

Pursuant to the authority vested in the Commissioner of Health by section 1701 of the Public Health Law, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to add a new Chapter XIV, Part 1006 to be effective upon publication of a Notice of Adoption in the New York State Register.

A new Chapter XIV, Part 1006 is added to read as follows:

Chapter XIV Vapor Products

Part 1006. Ingredient Disclosures for Vapor Products and E-Cigarettes

1006.1. Definitions.

As used in this Part:

(a) "Vapor products" shall mean any vapor product, as defined by Public Health Law § 1399-aa, intended or reasonably expected to be used with or for the consumption of nicotine.

(b) "Electronic cigarette" or "e-cigarette" shall mean an electronic cigarette or e-cigarette as defined by Public Health Law § 1399-aa, intended, or reasonably expected to be used with or for the consumption of nicotine. This will include heat-not-burn devices that heat tobacco below the point of combustion, releasing an aerosol that is inhaled by the user.

(c) "Ingredient" shall mean each of the following:

- (1) any intentionally added ingredient present in any quantity in a vapor product;
- (2) a byproduct or contaminant, present in a vapor product in any quantity equal to or greater than one-half of one percent of the content of such product by weight;

(3) a byproduct present in a vapor product in any quantity less than one-half of one percent of the content of such product by weight, provided such element or compound is a chemical of concern; and

(4) a contaminant present in a vapor product in any quantity less than one-half of one percent of the content of such product by weight, provided such element or compound is a chemical of concern.

(d) "Intentionally added ingredient" shall mean any element or compound that a manufacturer has intentionally added to a vapor product at any point in such product's supply chain, or at any point in the supply chain of any raw material or ingredient used to manufacture such product.

(e) "Byproduct" shall mean any element or compound in the finished vapor product, or in the vapor produced during consumption of a vapor product, which:

(1) was created or formed during the manufacturing process as an intentional or unintentional consequence of such manufacturing process at any point in such product's supply chain, or at any point in the supply chain of any raw material or ingredient used to manufacture such product; or

(2) is created or formed as an intentional or unintentional consequence of the use of an e-cigarette or consumption of a vapor product. "Byproduct" shall include, but is not limited to, an unreacted raw material, a breakdown product of an intentionally added ingredient, a breakdown product of any component part of an e-cigarette, or a derivative of the manufacturing process.

(f) "Contaminant" shall mean any element or compound present in a vapor product as an unintentional consequence of manufacturing. Contaminants include, but are not limited to, elements or compounds present in the environment which were introduced into a product, a raw material, or a product ingredient as a result of the use of an environmental medium, such as naturally occurring water, or other materials used in the manufacturing process at any point in a product's supply chain, or at any point in the supply chain of any raw material or ingredient used to manufacture such product.

(g) "Manufacturer" shall mean any person, firm, association, partnership, limited liability company, or corporation which produces, prepares, formulates, or compounds a vapor product or e-cigarette, or whose brand name is affixed to such product. In the case of a vapor product or e-cigarette imported into the United States, "manufacturer" shall mean the importer or first domestic distributor of such product if the entity that manufactures such product or whose brand name is affixed to such product does not have a presence in the United States.

(h) "Chemical of Concern" shall mean vitamin E acetate (CAS RN 7695-91-2) as well as any element or compound identified on the following lists:

(1) United States Food and Drug Administration's Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke, as published in the Federal Register on April 3, 2012 (77 Fed. Reg. 20034 – 20037) and available for public inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237; and

(2) United States Food and Drug Administration’s proposed additions to the Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke as published in the Federal Register on August 5, 2019 (84 Fed. Reg. 38032 – 38035) and available for public inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, NY 12237.

(i) “Toxic metal” shall mean any metal that has been shown to be present in vaping liquid, e-cigarette aerosols, cause adverse human health effects following exposure, and/or found in human biomonitoring. This shall include, but not be limited to aluminum, antimony, arsenic, cadmium, cobalt, chromium, copper, iron, lead, manganese, nickel, selenium, tin, and zinc.

1006.2. Ingredient Disclosure

(a) Manufacturers of vapor products or e-cigarettes distributed, sold, or offered for sale in this state, whether at retail or wholesale, shall furnish to the Commissioner for public record and post on such manufacturer's website, in a machine-readable format, the information described in this Section.

(b) (1) For each vapor product, the information posted pursuant to this section shall include, at a minimum:

(i) Manufacturer information including name and address of the business entity and contact information for a point-of-contact, including name, address, telephone number, and email address.

(ii) A list naming each ingredient of such vapor product. The ingredients must be listed in descending order of predominance by weight in such product, except that ingredients

present at a weight below one percent may be listed following other ingredients without respect to the order of predominance by weight.

(iii) The nature and extent of investigations and research performed by or for the manufacturer concerning the effects on human health of such product or its ingredients. This includes but is not limited to health-related documents required by section 387d of Title 21 of the United States Code (a copy of which is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237). Any investigations and research that was developed after the required submission of health-related documents to the United States Food and Drug Administration must also be posted.

(iv) Where applicable, a statement disclosing that an ingredient of such product is a chemical of concern.

(v) For each ingredient that is a chemical of concern, an evaluation of the availability of potential alternatives and potential hazards posed by such alternatives.

(2) For each e-cigarette, the information posted pursuant to this section shall include, but shall not be limited to:

(i) Manufacturer information including name and address of the business entity and contact information for a point-of-contact, including name, address, telephone number, and email address.

(ii) A list naming any toxic metal as a constituent of any heating element included in such e-cigarette.

(iii) A list naming each byproduct that may be introduced into vapor produced during the normal use of such e-cigarette.

(iv) The nature and extent of investigations and research performed by or for the manufacturer, or that the manufacturer is aware of, concerning the effects on human health of such product or such ingredients. This includes but is not limited to health-related documents required by section 387d of Title 21 of the United States Code (a copy of which is available for copying and inspection at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237). Any investigations and research that was developed after the required submission of health-related documents to the United States Food and Drug Administration must also be posted.

(v) Where applicable, a statement disclosing that an ingredient is published as a chemical of concern.

(vi) For each constituent of any heating element identified as a toxic metal and ingredient published as a chemical of concern, an evaluation of the availability of potential alternatives and potential hazards posed by such alternatives.

1006.3 Proprietary Information

(a) For purposes of this Part only, proprietary information may consist of any information subject to disclosure pursuant to this Part the disclosure of which would compromise a manufacturer's competitive position. Any proprietary information submitted or divulged to the Department of Health pursuant to this Part shall not be available for, or subject to, public disclosure. Proprietary information shall include, but is not limited to, any:

(1) Commercially valuable plan, formula, process, or device that is used for the making,

preparing, or processing of vapor products, e-cigarettes, or their components, and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the proprietary information and the productive process; or

(2) Valuable data or information which is used in a manufacturer's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

(b) A manufacturer submitting information to the Department pursuant to this Part may designate part or all of the information in such records as exempt from disclosure. The Manufacturer may make this designation either at the time the records are submitted to the Department or within a reasonable time thereafter. Such designation must be in writing and must set forth the reasons why the information should be excepted from disclosure as proprietary information, including, as appropriate:

- (1) the specific information requested to be considered proprietary information, including, where applicable, page, form, line, chart or table designation;
- (2) the confidential nature of the record, including a description of the nature and extent of the injury to the manufacturer's competitive position such as unfair economic or competitive damage which would be incurred were the information to be disclosed;
- (3) whether the information is treated as confidential by the manufacturer, including whether it has been made available to any other manufacturer or to the public;
- (4) whether any patent, copyright, or similar legal protection exists for the information;
- (5) whether the public disclosure of such information is otherwise restricted by law, and the specific source and contents of such restrictions;

(6) the date upon which such information will no longer need to be kept confidential, if applicable;

(7) whether the request itself constitutes information which, if disclosed, would defeat the purpose for which proprietary status is sought;

(8) whether the information is known outside of the business of the manufacturer, and the extent to which the record is known by the employees and others involved in the business of the manufacturer;

(9) the value of the information to the manufacturer and to its competitors;

(10) the amount of effort or money expended by the manufacturer in developing the information, and the ease or difficulty with which the information could be properly acquired or duplicated by others;

(11) any other factors considered relevant.

(c) When information designated as proprietary information has been submitted to the Department, it shall be excepted from disclosure and maintained apart by the Department from all other records until 15 days after the entitlement to such exception has been finally determined by the Commissioner or such further time as ordered by a court of competent jurisdiction.

(d) A denial of an exception from disclosure requested pursuant to this section shall be final.

(e) The Commissioner shall not approve any exceptions under this section with respect to any ingredient that is a chemical of concern on one or more lists identified by the Commissioner.

1006.4 Schedule of Disclosure

Manufacturers shall furnish the information required to be posted pursuant to this section within thirty days of the effective date hereof, and every two years thereafter. In addition, such

manufacturers shall furnish such information: prior to the sale of any new vapor product or e-cigarette; when the formulation of a currently disclosed product is changed such that the predominance of the ingredients in such product is changed, prior to the product being sold at retail; or at such other times as may be required by the Commissioner.

1006.5 Penalties

Any manufacturer who violates any of the provisions of, or who fails to perform any duty imposed by this Part shall be liable, in the case of a first violation, for a civil penalty not to exceed five thousand dollars. In the case of a second or any subsequent violation, the liability shall be for a civil penalty not to exceed ten thousand dollars for each such violation.

Regulatory Impact Statement

Statutory Authority:

The Commissioner of Health is authorized by Section 1701 of the Public Health Law (PHL) to promulgate regulations implementing Article 17 of the Public Health Law, pertaining to the public disclosure of the ingredients of vapor products and electronic cigarettes.

Legislative Objectives:

The legislative objective of PHL Article 17 is to increase public awareness of the ingredients found in vapor products and electronic cigarettes, and to improve the public health by ensuring consumers are aware when such ingredients are potentially harmful.

Needs and Benefits:

On August 16, 2019, the New York State Department of Health issued a statewide health advisory to health care providers following reports regarding severe pulmonary illness in people who had reported use of vapor products prior to symptom onset. New York State took immediate action in an effort to identify commonalities among the cases, provide guidance to health care providers, and issue warnings to consumers to halt use of vaping products until the cause of illness could be identified. While a definitive cause for this vaping associated pulmonary illnesses has not be identified, it was postulated that use of vitamin E acetate as a diluent in the vaping liquid was the likely source of the surge in cases.

This public health crisis highlighted the lack of vaping and electronic cigarette ingredient information available to the public, health care providers, or public health professionals working to identify a potential cause for these illnesses. While the U.S. Food and Drug Administration

requires vaping and electronic cigarette manufacturers to submit an ingredient list for each of their products, there is no requirement for the ingredient information to be made easily accessible to the public.

In order to educate New Yorkers about the contents of the vaping products and electronic cigarettes they purchase for use, and to help protect the public health where such products contain chemicals of concern, the Legislature enacted a new Article 17 of the PHL, in Chapter 56 of the Laws of 2020, which requires manufacturers to disclose to the public all ingredients used to make both the vaping liquid and the components of the electronic cigarette. Additionally, the law requires manufacturers to disclose to the public any byproduct or contaminant present in the vaping liquid, electronic cigarette, or vaping aerosol produced when the e-cigarette is used. The proposed regulations are necessary to implement this law.

In particular, the proposed regulations identify chemicals of concern that pose a greater potential for human health risks from exposure. This regulation will require manufacturers to highlight if any portion of their product (the vaping liquid, electronic cigarette, or the aerosol emitted from these products) contains an intentionally added ingredient, a byproduct, or a contaminant that has been identified as a chemical of concern. This will allow New Yorkers to make informed decisions about the products they purchase for use. It will also encourage manufacturers to find innovative ways to either replace or remove substances with greater potential for harm from vaping products and electronic cigarettes sold in NYS. Additionally, having ingredient, byproduct, and contaminant information readily available for vaping products and electronic cigarettes that are sold for use in NYS will provide a valuable source of information if these types of devices are associated with an outbreak of illnesses in the future.

In accordance with PHL Article 17, the proposed regulations provide for procedures necessary to protect the confidentiality of vapor product manufacturer's proprietary information, except with regard to those ingredients identified in the proposed regulation as chemicals of concern.

Costs to Private Regulated Parties:

There will be costs to private regulated parties associated with compliance with this proposed rule. The requirements in this proposed rule do not deviate from requirements set forth in Article 17 of the Public Health Law. Costs to manufacturers would include analyzing their vaping liquid, e-cigarette device, and the aerosol produced by the device for the presence of chemicals of concern, toxic metals, contaminants, and byproducts that are not already known to the manufacture (e.g., the manufacture would already know the presence of intentionally added ingredients or contaminants that were disclosed to the manufacturer from the source of their raw materials). Costs will also be associated with the requirement to conduct and submit an evaluation of the availability of potential alternatives to any chemical of concern or toxic metal identified in their product or the aerosol produced by their product and the potential hazards posed by alternatives. Additionally, there will be costs associated with development of a public-facing website to disclose all intentionally added ingredients (regardless of the amount present), toxic metals, contaminants (great than or equal to 0.5% by weight of the product or at any amount if it is a chemical of concern), and byproducts (great than or equal to 0.5% by weight of the product or at any amount if it is a chemical of concern), and flagging these as chemicals of concern or toxic metals if applicable. Manufacturers have already been required to disclose their ingredients and health-related studies to the U.S. Food and Drug Administration (US FDA) so

these requirements will not constitute an additional cost to the manufacturers. Additionally, the department's list of chemicals of concern comes from the US FDA's established list of harmful or potentially harmful constituents of tobacco products (93 chemicals) as well as their proposed list of 19 additional chemicals that would be specific to vapor products and electronic cigarettes. Manufacturers are already required to report the levels of these harmful or potentially harmful chemicals to the US FDA. The Department recognizes that this requirement will add additional costs to private regulated parties because the US FDA has allowed manufacturers to test for and disclose a reduced number of these chemicals since 2012 (US FDA issued industry guidance in 2012 identifying a subset of 20 chemicals that industry would be required to test for and disclose). The proposed regulation does not adopt this truncated list of chemicals and therefore manufacturers would be required to test for and disclose the presence of any chemical from the full list of chemicals of concern.

Costs to State Government and Local Government:

The Department of Health will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost however may be offset by fines and penalties imposed pursuant to the Public Health Law.

Local government will incur no new costs.

Local Government Mandates:

The proposed regulation imposes no new mandates on local governments.

Paperwork:

All manufacturers of vapor products will be required to report to the Commissioner the ingredients of their products, and related health studies as defined herein. However, manufacturers of vapor products are already required to report this information to the U.S. Food and Drug Administration. As such, additional paperwork is anticipated to be minimal.

Duplication:

The proposed regulations would not duplicate any State or federal regulations.

Alternatives:

The proposed regulations implement mandatory disclosure requirements imposed by PHL Article 17. As such, no alternatives were considered.

Federal Standards:

21 U.S.C. 387d, and regulations promulgated thereunder, requires that vapor product manufactures disclose their product's ingredients and health-related studies to the U.S. Food and Drug Administration.

Compliance Schedule:

The regulation will be effective upon publication of a Notice of Adoption in the New York State Register.

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

All vapor product manufacturers will be required to comply with the proposed rule, which implements the requirements of PHL Article 17. Some vapor product manufacturers may be small businesses; however, the effect of the rule is anticipated to be minimal as the requirements largely mirror federal reporting requirements.

No local governments will be impacted by the proposed regulations.

Compliance Requirements:

The proposed regulations will require manufacturers of vapor products to disclose, to the Commissioner and to the public, their product's ingredients as well as health-related studies regarding such ingredients.

Professional Services:

As vapor product manufacturers are already required to report ingredients and health-related studies to the U.S. Food and Drug Administration, additional professional services should not be necessary.

Compliance Costs:

There will be costs to private regulated parties associated with compliance with this proposed rule. The requirements in this proposed rule do not deviate from requirements set forth in Article 17 of the Public Health Law. Costs to manufacturers would include analyzing their

vaping liquid, e-cigarette device, and the aerosol produced by the device for the presence of chemicals of concern, toxic metals, contaminants, and byproducts that are not already known to the manufacturer (e.g., the manufacturer would already know the presence of intentionally added ingredients or contaminants that were disclosed to the manufacturer from the source of their raw materials). Costs will also be associated with the requirement to conduct and submit an evaluation of the availability of potential alternatives to any chemical of concern or toxic metal identified in their product or the aerosol produced by their product and potential hazards posed by alternatives. Additionally, there will be costs associated with development of a public-facing website to disclose all intentionally added ingredients (regardless of amount present), toxic metals, contaminants (great than or equal to 0.5% by weight of the product or at any amount if it is a chemical of concern), and byproducts (great than or equal to 0.5% by weight of the product or at any amount if it is a chemical of concern), and flagging these as chemicals of concern or toxic metals if applicable. Manufacturers have already been required to disclose their ingredients and health-related studies to the U.S. Food and Drug Administration (US FDA) so these requirements will not constitute an additional cost to the manufacturers. Additionally, the department's list of chemicals of concern comes from the US FDA's established list of harmful or potentially harmful constituents of tobacco products (93 chemicals) as well as their proposed list of 19 additional chemicals that would be specific to vapor products and electronic cigarettes. Manufacturers are already required to report the levels of these harmful or potentially harmful chemicals to the US FDA. The Department recognizes that this requirement will add additional costs to private regulated parties because the US FDA has allowed manufacturers to test for and disclose a reduced number of these chemicals since 2012 (US FDA issued industry guidance in 2012 identifying a subset of 20 chemicals that industry would be required to test for and

disclose). The proposed regulation does not adopt this truncated list of chemicals and therefore manufacturers would be required to test for and disclose the presence of any chemical from the full list of chemicals of concern.

Economic and Technological Feasibility:

There are no economic or technology impediments to any of the proposed rule changes.

Minimizing Adverse Impact:

Adverse impacts on manufacturers are expected to be minimal. Manufacturers have already been required to disclose their ingredients and health-related studies to the U.S. Food and Drug Administration.

Small Business and Local Government Participation:

A copy of the draft proposed rule was sent via e-mail to several professional associations representing vapor product manufacturers for input.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. The penalties described in the regulations mirror those already established in PHL Article 17. As such, this proposed regulation does not create a new penalty or sanction, and no cure period is necessary.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (<https://www.census.gov/quickfacts/>). At present, it is unknown how many vapor product manufacturers are located in these counties.

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010. At present, it is unknown how many vapor product manufacturers are located in these counties.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

All manufacturers of vapor products will be required to report to the Commissioner the ingredients of their products, and related health studies as defined herein. However, manufacturers of vapor products are already required to report this information to the U.S. Food and Drug Administration. As such, additional recordkeeping is anticipated to be minimal.

As vapor product manufacturers are already required to report ingredients and health-related studies to the U.S. Food and Drug Administration, additional professional services should not be necessary.

Costs:

The cost to manufacturers is expected to be minimal. Manufacturers have already been required to disclose their ingredients and health-related studies to the U.S. Food and Drug Administration. Additionally, the department's list of chemicals of concern comes from the U.S. Food and Drug Administration's established list of harmful or potentially harmful constituents of tobacco products (93 chemicals) as well as their proposed list of 19 additional chemicals that would be specific to vapor products and electronic cigarettes. Manufacturers are already required to report the levels of these harmful or potentially harmful chemicals to the U.S. Food and Drug Administration. The only additional requirement for manufacturers resulting from these regulations is to post each product's ingredient, byproduct, and contaminant information on their website. They must also highlight if any of their ingredients, byproducts, or contaminants have been identified as a chemical of concern.

Minimizing Adverse Impact:

Adverse impacts on manufacturers are expected to be minimal. Manufacturers have already been required to disclose their ingredients and health-related studies to the U.S. Food and Drug Administration.

Rural Area Participation:

A copy of the draft proposed rule was sent via e-mail to several professional associations representing vapor product manufacturers for input.

Job Impact Statement

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (the Department) received several comments to the proposed rulemaking adding a new Part 1006 to Title 10 of the Code, Rules and Regulations of the State of New York relating to ingredient disclosures for vapor products and e-cigarettes. The proposed rule implements requirements for ingredient disclosure set forth in Section 1701 of the Public Health Law (PHL). Public comments were received from three industry stakeholders.

Comments were primarily focused on the need to clarify definitions and provide additional guidance, as well as considerations for how the United States Food and Drug Administration (US FDA) is proceeding with regulation of these products. In response to these comments, revisions were made to the proposed rule to clarify certain definitions. Commenters also expressed concerns with requirements in the proposed regulation that were identical to requirements within PHL § 1701. No revisions were made to the proposed rule in response to these comments and the commenters were referred back to PHL § 1701. Additionally, commenters suggested that the fiscal implications for companies from the proposed rule were not adequately addressed in the Regulatory Impact Statement. The "Cost to Private Regulated Parties" and the "Compliance Costs" sections of the rulemaking package were modified to address these comments. The remaining comments challenged the state's legal authority to require vape and e-cigarette companies to disclose this information. No revisions were made to the proposed rule based on these comments.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (the Department) received several comments to the proposed rulemaking adding a new Part 1006 to Title 10 of the Code, Rules and Regulations of the State of New York relating to ingredient disclosures for vapor products and e-cigarettes. The proposed rule implements requirements for ingredient disclosure set forth in Section 1701 of the Public Health Law (PHL). Public comments were received from three industry stakeholders. Comments were related to clarification of definitions, the need for additional guidance, and considerations for how the United States Food and Drug Administration (US FDA) is proceeding with regulation of these products. Based on public comments, the Department made revisions to the proposed rule to clarify some of the definitions. All of the comments and the Department's responses are summarized below.

Section 1006.1 Comments: Definitions

COMMENT: One commenter stated that the definitions for “vapor product” and “e-cigarette” may create a loophole for non-combustible products, such as “heat-not-burn” products which do not use a liquid or gel, but heat solid dried tobacco below the point of combustion to create an aerosol that is inhaled.

RESPONSE: The Department revised the definition of “e-cigarette” in the proposed rule to clarify that the disclosure requirements will cover “heat-not-burn” products.

COMMENT: Commenters indicated that the definition of “ingredient” was broad and encompassed a much larger set of substances than what is considered an ingredient under the federal framework. Commenters noted that it is not feasible or practical to provide certain

requested information, particularly as it relates to byproducts and contaminants intentionally or unintentionally generated during use, manufacture and within the supply chain. Commenters recommended that “ingredient” be limited to those intentionally added by manufacturers.

RESPONSE: PHL § 1700 sets out the definition of “ingredient” and the definition of “ingredient” within the proposed rule does not deviate from PHL § 1700. No changes were made to the proposed rule as a result of these comments.

COMMENT: One commenter stated that the definition of “chemicals of concern” extended beyond federal law and would require manufacturers to identify chemicals for which the US FDA has not determined a meaningful way to publish such information.

RESPONSE: The proposed rule identifies chemicals of concern as those chemicals specifically listed by the US FDA as “Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke” as well as those chemicals specifically listed by the US FDA as proposed additions to that list. These lists were published in the Federal Register and are available for public inspection and copying at the Department’s Regulatory Affairs Unit. No changes were made to the proposed rule as a result of this comment.

COMMENT: Commenters noted that the proposed rule did not define the meaning of “all expected functions” as the term relates to intentionally added ingredients.

RESPONSE: Based on public comments, the Department has removed the requirement for disclosure of “all expected functions” from the proposed rule.

COMMENT: Commenters stated that the proposed rule did not define what constitutes a “toxic metal.”

RESPONSE: The Department revised the proposed rule to include a definition of “toxic metal.”

Section 1006.2 Comments: Ingredient Disclosure

COMMENT: Commenters stated that the scope of the information that would be required under the proposed rule was unclear. Commenters noted that manufacturers would be required to disclose health-related studies, but that it was unclear what specific information must be disclosed by manufacturers. Commenters also stated that manufacturers would be required to submit and disclose an evaluation of the availability of potential alternatives and potential hazards posed by such alternatives, but that the rule did not describe what such an evaluation must include or otherwise provide any standards for conducting such an evaluation.

RESPONSE: The Department intends to provide guidance on submission of health-related studies as well as the alternative chemicals assessment. The proposed rule offers an example of what a submission of health-related studies might look like through reference to the US FDA’s “Health Document Submission Requirements for Tobacco Products.”¹ No changes to the proposed rule have been made as a result of this comment.

COMMENT: Several commenters suggested that requiring manufacturers to disclose “all expected functions” of vapor product ingredients would require manufacturers to conduct additional assessments, and is more extensive than necessary to achieve the aims of PHL § 1701. This also includes requiring the disclosure of health-related documents related to investigations

¹ US FDA. 2017. Health Document Submission Requirements for Tobacco Products: Guidance for Industry. Accessed on 6/18/2021 at: <https://www.fda.gov/media/78616/download>.

and research into specific ingredients. One commenter recommended allowing manufacturers to submit a summary of health-related research as an alternative.

RESPONSE: As a result of these comments, the Department removed the requirement that the expected functions be included in the ingredient disclosure.

COMMENT: One commenter recommended allowing manufacturers to submit a summary of health-related research as an alternative.

RESPONSE: Article 17 of the PHL and the proposed rule require that the nature and extent of human health-related investigations and research be furnished to the Commissioner and posted on the manufacturer's website. A summary could be in line with this requirement, provided it details the nature and extent of the investigation and/or research. No changes to the proposed rule have been made as a result of this comment.

COMMENT: A commenter noted that the Federal statute does not require manufacturers to submit information to the US FDA concerning potential alternatives. The commenter stated that instead, the Federal Tobacco Control Act requires manufacturers to submit specific information to US FDA about the *actual* ingredients and constituents contained in their products and not information or hazard analyses for ingredients or constituents *not* in their products.

RESPONSE: Consistent with Article 17 of the PHL, the proposed rule requires manufacturers to submit an evaluation of alternative chemicals and potential hazards of these alternative chemicals if a manufacturer's product contains a chemical identified by the commissioner as a chemical of concern. If the manufacturer's product does not contain a chemical of concern, then it would not

be required to conduct and submit this evaluation. No changes to the proposed rule have been made as a result of this comment.

COMMENT: Several commenters suggested that the purpose of Article 17 of the PHL was to address concerns about illicit cannabis products and the use of vitamin E acetate as a potential cause of vaping related lung illnesses. Commenters noted that neither the statute nor the proposed rule impact these illicit vapor products.

RESPONSE: Article 17 of the PHL specifically identifies vapor products and e-cigarettes used for the consumption of nicotine. It does not include vapor products and e-cigarettes used for the consumption of tetrahydrocannabinol, the main psychoactive compound in cannabis. The Department modified the proposed rule to include vitamin E acetate as a chemical of concern, but no other changes to the proposed rule were made as a result of these comments.

COMMENT: Commenters expressed concern that the information required to be publicly disclosed could be seen as misleading and create unfair competition.

RESPONSE: Section 1701 of the PHL identifies what information is subject to public disclosure. The proposed rule does not deviate from these requirements. As such, no changes are necessary to the proposed rule.

COMMENT: One commenter indicated that the proposed rule lacks an actionable list of byproducts that could be tested using accredited test methods. The commenter stated that a lack of standardized methods for measurement of byproducts produced during the use of vapor products, and a lack of realistic tolerance estimates for test results, would not allow for

meaningful interpretation of reported values. Thus, the information could be inconsistent and not comparable across the product category.

RESPONSE: Subdivision 5 of Section 1700 of the PHL defines “byproducts” and requires manufacturers to disclose byproducts contained in either their vaping products or in the aerosol produced and inhaled by the end-user. The disclosure requirement is triggered if the byproduct is present at greater than or equal to 0.5% by weight of the product, or if the byproduct is included on the list of chemicals of concern identified in Section 1006.1(h) of the proposed rule. Article 17 of the Public Health Law does not require the creation of a list of potential byproducts that may be found in vaping products or the aerosols produced through use of such products. The potential presence of byproducts or aerosol will depend, among other factors, on the chemicals used to make the vaping product, the constituents of the e-cigarette, and the operating parameters of the device (e.g., temperature settings). Therefore, the Department cannot definitively state what byproducts will be present in these devices or in the aerosol through normal use of the device. Additionally, neither Article 17 of the PHL nor the proposed rule require manufacturers to disclose the actual concentration of the byproduct. Instead, manufacturers are only required to disclose a byproduct based on its presence in the vaping product or aerosol (greater than or equal to 0.5% by weight of the product or if the byproduct is included on the list of chemicals of concern). No changes were made to the proposed rule as a result of these comments; however, the Department will consider this comment when developing guidance and in future updates of the regulation.

Section 1006.3 Comments: Proprietary Information

COMMENT: Several commenters suggested revising the proposed rule’s definition of “proprietary information” to include all information that is subject to the trade secret exemption for disclosures under the federal Freedom of Information Act.

RESPONSE: The proposed rule implements the specific limits on treatment of proprietary information and the definition for such information found in PHL § 1701, which permits the withholding of information from public disclosure provided the disclosure of such information “would compromise such manufacturer’s competitive position.” No changes were made to the proposed rule as a result of this comment.

Section 1006.4 Comments: Schedule of Disclosure

COMMENT: Several commenters suggested delaying ingredient disclosures until the US FDA has finalized the federal regulatory framework for vapor products and e-cigarettes.

RESPONSE: The vapor product and e-cigarette ingredient disclosures required by PHL § 1701 are currently in effect and cannot be waived or delayed by the Department. The proposed rule is necessary to implement these requirements for ingredient disclosure. No changes were made to the proposed rule as a result of this comment.

Additional Comments:

COMMENT: Several comments were received questioning why disclosure of vapor product ingredients is necessary and questioning the purpose of such disclosure. Commenters noted that that publicly disclosing ingredient lists would provide little or no value without placing the data

in context, and could drive adult vapor users back to combustible cigarettes. Commenters also stated that the proposed rule requires manufacturers to submit information that has already been submitted to the US FDA through the Premarket Tobacco Product Application (PMTA) process. Commenters also claimed that extending these disclosure requirements to other ingredients and components in vapor products will not educate consumers in any meaningful way or alter their decision-making to an appreciable degree. Finally, commenters stated that there are no tangible benefits that would justify these extensive and burdensome requirements. Commenters mentioned that the public is already aware of the harms associated with tobacco and that there is no justification for the state-specific disclosure requirements.

RESPONSE: The legislative objective of Article 17 of the PHL is to increase public awareness of the ingredients found in vapor products and electronic cigarettes, and to improve public health by ensuring consumers are aware when such ingredients are potentially harmful. The proposed rule does not deviate from the requirements set forth in Article 17 of the PHL. No changes to the proposed rule are necessary as a result of these comments.

COMMENT: Commenters mentioned that the proposed rule imposes data development, reporting, and disclosure requirements that go beyond those set forth in the federal Tobacco Control Act. Commenters stated that this will require significant time and resources and therefore the proposed rule significantly underestimates costs to regulated parties. Commenters recommended that the Department reconsider the approach and adopt requirements that will not impose undue costs on manufacturers.

RESPONSE: The Department has updated the regulatory impact statement to acknowledge the cost to regulated parties.

COMMENT: One commenter noted that the required disclosure would create an unfair competitive environment because the information is largely not comparable across brands and manufacturers, even when product ingredients are listed in descending order based on weight. The commenter stated that all vapor products come with a level of risk and creating a publicly available list of ingredients without context will lead to adult consumers changing brands, or even returning to combustible cigarettes because they may mistakenly rank one ingredient as more acceptable for consumption than others.

RESPONSE: The public disclosure requirements were set forth in Article 17 of the PHL. The proposed rule does not deviate from these requirements. Therefore, no changes are necessary to the proposed rule as a result of this comment.

COMMENT: Several commenters stated that the proposed rule is preempted by federal statutes, including the federal Tobacco Control Act (TCA). The commenters noted that the TCA requires vapor product manufacturers to report information about harmful or potentially harmful constituents in their products to the US FDA, and that the US FDA has a premarket review process for vapor and e-cigarette products. According to the commenters, the proposed rule may interfere with the US FDA's regulatory efforts.

RESPONSE: The proposed rule implements ingredient disclosures for vapor products and e-cigarettes that are mandated by PHL § 1701. No changes were made to the proposed rule as a result of this comment.

COMMENT: Several commenters argued that the Department has not provided justification, in terms of public health or otherwise, for the proposed disclosure requirements.

RESPONSE: The proposed rule implements ingredient disclosures for vapor products and e-cigarettes that are mandated by PHL § 1701. As noted in the Regulatory Impact Statement, the objective of Article 17 of the PHL is to increase public awareness of the ingredients found in vapor products and improve public health by ensuring consumers are aware when such ingredients are potentially harmful. No changes were made to the proposed rule as a result of this comment.

COMMENT: Several commenters argued that the proposed rule compels speech in violation of the U.S. Constitution.

RESPONSE: The proposed rule implements ingredient disclosures for vapor products and e-cigarettes that are mandated by PHL § 1701. No changes were made to the proposed rule as a result of this comment.