

Governor

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Guidance for Vapor Product and E-cigarette Manufacturers Regarding Ingredient Disclosure

Ingredient disclosure requirements for vapor product and electronic cigarette (ecigarette) manufacturers went into effect on <u>July 1, 2020</u>. Regulations were adopted on May 18, 2022 to implement these requirements. This document is intended to provide a guide to compliance with the law and regulations.

What has changed?

Beginning January 1, 2021, <u>Public Health Law Article 17</u>, <u>Section 1701</u> requires manufacturers of vapor products or e-cigarettes distributed, sold, or offered for sale in New York State to disclose ingredient information on their public facing website and to the Commissioner of Health. The regulations that were adopted to implement this law can be found in <u>Part 1006 of Title 10</u> of the Official Compilation of Codes, Rules, and Regulations of the State of New York.

What is the intent of the law?

The intent of the law is to inform consumers more accurately about the ingredients and contents of vapor products and e-cigarettes, and to protect public health in the event such ingredients include chemicals of concern, identified by the Commissioner of Health.

What constitutes a chemical of concern?

The regulation identifies chemicals of concern based on their being included in the regulation or by reference to existing lists of chemicals from the U.S. Food and Drug Administration (FDA). Links to these lists can be found below, and a full list of chemicals of concern as they relate to this regulation can be found in Attachment A of this document.

<u>U.S. FDA Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List (April 2012)</u>

<u>U.S. FDA Harmful and Potentially Harmful Constituents in Tobacco Products;</u>
 <u>Established List; Proposed Additions (Federal Register August 5, 2019, Vol. 84, No. 150, Pg. 38032)</u>

How can manufacturers of vaping and e-cigarette products comply?

Manufacturers must disclose the following information on their public-facing website for each product that is distributed, sold, or offered for sale in New York State:

Vaping Products		
Ingredients	Chemicals of Concern	Health-related Research
For each product: • All intentionally added ingredients, • Known by-products or contaminants that are ≥0.5% by weight, and • Known by-products or contaminants that have been identified as chemicals of concern, regardless of content by weight.	For each product that contains a chemical of concern: • A statement that the ingredient is a chemical of concern. • An evaluation of the availability of potential alternatives and potential hazards of the alternatives.	A summary of the nature and extent of investigations and research on human health effects of the product or its ingredients.
E-Cigarette Devices		
Toxic Metals	Alternatives Evaluation	Health-related Research
For each product: • Identify if the heating element contains a toxic metal such as aluminum, antimony, arsenic, cadmium, cobalt, chromium, copper, iron, lead, manganese, nickel, selenium, tin, or zinc.	For each product that contains a toxic metal: • An evaluation of the availability of potential alternatives and potential hazards of the alternatives for the toxic metal.	A summary of the nature and extent of investigations and research on human health effects of the product or its ingredients or components.
Vapor Produced During Normal Use of Products By-products Chemicals of Concern Health-related Research		
By-products For each product: • A list of by-products, including metals, known by the manufacturer to be in the vapor produced during consumption of the vapor product.	Chemicals of Concern For each product that produces a chemical of concern in the vapor: • A statement that the byproduct is a chemical of concern. • An evaluation of the availability of potential alternatives and potential hazards of the alternatives.	A summary of the nature and extent of investigations and research on human health effects of the vapor produced by the product.

- The ingredients must be listed in descending order of predominance by weight, except those ingredients at a weight below one percent may be listed following other ingredients without respect to the order of predominance by weight.
- The ingredients list must contain the ingredient name and Chemical Abstracts Service (CAS) Registry Number, if one has been assigned.

- If any ingredients are being withheld as proprietary information, the manufacturer
 must include a statement clearly stating that disclosure of one or more
 ingredients has been withheld as proprietary information. Chemicals cannot be
 withheld as proprietary information if they are listed as a chemical of
 concern.
- The most recent date on which information was posted or updated on the website must be included.

<u>Are there requirements for how this information is provided on the manufacturer's website?</u>

- All information should be posted on the manufacturer's main website, domain name or URL used to communicate with consumers, or on a separate website, domain name or URL. Such site should be no more than one "click" away from the home page of the manufacturer's main website.
- All information should be posted in a form that is readily accessible to all users.
 Users should not be required to register or provide personally identifiable
 information to gain access. Access to information should not be limited through
 using CAPTCHA or similar challenge-response test technologies, visual,
 auditory, or otherwise. Information disclosed should not be restricted from
 indexing by search engines, such as Google and Bing.
 - The website is permitted to have the user attest to being of a legal age to purchase the product(s).
- All information should be machine readable by automated systems, including, but not limited to, web browsers, accessibility software to aid the disabled, automated scripts, and other software programs or applications. Research documents can be posted as PDFs but should strive to meet these recommendations to the maximum extent practicable.
- All posted information should conform to the most current version of the Web Content Accessibility Guidelines (WCAG) adopted by the WCAG Working Group of the World Wide Web Consortium. Version 2.0 of the WCAG has been adopted as a standard by the International Organization for Standardization (ISO) (ISO/IEC 40500:2012). WCAG Guideline 4.1 "Maximize compatibility with current and future user agents, including assistive technologies" describes how to validate conformance with the Guidelines. Technologies that prevent data from being machine read or browsed are not acceptable. Research documents can be posted as PDFs but should strive to meet these accessibility recommendations to the maximum extent practicable.

- Information should be posted in English. Posting information in multiple additional languages, including Spanish and the other 10 most common languages spoken in New York State, is encouraged.
- Products with different ingredient formulations, for example, different flavoring ingredients, should be listed as separate products. Products with identical ingredient formulations, but in different size packages, can be listed as one product.

What information must be disclosed to the NYS Department of Health?

Manufacturers must disclose the following information to the Department of Health for each product that is distributed, sold, or offered for sale in the state. This information can be submitted at doh.sm.VapingIngredientDisclosure@health.ny.gov.

- Manufacturer information, including the complete name of the manufacturer of the final product and the final domestic distributor of the product (if they are different).
- Name, title, email address, telephone number and mailing address for the manufacturer, domestic distributor, or agent submitting ingredient information on behalf of a manufacturer or domestic distributor.
- The facility establishment identifier number assigned to your establishment by the U.S. FDA.
- A list of vapor products or e-cigarettes that are currently sold or will be sold in New York including any additional identifiers needed to identify the product (e.g., stock-keeping units, Universal Product Codes, catalog numbers).
- A link to the webpage where manufacturers are providing disclosure to the public of the ingredients for each product and any investigations or research into the effects on human health of such products or ingredients.
- A full disclosure of all chemicals in each product even if the chemicals are being withheld as proprietary information. Chemicals cannot be withheld as proprietary information if they are listed as a chemical of concern.
- A full disclosure of toxic metals used in the heating element for e-cigarette products.
- A full disclosure of chemicals that are known by the manufacturer to be present in the aerosol of the product.
- A statement, if applicable, that disclosure for one or more ingredients has been withheld as proprietary information to protect the manufacturers competitive position.

<u>Is there a requirement to test for the presence of these chemicals of concern in each product?</u>

No. The regulation does not require that manufacturers test for the presence of these chemicals of concern in each product. If the manufacturer has knowledge of the presence of these chemicals in their product(s) or produced in the vapor through normal use of the product(s), they must be included in the ingredient disclosure list with a statement that they have been identified as a chemical of concern.

Is an alternatives evaluation required for all chemicals of concern?

An evaluation of alternatives is required for all chemicals of concern or toxic metals used in the product(s) that the manufacturer will be distributing, selling, or offering for sale in the state. Manufacturers are not required to provide an alternatives evaluation for chemicals or toxic metals that are not contained in their products.

<u>Is a summary of the health-related research acceptable?</u>

Yes, a summary of the health-related research is acceptable if it identifies the studies, reasons for the studies, and study outcome(s).

What would be considered proprietary information with respect to these disclosure requirements?

Section 1006.3 of the regulation defines what may be considered proprietary information with respect to these disclosure requirements. It is important to note that any chemical that has been identified as a chemical of concern for the purpose of these disclosures cannot be held as proprietary information. If any of these chemicals are contained in the vapor products or e-cigarettes that are being sold in New York State; or if they are known to be emitted through the vapor during normal use of the product, they must be disclosed to the public on the manufacturer's website with a note that the chemical has been identified as a chemical of concern.

More information:

New York State Department of Health Bureau of Toxic Substance Assessment doh.sm.VapingIngredientDisclosure@health.ny.gov

Attachment A

Chemicals of Concern for the Purpose of Vaping and E-cigarette Ingredient Disclosures

Identified in the Regulation:

Vitamin E acetate

U.S. FDA Harmful or Potentially Harmful Constituent – Established List

Acetaldehyde

Acetamide

Acetone

Acrolein

Acrylamide

Acrylonitrile

Aflatoxin B1

4-Aminobiphenyl

1-Aminonaphthalene

2-Aminonaphthalene

Ammonia

Anabasine

o-Anisidine

Arsenic

 $A-\alpha-C$ (2-Amino-9H-pyrido[2,3-b]indole)

Benz[a]anthracene

Benz[j]aceanthrylene

Benzene

Benzo[b]fluoranthene

Benzo[k]fluoranthene

Benzo[b]furan

Benzo[a]pyrene

Benzo[c]phenanthrene

Beryllium

1,3-Butadiene

Cadmium

Caffeic acid

Carbon monoxide

Catechol

Chlorinated dioxins/furans

Chromium

Chrysene

Cobalt

Coumarin

Cresols (o-, m-, and p-cresol)

Crotonaldehyde

Cyclopenta[c,d]pyrene

U.S. FDA Harmful or Potentially Harmful Constituent – Established List (continued)

Dibenz[a,h]anthracene

Dibenzo[a,e]pyrene

Dibenzo[a,h]pyrene

Dibenzo[a,i]pyrene

Dibenzo[a,l]pyrene

2,6-Dimethylaniline

Ethyl carbamate (urethane)

Ethylbenzene

Ethylene oxide

Formaldehyde

Furan

Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole)

Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]imidazole)

Hydrazine

Hydrogen cyanide

Indeno[1,2,3-cd]pyrene

IQ (2-Amino-3-methylimidazo[4,5-f]quinoline)

Isoprene

Lead

MeA- α -C (2-Amino-3-methyl)-9H-pyrido[2,3-b]indole)

Mercury

Methyl ethyl ketone

5-Methylchrysene

4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)

Naphthalene

Nickel

Nicotine

Nitrobenzene

Nitromethane

2-Nitropropane

N-Nitrosodiethanolamine (NDELA)

N-Nitrosodiethylamine

N-Nitrosodimethylamine (NDMA)

N-Nitrosomethylethylamine

N-Nitrosomorpholine (NMOR)

N-Nitrosonornicotine (NNN)

N-Nitrosopiperidine (NPIP)

N-Nitrosopyrrolidine (NPYR)

N-Nitrososarcosine (NSAR)

Nornicotine

Phenol

PhIP (2-Amino-1-methyl-6-phenylimidazo[4,5-b]pyridine)

Polonium-210

U.S. FDA Harmful or Potentially Harmful Constituent – Established List (continued)

Propionaldehyde

Propylene oxide

Quinoline

Selenium

Styrene

o-Toluidine

Toluene

Trp-P-1 (3-Amino-1,4-dimethyl-5H-pyrido[4,3-b]indole)

Trp-P-2 (1-Methyl-3-amino-5H-pyrido[4,3-b]indole)

Uranium-235

Uranium-238

Vinyl acetate

Vinyl chloride

U.S. FDA Harmful or Potentially Harmful Constituent – Proposed Additions

Acetic acid

Acetoin

Acetyl propionyl

Benzyl acetate

Butyraldehyde

Diacetyl

Diethylene glycol

Ethyl acetate

Ethyl acetoacetate

Ethylene glycol

Furfural

Glycerol

Glycidol

Isoamyl acetate

Isobutyl acetate

Methyl acetate

n-Butanol

Propionic acid

Propylene glycol