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Statutory authorities
Tobacco and Vaping Products Act
Canada Consumer Product Safety Act

Sponsoring department
Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Executive summary

Issues: Nicotine is the substance in tobacco products that causes dependence and drives the long-term use of these harmful products. There are concerns that the use of vaping products with nicotine by youth and non-users of tobacco products could lead to the use of tobacco products. Currently, there are no regulations that require information to be displayed on vaping products or their packaging about the presence or absence of nicotine and, for those products that contain nicotine, a warning about the addictiveness of nicotine.

Nicotine is highly toxic when ingested. Health Canada is aware of four fatalities of young children outside Canada and several non-fatal poisoning incidents in Canada related to the ingestion of vaping substances containing nicotine. Some requirements to help protect against vaping substance ingestion are already in place under the *Canada Consumer Product Safety Act* (CCPSA), but there are gaps in protection, particularly regarding refillable vaping devices and their parts.

Description: Health Canada is proposing that a single set of regulations be made under the authorities of the *Tobacco and Vaping Products Act* (TVPA) and the CCPSA. The proposed Regulations would set out the requirements in two parts: labelling requirements pursuant to the TVPA, and labelling and child-resistant container requirements pursuant to the CCPSA. The proposed labelling requirements include a list of ingredients, and, depending on the presence of nicotine and its concentration, a health warning that nicotine is highly addictive, the concentration of nicotine, and warnings regarding the toxicity of nicotine when ingested. In addition, the proposed Regulations would set out expressions that may be used on the product or package to indicate when a vaping product is without nicotine. The proposed Regulations would also require refillable vaping products, including devices and their parts, to be child resistant.

Cost-benefit statement: The proposed Regulations will impose costs on the vaping industry

and the Government of Canada. A cost-benefit analysis estimated that the annualized average costs for industry related to the proposed labelling provisions would be $260,500, and those for the child-resistant container provisions would be $350,000. The proposed labelling requirements would result in benefits by increasing awareness of the health hazards of vaping products and would enable the people of Canada to make informed choices regarding their use, including avoiding exposure to nicotine. The combination of mandating toxicity warnings and child-resistant container requirements would also provide benefits by helping to protect against poisoning incidents and fatalities. The analysis suggested that the benefits of the child-resistant container provisions would exceed their costs if one emergency room visit was avoided every 7 to 29 days or one death was avoided every 24 to 92 years.

"One-for-One" Rule and small business lens: The small business lens applies. The "One-for-One" Rule applies, as manufacturers and importers would have to obtain and maintain records with respect to the child-resistant container requirements. Nonetheless, having a single, product-specific regulation, which sets out labelling requirements using authorities under the CCPSA and the TVPA, would help to reduce the burden on small businesses. A coming-into-force period of 180 days is proposed, which would also benefit small businesses.

Domestic and international coordination and cooperation: The proposed Regulations would implement measures that are similar to those taken in the European Union for vaping products containing nicotine, which are required to display, among other things, a health warning regarding the addictiveness of nicotine and to provide information on the toxicity of nicotine. The proposed child-resistant requirements for refillable devices, and for stand-alone containers of vaping substances containing nicotine, are similar to the controls currently in place in the European Union. In the United States, a health warning regarding the addictiveness of nicotine is required for vaping products containing nicotine, and stand-alone containers of vaping substances containing nicotine must be child resistant.

Issues

An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts (referred to hereafter as "the Act") received royal assent on May 23, 2018. The Act established a new legislative framework in Canada to regulate vaping products, which consist of vaping substances, vaping devices and their parts. Vaping products are regulated under the *Tobacco and Vaping Products Act* (TVPA) and either the *Food and Drugs Act* (FDA) or the *Canada Consumer Product Safety Act* (CCPSA), depending on whether or not the product is marketed for a therapeutic use. As discussed below, this new framework has highlighted issues on which Health Canada proposes to take action as outlined in the proposed *Vaping Products Labelling and Packaging Regulations* (hereafter "proposed Regulations" or "proposal").

Nicotine toxicity

Nicotine is a highly toxic substance when ingested. A 2016 market study by Health Canada indicated that 86% of vaping substances marketed in Canada contain nicotine. Young children are curious by nature and explore their world with all their senses, including taste. [1] To the knowledge of Health Canada, ingestion of vaping substances containing nicotine has resulted in four reported fatalities in young children. These incidents occurred in Israel in 2013, the United States in 2015, South Korea in 2016 and Australia in 2019. Additionally, Health Canada is aware of a number of non-fatal poisoning incidents, including in Canada. The Canadian Hospitals Injury Reporting and Prevention Program data show that while there were no reports of injuries prior to 2013, there were 32 reported injuries related to vaping products between January 2013 and August 2018. [2] Seventy-eight percent (78%) of the injuries reported were poisonings from ingesting vaping substance, and 92% of those were among children aged four years or younger. Nearly two thirds (64%) of the vaping substances poisoning cases, among all age groups, specified that nicotine was involved. The rise in paediatric poisoning cases in Canada in recent years corresponds to a rise in sales of refillable vaping devices.

[3]

Current requirements for vaping products under the Canada Consumer Product Safety Act

Upon royal assent of the Act, vaping products that contain nicotine, and are not marketed for a therapeutic use, were considered consumer products and subject to the CCPSA. These vaping products must comply with CCPSA provisions, which prohibit the manufacture, importation, advertisement or sale of consumer products that are a danger to human health or safety. Further, vaping substances containing nicotine at certain concentrations became subject to the *Consumer Chemicals and Containers Regulations, 2001* (CCCR, 2001). These Regulations set out child-resistant container and toxicity warning requirements for stand-alone containers of vaping substances containing nicotine. The mandatory requirements imposed under the CCPSA and the CCCR, 2001 are intended to address risks posed by the acute toxicity of nicotine when ingested. Health Canada is currently enforcing these requirements. As described above, the existing requirements for vaping products regulated under the CCPSA allow Health Canada to address many of the risks posed by the acute toxicity of ingested nicotine.

However, there is one additional risk that is not currently addressed through the existing mandatory requirements. Vaping devices and their parts, including refillable tanks, do not need to meet the requirements from the CCCR, 2001 as a result of an exemption in the CCPSA that was put in place and came into force in May 2018. This exemption was put in place upon royal assent of the Act to allow industry time to source products that would meet the child-resistant container requirements.

Addictiveness of nicotine

Nicotine is a highly addictive substance. It is the substance in tobacco products that causes the addiction that drives long-term use and, as a result, repeated exposure to toxic chemicals in tobacco and its emissions. Vaping products deliver nicotine via inhalation of an aerosol formed when a nicotine-containing vaping substance is heated. In 2018, the United States National Academies of Sciences, Engineering and Medicine concluded that “there is substantial evidence that e-cigarette use results in symptoms of dependence on e-cigarettes.” [4]

Additional labelling concerns

A study conducted for Health Canada in 2017 showed diverse labelling practices among vaping product manufacturers. In particular, while the nicotine concentration did appear on most products, or their packaging, there was no consistency in how the information was presented. When present, there was also wide variation in the health warnings with few products indicating that nicotine is addictive. Given these additional findings and the concerns they raise, there is a need to use the powers of the TVPA to require that consumers be consistently informed about the presence of nicotine in a vaping product and about the addictiveness of nicotine. Also, prescribed expressions would be allowed to indicate that a vaping product is without nicotine.

Background

Tobacco use is the leading preventable cause of premature death and disease in Canada. Each year, 45 000 people in Canada die from smoking-related disease. Canada’s Tobacco Strategy aims to protect the health of the people of Canada, especially young people, from the dangers of tobacco use, including by helping the people of Canada quit smoking or reduce the harms of nicotine addiction.

While scientific knowledge is evolving, there is a consensus in the scientific community that for people who smoke, completely switching to vaping is less harmful than smoking conventional cigarettes. However, while vaping products may bring public health benefits if they reduce tobacco-related death and disease by helping adult tobacco users either quit or switch completely to a less harmful source of nicotine, these products are not harmless.

Most vaping products contain nicotine, which is highly addictive. Children and youth are especially susceptible to the risk of dependence.

Youth experimentation with and uptake of vaping could lead to tobacco use. Over a dozen studies show that among never-smoking youth, vaping significantly increases the risk of tobacco initiation.

Vaping products are also particularly harmful to youth and non-smokers because while they are less harmful than cigarettes, they emit chemicals during use that could negatively affect the health of youth and non-smokers. The long-term health effects of vaping products are still unknown, and there is limited research on the effects of second-hand vapour.

Furthermore, nicotine is a highly toxic substance when ingested. Vaping products therefore pose health and safety risks, especially to young children who may gain access to the product and its contents in a household.

Vaping products were introduced commercially to the global marketplace in 2006. Over the past decade, Canada and the world have seen a rise in the popularity of vaping products. Vaping products are referred to by many different names, including e-cigarettes, electronic nicotine delivery systems, vapes, vape pens, etc., and vary in design and appearance. For the purposes of the proposed Regulations, vaping products consist of vaping substances, vaping devices and their parts. The vaping substance, which includes substances commonly called e-liquids, is contained in a reservoir or tank within the device, and is normally drawn into an atomizer that creates an aerosol that is inhaled by the user. Technology continues to evolve rapidly in this area and there are many types of vaping device designs, such as

- closed devices that are not refillable;
- open devices that are refillable;
- devices that use cartridges that are prefilled and disposable;
- devices that use cartridges that are refillable; and
- devices that are completely customizable.

Vaping substances are primarily composed of propylene glycol and/or glycerol (sometimes referred to as vegetable glycerine), flavouring ingredients and often nicotine. A large number of vaping substances are available in Canada, with new formulations continually being introduced. Vaping substances may be sold in a stand-alone container ready-mixed by the manufacturer or custom-mixed in vaping shops. Vaping substances are also available in prefilled cartridge formats that are not intended to be refilled. Vaping substances are a recurring purchase, since they are consumed during vaping and are essential to the practice.

Legislative background

In May 2018, the Act amended the *Tobacco Act* to extend its scope to the manufacture, sale, labelling, and promotion of vaping products and to change its title to the *Tobacco and Vaping Products Act* (TVPA). Its purpose statement was also modified to include, among others, the goals of preventing the public from being deceived or misled with respect to the health hazards of using vaping products, and of enhancing public awareness of those hazards.

As defined in section 2 of the TVPA, *vaping product* means

> “(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, cannabis, as defined in subsection 2(1) of the *Cannabis Act*, cannabis accessories, as defined in that subsection, tobacco products or their accessories."

Under the TVPA, the packaging, manufacture and sale of vaping products are prohibited unless the product and/or its package display, in the prescribed form and manner, the information required by regulations.

The Act also amended the CCPSA by replacing the previous wording of items 3 and 4 of Schedule 1 of that Act with the following:

3. Devices within the meaning of section 2 of the *Food and Drugs Act*, except a *vaping product* within the meaning of section 2 of the *Tobacco and Vaping Products Act* that is not subject to the *Food and Drugs Act*.

4. Drugs within the meaning of section 2 of the *Food and Drugs Act*, except a *vaping product* within the meaning of section 2 of the *Tobacco and Vaping Products Act* that is not subject to the *Food and Drugs Act*.

Pursuant to these amendments, Health Canada is authorized to administer the CCPSA for the purposes of addressing health or safety issues relating to vaping products including those containing nicotine, but not vaping products within the meaning of section 2 of the TVPA that are subject to the FDA.

Vaping products with or without nicotine that are marketed for a therapeutic use continue to be regulated under the FDA, while being regulated under the TVPA, except where expressly excluded by the *Regulations Excluding Certain Vaping Products Regulated Under the Food and Drugs Act from the Application of the Tobacco and Vaping Products Act*.

Interim application of the CCCR, 2001, under the CCPSA

At this time, Health Canada has identified nicotine to be the only known ingredient of concern in vaping substances, related to toxicity by ingestion. Health Canada has assessed the toxicity of nicotine when ingested and, on the basis of that assessment, has determined the following:

1. Vaping substances, which are to be sold as consumer products, containing equal to or more than 66 mg/mL nicotine [5] meet the classification of "very toxic" under the CCCR, 2001 and are prohibited from manufacture, import, advertising or sale under section 38 of the CCCR, 2001.

2. Vaping substances, which are to be sold as consumer products, containing between 10 mg/mL and less than 66 mg/mL nicotine meet the classification of "toxic" and are subject to all applicable requirements under the CCCR, 2001, for toxic chemicals. Stand-alone containers of vaping substances intended for sale at retail are required to be sold in child-resistant containers, and to be labelled in accordance with the applicable CCCR, 2001 requirements, including a toxic hazard symbol on the container's main display panel.

Applicability of sections 7 and 8 of the CCPSA

The CCCR, 2001 classification scheme for the determination of toxicity does not apply to ingredients present in concentrations of less than 1% (which in the proposed Regulations is expressed as 10 mg/mL). Therefore, the CCCR, 2001 do not apply to vaping substances containing less than 10 mg/mL nicotine. However, a risk assessment conducted by Health Canada determined that nicotine at concentrations between 0.1 mg/mL and less than 10 mg/mL is potentially toxic when ingested and may contravene sections 7 and 8 of the CCPSA. As a consequence, in order to address this risk, Health Canada has communicated to industry that vaping substances within this range must adhere to all requirements of the CCCR, 2001 for "toxic" products, including the requirements for a child-resistant container.

Until the proposed Regulations come into force, the existing requirements and prohibitions will continue to apply to vaping substances that contain nicotine at concentrations of 0.1 mg/mL or more.

Recommendations regarding vaping products regulations

Canada is a Party to the World Health Organization Framework Convention on Tobacco Control (FCTC). Although vaping products are not captured in the scope of the FCTC, the World Health Organization (WHO) issued a report in 2016 on vaping products in response to a request made by the Conference of the Parties to the FCTC. [6] Among other things, the report recommends that Parties that have not banned the importation, sale, and distribution of Electronic Nicotine Delivery Systems (ENDS) / Electronic Non-Nicotine Delivery Systems consider the following options to minimize health risks to users and non-users:

- Regulate appropriate labelling of devices and vaping substances;
- Require health warnings about potential health risks deriving from their use. Health warnings may additionally inform the public about the addictive nature of nicotine in ENDS; and
- Reduce the risk of accidental acute nicotine intoxication by requiring tamper evident / child-resistant packaging for vaping substances and leak-proof containers for devices and vaping substances, and limiting the nicotine concentration and total nicotine amount in devices and vaping substances.

Countries have adopted various regulatory strategies with respect to vaping products. According to a policy scan prepared by the Institute for Global Tobacco Control, there are 98 countries that have national/federal laws regulating vaping products, including laws related to the sale (including minimum age), advertising, promotion, sponsorship, packaging (child-resistant packaging, health warning labelling, and trademark), product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavours), reporting/notification, taxation, use (vape-free) and classification of vaping products. [7] Of these countries, 29 have banned the sale of all types of vaping products and an additional 7 countries prohibit the sale of vaping products containing nicotine. [8] In the countries that permit vaping products, 38 mandate the placement of health warnings on packaging and 31 have regulations on child-resistant packaging. [9]

In March 2015, Canada's House of Commons Standing Committee on Health issued its report titled "Vaping: Towards a regulatory framework for e-cigarettes." [10] The Committee put forth 14 recommendations, one of which invited the Government of Canada to "… require that electronic cigarette components be sold in child-resistant packaging, and that all packaging clearly and accurately indicate the concentration of nicotine and contain appropriate safety warnings about the product."

Objectives

The objectives of this proposal are twofold, drawing from the authorities of the TVPA and the CCPSA.

The first objective of the proposal is to use the authorities set out in the TVPA to help protect young persons and non-users of tobacco from exposure to, and dependence on, nicotine and to help prevent vaping product use from leading to the use of tobacco products. More specifically, this proposal would enhance awareness of the health hazards of using vaping products and prevent the public from being deceived or misled with respect to the health hazards posed by their use.

The second objective of the proposal is to use the authorities set out in the CCPSA to help protect the health and safety of young children by reducing the risk that they ingest vaping substances containing toxic concentrations of nicotine. More specifically, this proposal would make a new regulation that

- prohibits vaping products with nicotine concentrations of 66 mg/mL or more;
- requires stand-alone containers of vaping substances containing nicotine in a concentration of 0.1 mg/mL or more to be child resistant and display toxicity warnings on product labels;
- requires refillable vaping devices and their parts to be child resistant; and
- requires all vaping substances to display an ingredient list on product labels.

Description

The proposed Regulations set out requirements under the authority of the TVPA and the CCPSA. The provisions proposed under the TVPA would apply to vaping products and their packaging that are

intended for retail sale or otherwise furnished to a consumer in Canada. As mentioned in the "Legislative background" section, the TVPA applies to all vaping products, including those regulated under the FDA, unless expressly excluded. With respect to the labelling requirements set out in this proposal under the authority of the TVPA, they would not apply to those vaping products regulated under the FDA. The proposed provisions under the CCPSA would apply only to vaping products that are consumer products, that is, those not subject to the FDA.

Proposals under the authority of the Tobacco and Vaping Products Act

1. *Vaping products containing nicotine*

There are two labelling elements being proposed under the TVPA for vaping products that contain nicotine: a nicotine concentration statement and a health warning about the addictiveness of nicotine. These labelling elements would be required on vaping products and/or their packaging, as the case may be, when the vaping product contains nicotine. This would include those vaping products that, in Canada, are intended for retail sale or to otherwise be furnished. [11] In certain cases, the use of tags or leaflets would be permitted.

The information required by the proposed Regulations would have to be displayed in both official languages and would have to respect legibility and visibility requirements.

For vaping substances in liquid form, this proposal would set out a method, namely Health Canada's Method C57.1: *Determination of Nicotine at Low Concentration in Liquids used in Electronic Nicotine Devices by GC-MSD/FID* dated May 31, 2018, that could be used by regulatees to determine whether the substance contains nicotine. [12] This method would be incorporated by reference into the proposed Regulations in a version that can be amended from time to time. Therefore, it is the latest version of Method C57.1 that would apply. This method would also be used by Health Canada, for compliance and enforcement purposes, to determine when a vaping product would be required to display the nicotine concentration and health warning on the product or its packaging. The title of this method is published on the Government of Canada website, and the method is available upon request from the Government of Canada. [13]

a) Nicotine concentration statement

A statement of the nicotine concentration of vaping products that contain nicotine would be required on the main display panel of the product or package. In certain cases, such as vaping devices and parts that contain vaping substances with nicotine, this information could be displayed on a tag attached to the product. For the nicotine concentration statement, the word "Nicotine" would be required and the concentration would be expressed in mg/mL for all forms of vaping substances.

b) Health warning

The nicotine addictiveness warning would be "WARNING: Nicotine is highly addictive." ("AVERTISSEMENT : La nicotine crée une forte dépendance." in French). This health warning would be required to appear on the main display panel of the product or package in both official languages. When a vaping product is sold without packaging or if the packaging or product is very small, this information could be displayed on a tag or in a leaflet, as the case may be.

The proposed health warning would be provided in a separate document entitled "List of Health Warnings for Vaping Products" and would be made available upon request. This document would be incorporated by reference in the proposed Regulations in a version that can be amended from time to time. This would give Health Canada more flexibility to amend the document as new scientific evidence emerges on vaping products. Stakeholders would be notified of any proposed change to the list of health warnings. The proposed Regulations would allow for a 180-day transitional period after any change to the list to allow time to modify the health warnings that are used on the product and its packaging.

2. *Vaping products that do not contain nicotine*

When a product does not contain nicotine, one of the following expressions could be used on the

product or its package. These expressions are the following:

- Nicotine-free / Sans nicotine
- No nicotine / Aucune nicotine
- Does not contain nicotine / Ne contient pas de nicotine

The use of one of these expressions on the product or package would be voluntary.

Proposals under the authority of the Canada Consumer Product Safety Act

The proposal maintains and extends the prohibition on the manufacture, importation, advertisement or sale of vaping products containing 66 mg/mL or more of nicotine, which is already in force under the CCCR, 2001. Since nicotine is the only ingredient that is acutely toxic by ingestion known to be present in vaping substances, this proposal provides an opportunity to avoid using general toxicity classification criteria and instead sets out the appropriate nicotine concentration considered to be very toxic.

The proposal sets out requirements for vaping substances containing nicotine in a concentration of 0.1 mg/mL or more to be packaged in a child-resistant container. Such containers would also be required to display a toxicity warning including the toxic hazard symbol. These requirements would not apply if the container does not permit exposure to the non-aerosolized form of nicotine under reasonably foreseeable use. The proposal also sets out requirements for refillable vaping devices and their parts to be child resistant.

Each of the elements above is discussed specifically in the following sections.

Prohibitions

Health Canada has conducted a risk assessment on the acute toxicity of nicotine when ingested. The assessment determined that any vaping substance containing 66 mg/mL or more of nicotine is excessively toxic if ingested. Therefore, it is proposed to continue to prohibit any vaping product containing nicotine at these concentrations from being manufactured, imported, advertised or sold.

Requirements

The proposal sets out a child-resistant container requirement for any vaping product that may hold a vaping substance containing nicotine in a concentration of 0.1 mg/mL or more. The proposed child-resistant container requirements are modelled on those found in the CCCR, 2001. The child-resistant container requirement would be applied to refillable vaping devices and their parts, including component tanks or reservoirs that may hold vaping substances, and to stand-alone containers of vaping substances containing nicotine in a concentration of 0.1 mg/mL or more. The proposal would include a requirement for importers and manufacturers to obtain and maintain records to demonstrate that the container meets the child test protocol requirements in one of the prescribed acceptable standards. The person responsible for the vaping product would be required to maintain documentation to demonstrate that the closure on the container maintains its function for the lifetime of expected use. This person would also be required to include labelling, on the closure or display surface of the container, that instructs proper operation of the closure by the user. Finally, any documentation would have to be kept for a period of at least three years.

Any container of a vaping substance containing nicotine in a concentration of 0.1 mg/mL or more would have to have the toxic hazard symbol appear on the container and outer package, as applicable. A cautionary statement next to it would be required to state, in both official languages: “**POISON:** if swallowed, call a Poison Control Centre or Doctor immediately.” (“**POISON :** en cas d’ingestion, appeler immédiatement un centre antipoison ou un médecin,” in French). The hazard symbol and statement is designed to draw a person’s attention to the fact that nicotine is acutely poisonous if ingested, and to provide emergency instruction should poisoning occur.

All vaping substances, whether or not they contain nicotine, would be required to display a list of ingredients to allow consumers to make informed choices regarding the products they choose to use.

Exceptions

The proposed Regulations establish various exceptions to the requirements laid out above. The child-resistant container requirements and toxicity warning labelling would not be required when exposure to the vaping substance is not reasonably foreseeable, such as when the product is not refillable. In addition, refillable vaping devices and their parts would not be subject to labelling requirements for toxicity warning, unless they are sold prefilled with a vaping substance containing nicotine in a concentration of 0.1 mg/mL or more. In such cases, the toxicity warning would still be required on the outer package, and where there is no outer package, the information would be required on a tag attached to the product.

The proposal sets out an exception such that persons responsible for the importation of a vaping product that does not comply with a requirement of the proposed Regulations may import the product for the purposes of bringing it into compliance. This exception is considered necessary in order not to impede industry business models such as bringing foreign products into compliance with Canadian requirements for sale in Canada or export to another country.

Application of the CCCR, 2001

In order to clearly and efficiently regulate vaping products subject to the CCPSA under a new, product-specific regulatory instrument, the proposal would alter the application of the CCCR, 2001.

Exclusion of vaping products from the application of the CCCR, 2001

Currently, to satisfy Part 1 of the CCCR, 2001, which addresses toxic consumer chemical products, there are toxicity labelling and child-resistant container requirements that apply to vaping substances containing nicotine sold in stand-alone containers. In order for the labelling and child-resistant container requirements for vaping products to appear in only one regulation authorized under the CCPSA, the regulatory proposal would consequentially and specifically exclude these products from the application of the CCCR, 2001. However, these products will continue to be subject to the provisions of the CCPSA.

An order to repeal subsection 4(4) of the CCPSA

An order to repeal subsection 4(4) of the CCPSA (which excludes vaping devices and their parts from the application of the provisions of the CCCR, 2001) upon coming into force of the proposed Regulations is also proposed, since the addition of this subsection is an interim measure intended to be in effect until product-specific Regulations were published. Since the regulatory proposal would remove the application of the CCCR, 2001 to vaping products in its entirety, subsection 4(4) of the CCPSA would become redundant. Subsections 75(3) and 80(8) of the Act provide for the repeal of this subsection on a date to be set by the Governor in Council.

Coming into force

The proposed Regulations would come into force on the 180th day after the day on which they are published in the *Canada Gazette*, Part II. The interim measures under the CCCR, 2001 will continue to apply to vaping substances containing nicotine subject to the CCPSA until such time as the proposed Regulations come into force.

During the 180-day period between publication in the *Canada Gazette*, Part II, and the coming into force date, a stand-alone container of a vaping substance may meet the toxicity warning requirements in the proposed Regulations or those in the CCCR, 2001.

Regulatory development

Consultation

In August 2017, Health Canada published a consultation paper on potential regulatory measures that were under consideration for vaping products. [14] Ten potential measures for the regulation of vaping products were set out, four of which relate to the objectives of this proposal. These were

- that all vaping products that contain nicotine display their nicotine concentration in milligrams/millilitre (mg/mL);
- that any vaping product be considered to contain nicotine if nicotine is present at a concentration of 0.1 mg/mL or higher;
- 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.”; and
- that products that contain vaping substances display a complete list of ingredients in descending order by weight.

In response to this consultation, a total of 105 comments were received from academics; the public; other levels of government; industry, including the health products, vaping and tobacco industries; non-governmental organizations; public health groups; and retailers, including vape shops. Support was strong for all four labelling measures.

With regard to the health warnings, some stakeholders felt that certain aspects should be similar to tobacco labelling. These suggestions included that the warnings be graphic in nature, be rotated, occupy a minimum percentage of the package and that the packaging be plain in colour and design. In addition, some stakeholders indicated that the warnings for vaping products must be balanced with other messaging, such as relative risk statements, in order to support harm reduction and that the warnings must stay current with the science.

The industry expressed concerns that some smaller businesses would need sufficient time to deplete stock of existing labels. In addition, requiring that all flavouring ingredients be identified in the list of ingredients would be difficult for the industry, and it was suggested that the use of the term “flavour” in the list of ingredients would make it easier for industry. Concerns were also raised about the methodology and its ability to detect nicotine at a concentration of 0.1 mg/mL. Industry suggested that a minimum of 0.5 mg/mL should be considered for the amount of nicotine to require the health warnings and that the amount of nicotine should be displayed either in percent or mg/mL. In contrast, some public health groups and municipal/provincial/territorial governments commented that a vaping product should be considered to contain nicotine at any detectable level, as opposed to the proposed 0.1 mg/mL.

A summary of the comments received is available on the Government of Canada website. [15]

In response to comments about the need to stay current with the science, Health Canada is proposing to incorporate by reference the proposed *List of Health Warnings for Vaping Products* in a version that can be amended from time to time. This would allow Health Canada to be flexible and responsive to emerging science and technology for modifying the proposed health warnings. When a change to the *List of Health Warnings for Vaping Products* is made, a transitional period of 180 days would be allowed for industry to comply with the change. Since there is only one health warning proposed at this time, there is no need for rotation of health warnings. To accommodate the concern that vaping products and their packaging can often be very small in size, the proposed Regulations would permit the use of tags and leaflets in certain cases.

In response to industry’s concerns about the listing of all flavour ingredients, the term “flavour” (“arôme” in French) must be indicated in the list of ingredients rather than the common name for the flavouring ingredients. In addition, in response to concerns raised about the availability of laboratory methods to determine the amount of nicotine at or below 0.1 mg/mL, a test method, Method C57.1: *Determination of Nicotine at Low Concentration in Liquids used in Electronic Nicotine Devices by GC-MSD/FID*, has been developed by Health Canada to determine nicotine at low concentrations. The title of this method is published on the Government of Canada website, and the method is available upon request from the Government of Canada. [16]

In response to concerns about a sufficient transition time to implement the requirements, a transitional period of 180 days would also be provided to allow industry to deplete their stock of existing products and labels.

The statement “Use of nicotine during pregnancy may harm the fetus” is not included in the current proposal due to feedback received from scientific experts that there were limitations in the current scientific knowledge to support its inclusion for vaping products at this time.

The consultation document provided general information about the application of the CCPSA and the CCCR, 2001 to vaping products. The document indicated that the CCCR, 2001 would apply to all vaping products containing between 10 mg/mL and less than 66 mg/mL of nicotine. While concentrations of nicotine between 10 mg/mL and less than 66 mg/mL would be captured by the CCCR, 2001, a risk assessment of the toxicity of nicotine when ingested provides support for the position that vaping substances containing between 0.1 mg/mL and less than 10 mg/mL of nicotine that lack suitable toxicity labelling and child-resistant containers may constitute a danger to human health or safety for the purposes of sections 7 and 8 of the CCPSA. The consultation document also signalled that the packaging and labelling requirements would apply to all vaping products that do, or that may, contain nicotine, including refillable vaping devices.

In addition, a Notice to Industry was posted online and mailed to stakeholders in October 2017. This notice outlined, in greater detail, the regulatory requirements of the CCCR, 2001 for child-resistant containers and toxicity labelling for vaping products that would be effective upon royal assent of the Act.

While there was strong support for child-resistant containers to be required for vaping substances containing nicotine, there was strong opposition to requiring vaping devices to meet child-resistant container requirements. Industry stakeholders stated that virtually all vaping devices are imported from China, that there were very few vaping device models available that would meet the child-resistant container requirements, and that manufacturers would be unwilling to develop compliant models for the small Canadian market. Several industry stakeholders indicated that requiring vaping devices to meet child-resistant container requirements would have a devastating effect on the Canadian vaping industry. As a result, the Act was amended by Parliament to exempt from the CCCR, 2001, as an interim measure, devices and parts as defined in paragraphs (a) to (c) of the definition of a vaping product in section 2 of the TVPA.

Comments received were supportive of toxicity labelling on vaping substances, although some stakeholders expressed general concern that limited label space may make compliance with the CCPSA and other government labelling requirements problematic.

Health Canada posted the *Guidance on Vaping Products Not Marketed for a Therapeutic Use* on May 23, 2018, and notified industry members of its availability. [17] This document signalled Health Canada’s intention to introduce specific regulations for vaping products under the CCPSA. Industry stakeholders were also provided the opportunity to take part in a webinar on this issue and were able to seek further clarification of the proposal during the webinar’s question and answer session. Health Canada inspectors continue to be available to respond to questions from industry.

Public opinion research

Health Canada conducted public opinion research (POR) on the labelling elements that are set out in this proposal. The research was conducted in two phases and the participants included smokers and vapers.

The findings from phase 1, the exploratory stage, showed a large gap related to vaping product information among both vapers and smokers, in particular the lack of knowledge about the health effects and health hazards of using vaping products. There was a clear interest on the part of those using vaping products and smokers that do not vape to learn more about vaping.

In phase 2, labels showing the labelling elements considered under the authority of both the TVPA and CCPSA were tested on various vaping product and packaging configurations. The labelling elements tested included a nicotine concentration statement, a message on the addictiveness of nicotine, the CCCR, 2001 toxic hazard symbol shown with and without the word POISON, a first aid treatment statement and a list of ingredients. In addition, variations in the wording of the health warning on nicotine addictiveness and the expressions that would indicate that the product does not

contain nicotine were tested.

Participants indicated that they were interested in mandatory labelling information that would include an ingredient list, the nicotine content, and warnings or information related to health hazards. However, as presented in the mock-ups used in the POR, the information conveyed was not fully understood and some labelling elements were interpreted in multiple ways. Participants were often unable to clearly identify and differentiate the risks conveyed by the various labelling elements, which resulted in the meaning of each individual statement or component being weakened. In addition, some of the labelling elements were considered too vague or incomplete to provide effective guidance to consumers.

In response to the findings of the POR testing, modifications to the placement and wording of certain labelling elements of the proposal were made.

These changes include

- The proposed warning would read, in both official languages: "**POISON:** if swallowed, call a Poison Control Centre or Doctor immediately." ("**POISON :** en cas d'ingestion, appeler immédiatement un centre antipoison ou un médecin." in French).
- The statement above works by combining the specific hazard statement of "POISON" with the first aid statement to better clarify the risk posed by the nicotine in the vaping substance. That is, ingestion of the nicotine in the vaping substance is acutely toxic. This warning would be placed alongside the hazard symbol anywhere on the display surface, which is different, in terms of the location of the warning, from the requirements in the CCCR, 2001 where it must be located on the main display panel.
- The nicotine concentration statement would be co-located with the addictiveness warning, in all cases except those when the label is very small. Placing these two messages together provides the consumer with the complete messaging (i.e. this product contains nicotine and nicotine is addictive) while limiting the amount of information that must be repeated on a small label.

Modern treaty obligations and Indigenous engagement and consultations

All people of Canada, including Indigenous peoples, would benefit from the public health and product safety approach taken in these proposed Regulations. Child-resistant container requirements would provide protection to young children from nicotine poisoning, and labelling requirements for vaping products would provide information on the health hazards of using vaping products containing nicotine to enhance public awareness and prevent the public from being deceived or misled with respect to these hazards.

Instrument choice

Option 1: Status quo

Under this option, Health Canada would continue to rely on the CCCR, 2001 for vaping substances containing nicotine in concentrations of 10 mg/mL or more. Further, sections 7 and 8 of the CCPSA would still need to be relied upon for vaping substances containing nicotine in concentrations between 0.1 mg/mL and less than 10 mg/mL, since these concentrations are potentially toxic when ingested but are not addressed by the CCCR, 2001. Some regulated parties may find this approach to be overly complex and unclear. In addition, there are some features of the CCCR, 2001 that limit their suitability to address the ingestion toxicity risk posed by vaping substances containing nicotine, including

1. Given that subsection 4(4) of the CCPSA excludes vaping devices and their parts from the scope of the CCCR, 2001, the authorities of the CCCR, 2001 cannot be applied to require refillable tanks of open vaping devices and their parts to be child resistant.

2. The CCCR, 2001 prescribe a criteria-based system that addresses the inherent hazards associated with a consumer chemical product. Under the current system, the entirety of the CCCR, 2001 applies to vaping substances, which means that each responsible person must evaluate their

substances against hazard categories and exposure routes that are not likely applicable, such as corrosivity. This presents an unnecessary burden on industry given that Health Canada has identified nicotine to be the only known ingredient of concern in vaping substances, related to toxicity by ingestion.

3. Nicotine is potentially toxic when ingested at concentrations below 10 mg/mL; however, the authorities of the CCCR, 2001 are not applicable in cases where a toxic ingredient is present in a concentration below that limit.

4. The POR completed in 2018 revealed that some elements of the toxicity warning were confusing to people who use vaping products. In some cases, they interpreted the warning to mean that inhaling the aerosol was poisonous, rather than the intended message that ingesting the liquid was poisonous.

***Products that pose a danger to human health or safety under the* Canada Consumer Product Safety Act**

On the basis of a risk assessment conducted by the Department, Health Canada has determined that vaping substances containing nicotine in a concentration of 0.1 mg/mL or more may pose a danger to human health or safety and has initiated compliance and enforcement action. However, because the danger to human health or safety provisions of the CCPSA are of general application to consumer products and do not refer specifically to vaping products, some industry members may not be aware of the extent of their obligation to ensure that containers of vaping substances containing nicotine in a concentration of 0.1 mg/mL or more have effective protections against ingestion risks.

Industry practice in Canada

In Canada, the Electronic Cigarette Trade Association recommends that manufacturers voluntarily display the nicotine concentration and a list of ingredients on the product label. Currently, regulations administered by Health Canada do not set out requirements to inform consumers that a vaping product contains nicotine, what amount of nicotine is present or that nicotine is highly addictive. A 2017 study conducted for Health Canada showed diverse labelling practices among manufacturers. While information about the amount of nicotine did appear on most products, there was no consistency in how that information was presented. The absence of regulations specific to this type of information could lead to consumers being deceived or misled with respect to the health hazards of using vaping products.

For the reasons outlined above, Option 1 is not the preferred option.

Option 2: Introduction of Vaping Products Labelling and Packaging Regulations under the TVPA and the CCPSA

The second option involves making a new proposed regulation, jointly made under the TVPA and the CCPSA. The proposed Regulations would set out requirements for vaping products that address the acute toxicity of nicotine when ingested, and would include child-resistant container and labelling requirements for toxicity, modelled after those in the CCCR, 2001 of the CCPSA. These proposed Regulations would also include mandatory labelling requirements that would support the purposes of the TVPA.

This is the option represented by the current regulatory proposal. It was chosen for the following reasons:

1. Relying on the application of the provisions of the CCPSA, for vaping substances containing nicotine in concentrations between 0.1 mg/mL and less than 10 mg/mL, and relying on the CCCR, 2001, for vaping substances containing nicotine in concentrations of 10 mg/mL or more, to address the nicotine ingestion risk is likely to cause confusion for industry. Setting out specific regulatory requirements would provide greater clarity, certainty and predictability for industry, as well as for Health Canada officials engaged in compliance and enforcement activities.

2. Exposure to nicotine is possible when refillable vaping devices or their parts are not child resistant. These products do not need to meet the requirements of the CCCR, 2001 through an exemption in

the CCPSA that came into force in May 2018. Child-resistant devices are now available on the global marketplace, but in order for Health Canada to remove the exemption and address the nicotine ingestion risk, a new regulation must be introduced.

3. For vaping products that are regulated under both the TVPA and the CCPSA, there are currently no labelling requirements to inform consumers regarding the addictiveness of nicotine, to display the nicotine concentration in a standardized format or to provide a list of ingredients. The CCCR, 2001 only require a product label to disclose hazardous ingredients that contribute to the classification conclusion and that are present at a concentration of 1% or more.

4. Introduction of a single, product-specific regulation for vaping products would enable Health Canada to more readily address future health or safety risks captured by the scope of the CCPSA, such as other toxicological, mechanical or electrical risks related to vaping products, through amendments to that regulation. This would also benefit industry by having all CCPSA requirements for vaping products under one regulation.

5. Introduction of a single, product-specific regulation that sets out labelling requirements using authorities set out in the TVPA and the CCPSA would make the regulatory framework easier to understand for industry as well as for Health Canada officials engaged in compliance and enforcement activities.

Regulatory analysis

Benefits and costs

A cost-benefit analysis (CBA) was commissioned by Health Canada to quantify the expected costs and benefits of the proposed Regulations. The CBA was finalized in March 2018 and was based on market data collected in 2016. [18] In response to a rapidly evolving vaping product market, and concerns that had been raised by industry, a supplemental cost analysis was completed in March 2019. The supplemental analysis focussed solely on providing updated cost information related to the availability of child-resistant refillable vaping devices and included updated text for specific sections of the 2018 report. The CBA report and the supplementary cost-analysis report are available upon request to the departmental contact.

The supplemental report provided the accounting statement for 30 years, from 2016 to 2046, as shown in Table 1. The table reflects the central case for each industry cost category: labelling of vaping substances, labelling of vaping devices and their parts, child-resistant vaping substance containers and child-resistant vaping devices and their parts. It presents the costs in 2016 Canadian dollars and uses a 7% discount rate for the 30-year projection. The statement shows the estimated annualized average cost to industry to comply with the requirements of the proposed Regulations of $610,500, and the estimated total present value cost of $7,580,500.

The accounting statement also shows the estimated costs to Government for compliance promotion, monitoring and enforcement of the proposed Regulations. There was greater certainty for the government costs, and these were reflected in the 2018 CBA report only as central values. The statement shows the estimated annualized average cost to Government to promote, monitor and enforce the proposed Regulations of $223,000, and the estimated total present value cost of $2,965,000.

The statement shows the estimated annualized average total cost of the proposed Regulations as $833,500, and the estimated total present value cost of $10,545,500.

Positive and negative impacts of the proposal on consumers and industry, which were quantified but not monetized, are also listed in Table 1 as well as qualitative impacts.

Table 1: Accounting statement for overall proposed *Vaping Products Labelling and Packaging Regulations*

Accounting Statement		Year 1	Year 2	Year 3	Year 4 Through 30	Total PV	Annualized Average
A. Quantified impacts (2016 Canadian dollars, 7 % discount rate, 30-year project life)							
Costs							
Costs to industry	Labelling of vaping substances	3,159,500	0	0	0	3,159,500	254,500
	Labelling of vaping devices and parts	75,000	0	0	0	75,000	6,000
	Child resistance for vaping substances	58,000	62,000	65,000	68,000	886,000	71,000
	Child resistance for vaping devices	3,460,000	0	0	0	3,460,000	279,000
	Subtotal	**6,752,500**	**62,000**	**65,000**	**68,000**	**7,580,500**	**610,500**
Costs to Government	Labelling requirements: compliance promotion, monitoring and enforcement	134,000	248,000	248,000	248,000	2,818,000	212,000
	Child resistance requirements: compliance promotion, monitoring and enforcement	26,000	28,000	28,000	28,000	147,000	11,000
	Subtotal	**160,000**	**276,000**	**276,000**	**276,000**	**2,965,000**	**223,000**
Total costs		**6,912,500**	**338,000**	**341,000**	**344,000**	**10,545,500**	**833,500**
B. Quantified impacts not monetized							

Positive impacts	Public health benefits are expected from reducing poisoning incidents and fatalities, especially to young children who may gain access to the vaping substances containing nicotine. A break-even analysis for the child-resistant container provisions suggests that avoiding one death every 24 to 92 years or one emergency room visit every 7 to 29 days may yield benefits commensurate to the costs estimated for the proposed child-resistant container requirements.
Negative impacts	**Consumers**: Industry compliance costs may be passed through to consumers in the form of higher vaping substance and device prices, although the anticipated percentage increase in retail price is minor.
	Industry: Lost producer surplus for manufacturers and importers of vaping substances and devices, although these losses appear minor in comparison to industry revenue. Compliance costs for vaping substances are less than 0.5 % of industry revenue.
C. Qualitative impacts	
Positive impacts	**Consumers:** The proposed toxicity warning explains the toxicity exposure route in simple language and may improve consumers' understanding that the acute toxicity risk posed by nicotine is related to ingesting it, not inhaling it. The proposed nicotine concentration statement and the addictiveness warning are expected to increase consumers' awareness of the presence of nicotine in certain vaping products and that nicotine is highly addictive. This information could assist consumers, in particular non-smokers and youth, in making an informed choice regarding the use of these products. Initiation of vaping by non-smokers and youth could potentially lead to nicotine addiction and a transition to tobacco product use. However, a slight decrease in the initiation rate of vaping products among non-smokers and youth could result in public health benefits. The bulk of these potential public health benefits would be derived from reducing the number of deaths attributable to cigarette use and exposure to second-hand smoke over a 30-year period.
	Industry: The proposed Regulations streamline the regulatory framework by combining the labelling requirements from the TVPA and the CCPSA into a single, product-specific regulation that may make it easier for industry to understand how to comply. The proposal would result in the new labelling requirements authorized by different Acts coming into force at the same time and this may enable industry to adjust their labels only once.
Negative impacts	**Consumers**: Some consumers may experience a loss in economic welfare as a result of a reduction in the variety of vaping products available on the market. Aversion to health and safety messaging could potentially reduce consumer welfare. A loss of consumer surplus may occur if companies remove refillable vaping devices from the market or increase their prices in response to the proposed requirements related to child resistance.
	Industry: Child-resistant container requirements for refillable vaping devices may hasten consumer migration to closed devices, imposing negative impacts on vape shops and small vaping substance manufacturers. Some closures among small vaping substance manufacturers are possible.

Costs

In Canada, vaping devices are almost exclusively imported, with China being the largest producer. This is not the case with vaping substances. Most vaping substances are manufactured in Canada,

with the United States being the main source of imported substances. The estimation of costs to industry is challenging because the vaping industry is relatively new and continues to evolve. The CBA found that the information on industry characteristics was limited and that market conditions are rapidly evolving. Further changes in the vaping market are anticipated. These uncertainties have implications for the CBA, which are outlined below:

- Quantitative estimates of industry compliance costs were provided as lower- and upper-bound values, with the resulting broad ranges reflecting the considerable uncertainty in the underlying parameters.
- When reliable information was lacking, qualitative analysis was used to characterize the anticipated key outcomes. This was especially true for the assessment of the secondary impacts.
- Estimates were based on a snapshot of the industry as it existed in 2016. A variety of factors may influence the evolution of the vaping industry and the long-term outcome is difficult to forecast. To address recent changes in the availability of child-resistant devices and update relevant cost estimates, a supplemental CBA was completed in March 2019.
- The analysis does not differentiate between costs that would be carried by foreign suppliers of vaping products and costs that would be carried by domestic producers.

Several assumptions were made in the CBA including

- an analytical period of 30 years spanning from 2016 to 2046 was adopted;
- an annual discount rate of 7%;
- a base year of 2016 to which costs are discounted;
- monetized values are expressed in 2016 Canadian dollars; and
- the costs carried by foreign suppliers would be passed on to Canadian importers.

The CBA estimated the costs to industry across four elements of the proposed Regulations: labelling of vaping substances, labelling of vaping devices and their parts, child-resistant vaping substance containers and child-resistant vaping devices and their parts.

The 2018 and 2019 CBA reports provided lower- and upper-bound values for costs to industry across the labelling and the child-resistance requirements of the proposal. Health Canada has selected a simple average, lower- or upper-bound value as the central value for each industry cost category based on the Department’s understanding of the most likely outcomes for industry. An explanation of the central value applied to each cost category is provided in the following sections.

Compliance for labelling of vaping substances

The central value for the annualized average cost to industry to implement the labelling requirements for stand-alone containers of vaping substances was estimated to be $254,500, and the total present value cost was estimated to be $3,159,500. A mid-range cost estimate was generated by calculating a simple average from the lower- and upper-cost estimates, which were $55,000 and $454,000 for the annualized average, and $689,000 and $5,630,000 for the present value. A mid-range cost estimate was applied, given that industry has already adjusted to the labelling requirements for the toxicity warning and nicotine content, as applicable, since these requirements have been in place, under the CCCR, 2001 provisions, as of May 23, 2018. The mid-range estimate reflects the label redesign and printing that may be required to comply with proposed labelling elements that are new. A new element for all products is the ingredient list. For products that contain nicotine, the new elements are the nicotine concentration statement, the nicotine addictiveness warning, and the modified toxicity warning. Therefore, industry would bear some costs. It is estimated that the costs would be centralized between the low and high estimates provided in the CBA.

Compliance for labelling of vaping devices and their parts

The central value for the annualized average cost to industry to implement the labelling requirements

for vaping devices and their parts was estimated at $6,000, and the total present value cost was estimated at $75,000. These central values were identified using the upper estimates from the ranges for this cost category: $1,000 and $6,000 for the annualized average, and $17,000 and $75,000 for the present value. While some prefilled vaping devices and their parts may already have labels that present an ingredient list, the nicotine concentration and warnings about the addictiveness of nicotine, as applicable, some label or package redesign may be required. It is appropriate to use the upper-cost estimates for these proposed labelling requirements since they would be new for industry.

Compliance for child-resistant stand-alone containers of vaping substances

The central value for the annualized average cost to industry to implement the child-resistant container requirements for stand-alone containers of vaping substances containing nicotine was estimated at $71,000, and the total present value cost was estimated at $886,000. These central values were identified using the lower estimates from the ranges for this cost category: $71,000 and $301,000 for the annualized average, and $886,000 and $3,739,000 for the present value. It is appropriate to use the low-cost estimates for the child-resistant containers of vaping substances containing nicotine, given that the CBA was completed prior to royal assent of the Act, when there was no Canadian requirement for child-resistant containers. The child-resistant container requirements for stand-alone containers of vaping substances containing nicotine as described in the proposed Regulations are currently in effect and have been enforced. For example, after May 23, 2018, Health Canada contacted 269 establishments across Canada and inspected 497 stand-alone containers of vaping substances containing nicotine as part of an initial compliance and enforcement project related to the child-resistant container requirements of the CCCR, 2001. The results of the inspections showed 95.4% compliance with the child-resistant container requirements. Therefore, the lower-cost estimate was applied for the central value in this cost category, since the majority of products on the market is already in compliance.

Compliance for child-resistant refillable vaping devices and their parts

The central value for the annualized average cost to industry to implement the proposed requirements for refillable tanks of vaping devices and their parts that may hold a vaping substance to be child-resistant was estimated at $279,000, and the total present value cost was estimated at $3,460,000. These central values were identified using the upper estimates from the ranges for this cost category: $28,000 and $279,000 for the annualized average, and $346,000 and $3,460,000 for the present value. It is appropriate to use the upper cost estimates for the child-resistant container requirements for refillable tanks of vaping devices and their parts, since these proposed requirements would be new for industry and they would be required to test the devices or parts to one of the child test protocols identified in the proposed Regulations.

It is noted that during the initial CBA, industry representatives indicated that technical solutions for making refillable vaping devices child-resistant were lacking, and that they foresaw difficulties in convincing overseas manufacturers to modify designs exclusively for the Canadian market. Based on responses from industry, the initial CBA noted that detailed estimates of the cost of meeting this requirement were not available. However, the report presented a qualitative estimate, based on a single manufacturer’s comment estimating a cost for product redesign of $750,000 per device model. The industry representatives whose commentary contributed to the CBA appear not to have been aware that the European Union published a directive in 2014 requiring its Member States to set out regulations for vaping products, including a requirement that refillable vaping devices be child-resistant. [19]

A supplemental cost analysis, completed in March 2019, was undertaken to provide updated cost information related to the availability of child-resistant refillable vaping devices. The analysis focused on vaping device brands popular on the Canadian market. Relevant devices on retail websites were identified to draw a comparison between similarly designed products that were child-resistant compared to products that were not child-resistant. Similarity was based on the product’s category, style, tank capacity, coil-resistance and battery wattage. The supplemental analysis indicated that child-resistant devices were not more or less expensive than comparable devices that were not child-resistant. They were relatively cost comparable. The supplemental report concludes that it is no

longer the case that device makers may need to invest in complex redesigns and coordinate the implementation of these new designs with overseas manufacturers. Evidence suggests that Canadian retailers would simply need to stock child-resistant devices, with little or no direct compliance costs for manufacturers or importers.

Costs to Government

Costs to the Government would include the costs of compliance promotion, compliance monitoring and enforcement actions. Initial implementation costs for child-resistant containers and labelling compliance activities are estimated to be $160,000 and annual costs at $276,000 in the first five years and $180,000 per year afterwards. The annualized average cost for the administration of the child-resistant container and labelling requirements is estimated at $223,000, and the present value cost is estimated at $2,965,000. It is noted that Health Canada has been actively promoting, monitoring and enforcing several elements of the proposal already in effect under the CCPSA since royal assent of the Act. As a result, the Government may have already assumed many of the initial costs.

Costs to consumers

No quantified direct costs to consumers were indicated by the cost-benefit analysis. Major identified impacts affecting consumers included a possible lack of product diversity, both in terms of vaping substances and vaping devices. This was related to the assumption that increasing costs of compliance could see a decrease in product diversity both directly, from higher costs of compliance, and indirectly, due to a possible decrease in the size of industry. Another major impact identified was the possible higher cost of vaping products due to compliance costs being passed on to the consumer.

Benefits

Many of the same challenges of analyzing costs were present when attempting to calculate potential benefits of the regulatory proposal. Therefore, a quantitative estimate of the direct impact to the proposed Regulations was not possible. The CBA presents several illustrative benefits analyses.

The proposals under the authority of the TVPA to display information on vaping products and their packaging would enhance awareness of the health hazards posed by using vaping products and would prevent the public from being deceived or misled with respect to these health hazards. By informing the people of Canada about nicotine concentrations in a consistent manner, and by making them aware that nicotine is highly addictive, it is expected that the proposal would contribute to increasing awareness about the addictiveness of vaping products and would enable Canadians to make an informed choice regarding the use of these products, including avoiding exposure to nicotine. The proposed labelling requirements would result in public health benefits when they assist youth and non-users of tobacco products to avoid vaping product use and when they contribute to an adult smokers' decision to completely switch to vaping.

A relatively small effect on the initiation of vaping product use would be sufficient to produce public health benefits equivalent to or greater than the estimated costs. The bulk of the public health benefits stem from a reduction of deaths attributable to cigarette use and exposure to second-hand smoke over a 30-year period.

The proposals under the authority of the CCPSA to prohibit vaping products containing very toxic concentrations of nicotine, and to require child-resistant containers and labelling on products to warn that nicotine is toxic when ingested, would provide benefits by helping to protect against poisoning incidents and fatalities, especially among young children who may gain access to the products and their contents in a household. Given that child-resistant containers are not childproof, the labelling, which includes the toxic hazard symbol, is important as a consistent reminder for parents and caregivers to securely close the container, and to keep it stored out of sight and reach of children. Health Canada encourages parents, caregivers and educators to teach children at an early age that the hazard symbol means "Danger. Don't touch it." [20] The general success of child-resistant

container requirements in decreasing childhood poisoning is discussed in the *Pediatric Poisoning Fatalities from 1972 through 2014* report prepared by the Consumer Product Safety Commission of the United States. [21] The report states that the year after the *Poison Prevention Packaging Act* came into force, there was a marked decrease in pediatric poisoning incidents. Noting that the report only considers fatalities, it shows that five years immediately after the Act came into force, pediatric fatalities had dropped by 56%. Compared to 216 pediatric poisoning fatalities in 1972, the rates continued to drop each year to the long-term average of approximately 27 pediatric fatalities a year in 2014. Fatalities are the most extreme consequence of poisoning incidents; the number of poisoning incidents themselves would have been substantially higher.

The model used in the CBA to work out a breakeven analysis for the child-resistant container provisions applied the value of a statistical life [22] and estimated an emergency room visit to cost $6,560 per incident. The CBA concluded that avoiding one death every 24 to 92 years or one emergency room visit every 7 to 29 days would be equivalent to the annual costs associated with implementing the child-resistant container provisions in the proposal.

Small business lens

The small business lens applies, as there are impacts on small businesses associated with this proposal.

Table 2 presents a summary of costs estimated for small businesses in Canada as a result of the proposed Regulations. It is assumed that 99% of the 2 250 vaping businesses, or approximately 2 228, are small businesses that would be impacted by the proposal. The table presents the estimated costs in 2016 Canadian dollars and uses a 7% discount rate for the 30-year projection. The administrative costs were estimated using 2012 dollars and converted to 2016 dollars using the Bank of Canada inflation calculator. [23]

Table 2: Small business lens summary

Number of small businesses impacted	2 228
Number of years	30 years
Base year for costing	2016

Compliance costs	**Annualized value ($)**	**Present value ($)**
Labelling of vaping substances	251,955	3,127,905
Labelling of vaping devices and parts	5,940	74,250
Child-resistance for vaping substances	70,290	877,140
Child-resistance for vaping devices	276,210	3,425,400
Total	**604,395**	**7,504,695**
Administrative Costs	**Annualized Value ($)**	**Present Value ($)**

Child-resistance documentation for vaping devices (only applicable to device manufacturers and importers). Assume 50 businesses, and 45 small businesses.	3,151	56,499
Total	**3,151**	**56,499**
Total cost (all impacted small businesses)	**607,546**	**7,561,194**
Cost per impacted small business	**273**	**3,394**

At the time Health Canada conducted consultations on this regulatory proposal and at the time the CBA was developed, the vaping industry was dominated by small businesses. Health Canada has modified the proposal in response to the comments received during the consultation, POR and CBA processes. The modifications were intended to reduce the compliance burden on small businesses associated with the cost of changing and implementing the new product labels, as well as the costs associated with the child-resistant requirements for refillable vaping devices and their parts.

The coming into force of the exemption set out in subsection 4(4) of the CCPSA delayed the implementation of the child-resistant requirement for refillable vaping devices and their parts, and has allowed time for industry to source products to meet this requirement.

Health Canada's plan for a joint regulation that sets out labelling requirements using authorities under the CCPSA and the TVPA is another modification to benefit small businesses. This approach would set out all requirements in a single, product-specific regulation, therefore making the regulatory framework easier to understand. These proposed Regulations would also include the development of tools to facilitate compliance with the regulations, such as the test method to determine compliance with the TVPA labelling requirements, and requiring flavouring in vaping substances to be collectively identified using the term "flavour" ("arôme" in French) in the list of ingredients.

Health Canada has assessed the administrative burden that this proposal would place on small businesses. This assessment was based on the compliance and enforcement program undertaken in 2018, and limited Canadian market intelligence. Health Canada is assuming that a large majority of vaping device manufacturers and importers are small businesses as defined by Statistics Canada. The CBA that was completed in March 2018 identified that there were an estimated 30 to 50 device manufacturers or importers active in the Canadian market. Assuming the upper range for the number of manufacturers and importers, Health Canada estimates that 90%, or 45 small businesses, will be affected. The supplemental CBA report completed in March 2019 indicated that there is a range of between 67 and 168 models of open vaping devices on the Canadian market. This can be averaged to a midrange estimate of three vaping devices per manufacturer or importer.

One-for-one rule

The one-for-one rule applies since there is an incremental increase in the administrative burden on business, and a new regulatory title (title in) is being introduced. The proposed Regulations include a requirement for importers and manufacturers to obtain and maintain records to demonstrate that containers of vaping substances containing nicotine meet the child test protocol in a prescribed standard. This requirement is currently in force for stand-alone containers of vaping substances that contain nicotine. The proposal would set out these requirements for refillable vaping devices and refillable vaping device parts that may contain vaping substances containing nicotine. As a result, the proposal would impose a new administrative burden on manufacturers and importers of vaping devices or their parts.

For the purposes of this section, it has been assumed each manufacturer or importer of vaping devices has three vaping devices that require testing, and that testing is completed every three years. In this case, the activities related to record keeping are contracting a testing facility (approximately 2

hours/year), maintaining a test report (approximately 30 minutes/year) and producing a test report upon the request of an inspector (approximately 30 minutes/year). It is assumed that the staff level involved with contracting activities and producing a test report for inspection and enforcement purposes would be management, at a labour rate of $46.26 per hour (Statistics Canada, Labour Force Survey). Clerical duties involved with maintaining a test report, such as storing, copying and distributing are calculated at a labour rate of $25.30 per hour (Statistics Canada, Labour Force Survey). The annualized administrative cost (discounted to 2012 and expressed in 2012 Canadian dollars) is estimated to be $2,998 for industry as a whole, or $60 per business.

The labelling portion of this regulatory proposal would not increase the administrative burden on businesses as there are no associated reporting or record-keeping requirements.

Regulatory cooperation and alignment

Both the European Union and the United States require vaping products containing nicotine to have specific information on the product label. In addition to other provisions, the European Union requires a warning about the addictiveness of nicotine, a list of ingredients and information on the toxicity of nicotine. The United States Food and Drug Administration requires a nicotine addictiveness statement to be displayed on products containing nicotine and recommends that a nicotine exposure warning be displayed on products to help prevent poisoning.

With regard to the nicotine addictiveness statement, the exact wording required by the European Union and the United States is different. Both their statements were tested by Health Canada during the POR. The longer warning used in the United States was preferred in the POR testing since it presents a clear link between the presence of nicotine and the addictiveness statement. However, in consideration of the limited space for labelling on vaping products and in order to respect Canada's official language requirements, the shorter nicotine addictiveness statement (i.e. "WARNING: Nicotine is highly addictive." and "AVERTISSEMENT : La nicotine crée une forte dépendance." in French) co-located on the main display panel with the nicotine concentration statement is being proposed.

The proposed Regulations would require vaping devices and their parts to be child resistant, as well as stand-alone containers of vaping substances containing nicotine in a concentration of 0.1 mg/mL or more to be child resistant. This is similar to requirements in the European Union, whereas the United States only requires stand-alone containers of vaping substances containing nicotine to be child resistant.

Strategic environmental assessment

In accordance with the *Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals*, a preliminary scan concluded that a strategic environmental assessment is not required.

Gender-based analysis plus

At this time, given that vaping products were introduced to the global marketplace just over a decade ago, the long-term health impacts of their use are not yet known. The proposed labelling requirements provide information about the known health hazards linked to nicotine, namely its addictiveness and its toxicity when ingested. This information is relevant to all people of Canada, irrespective of gender-based analysis plus (GBA+) considerations.

The proposed child-resistant container requirements help to protect young children from ingesting a vaping substance containing toxic concentrations of nicotine. They consider the impact of age. Young children, due to their curiosity, oral exploration and their low body weights, are particularly vulnerable to nicotine poisoning through ingestion. The nicotine concentration limit of 0.1 mg/mL, which triggers the child-resistant container and toxicity warning requirements, was identified considering the body weight of young children. The proposed requirements help to protect young children from gaining access to vaping substances containing toxic concentrations of nicotine irrespective of their height,

weight, age or sex. The child-resistant container test protocol assesses the abilities of young children of an even distribution of sex and age in two-month intervals for children between the ages of 42 and 52 months. While the child-test protocol requires test subjects to be healthy with no evident disability that may affect their manual dexterity, the effect of this qualification is to provide protection for children in the full range of manual dexterity abilities.

Rationale

Vaping products present both a challenge and an opportunity for public health in Canada. Vaping products are harmful, particularly to the health of youth and non-users of tobacco products. For adult tobacco users (e.g. smokers) who completely switch to vaping, these products offer a less harmful alternative to tobacco use.

This proposal would require vaping products, which contain nicotine, and their packaging, to display information about their nicotine concentration and about the addictiveness of nicotine. Health warnings have long been used as a means to educate consumers about the risks associated with harmful products. The proposed nicotine concentration statement and the health warnings are intended to enhance awareness of the health hazards posed by using vaping products and to prevent the public from being deceived or misled with respect to these health hazards. In addition, the proposed Regulations would set out expressions that may be used on the product or package to indicate when a vaping product is without nicotine. This information would allow the consumer to make an informed choice about the products that they choose to use.

In 2017, Health Canada consulted the public on how to regulate vaping products in Canada. Health Canada provided 10 measures for consideration, 4 of which pertain to the labelling elements of this proposal. Currently, vaping products are not required to have a statement that informs about the addictiveness of nicotine, have a standardized statement of nicotine concentration, or display a list of ingredients. This proposal contains measures that align Canadian policy for required labelling on vaping substances containing nicotine with policy objectives in the United States and the European Union.

In 2017, Health Canada also stated that, in application of the Act, the CCPSA would pertain to vaping products that are not marketed for a therapeutic use. Vaping substances containing nicotine would be specifically regulated by the CCCR, 2001 to help protect young children against the acute poisoning risk. These Regulations would supplement the obligations placed on regulated parties by sections 7 and 8 under the CCPSA concerning the prohibitions of the manufacture, importation, advertisement or sale of a consumer product that is a danger to human health or safety. However, these were accepted as interim measures that would be applied until product-specific regulations could be developed. This proposal would implement these health and safety measures in an accessible and transparent manner.

A CBA determined that the costs to industry associated with compliance with the child-resistant container and labelling provisions contained within this proposal are estimated at $610,500 on an annualized average basis.

The impact on industry is expected to be minor. Industry has been aware, since October 2017, of Health Canada’s potential options for vaping product regulation. The measures under consideration presented in the consultation were generally well received by all stakeholders. International trading partners already require similar provisions be met for nicotine concentration and addictiveness warnings as well as an ingredient list. A preliminary Health Canada compliance and enforcement program demonstrated a high degree of compliance with the child-resistant requirements on stand-alone containers of vaping substances containing nicotine. Prior to 2017, industry members indicated that requiring devices to be child resistant would have a significant impact on their costs. However, limited market intelligence collected in 2019 has shown that vaping devices that are child resistant are available at comparable costs.

Implementation, compliance and enforcement, and service

standards

The proposed Regulations would be made under the authority of both the TVPA and the CCPSA, and would clearly set out which prohibitions or requirements exist under which Act's authority. The requirements would come into force on the 180th day after the day on which they are published in the *Canada Gazette*, Part II. During the 180-day period between publication in the *Canada Gazette*, Part II, and the coming-into-force date, a stand-alone container of a vaping substance may meet the toxicity warning requirements in the proposed Regulations or those in the CCCR, 2001.

Health Canada would engage in proactive outreach to industry to promote compliance. Health Canada would develop information and educational materials to assist industry stakeholders in understanding and complying with the new requirements. These materials would be distributed to industry to inform them of the changes, and opportunities to seek clarification on the requirements would be provided. The testing methods used by Health Canada to determine nicotine concentration in vaping substances are available to facilitate compliance as well as verification.

The proposed Regulations would not result in any major changes to Health Canada's compliance and enforcement activities. Compliance and enforcement activities related to the proposed Regulations would follow established Health Canada approaches and procedures, including sampling and testing of products, inspections at retail locations, follow up on incidents reported by the Canadian public and public health organizations, as well as follow up on mandatory incident reports by industry. Non-compliant products would be subject to the actions available to Health Canada inspectors under the appropriate powers of either the TVPA or CCPSA. For the proposals under the authority of the TVPA, appropriate measures would be taken, which could range from warning letters, negotiated compliance, seizures and possible prosecution. Actions under the CCPSA may include a voluntary commitment to product correction by industry, negotiation with industry for the voluntary removal of non-compliant products from the market, seizure, orders for recall or other measures, administrative monetary penalties, and possible prosecution.

A compliance monitoring and enforcement program would likely be initiated within six months to one year after the requirements come into force.

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PROPOSED REGULATORY TEXT

Notice is given that the Governor in Council,

(a) pursuant to sections 17 [a] and 33 [b] of the *Tobacco and Vaping Products Act* [c], proposes to make the following provisions of the annexed *Vaping Products Labelling and Packaging Regulations*:

(i) sections 1 and 4,

(ii) the provisions of Part 1, and

(iii) section 71;

(b) pursuant to section 37 [d] of the *Canada Consumer Product Safety Act* [e], proposes to make

the following provisions of the annexed *Vaping Products Labelling and Packaging Regulations*:

(i) sections 2 to 4, and

(ii) the provisions of Parts 2 to 4.

Interested persons may make representations concerning the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Rob Graham, Consumer Product Safety Directorate, Healthy Environments and Consumer Safety Branch, Health Canada, Address Locator: 4908B, 269 Laurier Avenue West, Ottawa, Ontario K1A 0K9 (fax: 613-952-2551; email: rob.graham@canada.ca (mailto:rob.graham@canada.ca)).

Ottawa, June 6, 2019

Julie Adair
Assistant Clerk of the Privy Council

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Vaping Products Labelling and Packaging Regulations

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Vaping Products Labelling and Packaging Regulations

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2 Part 2 of these Regulations sets out provisions that apply to vaping products that are subject to the *Canada Consumer Product Safety Act*.

Part 3

3 Part 3 of these Regulations sets out a consequential amendment to the *Consumer Chemicals and Containers Regulations, 2001*.

Part 4

4 Part 4 of these Regulations sets out the day on which these Regulations come into force.

PART 1

Labelling — Awareness of Health Hazards Arising from the Use of Vaping Products

Interpretation

Definitions

5 (1) The following definitions apply in this Part.

display surface means the portion of the surface area of a vaping product or package on which the information referred to in this Part can be displayed. It does not include the surface area of the bottom, of any seam or of any concave or convex surface near the top or the bottom of a vaping product or package. (*aire d'affichage*)

exterior package means a package that contains a vaping product and that is displayed or visible under normal or customary conditions of sale or use of a vaping product. (*emballage extérieur*)

interior package means the innermost package of a vaping product, including a blister pack. (*emballage intérieur*)

kit means a package that contains a collection of two or more units of vaping products. (*trousse*)

main display panel means the part of the display surface that is displayed or visible under normal or customary conditions of sale or use. It includes

(a) in the case of a vaping product or package that has a rectangular cuboid shape, one of the largest sides of the display surface;

(b) in the case of a cylindrical vaping product or package, the larger of

(i) the area of the top, or

(ii) 40% of the area obtained by multiplying the circumference of the vaping product or package by the height of the display surface;

(c) in the case of a bag, the largest side of the bag; and

(d) in the case of any other vaping product or package, the largest surface of the vaping product or package that is not less than 40% of the display surface. (*aire d'affichage principale*)

manufacturer does not include an individual or entity that only packages or only labels vaping products on behalf of a manufacturer. (*fabricant*)

vaping device means a vaping product within the meaning of paragraphs (a) and (b) of the definition *vaping product* in section 2 of the *Tobacco and Vaping Products Act*. (*dispositif de vapotage*)

vaping part means a vaping product within the meaning of paragraph (c) of the definition *vaping product* in section 2 of the *Tobacco and Vaping Products Act*. (*pièce de vapotage*)

vaping substance means a vaping product within the meaning of paragraph (d) of the definition *vaping product* in section 2 of the *Tobacco and Vaping Products Act*. (*substance de vapotage*)

Interpretation — package

(2) In this Part, a reference to an exterior package or interior package does not include package liners or shipping containers or any outer wrapping, including a box, that is not displayed or visible under normal or customary conditions of sale or use of a vaping product.

Interpretation — refill vaping product

(3) In this Part, a reference to a vaping product that is intended to be used for the purpose of refilling another vaping product does not include a reference to a vaping part or vaping device.

Application of meanings in *Tobacco and Vaping Products Act*

(4) All other words and expressions used in this Part have the same meaning as in the *Tobacco and Vaping Products Act*.

Application

Retail sale of vaping products

6 This Part applies to every vaping product that is intended for retail sale in Canada, as well as to its packaging.

Furnishing vaping products

7 This Part also applies to every vaping product that is intended to otherwise be furnished, as well as to its packaging.

Non-application

8 This Part does not apply to vaping products that are regulated under the *Food and Drugs Act*.

Purpose

Labelling under the *Tobacco and Vaping Products Act*

9 (1) For the purposes of sections 15.1 and 15.2 of the *Tobacco and Vaping Products Act*, this Part sets out the requirements that manufacturers of vaping products must meet

(a) in respect of information that is required to be displayed about vaping products and their emissions and about the health hazards and health effects arising from the use of those products and from their emissions; and

(b) in respect of the manner of displaying the information referred to in paragraph (a) on vaping products and on their packages, as well as on leaflets and tags attached to vaping products.

Permitted expressions

(2) For the purposes of sections 30.42 and 30.45 of the *Tobacco and Vaping Products Act*, this Part also sets out the requirements that manufacturers of vaping products must meet in respect of the manner of displaying certain non-mandatory expressions on vaping products and on their packages.

Vaping Products Containing Nicotine

Nicotine Concentration Statement

Requirement — vaping product containing nicotine

10 A nicotine concentration statement is required by this Part for every vaping product that contains nicotine.

Nicotine concentration statement

11 (1) The nicotine concentration statement that is required for a vaping product must set out the following information:

(a) the concentration of nicotine in the vaping substance, expressed in milligrams per millilitre; and

(b) the information referred to in paragraph (a), preceded by the word “Nicotine — ” and followed by the unit of measure, “mg/mL”.

Presence of nicotine — vaping substance in liquid form

(2) Method C57.1, entitled *Determination of Nicotine at Low Concentration in Liquids used in Electronic Nicotine Devices by GC-MSD/FID*, as amended from time to time and published by the Government of Canada, may be used to determine if a vaping substance that is in the form of a liquid contains nicotine.

Placement — vaping device and vaping part

12 The nicotine concentration statement for a vaping product that is a vaping device or a vaping part, and that is not packaged, must be displayed on the main display panel of the vaping product or on a tag.

Placement — packaged vaping device and vaping part

13 (1) The nicotine concentration statement for a vaping product that is a vaping device or a vaping part, and that is packaged, must be displayed on the main display panel of the exterior package.

Multiple layers of packaging

(2) If a vaping device or vaping part is packaged in multiple layers of packaging, the nicotine concentration statement must also be displayed

(a) on the main display panel of the vaping device or vaping part, as the case may be; or

(b) on the main display panel of the interior package.

Placement — refill vaping product

14 (1) The nicotine concentration statement for a vaping product that is intended to be used for the purpose of refilling another vaping product must be displayed on the main display panel of that refill vaping product.

Placement — packaged refill vaping product

(2) If the refill vaping product is packaged, the nicotine concentration statement that is required for the vaping product must also be displayed on the main display panel of the exterior package.

Placement — vaping products in kit

15 (1) The nicotine concentration statement for a vaping product that is a vaping device or a vaping part, and that is packaged in a kit, must be displayed

(a) on the main display panel of the vaping device or vaping part, as the case may be;

(b) on the main display panel of the interior package of the vaping device or vaping part, as the case may be; or

(c) on a tag.

Kit — refill vaping product

(2) If a vaping product is intended to be used for the purpose of refilling another vaping product and it is packaged in a kit, the nicotine concentration statement that is required for that refill vaping product must be displayed on its main display panel.

Placement — kit

16 (1) If vaping products that contain nicotine are packaged in a kit, the nicotine concentration statement that is required for each of those vaping products must be displayed on the main display panel of the kit.

One nicotine concentration statement

(2) However, if two or more of the vaping products in the kit have the same concentration of nicotine, the applicable nicotine concentration statement for those vaping products need only be displayed once on the main display panel of the kit.

Placement — prepackaged product

17 If a vaping product is a *prepackaged product*, as defined in subsection 2(1) of the *Consumer Packaging and Labelling Act*, and its identity is shown in terms of its common or generic name or in terms of its function as required under subparagraph 10(b)(ii) of that Act, the nicotine concentration statement must be displayed immediately below that name or function.

Health Warning

Requirement — vaping product containing nicotine

18 A health warning is required by this Part for every vaping product that contains nicotine.

List of health warnings

19 (1) The health warning that is required for a vaping product by this Part is the applicable health warning set out for that vaping product in the document entitled *List of Health Warnings for Vaping Products*, as amended from time to time and published by the Government of Canada.

Amendment

(2) For the purposes of this Part, any amendment to the *List of Health Warnings for Vaping Products* is deemed to be made on the day on which the amended version of that list is published by the Government of Canada.

Amended health warning — transitional provision

20 Despite these Regulations, if a health warning that is set out in the *List of Health Warnings for Vaping Products*, as it read immediately before the day on which the amended version of that list is published by the Government of Canada, is displayed in accordance with this Part, it may continue to be so displayed during the period of 180 days after the day on which the amended list is published.

Placement — vaping device and vaping part

21 The health warning for a vaping product that is a vaping device or a vaping part, and that is not packaged, must be displayed on the main display panel of the vaping product or on a tag.

Placement — packaged vaping device and vaping part

22 (1) The health warning that is required for a vaping product that is a vaping device or vaping part, and that is packaged, must be displayed on the main display panel of the exterior package.

Exception — small exterior package

(2) However, if the main display panel of the exterior package has an area of less than 15 cm^2, the health warning may be displayed elsewhere on the display surface of the exterior package or in a leaflet.

Multiple layers of packaging

(3) If a vaping device or vaping part is packaged in multiple layers of packaging, the health warning must also be displayed on one of the following locations:

(a) if the main display panel of the interior package is at least 15 cm^2,

(i) on the main display panel of the vaping device or vaping part, as the case may be, or

(ii) on the main display panel of the interior package; and

(b) if the main display panel of the interior package has an area of less than 15 cm^2,

(i) elsewhere on the display surface of the interior package, or

(ii) in a leaflet.

Placement — refill vaping product

23 (1) The health warning for a vaping product that is intended to be used for the purpose of refilling another vaping product must be displayed on the main display panel of that refill vaping product.

Exception — small refill vaping product

(2) However, if the main display panel of the refill vaping product has an area of less than 15 cm^2, the health warning may be displayed on a tag.

Placement — packaged refill vaping product

(3) If the refill vaping product is packaged, the health warning that is required for that vaping product must also be displayed on the main display panel of the exterior package.

Placement — vaping products in kit

24 (1) The health warning for a vaping product that is a vaping device or a vaping part, and that is packaged in a kit, must be displayed on

(a) the main display panel of the vaping device or vaping part, as the case may be;

(b) the main display panel of the interior package of the vaping device or vaping part, as the case may be; or

(c) a tag.

Kit — refill vaping product

(2) If a vaping product is intended to be used for the purpose of refilling another vaping product and it is packaged in a kit, the health warning that is required for that refill vaping product must be displayed

(a) on the main display panel of that refill vaping product; or

(b) on a tag, if the main display panel of the refill vaping product has an area of less than 15 cm^2.

Placement — kit

25 (1) If a vaping product that contains nicotine is packaged in a kit, the health warning that is required for that vaping product must be displayed on the main display panel of the kit.

One health warning

(2) However, if two or more of the vaping products in the kit contain nicotine, the required health warning need only be displayed once on the main display panel of the kit.

Attribution

26 If a manufacturer or retailer attributes a health warning that is required by this Part, the manufacturer or retailer must do so by displaying the phrase “Health Canada” immediately beside or below the English version of the health warning and the phrase “Santé Canada” immediately beside or below the French version of the health warning.

Vaping Products Without Nicotine

Expression Indicating Vaping Product is Without Nicotine

Permitted expressions

27 Only one of the following expressions may be displayed if a vaping product does not contain nicotine:

(a) “Nicotine-free” in the English version of the expression and “sans nicotine” in the French version of the expression;

(b) “No nicotine” in the English version of the expression and “aucune nicotine” in the French version of the expression; or

(c) “Does not contain nicotine” in the English version of the expression and “ne contient pas de nicotine” in the French version of the expression.

Placement and visibility

28 An expression referred to in section 27 may be displayed if

(a) it is displayed on only the display surface of a vaping product or of any package containing the vaping product; and

(b) it is displayed in such a manner that the text of the expression does not conceal or obscure any information that is required to be displayed by or under the *Tobacco and Vaping Products Act* or any other Act of Parliament or any Act of the legislature of a province.

Presentation of Information

Official languages

29 Any health warning that is required, as well as any expression that is permitted, must be displayed in both official languages, in the same manner.

Required Information — Technical Specifications

General

Integrity

30 (1) The customary method of opening a vaping product or package must not sever, otherwise damage or render illegible any letter, word or part of the information that is required or permitted to be displayed by this Part.

Exception — blister pack

(2) Subsection (1) does not apply to an interior package that is a blister pack.

Visibility

31 Any information that is required must not be concealed or obscured by any other information that is required to be displayed by or under the *Tobacco and Vaping Products Act* or any other Act of Parliament or any Act of the legislature of a province.

Permanence

32 Any information that is required and any expression that is permitted must be irremovable.

Legibility

33 A nicotine concentration statement and health warning must meet the following legibility requirements:

(a) the text must be displayed in black type on a white background; and

(b) the text must be printed in a standard sans-serif type that is not compressed, expanded or decorative.

Nicotine Concentration Statement

Specific legibility rules

34 (1) In the case of a nicotine concentration statement that is displayed on a vaping product or package, the text must be displayed

(a) in a type that has a minimum height of 2 mm and a minimum body size of 6 points, if the main display panel has an area of 10 cm^2 or more; and

(b) in a type that has a minimum height of 1.5 mm and a minimum body size of 4.5 points, if the main display panel has an area of less than 10 cm^2.

Measurement of height of type

(2) The height of the type referred to in subsection (1) must be determined by measuring an upper case letter or a lower case letter that has an ascender or a descender, such as “b” or “p”.

Health Warning

Official languages — new line of text

35 The text of a health warning in one official language must be located immediately beside or below the text of the health warning in the other official language and the two texts must not be combined.

Official languages — vaping product and package

36 In the case of a vaping product or package, the text of the health warning in both official languages must be displayed on the same main display panel or display surface, as the case may be.

Visibility

37 The text of a health warning that is displayed on a vaping product or package must be displayed in such a manner that,

(a) in the case of a cylindrical vaping product or package, it does not extend beyond the main display panel of the vaping product or package;

(b) in the case of a vaping product or package that has a rectangular cuboid shape, it is displayed on the main display panel of the vaping product or package; and

(c) in the case of a bag or any other package, it is readable in its entirety without further manipulation of the bag or package.

Specific legibility rules

38 (1) In the case of a health warning that is displayed on a vaping product or package, the text of the health warning must be displayed,

(a) in a type that has a minimum height of 2 mm and a minimum body size of 6 points, if the main display panel has an area of 45 cm^2 or less; and

(b) in a type that has a height and body size that results in the health warnings in both official languages occupying not less than 35% of the main display panel, if the main display has an area of more than 45 cm^2.

Measurement of height of type

(2) The height of the type referred to in subsection (1) must be determined in accordance with subsection 34(2).

Leaflet and Tag

Display of information

39 The text of any required information that is displayed on a tag or in a leaflet must be

(a) positioned as close as possible to the top edge of the surface of the tag or leaflet, in such a manner that any nicotine concentration statement is immediately above the health warning, if any; and

(b) displayed in such a manner that the text is readable in its entirety without further manipulation of the tag or leaflet.

Specific legibility rule

40 (1) The text of any required information that is displayed on a tag or in a leaflet must be displayed in a type that has a minimum height of 2 mm and a minimum body size of 6 points.

Measurement of height of type

(2) The height of the type referred to in subsection (1) must be determined in accordance with subsection 34(2).

Leaflet

41 Any leaflet that displays a health warning that is required for a vaping product must be inserted in the package containing the vaping product.

Tag — visibility

42 A tag must not conceal or obscure any information that is required to be displayed on the vaping product or its package by or under the *Tobacco and Vaping Products Act* or any other Act of Parliament or any Act of the legislature of a province.

Tag — safe handling

43 A tag must not interfere with the normal use or safe handling of the vaping product.

Attribution

Continuous text

44 (1) The text of the attribution of a health warning must be displayed in such a manner that there is no intervening image or other text between the text of the attribution and that of the health warning.

Specific legibility rules

(2) The attribution of a health warning must meet the following legibility requirements:

(a) those set out in section 33, except that the text of the attribution must not be displayed in bold type; and

(b) those set out in section 38 or 40, as the case may be, except that the text of the attribution

may be displayed in a type that has a height that is smaller by up to 0.2 mm than the height of the type of the health warning.

Non-Mandatory Information — Technical Specifications

Expressions referred to in section 27 — legibility

45 The text of an expression that indicates a vaping substance does not contain nicotine and referred to in section 27 must meet the legibility requirements set out in sections 33 and 34.

PART 2

Protection of Human Health or Safety

Interpretation

Definitions

46 (1) The following definitions apply in this Part.

display surface means the portion of the surface area of an immediate container or of an exterior package on which the information required by this Part can be displayed. It does not include the surface area of the bottom, of any seam or of any concave or convex surface near the top or the bottom of the immediate container or exterior package. (*aire d'affichage*)

exterior package means a package, other than an immediate container, that contains a vaping product and that is displayed or visible under normal or customary conditions of sale of a vaping product to a consumer. (*emballage extérieur*)

hazard symbol means the pictograph and its frame as set out in Schedule 1. (*pictogramme de danger*)

immediate container means the container, including a vaping device or vaping part, in which a vaping substance is directly placed or in which it is reasonably foreseeable that such a substance will be directly placed. (*contenant immédiat*)

main display panel means the part of the display surface that is displayed or visible under normal or customary conditions of sale to the consumer. It includes

(a) in the case of a rectangular immediate container or exterior package, the largest side of the display surface;

(b) in the case of a cylindrical immediate container or exterior package, the larger of

(i) the area of the top, or

(ii) 40% of the area obtained by multiplying the circumference of the immediate container or exterior package, as the case may be, by the height of the display surface;

(c) in the case of a bag, the largest side of the bag; and

(d) in the case of any other immediate container or exterior package, the largest surface of the immediate container or exterior package, as the case may be, that is not less than 40% of the display surface. (*aire d'affichage principale*)

responsible person means

(a) the manufacturer that, in Canada, manufactures a vaping device or vaping part or places a vaping substance in its immediate container; and

(b) the importer, in the case of a vaping device or vaping part that is imported or a vaping substance that is imported in its immediate container. (*responsable*)

vaping device means a vaping product within the meaning of paragraphs (a) and (b) of the definition *vaping product* in section 2 of the *Tobacco and Vaping Products Act*. (*dispositif de vapotage*)

vaping part means a vaping product within the meaning of paragraph (c) of the definition *vaping product* in section 2 of the *Tobacco and Vaping Products Act*. (*pièce de vapotage*)

vaping product has the same meaning as in section 2 of the *Tobacco and Vaping Products Act*. (*produit de vapotage*)

vaping substance means a substance within the meaning of paragraph (d) of the definition *vaping product* in section 2 of the *Tobacco and Vaping Products Act*. (*substance de vapotage*)

Interpretation of "should"

(2) Where the word "should" is used in a standard referenced in this Part it is to be read as imperative, unless the context requires otherwise.

Application of meanings in *Canada Consumer Product Safety Act*

(3) All other words and expressions used in this Part have the same meaning as in the *Canada Consumer Product Safety Act*.

Application

Vaping products — consumer products

47 (1) This Part applies to vaping products that are consumer products.

Non-application

(2) This Part does not apply to vaping products that are subject to the *Food and Drugs Act*.

Purpose

Requirements under the *Canada Consumer Product Safety Act*

48 For the purposes of section 6 of the *Canada Consumer Product Safety Act*, this Part sets out requirements that must be met by vaping products that are consumer products.

Exception

Importation to bring into compliance or to export

49 (1) A person may import a vaping product that does not comply with a requirement of this Part for the purpose of

(a) bringing the product into compliance with the requirement;

(b) reselling the product to a manufacturer in Canada who will bring it into compliance with the requirement; or

(c) exporting the product to another country.

Credible evidence

(2) A person who imports a vaping product for a purpose described in subsection (1) must, on the request of an inspector, provide credible evidence to the inspector that it is being brought into compliance with this Part or is being exported, as the case may be.

Requirements

List of ingredients — contents

50 (1) A list of ingredients is required for every vaping substance and must set out the following information:

(a) the common name, without abbreviation, of each ingredient that is present in the vaping substance; and

(b) the information referred to in paragraph (a), preceded by

(i) the word “Ingredients:” in the English version of the list, and

(ii) the word “Ingrédients :” in the French version of the list.

List of ingredients — “flavour”

(2)