-258.

Hess CA, Olmedo P, Navas-Acien A, Goessler W, Cohen JE, Rule AM. E-cigarettes as a source of toxic and potentially carcinogenic metals. *Environ. Res.* 2017;152:221-225.

Hess IM, Lachireddy K, Capon A. A systematic review of the health risks from passive exposure to electronic cigarette vapour. *Public Health Res. Pract.* 2016;26(2):2621617.

Krüsemann EJZ, Havermans A, Pennings JLA, de Graaf K, Boesveldt S, Talhout R. Comprehensive overview of common e-liquid ingredients and how they can be used to predict an e-liquid's flavour category. *Tob. Control.* 2021;30:185-191.

Li L, Lin Y, Xia T, Zhu Y. Effects of electronic cigarettes on indoor air quality and health. *Annu. Rev. Public Health.* 2020;41:363-380.

McCabe SE, Boyd CJ, Evans-Polce RJ, McCabe VV, Veliz PT. School-level prevalence and predictors of e-cigarette use in 8th, 10th, and 12th grade U.S. youth: results from a national survey (2015–2016). *J. Adolesc. Health.* 2020;67(4):531-541.

Nath S, Geraghty P. Should we worry about children's exposure to third-hand by-products generated from electronic nicotine delivery systems? *ERJ Open Res.* 2020;6(2)

National Institute for Occupational Safety and Health. Nicotine: systemic agent. Accessed March 28, 2024. [https://www.cdc.gov/niosh/ershdb/emergencyresponsecard\\_29750028.html](https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750028.html)

National Oceanic and Atmospheric Administration. Marine Debris Tracker App. Office of Response and Restoration. Accessed March 28, 2024. <https://marinedebris.noaa.gov/partnerships/marine-debris-tracker>

Palmisani J, Di Gilio A, Palmieri L, Abenavoli C, Famele M, Draisci R, de Gennaro G. Evaluation of second-hand exposure to electronic cigarette vaping under a real scenario: measurements of ultrafine particle number concentration and size distribution and comparison with traditional tobacco smoke. *Toxics.* 2019;7(4):59.

Panitz D, Swamy H, Nehrke K. A C. elegans model of electronic cigarette use: physiological effects of e-liquids in nematodes. *BMC Pharmacol. Toxicol.* 2015;16:32.

Public Health Law Center. U.S. e-cigarette regulation: a 50-state review. Mitchell Hamline School of Law. Accessed March 28, 2024. <https://www.publichealthlawcenter.org/resources/us-e-cigarette-regulations-50-state-review>

Roberts ME, Keller-Hamilton B, Ferketich AK, Berman L. Juul and the upsurge of e-cigarette use among college undergraduates. *J. Am. Coll. Health*. 2022;70(1):9-12.

Seckar JA, Stavanja MS, Harp PR, Yi Y, Garner CD, Doi J. Environmental fate and effects of nicotine released during cigarette production. *Environ. Toxicol. Chem*. 2008;27:1505-1514.

Springer AE, Davis C, Van Dusen D, Grayless M, Case KR, Craft M, Kelder SH. School socioeconomic disparities in e-cigarette susceptibility and use among central Texas middle school students. *Prev. Med. Rep*. 2018;11:105-108.

Stallings-Smith S, Ballantyne T. Ever use of e-cigarettes among adults in the United States: a cross-sectional study of sociodemographic factors. *Inquiry*. 2019;56:46958019864479.

Tan A, Mello S, Sanders-Jackson A, Bigman C. Knowledge about chemicals in e-cigarette secondhand vapor and perceived harms of exposure among a national sample of U.S. adults. *Risk Anal*. 2017;37(6):1170-1180.

U.S. Environmental Protection Agency. Household hazardous waste (HHW). Accessed March 28, 2024. <https://www.epa.gov/hw/household-hazardous-waste-hhw>

U.S. Environmental Protection Agency. Learn the basics of hazardous waste. Accessed March 28, 2024. <https://www.epa.gov/hw/learn-basics-hazardous-waste>

U.S. Environmental Protection Agency. Resource Conservation and Recovery Act (RCRA) Overview. Accessed March 28, 2024. <https://www.epa.gov/rcra/resource-conservation-and-recovery-act-rcra-overview>

U.S. Environmental Protection Agency. Categories of hazardous waste generators. Accessed March 28, 2024. <https://www.epa.gov/hwgenerators/categories-hazardous-waste-generators>

U.S. Environmental Protection Agency. National overview: facts and figures on materials, wastes and recycling. Accessed March 28, 2024. <https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/national-overview-facts-and-figures-materials#Generation>

U.S. Environmental Protection Agency. Where are the management standards for hazardous waste pharmaceuticals and amendment to the P075 listing for nicotine in effect? Accessed March 28, 2024. <https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>

U.S. Environmental Protection Agency. How to Safely Dispose of E-Cigarettes: Information for Individuals Accessed March 28, 2024. <https://www.epa.gov/hw/how-safely-dispose-e-cigarettes-information-individuals>

Vallone DM, Cuccia AF, Briggs J, Xiao H, Schillo BA, Hair EC. Electronic cigarette and JUUL use among adolescents and young adults. *JAMA Pediatr*. 2020;174(3):277-286.

Venugopal PD, Morse AL, Tworek C, Chang HW. Socioeconomic disparities in vape shop density and proximity to public schools in the conterminous United States, 2018. *Health Promot. Pract.* 2020;21(Suppl 1):9S-17S.

Visser WF, Klerx WN, Cremers HWJM, Ramlal R, Schwillens PL, Talhout R. The health risks of electronic cigarette use to bystanders. *Int. J. Environ. Res. Public Health.* 2019;16(9):1525.

Yu E, Lippert AM. Race/ethnicity modifies the association between school prevalence of e-cigarette use and student-level use: results from the 2014 US National Youth Tobacco Survey. *Health Place.* 2017;46:114-120.

Zervas E, Matsouki N, Kyriakopoulos G, Pouloupoulos S, Ioannides T, Katsaounou P. Transfer of metals in the liquids of electronic cigarettes. *Inhal. Toxicol.* 2020;32(6):240-248.

**CONFIDENTIAL APPENDIX 1: Market Volume Projections for the New Products**

Product	Unit	Market Volume Projections	
		First-Year	Fifth-Year
NJOY ACE POD MENTHOL 2.4%	PODS	(b)	(4)
NJOY ACE POD MENTHOL 5%	PODS	(b)	(4)
<b>Total</b>			