



# PROPOSALS FOR THE REGULATION OF VAPING PRODUCTS

DOCUMENT FOR CONSULTATION  
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Health  
Canada

Santé  
Canada

Canada 

# PROPOSALS FOR THE REGULATION OF VAPING PRODUCTS

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## EXECUTIVE SUMMARY

Health Canada is considering introducing regulations on vaping products pursuant to the proposed Tobacco and Vaping Products Act (TVPA). The proposed TVPA is part of Bill S-5, an Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts, which was presented to Parliament in November 2016.

This consultation document contains 10 proposed measures for vaping product regulations under the proposed TVPA. These proposed measures range from specifying which information is to be displayed on labels and which information is to be reported to the department, to imposing further restrictions on permitted advertising and to authorizing statements on relative health risks. All interested organizations and individuals are invited to review the measures being considered, and to provide their feedback by October 27, 2017.

The document also provides information on the applicability of the *Food and Drugs Act* and *Canada Consumer Product Safety Act* to vaping products under the framework proposed by Bill S-5.

## 1.0 INTRODUCTION

There has been a steady rise in the popularity of vaping products since their introduction a decade ago. A recent analysis commissioned by Health Canada estimates the total vaping market in Canada to be in excess of \$500M.<sup>1</sup> The number of brands and types of vaping products continues to evolve and new magazines, websites and vaping conventions continue to be introduced.

Surveillance data from 2015 shows that 3% (946,000) of Canadians aged 15 years of age and older reported using an e-cigarette<sup>i</sup> in the past 30 days. For youth aged 15 to 19, the prevalence of past-30-days use is 6% (131,000). In comparison, 13% (271,000) of youth aged 15 to 19 used at least one tobacco product in the past 30 days that same year. The data also shows that half (50% or 893,000) of current or former smokers who had tried an e-cigarette reported using it as a cessation aid in the past two years.<sup>2</sup>

Vaping products present both a challenge and an opportunity for public health in Canada.

Despite emitting fewer harmful substances than cigarettes<sup>3</sup>, vaping products are harmful. For instance, many contain nicotine, which is toxic and addictive; the aerosol they emit may contain chemicals which could negatively affect health; and there are demonstrated safety concerns associated with their use. As well, there are concerns about the appeal of vaping products to youth and the detrimental impacts that nicotine exposure during adolescence has on the developing brain.<sup>4</sup> The long-term health effects are unknown, and there is limited research on the effects on bystanders.

The opportunity presented by vaping products is that they may provide adult smokers with a less harmful alternative to tobacco. Tobacco use is the leading preventable cause of premature death and disease in Canada, killing one in two long-term users.

In March 2015, the House of Commons Standing Committee on Health issued its report titled “Vaping: Towards a regulatory framework for e-cigarettes.”<sup>5</sup> After holding eight meetings with 33 witnesses, the Committee put forth 14 recommendations, one of which invited the Government of Canada to “work with all affected stakeholders to establish a new legislative framework (under the *Tobacco Act*, new legislation, or other relevant statutes) for regulating electronic cigarettes and related devices.”

In order to respond to the Committee’s report, the Government of Canada introduced [Bill S-5, an Act to amend the Tobacco Act and the Non-smokers’ Health Act and to make consequential amendments to other Acts](#), in Parliament in November 2016.<sup>ii</sup> The Bill’s framework for vaping products is based on the following principles:

- Protecting youth and non-users of tobacco products from nicotine addiction and inducements to tobacco use;
- Allowing adults, in particular adult smokers, to access vaping products as a less harmful alternative to tobacco;
- Providing a mechanism to address potential health and safety risks from nicotine-containing vaping products without therapeutic claims;
- Preserving the current regulatory process through the FDA for vaping products marketed for a therapeutic use, such as smoking cessation.

Under the framework proposed by Bill S-5, vaping products would be required to meet the applicable provisions of either the *Food and Drugs Act* (FDA) or the *Canada Consumer Product Safety Act* (CCPSA), depending on how the product is marketed (i.e. with or without therapeutic claims). Information on the

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<sup>i</sup> The term “e-cigarette” is used where the source that was consulted uses either “electronic cigarette” or this term.

<sup>ii</sup> An overview of the Bill is available here ([hyperlink](#))

applicability of these two pieces of legislation to vaping products can be found in section 3.0 INFORMATION ON OTHER APPLICABLE LEGISLATION.

Bill S-5 also contains provisions that would amend the *Tobacco Act*, including changing its title to “Tobacco and Vaping Products Act” (TVPA). The proposed TVPA would regulate the manufacture, sale, labelling and promotion of vaping products as a separate set of products<sup>iii</sup>.

This document sets out 10 proposed measures for the first phase of vaping product regulations to be made pursuant to the proposed TVPA. Health Canada invites all interested organizations and individuals to review the measures being considered, and to provide their feedback by October 27, 2017 (see section 4.0 FEEDBACK REQUESTED for details on how to do so).

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<sup>iii</sup> Questions and answers on the proposed TVPA are available here ([hyperlink](#))

## 2.0 REGULATING VAPING PRODUCTS UNDER THE PROPOSED TVPA

### 2.1 What are vaping products?

The term “vaping products”<sup>iv</sup> refers to both vaping devices (including individual parts such as atomizers, etc.) and vaping liquids<sup>v</sup>.

Vaping devices, also known as e-cigarettes and electronic nicotine delivery systems, vary in design and appearance. Most vaping devices consist of a battery, a heating element, a tank or reservoir, and a mouthpiece. They work by heating vaping liquid to form an aerosol that is inhaled by the user.

Vaping liquids are marketed in a wide variety of flavours, and are primarily composed of propylene glycol and/or glycerol (sometimes referred to as vegetable glycerin), and often contain flavourings and nicotine.

There has been, and continues to be, a great deal of change and innovation in this market, with continuing evolution of the products, as well as the preferences and activities of the user community.

### 2.2 Regulatory proposals on labelling

*These proposals apply to all vaping products.*

#### a. Nicotine content

It is important for consumers to know if the vaping product they are buying contains nicotine, and that information provided regarding nicotine content be accurate.

One of the recommendations from the March 2015 report of the House of Commons Standing Committee on Health was that “all packaging of vaping products clearly and accurately indicate the concentration of nicotine along with appropriate safety warnings”.

Studies measuring the levels of nicotine in vaping liquids have found that the actual concentration sometimes deviates substantially from the concentration stated on the product label.<sup>6,7</sup> Of particular concern, there have been cases where nicotine was found in vaping liquids labelled as nicotine-free.

Existing voluntary standards set out maximal concentrations for “nicotine-free” liquids. The British Standards Institute PAS 54115:2015 sets a threshold of less than 0.1 mg/ml (<0.01%<sup>vi</sup>) in e-liquid<sup>8</sup>, while the Association Française de Normalisation (AFNOR) standard on e-cigarettes<sup>9</sup> sets a limit of less than 0.5 mg/ml.

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<sup>iv</sup> Under the proposed TVPA, a *vaping product* is “(a) a device that produces emissions in the form of an aerosol and is intended to be brought to the mouth for inhalation of the aerosol (b) a device that is designated to be a vaping product by the regulations; (c) a part that may be used with those devices; and (d) a substance or mixture of substances, whether or not it contains nicotine, that is intended for use with those devices to produce emissions. It does not include devices and substances or mixtures of substances that are excluded by the regulations, tobacco products or their accessories.

<sup>v</sup> The term “vaping liquid” is used throughout this document, however regulatory proposals would apply to all substances and mixtures of substances intended for use with vaping devices, regardless of physical state.

<sup>vi</sup> For simplicity, conversions between units of mg/ml and % weight/volume have been approximated using a density of 1 g/ml. Accurate conversion between units will depend on the density of the vaping liquid.

For their part, the United States Food and Drug Administration specify in draft guidance to industry that there should be no nicotine at detectable levels for an electronic nicotine delivery system to be considered as not containing nicotine.<sup>10</sup>

**Proposal No. 1: Health Canada proposes that all vaping products which contain nicotine display their nicotine concentration in milligrams/millilitre (mg/ml).**

**Proposal No. 2: To prevent consumers from being misled about the presence or absence of nicotine, Health Canada proposes that any vaping product be considered to contain nicotine if nicotine is present at a concentration of 0.1 mg/ml or higher.**

## **b. Warning statements and list of ingredients**

Product labels provide a means of direct communication to the consumer. Labels can provide basic information like the product name and quantity, but they can also be used to convey key information related to health and safety, serving as an important public health communication tool. Information found on labels can help the user understand the product, become aware of any potential hazards associated with the product or its use, and adopt behaviours that minimize these hazards.

Nicotine is toxic and addictive, and has detrimental effects on the developing brain<sup>4</sup> and the developing fetus.<sup>11, 12</sup> Health Canada proposes that any vaping product (including vaping refill liquids, or pre-filled vaping devices, or parts) containing nicotine at a concentration of 0.1 mg/ml or more would be required to display a warning relating to the health effects of nicotine. Manufacturers<sup>vii</sup> would be able to attribute this warning to Health Canada using a format prescribed in the proposed regulations.

In addition to nicotine, vaping products may contain carriers, flavourings and other ingredients. Consumers need to be aware of these ingredients in order to make informed decisions about their health. In order to enhance consumer information and protection, Health Canada proposes that a complete list of ingredients be displayed on all products containing a vaping liquid, similar to labelling for cosmetics.

**Proposal No. 3: Health Canada proposes to require that vaping products that contain nicotine display a warning such as: “WARNING: This product contains nicotine. Nicotine is an addictive substance. Use of nicotine during pregnancy may harm the fetus.”**

**Proposal No. 4: Health Canada proposes to require that products that contain a vaping liquid display a complete list of ingredients in descending order by weight.**

The information would be required in both official languages, and would need to be displayed in a prescribed manner and location on the package and/or on the product itself.

In consideration of space limitations, the proposed regulations may allow for the display of information on a leaflet in, or affixed to, the package, or on a tag attached to the product or package. Colour, font size, and location would also be prescribed to ensure that the required information is legible.

For additional context, **Appendix A** contains a summary of labelling requirements currently applicable to the United States and the European Union.

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<sup>vii</sup> For the purpose of this document, the term “manufacturers” includes importers.

As additional information may be required on labels and packaging of vaping products, please see section 3.0 INFORMATION ON OTHER APPLICABLE LEGISLATION for details.

## 2.3 Regulatory proposals on information reporting

*These proposals apply to all vaping products.*

### a. Information to be reported to the Minister of Health

Vaping products were introduced relatively recently to the Canadian market, and Health Canada intends to gather more information about vaping products and the vaping product market.

Health Canada would use the information submitted by manufacturers and importers to develop and refine future policies and regulations regarding vaping products. The information would allow Health Canada to:

- Monitor vaping product trends, including product types and design characteristics
- Monitor how vaping products are marketed
- Track the evolution of the vaping industry and associated market
- Assess the impact of vaping products on the overall tobacco market
- Support internal and external research efforts regarding vaping products

**Proposal No. 5: Health Canada proposes that manufacturers be required to report the information set out below at the frequency specified:**

INFORMATION	FREQUENCY
The name of the business and contact person	Annually
Details about each vaping device or liquid, including the product name, model number and nicotine concentration	Upon introduction of each product, and annually thereafter
Details about the design of each vaping device, including engineering drawings and information about the materials and components used	Upon introduction of each product, and annually thereafter
Contents of vaping liquids, including quantities of each ingredient	Upon introduction of each product, and annually thereafter
Information on research and development activities	Annually
Information on promotional activities	Annually
Sales data for each product	Quarterly

Health Canada proposes that these reports be submitted in either French or English and in a legible and readily accessible electronic format.

It is proposed that reports would be required for all vaping products on the market at the time regulations come into force.



Retailers would not be required to report information unless they are involved in activities which would classify them as a “manufacturer”, per the definitions set out in the proposed TVPA<sup>viii</sup>.

Reporting requirements (other than for sales data) would apply to all vaping products, whether the vaping products are for sale or not. This would include those products that are in development (that is, manufacturers would be required to report annually on research and development activities).

For additional context, **Appendix B** provides a summary of current reporting requirements for vaping products in the United States and the European Union.

## **b. Requests for supplemental information**

From time to time, Health Canada may need additional information from a manufacturer concerning a report they have submitted. As provided for in the proposed TVPA, the Minister of Health would be authorized, subject to the regulations, to request from manufacturers such supplementary information. Manufacturers would be required to submit the supplementary information in the form, manner and within the time frame specified by the Minister.

**Proposal No. 6: Health Canada proposes that manufacturers of vaping products be required to provide supplementary information in a form, manner and within the time frame specified, once notified by the Minister. The form, manner and time frame allowed for manufacturers to provide the supplementary information would be specified in the request and could vary according to the nature of the information requested.**

## **c. Measures to enhance compliance with reporting requirements**

Health Canada wishes to put in place measures to help ensure that manufacturers will provide complete reports in a timely manner. The proposed TVPA provides the Minister of Health with the authority to suspend the sale of a vaping product when the manufacturer fails to submit the required information.

**Proposal No. 7: Health Canada proposes that manufacturers of vaping products be given a period of no more than 30 calendar days to address any deficiency in the reporting of information prescribed by the regulations, once they are notified of the deficiency by Health Canada. Should the manufacturer fail to address the deficiency, or should the information provided continue to be deficient, the sale of the product in question would be suspended until the missing information is submitted to Health Canada, and the manufacturer would be informed accordingly.**

## **d. Record-keeping practices by manufacturers**

Health Canada anticipates that there will be instances when, at some time after a report has been submitted, a manufacturer may need to make records available for subsequent review or auditing by Health Canada inspectors. The proposed TVPA would require that every manufacturer of vaping products keep, in the prescribed manner and for the prescribed time period, all records and documents used to prepare the information they report to the Minister of Health.

**Proposal No. 8: Health Canada proposes that manufacturers of vaping products be required to maintain all records and documents used to prepare their information reports for a period of six (6) years after the end of the year to which the document relates. This documentation would have to be kept in a form and manner prescribed by the regulations, so that it could be readily accessed and viewed in Canada during audits.**

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<sup>viii</sup> Manufacturer, in respect of a vaping product, includes any entity that is associated with a manufacturer, including an entity that controls or is controlled by the manufacturer or that is controlled by the same entity that controls the manufacturer.

This proposal pertains to the proposed TVPA. Vaping product manufacturers may be subject to other record retention requirements imposed by other legislation and would need to comply with all applicable requirements.

## 2.4 Regulatory proposal on relative risk statements

*This proposal does not apply to vaping products that are authorized for sale under the Food and Drugs Act.*

The proposed TVPA prohibits the promotion of a vaping product, including by means of the packaging, in a manner that suggests that its use may convey a health benefit or by comparing health effects arising from the use of the product with those arising from the use of a tobacco product.

The purpose of this prohibition is to prevent the public from being deceived or misled with respect to the health hazards of using vaping products. It also seeks to protect young persons and non-users of tobacco products from inducements to use vaping products. This proposed prohibition responds to the recommendation from the House of Commons Standing Committee on Health that a new legislative framework prevent unsubstantiated therapeutic claims.

Exceptions to this prohibition can be established by regulations. Regulations could set out a selection of authorized statements regarding the relative health risks of vaping products (including comparisons to health effects arising from the use of tobacco products), as well as the conditions upon which manufacturers, retailers and others could use these statements in vaping product promotions, including on product packages.

The authorized statements would help prevent consumers from being misled about the health hazards of vaping products. They would be supported by science and promote public health objectives by allowing tobacco users to be better informed about the relative health risks of using vaping products.

The proposed selection of authorized statements, and any changes made to them, would be subject to a public consultation period sufficient to allow for comments from stakeholders.

**Proposal No. 9: Health Canada proposes to establish regulations that would specify the conditions upon which manufacturers, retailers and others could use authorized relative risk statements in vaping product promotions. The regulations would incorporate by reference a selection of authorized statements regarding the relative health risks of using vaping products or comparing the potential health effects arising from the use of a vaping product relative to that of a tobacco product. As the authorized statements may need to be amended from time to time to keep up with scientific knowledge, these regulations would also set out the requirement for public consultations on such amendments.**

## 2.5 Regulatory proposal on advertising restrictions

*This proposal applies to all vaping products.*

The proposed TVPA would prohibit certain types of advertising, such as:

- advertising that could, on reasonable grounds, be considered to be appealing to young persons;
- lifestyle advertising, with some exceptions;
- advertising that consists of testimonials, endorsements, sponsorship promotion or false promotion.

Information and brand-preference advertising of vaping products would not be prohibited, but it would be further restricted through regulations. Regulations made under the proposed TVPA respecting the advertising of vaping products could, for instance, address the type, medium (e.g. television, radio) and content of permitted advertisements.

**Proposal No. 10:** Health Canada proposes to establish regulations to help limit youth exposure to information and brand-preference advertising of vaping products. These regulations would include restrictions on the type, medium and content of advertising of vaping products. In line with the objectives of the proposed TVPA, the restrictions would be based on limiting advertising that has a high likelihood of being viewed by youth, while still allowing vaping product manufacturers to advertise their products and brands to adult smokers. Restrictions would therefore seek to limit advertising in or near locations that are attended predominantly by youth, such as schools, parks, recreational and sporting facilities. Restrictions would also be placed on advertising in certain media, for example by either prohibiting advertisements on television and radio or restricting the times of the day when such ads may appear or be heard to limit youth exposure to them.

## 3.0 INFORMATION ON OTHER APPLICABLE LEGISLATION

Under the framework proposed by Bill S-5, vaping products marketed for a therapeutic use would continue to be regulated under the FDA, and would also be subject to the proposed TVPA.

Vaping products that are not subject to the FDA (i.e. not marketed for a therapeutic use) would be subject to all of the requirements of the CCPSA and its applicable regulations, and would also be subject to the proposed TVPA. These products would include vaping liquids and disposable devices that contain nicotine, and reusable devices that may be used with nicotine.

### 3.1 The *Canada Consumer Product Safety Act*

The CCPSA contains specific requirements for manufacturers, importers and sellers of all consumer products. These include mandatory incident reporting and mandatory record retention. In addition, the CCPSA includes authorities such as the ability to order mandatory recalls. It is prohibited to manufacture, import, advertise or sell any consumer product that is a "danger to human health or safety" (general prohibition) as defined in the CCPSA (see paragraphs 7(a) and 8(a)). Further information is available in the [CCPSA Quick Reference Guide](#)<sup>ix</sup>.

#### a. Child-resistant containers

Should Bill S-5 come into force, all vaping products that are not subject to the FDA ( i.e. marketed without therapeutic claims) would be subject to all of the requirements of the CCPSA and its applicable regulations, including the *Consumer Chemicals and Containers Regulations, 2001* (CCCR, 2001). The CCCR, 2001 set out a classification-based approach to establishing rules for consumer chemicals, including a prohibition against the sale of very toxic substances and requirements for labelling and child-resistant containers for toxic substances.

Health Canada has reviewed the toxicity of nicotine, and has determined the following classifications under the Toxic Products category of the CCCR, 2001:

1. Vaping liquids, which are to be sold as consumer products, containing equal to or more than 66 mg/ml (6.6%) nicotine meet the classification of "very toxic" under CCCR, 2001 and will be prohibited from import, advertising or sale under section 38 of the CCCR, 2001.
2. Vaping liquids, which are to be sold as consumer products, containing between 10 mg/ml (1.0%) and 66 mg/ml (6.6%) nicotine meet the classification of "toxic". These will be required to be sold in child-resistant containers, and labelled in accordance with the CCCR, 2001.

When nicotine is present in vaping liquids at concentrations below 10 mg/ml (1.0%), the CCCR, 2001 classification of toxicity does not apply. However, nicotine is potentially toxic via oral exposure at concentrations below 1%. Health Canada has determined that vaping liquids containing nicotine between 0.1 mg/ml (0.01%) and 10 mg/ml (1.0%) that do not adhere to all requirements of the CCCR, 2001 for "toxic" products, including the requirements for a child-resistant container, likely pose a danger to human health or safety<sup>x</sup> under sections 7 and 8 of the CCPSA. Under sections 7 and 8 of the CCPSA, it

<sup>ix</sup> Health Canada. *Canada Consumer Product Safety Act* Quick Reference Guide [http://www.hc-sc.gc.ca/cps-spc/pubs/indust/ccpsa\\_ref-lcspc/index-eng.php](http://www.hc-sc.gc.ca/cps-spc/pubs/indust/ccpsa_ref-lcspc/index-eng.php)

<sup>x</sup> The CCPSA defines "danger to human health or safety" as "any unreasonable hazard — existing or potential — that is posed by a consumer product during or as a result of its normal or foreseeable use and that may reasonably be expected to cause the

is prohibited to manufacture, import, advertise or sell a consumer product that is a danger to human health or safety.

## **b. Labelling requirements**

In addition to the proposed requirements above, should Bill S-5 come into force, all vaping products brought under the CCCR, 2001 will be required to comply with the labelling requirements, which may include:

- hazard symbols,
- warning statements,
- safety instructions, and
- first aid statements.

Further, due to the known toxicity of nicotine, vaping liquids containing nicotine between 0.1 mg/ml (0.01%) and 10 mg/ml (1%) that do not adhere to all requirements of the CCCR, 2001 for “toxic” products, including labelling requirements, would likely pose a danger to human health or safety. Under sections 7 and 8 of the CCPSA, it is prohibited to manufacture, import, advertise or sell a consumer product that is a danger to human health or safety.

Products that do not meet the requirements of the CCCR, 2001 highlighted above are subject to compliance and enforcement actions which may include seizure, orders to take corrective action, mandatory recall of products, administrative monetary penalties and criminal prosecution.

Requirements that certain information be presented on the label do not preclude manufacturers and importers from including other pieces of information, including expiry dates, lot numbers, contact information or other items.

## **c. Regulatory path forward**

Health Canada will continue to monitor the marketplace for toxicological, electrical, flammability, or other hazards associated with vaping products, and may take further action regarding any product determined to be a danger to human health or safety.

Health Canada intends to develop additional regulations under the authority of the CCPSA to address health or safety risks posed by vaping products. These may include safety requirements for hardware components, such as the vaping device, batteries and chargers.

## **3.2 The Food and Drugs Act**

Vaping products for use in association with nicotine and with therapeutic or health claims, such as smoking cessation, are subject to the FDA and its applicable regulations. These products require market authorization prior to being imported, advertised or sold in Canada. Market authorization is granted by Health Canada following successful review of scientific evidence demonstrating safety, quality and efficacy with respect to the intended purpose of the therapeutic or health product. This evidence is to be provided by the sponsor seeking market authorization. The requirements under the FDA would be

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death of an individual exposed to it or have an adverse effect on that individual’s health — including an injury — whether or not the death or adverse effect occurs immediately after the exposure to the hazard, and includes any exposure to a consumer product that may reasonably be expected to have a chronic adverse effect on human health.”

maintained in conjunction with the framework proposed by Bill S-5. Health Canada is exploring regulatory options for vaping products with therapeutic or health claims in light of Bill S-5.

Currently, nicotine is listed as a prescription drug on the Prescription Drug List (PDL) and as such, nicotine-containing vaping products are classified as prescription drugs, unless specifically exempted from the PDL.

There are nicotine-containing products authorized for therapeutic or health use in Canada. These products, which include nicotine chewing gum, lozenges, transdermal patches and inhalation devices, have been exempted from the PDL based on the successful review of scientific evidence provided by their sponsors. They are regulated as natural health products under the *Natural Health Products Regulations* and can be sold "over-the-counter".

## 4.0 FEEDBACK REQUESTED

Health Canada is seeking feedback from interested organizations and individuals about the regulatory proposals outlined in this consultation document, in particular:

- How could the measures proposed above be improved?
- Are there additional measures that should be considered for the initial set of regulations, and are there peer-reviewed studies or other information you can offer in support of these additional measures?
- Are there foreseeable unintended consequences of the regulatory measures described and proposed in this document?

Comments can be submitted as follows:

- By e-mail to [hc.pregs.sc@canada.ca](mailto:hc.pregs.sc@canada.ca)
- By mail, to the Tobacco Products Regulatory Office, Tobacco Control Directorate, Health Canada, AL 0301A, 150 Tunney's Pasture Driveway, Ottawa, Ontario K1A 0K9

All feedback received on or before October 27, 2017 will be considered in finalizing the regulatory proposals for vaping products (see **Appendix C** for an overview of the federal regulatory process). Health Canada will make the results of this consultation available online.

Privacy Notice: The personal information you provide to Health Canada is used to administer the regulatory process and is authorized under section 4 of the *Department of Health Act*. For more information, refer to the standard personal information bank [Outreach Activities PSU 938](#). In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information, and to file a complaint with the [Privacy Commissioner of Canada](#). For more information, contact Health Canada's Privacy Coordinator at [privacy-vie.privee@hc-sc.gc.ca](mailto:privacy-vie.privee@hc-sc.gc.ca).

Canada is a Party to the *World Health Organization Framework Convention on Tobacco Control*. Article 5.3 of the Convention obliges parties, in setting and implementing their public health policies with respect to tobacco control, to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law. Therefore, the Government of Canada must actively exclude tobacco industry influence with respect to tobacco control policy. **You must declare any perceived or actual conflicts of interest with the tobacco industry when providing input to this consultation. If you are part of the tobacco industry, an affiliated organization or an individual acting on their behalf, you must clearly state so in your submission.**

We are also interested in being made aware of perceived or actual conflicts of interest with the vaping and/or pharmaceutical industry. As such, we request that you please declare this, if applicable, when providing input. **If you are a member of the vaping and/or pharmaceutical industry, an affiliated organization or an individual acting on their behalf, you are asked to clearly indicate this in your submission.**

# APPENDIX A – OVERVIEW OF LABELLING REQUIREMENTS IN THE EUROPEAN UNION AND THE UNITED STATES

## European Union

The European Union Tobacco Products Directive<sup>13</sup> requires that unit packets and any outside packaging of e-cigarettes and refill containers show:

- A list of ingredients contained in the product in descending order of the weight
- An indication of the nicotine content of the product and the delivery per dose
- Batch number
- A recommendation to keep the product out of the reach of children
- One of the following health warnings: “This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers” or “This product contains nicotine which is highly addictive substance.”

Unit packets of e-cigarettes and refill containers must include a leaflet with information on:

- Instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers
- Contra-indications
- Warnings for specific risk groups
- Possible adverse effects
- Addictiveness and toxicity and contact details of the manufacturer or importer.

Vaping products are also subject to the EU Classification, Labelling and Packaging Regulations (EC) NO. 1272/2008. As summarized in a recent analysis<sup>14</sup>, the requirements that may apply to vaping products include:

- Name, address and telephone number of the supplier(s)
- The nominal quantity of the substance or mixture in the package where this is being made available to the general public, unless this quantity is specified elsewhere on the package
- Product identifiers
- Hazard pictograms, where applicable (shape of a square set at a point have a black symbol on a white background with a red frame)
- The relevant signal word, where applicable
- Hazard statements, where applicable
- Appropriate precautionary statements, where applicable
- A section for supplemental information, where applicable
- Tactile warning of danger in accordance with EN ISO 11683 and a child-resistant fastening.

## United States

In May 2016, the Food and Drug Administration issued a rule<sup>15</sup> to extend its authority over all products meeting the definition of a tobacco product, except accessories of the newly deemed products. The rule extended the Food and Drug Administration’s tobacco product authority to include e-cigarettes. In this rule, the Food and Drug Administration also included the requirement for a nicotine warning on tobacco products. One of the required warnings is: “WARNING: This product contains nicotine. Nicotine is an addictive chemical.”



## APPENDIX B – OVERVIEW OF INFORMATION DISCLOSURE REQUIREMENTS IN OTHER JURISDICTIONS

### European Union

The European Union has implemented a notification scheme for vaping products. Under the Tobacco Products Directive, manufacturers and importers are required to submit an electronic notification about their products six months prior to placing the product on the market. A new notification is to be submitted for each substantial modification of the product. The notification must include the following:

- Name and contact details of manufacturer and/or importer
- List of all ingredients contained in, and emissions resulting from the use of, the product by brand name and type, including quantities
- Toxicological data regarding product ingredients and emissions including the effects on the health of the consumer
- Information on nicotine dose and uptake
- Description of components of the product
- Description of the production process.

In addition, manufacturers and importers of vaping products in the EU must submit, on an annual basis:

- Sales volumes by brand name and type of product
- Information on preferences of various groups
- Mode of sale of the product
- Market surveys.

### United States

In May 2016, the Food and Drug Administration (FDA) issued a rule to extend its authority over all products meeting the definition of a tobacco product, except accessories of the newly deemed products. The rule extended FDA's tobacco product authorities to include e-cigarettes and their components and parts. This includes, but is not limited to, the requirement for premarket review and approval. Some of the information that must be provided as part of the premarket review includes:

- A full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation of the product
- Specimens of the labelling proposed to be used for the products
- Information on standards being met, or justification for any deviations from such standards
- A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product
- Full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products. While there is no universal requirement for post market reporting, there may be product-specific requirements applied as a condition of approval.

In addition, domestic manufacturers are required to register with the Food and Drug Administration, the name and place of business of any establishment engaged in the manufacture, preparation, compounding or processing of tobacco products and to provide a list of all tobacco products which are manufactured, prepared, compounded, or processed. Manufacturers, including importers, must also provide ingredients lists, reports of harmful or potentially harmful constituents and tobacco health documents (e.g. documents related to the health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents [including smoke constituents], ingredients, components, and additives).

## APPENDIX C – OVERVIEW OF THE FEDERAL REGULATORY PROCESS

In making regulations pursuant to the proposed Tobacco and Vaping Products Act, the following steps would generally apply:

1. Public consultation, where the proposal is made public and comments are invited from interested parties.
2. Pre-publication of the proposed regulations and accompanying Regulatory Impact Analysis Statement in the *Canada Gazette*, Part I, followed by a comment period of 30 or 75 days (the latter where the proposed regulations may affect international trade).
3. Consideration of comments received from the public and adjustment of the proposed regulations where appropriate.
4. Final approval by the Governor in Council.
5. Registration of the regulations and final publication in *Canada Gazette*, Part II.
6. Coming into force of the Regulations on the day of registration, unless the enabling statute or the Regulations themselves specify another effective date. For instance, the coming into force may happen six months after their publication, where a delay is necessary to meet Canada's trade obligations.

Note that regulations to be made under the proposed Tobacco and Vaping Products Act would only be proposed should Bill S-5 receive Royal Assent.

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