Comments from
Physicians for a Smoke-Free Canada on :

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Vaping Products Reporting Regulations

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Summary

Physicians for a Smoke-Free Canada generally supports the proposal to require vaping manufacturers to make regular reports to government regarding the volume and value of their sales.

This proposal is not adequate, however, to meet public health requirements and should be expanded to include information that is currently provided by vaping product manufacturers to European governments and to the U.S. Food and Drug Administration. Health Canada 's preference for a "stepped" approach is not recommended.

We recommend that:

1) **The new regulations include, at a minimum, requirements that manufacturers keep records on all of the aspects covered by s. 7.3(1) of the Tobacco and Vaping Products Act (see Appendix 2), and that the regulations also include the ability for the Minister to call for such records, under the authority of s. 7.3(2).**

   This approach would allow the government to ensure that information on the marketing activities, toxicity, emissions, research and development, consumer research or other core business activities of the industry will be retained, and that the department will have access to such information if they need it.

   It would mitigate the risks presented by the "stepwise" approach, which would otherwise set the start date for the collection of important information at the date of implementation of the next stage of regulations.

   It is consistent with the proposed approach to require record keeping that was included in the 2017 consultation paper (see Appendix 1).

2) **The new regulations include direction for the Minister to make available aggregated information on sales volume and value for each province/territory authorization within 60 days of receiving the information (i.e. June 30th, September 30th, December 30th, March 31st).**

3) **The regulations be improved to address the issues identified below and those identified by other public interest groups.**

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Observations

A. These regulations have been significantly delayed.

It has taken a half decade for the department to prepare and publish draft reporting regulations. This is a concerning delay given that the importance of such reports for government decision-making was signalled well before the *Tobacco and Vaping Products Act* was adopted in May 2018.

In 2017, the need for these regulations was signalled by government on at least four occasions:

1. On behalf of the government, the sponsor of the bill in the senate noted in her second reading speech in April 2017:

   > *Bill S-5 also includes provisions that require the manufacturers and importers to regularly submit to Health Canada information* ***on their products, their sales, and the research they do where required by regulation****.* ***These provisions are important because they will help the government make informed decisions****.*[1] *(emphasis added)*

2. Departmental officials informed the Senate Committee reviewing the bill that:

   > *In tobacco control for many years now we have collected data under the Tobacco Reporting Regulations. Those reporting regulations require industry to report to us on* ***sales data, new research, how they are promoting the products and other pieces of information. We use that robust data all the time to be able to understand what the market looks like and to make good policy decisions****. There is a regulatory authority that would allow us to collect similar data from the vaping industry. It would go through the full regulatory process before it's brought into place, including consultations on CG1 and CG2,* ***but there is an anticipation that we would need to be able to collect some data so that we could really understand what that market looks like and make informed decisions moving forward****.*[2] *(emphasis added*

3. A public consultation paper was released in August 2017, which outlined a broad reporting structure for vaping manufacturers. [3]

4. The department's forward regulatory plan published in October 2017 identified the intention to implement Vaping Reporting Regulations, with pre-publication indicated much earlier than the summer of 2022. .

B. These regulations have been significantly narrowed in scope.

Health Canada's proposals will require vaping manufacturers to report only on the volume and value of sales. They will not provide the department with the information on the design of their products, the emissions from their products, the toxicological properties of ingredients and emissions, their research, their marketing activities, etc.

As noted above, these aspects were identified as important to Parliament when it considered the law, and when it agreed to give the department delegated authority to develop reporting regulations. The Tobacco and Vaping Products Act provides that:[4]

> *7.3 (1) Every manufacturer shall submit to the Minister, in the prescribed form and manner and within the prescribed time, information that is required by the regulations about vaping products, their emissions and any research and development related to vaping products and their emissions, whether the vaping products are for sale or not. …*
>
> *7.8 The Governor in Council may make regulations…*
> *(c) prescribing information that manufacturers must submit to the Minister about vaping products and their emissions, including sales data and information on market research, product composition, ingredients, materials, health effects, hazardous properties and brand elements;*

Parliamentarians likely believed the representations that were made by the department. Had these lawmakers been honestly informed that the regulations would be delayed for many years and would be significantly narrowed, they would have been in a position to modify the proposed law to expand the application of tobacco reporting regulations or otherwise ensure that this objective would be met when the responsibility for completing these aspects of the law regulations was delegated to the department. Just as it is important that the Executive branch does not over-reach its statutory authority to regulate, it is important that it not mislead Parliament about its intention to under-reach its responsibility to regulate.

The objectives of the TVPA include to "prevent the public from being deceived or misled with respect to the health hazards of using vaping products" and to "enhance public awareness of those hazards." It is not possible for consumers of vaping products to know what chemicals they are inhaling if Health Canada does not require manufacturers to provide a description of the toxins produced by the goods they manufacture – and subsequently inform Canadians of these results, as anticipated in the TVPA.

C. The information that is required will not be a reliable foundation for policy.

Under the proposed regulations, "vaping product manufacturers would be required to submit their first sales report and their initial ingredients report one month after the first complete quarter of the year. After the first report, sales reports would be required quarterly. Ingredients reports would be required each time a new brand is made available for sale in Canada."

Neither the law nor the regulation defines "brand". Products sold under the same brand can differ over time, and manufacturers frequently change formulations or design elements of products that continue to be sold under the same brand name.

The regulation, as currently drafted, will not require manufacturers to provide Health Canada with information on changes to its ingredients.

By way of example, a company could change the chemicals used to produce *BRAND X Tobacco Flavour* e-liquid, and be under no obligation to report this to Health Canada under the proposed regulation.

REPORT ON INGREDIENTS

Brand information

5 (1) The report on ingredients must contain the following information for each brand of vaping product, including a brand of vaping product contained in a kit, referred to in any of paragraphs 2(1)(c) to (e) that a manufacturer sells in Canada:
(a) the unique product identifier;
(b) the brand name or the brand family name;
(c) any additional brand element or any descriptive term that distinguishes the vaping product from other vaping products in the report;
(d) the name of the vaping substance flavour; and
(e) the concentration of nicotine, if any, in milligrams per millilitre.

Ingredient information

(2) The report must also contain the following information for each ingredient that is used in the manufacture of the vaping substance:
(a) its common name;
(b) its chemical name, determined using the nomenclature established by the International Union of Pure and Applied Chemistry, if applicable;
(c) its registry number assigned by the Chemical Abstracts Service of the American Chemical Society, if applicable;
(d) the name and civic address of its supplier; and
(e) its concentration in the vaping substance, in milligrams per millilitre or millilitres per millilitre.

More than one substance in ingredient

(3) For greater certainty, if more than one substance was used in the manufacture of any ingredient mentioned in the report, the report must contain the information referred to in subsection (2), set out by ingredient, for each substance used in the manufacture of that ingredient.

D. The information that is required will not be interpretable and will not meet objectives of the TVPA.

Consumers of vaping products do not inhale ingredients. They inhale emissions.

Knowing the ingredients of a vaping liquid does not allow a consumer (or government official) to adequately understand the health risks associated with inhaling the chemicals produced by those ingredients when they are heated by the vaping device. Moreover, factors associated with the vaping device design (including the temperature of the heating device and other parameters) will affect the chemical reaction that converts ingredients into emissions.

The provision of information on ingredients, but not emissions, is inherently deceptive in that it leads the consumer to believe that they are inhaling the ingredients listed. One of the objectives of the TVPA is "to prevent the public from being deceived or misled with respect to the health hazards of using vaping products." To support the achievement of this objective, Health Canada should require the provision of information on vaping product emissions and should include testing and reporting obligations for these emissions in the new reporting regulations.

There are a wide variety of products on the vaping market, with many changes to the devices and liquids on offer. The information on the chemicals inhaled from one device-liquid-user-timeframe combination cannot be inferred to another. This heterogeneity and rapid development should encourage Health Canada to increase its regulatory monitoring of these products, not minimize data collection as it is now proposing.

E. The proposed reporting regulations give higher priority to the financial well-being of vaping manufacturers than they do to public health.

The decision to severely narrow the scope of the reporting regulations is explained in the RIAS as a concession to the concerns of suppliers.

> *In response to some of the concerns expressed, vaping product reporting regulations are being developed in a stepwise approach. The proposed Regulations would only require sales and ingredient reports. Additional vaping reporting requirements, including elements identified in the 2017 consultation document such as information on research and development and on promotional activities, are currently under consideration for future amendments to the proposed Regulations. This stepwise approach is designed to avoid increasing the administrative burden on vaping manufacturers all at once and to spread the impact on Health Canada's compliance monitoring activities over time. The ability of manufacturers to absorb the burden of additional reporting requirements will be considered during the development of any future amendments.*

Aspects of this explanation which raise concerns are:

1. The failure to acknowledge that there is almost certainly a delay of many years before "future amendments" will be considered. The time between the first two steps of this process (between the consultation paper in August 2017 and draft regulations in June 2022) is already 5 years. In this context, a "stepwise" approach has a generational impact.
2. The policy choice that the public health value of this information is of less importance to the department than "the administrative burden on vaping manufacturers." Health Canada explains that the decision to curtail reporting requirements was made "in response to some of the concerns expressed [by industry]." Although the department does not identify which concerns it found persuasive, it precedes this statement with a list of concerns that include: "vaping products are an important harm reduction tool", "[vaping products] should not be overregulated", "reporting regulations would be too burdensome for smaller vaping industry players" and the imposition of regulations would "force" manufacturers to act illegally.

In our view, the department is not justified in its decision to avoid collecting the information it needs to assess the public health impact of this market and to adapt public health protection policies and regulations accordingly. If there is a concern about the capacity or reasonableness of requesting very small producers to undertake expensive testing, an exemption can be made on the basis of revenue or market-share, as has been the case with tobacco testing requirements by the department. [5]

F. The delay and narrow scope of the regulations allows vaping manufacturers to externalize the costs of regulation.

Currently the burden of acquiring the necessary information to regulate the vaping market is on Health Canada. The RIAS, for example, refers to (unspecified) laboratory analyses of vaping products. These research efforts are inherent costs to the oversight of the vaping market, the major beneficiaries of which are the commercial enterprises whose activities trigger the need for the oversight.

Health Canada has chosen not to impose a regulatory fee on vaping manufacturers, although they have done so with some other regulated industries, including cannabis.[6]

If Health Canada is taking on the "burden" of reports on emissions and toxicology of e-cigarettes, instead of requiring manufacturers to test and disclose these results, then it should adopt a cost-recovery mechanism. The absence of either safeguard means that the Canadian tax-payer is subsidizing the industry by the cost of these important tests.

G. The commitment to provide public disclosure of information has been delayed for decades.

Seventeen years have passed since the House of Commons recommended that "That all information to be submitted to Health Canada under these regulations be made public. If need be, the Minister of Health should authorize its disclosure in the public interest in accordance with Section 20 (6) of the Access to Information Act."[7]

Despite amending the legislation to permit regulations which allow greater disclosure (Appendix B, s. 7.6), the proposed regulation make no concession to the public benefit of greater knowledge about and transparency over the tobacco industry. While it may be hoped that such measures will be included in future regulations, it should be noted that hopes for report disclosure are already old enough to drive.

H. The regulations ignore the availability of information that is already reported to other governments.

A large segment of the Canadian market for vaping products is managed by multinational companies which are already providing information on their products to governments in the European Union, the United States or China. Because they are already required to report to these other health regulators, the "burden" of providing the same information to Canadian authorities should not be considered unsurmountable.

Euromonitor estimates that about 60% of e-vapour products sold in Canada (by value) are produced by six companies, all of which are active in these other countries. In addition to the existence of reporting requirements in the European Union and the United States which are identified in the RIAS, China has also developed a range of tests and product requirements which must be adhered to by suppliers in that country.[8] The Chinese monopoly which supervises the market does not appear to require specific times when these test results must be reported, but does identify the report format and assigns responsibility of inspection and oversight to their tobacco market authorities.[9] Some of the reporting obligations in these other countries are identified in Table 1.

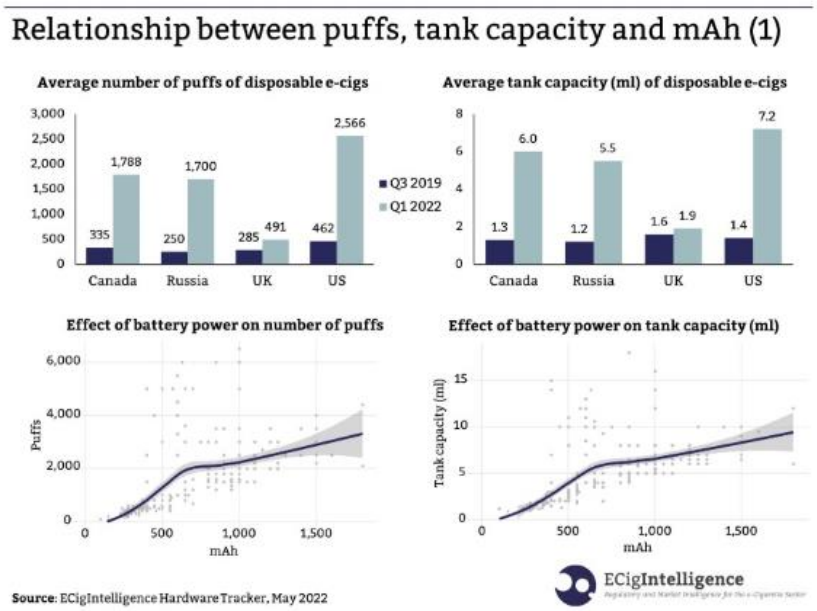
Table 1: Comparison of standards and reporting requirements for E-Cigarettes

I	Health Canada	European Union and United Kingdom[10] [11] [12]	United States[13] [14]	China [15] [16]
Information transferred by	*Reports filed after marketing, some updating required*	*Reports filed 6 months before marketing, with updates required*	*Reports filed before authorization and after marketing*	*Reports retained by companies and reviewed by authorities*
PRODUCT DESIGN OF DEVICES				
Standards		• Maximum volume of e-liquids in disposables/cartridges/tanks	• Demonstration that product is appropriate for the protection of public health	• standards set for general safety, electromagnetic, materials, batteries • Ban on refillable devices
Reporting		• Details on design, description of components, battery type, microprocessor, production process, controllability by user • Name and address of suppliers • Name and address of manufacturing facilities	• Full description required in application, subsequent changes must be reported	• Testing required, with inspection by authority with compliance
INGREDIENTS – E-LIQUIDS				
Standards	• List of 9 prohibited ingredients (amino acids, caffeine, colouring agents, fatty acids, glucuronolactone, probiotics, taurine, vitamins, mineral nutrients) • Maximum nicotine concentration 20 mg/ml	• Prohibition of ingredients that are carcinogenic, mutagenic or reproductive toxins. • Maximum nicotine concentration 20 mg/ml	• Demonstration that product is appropriate for the protection of public health	• A ban on ingredients that do not appear on a list of 100 authorized chemicals. • A ban on additives that increase health risks • A ban on colouring ingredients in vaping liquids • A ban on additives that are not technically necessary or that are used in greater quantity than required • Maximum nicotine concentration 20 mg/ml
Reporting	• Name of the vaping substance flavour • Name and address of supplier • Concentration of nicotine in mg/ml • Chemical name of each ingredient	• Volume and weight of e-liquid in ml/mg • Nicotine concentration in mg/ml • Chemical name of each ingredient (or FEMA or other number) • Function of the ingredient • Declaration whether non-vaporized ingredient has known toxic, carcinogenic, mutagenic or reproductive toxin qualities.	• Full description required in application, subsequent changes must be reported	• Testing required, with inspection by authority with compliance
EMISSIONS				
Standards			• Demonstration that product is appropriate for the protection of public health	• Maximum emission levels per puff set for nicotine, impurities, carbonyl compounds, some metals and other substances.
Reporting		• Availability of toxicological data. • Description of the measurement methods • Name of the emission produced during testing • Quantity of emissions produced during testing	• Full description required in application, subsequent changes must be reported	• Testing required, with inspection by authority with compliance

I	Health Canada	European Union and United Kingdom[10] [11] [12]	United States[13] [14]	China [15] [16]
		• in vitro and in vivo assays to evaluate the toxicological effects of the ingredient on the heart, blood vessels or respiratory tract		
RESEARCH AND DEVELOPMENT ACTIVITIES				
Reporting		• Studies on chemistry and/or toxicity of emissions. • Studies on carcinogenicity, mutagenicity or toxicity for reproduction of the ingredient • An analysis of the possible addictive properties of the ingredient • Existence of any other toxicological data not stated above.		
SALES				
Reporting	For each brand of vaping product and for each province and to each country exported • Number of packages and kits sold • Number of unpackaged units sold • Volume in litres of vaping substance sold • Dollar value		• U.S. sales reported in dollars, units, and volume with breakdowns by U.S. census region, major retail markets, and channels in which the product is sold • Demographic s of purchasers, such as age, gender, race or ethnicity, geographic region, and tobacco use status.	• Sales managed through centralized platform, data available to authorities. [17]
PROMOTIONAL ACTIVITIES				
			• (Marketing plans submitted with application) • Copies of all promotional copy g • Description of promotions by channel and product • Targeting of specific group(s) by age, demographics, psychographics • Use of owned, earned, shared, or paid media • Partners, influencers, bloggers, or brand ambassadors • Consumer engagements • Public-relations or other communications outreach • Advertising impressions, by channel, by product, and by audience demographics	
OTHER				
Reporting			Implementation and effectiveness of age-verification of purchasers, actions taken to restrict access to the products and promotions.	

I. The regulations ignore the availability of information that is already reported to and provided by commercial research organizations.

In the absence of government monitoring, commercial organizations like Euromonitor and Ecigintelligence have established communications channels on which they rely to provide information on the e-cigarette market in Canada and elsewhere. (Shown here is a report on the rapid increase in tank capacity of disposable e-cigarettes sold in Canada.[18])



The information available from these organizations, however, is very costly, and beyond the budget of many researchers, public health units or other agencies with public interest mandates. Moreover, access to the information is restricted by license condition. Because the research methods behind these reports is opaque, policy-makers may be reluctant to accept their findings as robust enough to support regulatory or policy changes.

The capacity of the private sector to produce information useful to their commercial clients is in contrast to the apparent unwillingness of health authorities in Canada (and elsewhere) to establish market monitoring processes designed to support health policy.

J. The proposed regulations will establish Canada as having the most lax reporting regulations of the large vaping markets.

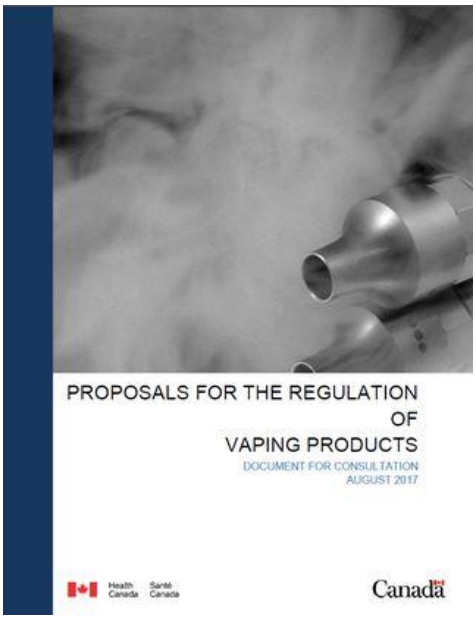
BAT reports that Canada is one of the five largest vapour markets (not including China).[19] The other countries are France, United Kingdom, Germany and the United States.

The RIAS states that "The proposed Regulations are aligned with information requirements in other countries that are either required to support a pre-market approval process or to meet post-market surveillance requirements." We disagree. As shown in Table 1, Canada is not aligned with the requirements in those countries: in Canada there remains no prenotification (to allow internal monitoring to be set up), no emissions or toxicological information (to allow assessment of public health impact of use), no marketing data (to allow assessment of federal and provincial policies and regulations on the vaping market). Under these regulations, Canada will be the only large vaping market to not require manufacturers to prepare and submit information related to the health risks created by their products and marketing actions.

Appendix 1: Extract from:

Health Canada. Consultation Paper. Proposals for the Regulation of Vaping Products.

August 2017.[20]



2.3 Regulatory proposals on information reporting

These proposals apply to all vaping products.

a. Information to be reported to the Minister of Health

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

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

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

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

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

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

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

Retailers would not be required to report information unless they are involved in activities which would classify them as a "manufacturer", per the definitions set out in the proposed TVPA.

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

b. Requests for supplemental information

From time to time, Health Canada may need additional information from a manufacturer concerning a report they have submitted. As provided for in the proposed TVPA, the Minister of Health would be authorized, subject to the regulations, to

request from manufacturers such supplementary information. Manufacturers would be required to submit the supplementary information in the form, manner and within the time frame specified by the Minister.

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

c. Measures to enhance compliance with reporting requirements

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

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

d. Record-keeping practices by manufacturers

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

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

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

Appendix 2: Relevant extract from

Tobacco and Vaping Products Act

Information required from manufacturer

7.3 (1) Every manufacturer shall submit to the Minister, in the prescribed form and manner and within the prescribed time, information that is required by the regulations about vaping products, their emissions and any research and development related to vaping products and their emissions, whether the vaping products are for sale or not.

Supplementary information

(2) The Minister may, subject to the regulations, request supplementary information relating to the information referred to in subsection (1), and every manufacturer shall submit the requested information in the form and manner and within the time specified by the Minister.

Public disclosure by manufacturer

7.5 Every manufacturer shall make available to the public, in the prescribed form and manner and within the prescribed time, information that is required by the regulations about vaping products and their emissions.

Public disclosure by Minister

7.6 The Minister shall make available to the public, in the prescribed manner and within the prescribed time, information that is required by the regulations about vaping products, their emissions and any research and development related to vaping products and their emissions.

Regulations

7.8 The Governor in Council may make regulations

(a) establishing standards respecting the characteristics of vaping products and their emissions, including the functions and the performance of the products, the sensory attributes — such as appearance and shape — of the products and their emissions, and the amounts and concentrations of substances that may be contained in the products or their emissions;

(b) respecting test methods, including methods to assess conformity with the standards;

(c) prescribing information that manufacturers must submit to the Minister about vaping products and their emissions, including sales data and information on market research, product composition, ingredients, materials, health effects, hazardous properties and brand elements;

(d) prescribing information that manufacturers must submit to the Minister about research and development related to vaping products and their emissions, including information on market research, product composition, ingredients, materials, health effects, hazardous properties and brand elements;

(e) respecting requests for supplementary information under subsection 7.3(2);

(f) respecting the prohibition under section 7.4, including providing for the suspension of the sale of a vaping product;

(g) prescribing the means, including electronic means, by which the information referred to in paragraphs (c) to (e) may be submitted to the Minister;

(h) prescribing, for the purposes of section 7.5, information that manufacturers must make available to the public, including information referred to in paragraph (c);

(i) prescribing, for the purposes of section 7.6, information that the Minister must make available to the public, including information referred to in paragraphs (c) and (d);

(j) prescribing anything that by this Part is to be prescribed; and

(k) generally for carrying out the purposes of this Part.

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