Guidance Document for Regulated Parties on Nicotine Concentration in Vaping Products

Nicotine Concentration in Vaping Products Regulations (NCVPR)
&
Vaping Products Labelling and Packaging Regulations (VPLPR)

Tobacco Control Directorate
Health Canada

Health Canada Santé Canada

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Disclaimer: This document does not constitute part of the *Tobacco and Vaping Products Act* (TVPA or the Act) or its associated regulations. It should be read in conjunction with the relevant sections of the Act and its regulations. The information in this document is not intended to substitute for, supersede, or limit the requirements under the applicable legislation. In the event of any discrepancy between the legislation and this document, the legislation shall prevail.

The glossary provided in this document is intended to provide clarity to regulated parties in understanding the compliance verification process undertaken by Health Canada. While the scope of the glossary, as presented in this guidance, applies to vaping products regulated pursuant to the Tobacco and Vaping Products Act (TVPA), Health Canada acknowledges that alternate or expanded definitions of the referenced terms may exist.

The reader is advised to consult other relevant legislation that may apply to them or their activities, such as any applicable federal, provincial, or territorial legislation.

This document may be updated from time to time without notice. As such, the reader is encouraged to consult the most recent version of this guidance available at: https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/product-safety-regulation/guidance-regulated-parties-nicotine-concentration-vaping-products.html

Également disponible en français sous le titre :
Document d'orientation à l'intention des parties réglementées sur la concentration en nicotine dans les produits de vapotage

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications-publications@hc-sc.gc.ca

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Table of Contents

Terms and Glossary

CCPSA: *Canada Consumer Product Safety Act*.

Manufacture: As defined in the *Tobacco and Vaping Products Act* (TVPA) – “in respect of a tobacco product or vaping product, includes the manufacture of a tobacco product or vaping product for export, as well as the packaging, labelling, distributing and importing of a tobacco or vaping product for sale in Canada”.

NCVPR: *Nicotine Concentration in Vaping Products Regulations* - Establishes a maximum nicotine concentration of 20 mg/mL for vaping products manufactured or imported for sale in Canada and prohibits the packaging and sale of vaping products if the nicotine concentration displayed on the product package exceeds the 20 mg/mL limit.

TVPA: *Tobacco and Vaping Products Act* - An Act to regulate the manufacture, sale, labelling and promotion of tobacco products and vaping products. The TVPA provides the legislative authority to make regulations which establish the requirements related, among others, to the manufacture and sale of tobacco products and vaping products in Canada.

VPLPR*: Vaping Products Labelling and Packaging Regulations* - Sets out the requirements for the labelling and packaging of vaping products in two parts:

> Part 1: Outlines the labelling requirements pursuant to the TVPA. It requires the display of two labelling elements for vaping products that contain nicotine: a health warning and a nicotine concentration statement. This part additionally sets out three permitted expressions which may be displayed on the product or its packaging to declare a product to be nicotine-free.
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> Part 2: Sets out the requirements pursuant to the *Canada Consumer Product Safety Act* (CCPSA). It requires child-resistant containers, information to warn about the toxicity of nicotine when ingested, and the display of a hazard symbol for nicotine containing vaping substances. This part additionally requires a list of

ingredients for all vaping substances on product labels regardless of nicotine content.

Purpose

This guidance is designed to provide information to facilitate compliance and help regulated parties understand and meet the requirements for nicotine concentration in vaping products as indicated in the *Nicotine Concentration in Vaping Products Regulations* (NCVPR) and the *Vaping Products Labelling and Packaging Regulations* (VPLPR). Health Canada's compliance and enforcement approach for vaping products may include laboratory evaluation of samples to determine their compliance with the applicable regulations. For vaping products which have been determined to be non-compliant with the nicotine concentration limits under the NCVPR or the VPLPR, regulated parties must take appropriate actions to bring these products into compliance.

This guidance provides several considerations that may be helpful in demonstrating compliance related to the actual nicotine concentrations of vaping products when these are sampled for a compliance assessment by Health Canada inspectors. This guidance also includes information describing the content of specific documentation that a regulated party may provide inspectors to assist in establishing the compliance of their products.

The documentation which may be provided by a regulated party to demonstrate compliance referenced in this guidance document is not necessarily considered exhaustive. Health Canada may request or consider information not specifically described in this guidance document.

Please note that guidance documents are administrative instruments not having the force of law. In the event of any inconsistencies with this document and the applicable legislation, the legislation shall prevail.

For consistency and transparency, this guidance document may be updated, as required, to reflect changes in the TVPA, its associated regulations, and any related

Health Canada compliance and enforcement policies.

Scope

This document applies to nicotine concentration requirements applicable to vaping products regulated under the NCVPR and VPLPR.

Background

Compliance and Enforcement - Overview

Health Canada inspectors conduct routine inspections of, among others, vaping product manufacturers, distributors, importers, and retailers, during which inspectors monitor compliance of vaping products with the TVPA, CCPSA, and their associated regulations. These inspections may lead to the sampling of vaping products for chemical analysis to determine their nicotine concentration.

When Health Canada inspectors find non-compliance(s), a range of enforcement measures may be taken, including but not limited to:

- Issuing a notice of non-compliance, also known as a “Warning Letter”;
- Seizure of non-compliant vaping products; and/or,
- Prosecution

Information on vaping product compliance and enforcement measures are available on Health Canada’s website: https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/compliance-enforcement.html

Assisting Health Canada Inspectors

Subsection 38(1) of the TVPA sets out the requirement relating to providing assistance to inspectors. The provision requires that the owner or person in charge of a place and every person found in that place during an inspection, provide all assistance reasonably required to enable the inspector to exercise their powers or perform their duties or

functions under the TVPA. Such assistance may include providing any documents or information, and access to data (e.g., laboratory testing results if applicable), that the inspector may reasonably require to exercise their powers or perform their duties or functions under the TVPA.

Please note that in accordance with subsection 39(1) of the TVPA, when conducting an inspection, an inspector may seize anything, including a vaping product, found in the place that they have reasonable grounds to believe was used in the contravention of the TVPA or is something in relation to which the TVPA was contravened.

Guidance

Nicotine Concentration Evaluation and Manufacturing Controls

The recommendations provided below aim to assist regulated parties in understanding some of the documentation, considerations and methods by which Health Canada inspectors may assess the nicotine concentration of vaping products.

Common Terms

Lot or Batch Numbers

A unique identification number or alpha numeric code which defines a specific production batch of a vaping product by a manufacturer. The lot number should enable tracing of the constituent parts or ingredients (i.e., nicotine) of a vaping product as described in a batch record (see below) or other production documents. The use of a batch or lot number identifier permits manufacturers and regulatory authorities to conclusively identify a batch of a specific product. It further permits establishments and inspectors to isolate a non-compliant product from those which may demonstrate no evidence of non-compliance.

Batch Records

Production documents that define the components contained within a specific vaping product batch and the manufacturing process used in the manufacture of that product. It

typically describes the suppliers and lot numbers of the vaping product constituents used in the manufacture of the finished product. The batch record may also describe manufacturing process controls including the verification of nicotine concentration in the vaping substance prior to the filling of the finished product containers. Additional information may include manufacturing elements (e.g., equipment used, personnel performing the manufacturing operations, process deviations, and labeling samples, etc.). Health Canada recommends the use of a batch record in documenting the relationship between the nicotine concentrate stock solution used, its concentration, the total batch volume, product name, flavour, and the product's batch number.

Certificates of Analysis

A certificate of analysis (CoA) is a formal document that details the results, specifications, and generally references the analytical methods used in completing a laboratory analyses of a substance or finished product. The document is signed by an authorized representative of the laboratory conducting the analyses which provides an assurance to the recipient that the item tested is as claimed to be, or has the features advertised by the producer.

For the purposes of verification by a Health Canada inspector, a certificate of analysis should clearly identify the vaping product manufacturer, product name, flavour, lot number, date of analysis, substance concentration being reported (i.e., nicotine), and laboratory name (including contact information) which performed the analysis. The certificate of analysis should ideally identify the accreditation status of the facility, the analytical method type used, the number of determinations performed, and the statistical significance of the results presented when more than one measurement determination is reported.

This document, if presented in a language other than French or English, must be accompanied by a certified translation.

Compliance Verification - NCVPR

Vaping Product Manufacture - Importers and Distributors of Vaping Products

Any manufacturer that manufactures or sells a vaping product that does not conform with the 20mg/mL nicotine concentration limit will be in contravention of section 7.2 of the TVPA. Importing and distributing are included in the definition of manufacture in the TVPA. To verify compliance with the NCVPR, importers and distributors of vaping products are encouraged to obtain documentation (i.e., certificates of analysis) from their suppliers to confirm their vaping products do not exceed the 20 mg/mL nicotine concentration limit. Such documentation should conclusively link laboratory testing results with the labeled product identifier. Should this information be unavailable, Health Canada recommends that importers and distributors of vaping products obtain confirmation of the nicotine concentration of their products by using suitably accredited laboratories who can apply the methods identified in the “Determining Nicotine Concentration” section below.

Vaping Product Manufacture - Formulators of Vaping Products

The Regulations establish a maximum nicotine concentration of 20 mg/mL for vaping products which will be applied to manufacturers of vaping products sold in Canada. Health Canada will use the ISO 20714 standard analytical method to determine compliance with the maximum nicotine concentration limit. Please note that while the ISO 20714 method is incorporated by reference into the NCVPR and as such, will be used by Health Canada to determine compliance, the NCVPR does not impose this specific testing methodology on industry. In order to verify compliance of their finished products, manufacturers may choose to use accredited laboratories who can apply the analytical method identified in section 4(1) of the NCVPR. Alternatively, manufacturers may choose to use other validated test methods for their own quality assurance purposes.

In addition, Health Canada encourages manufacturers which formulate vaping products to verify the concentration of nicotine stock solutions used to prepare dilutions of finished vaping products. This verification may include obtaining certificates of analysis from suppliers or in conducting independent laboratory testing of the stock nicotine solution (i.e., concentrated nicotine solution) prior to use. The ability to accurately determine the nicotine content of the concentrated solution used in the preparation of vaping products may significantly reduce the possibility of dilution errors.

Manufacturers are further encouraged to prepare batch records of the vaping products they produce with sufficient detail to identify the constituent nicotine stock solutions used, their concentration, and the subsequent dilutions prepared leading to the final product.

Health Canada has observed that many vaping products that are non-compliant with the nicotine concentration limit of 20mg/mL, are marketed as having a nicotine concentration of 20mg/mL. Manufacturers are encouraged to prepare these vaping product solutions slightly below the above limit to reduce the impact of potential dilution errors resulting in finished product solutions which exceed the 20 mg/mL limit during manufacturing.

Compliance Verification - VPLPR

The VPLPR includes requirements for specific labelling elements related to the nicotine concentration of the vaping product. As specified in the VPLPR, a vaping product that contains a nicotine concentration of 0.1 mg/mL or higher, is considered to contain nicotine.

Health Canada inspectors may conduct inspections to verify compliance and may sample vaping products, including those in which either a nicotine concentration statement is absent, nicotine is not declared in the ingredient list, or the manufacturer declares the product to be “nicotine-free” using any of the permitted nicotine free declarations described in section 23 of the VPLPR. Enforcement actions may be taken for vaping products that make these “nicotine-free” declarations but are found to exceed

the 0.1mg/mL nicotine limit.

Nicotine-Free Vaping Product Importers and Distributors

To demonstrate compliance with the VPLPR, importers, and distributors of “nicotine-free” vaping products are encouraged to obtain documentation (i.e., certificates of analysis) from their suppliers that indicate these vaping products do not contain nicotine at or above the 0.1 mg/mL limit. This documentation should clearly link laboratory testing results with the labelled lot specific product identifier. Should this information be unavailable, Health Canada recommends that importers and distributors of vaping products obtain confirmation of the nicotine content of their products by using suitably accredited laboratories who can apply appropriate testing methods to determine nicotine concentrations at this level.

Health Canada does not recommend the standard ISO 20714 analytical method that is incorporated by reference in the NCVPR to be used for the determination of low level nicotine content in VPLPR samples.

Nicotine-Free Vaping Product Manufacturers - Formulators of Vaping Products

Trace or low levels of nicotine present in “nicotine-free” solutions may occur via a number of possible routes such as cross-contamination resulting from mixing equipment or glassware used for previous manufacturing batches of nicotine containing vaping products. To minimize this route of cross-contamination, all equipment used for the production of nicotine containing vaping products should be thoroughly cleaned prior to use in the manufacture of “nicotine-free” products. Alternatively, a production process and equipment dedicated to nicotine-free products should be maintained wherever possible and used exclusively for such products.

Manufacturers of vaping products may choose to promote their products that do not contain nicotine by using one of the permitted expressions as presented in section 23 of the VPLPR on their products or packaging. A vaping product is considered to contain nicotine if nicotine is present at a concentration of 0.1mg/mL or more. Vaping product

manufacturers are responsible for providing information about their vaping products upon request that is accurate and not false or misleading. To verify the accuracy of the information about their vaping products, manufacturers are encouraged to use accredited laboratories who can apply the methods appropriate for the measurement of nicotine at these lower concentrations in finished product testing.

Health Canada encourages manufacturers of “nicotine-free” vaping products to verify the purity of any constituent solution component which may contain nicotine through previous cross-contamination. Manufacturers are further encouraged to prepare batch records of the vaping products they produce with sufficient detail to identify the constituent solutions, their manufacturers, composition, concentration, and note any deviations or observations raised in the manufacturing process resulting in the production of the final product.

Health Canada’s methodology for assessing a vaping product’s compliance with the NCVPR – Determining Nicotine Concentration

Vaping products sampled by inspectors to establish compliance with the nicotine concentration requirements in the NCVPR will be tested in Health Canada’s laboratories in accordance with the ISO 20714 standard as described in section 4 of the NCVPR. Samples will be tested in triplicate, reported as a mean value, and include an uncertainty range representative of a 95% confidence interval.

The upper and lower uncertainty boundary will be considered to determine a potential result range. Results obtained in which the lower uncertainty boundary value is below the regulatory limit will be considered as demonstrating no evidence of non-compliance. An example is shown in the following table:

Table 1: Determining nicotine concentration

Mean reported result	Result uncertainty (95 % confidence interval)	Corresponding Potential Result Range
20.42 mg/mL Nicotine	± 0.45 mg/mL	19.97 mg/mL – 20.87 mg/mL

The sample result presented above would be interpreted as demonstrating no evidence of non-compliance.

Any result in which the lower uncertainty boundary value is in excess of 20 mg/mL will be considered to exceed the regulatory limit and thus demonstrate evidence of non-compliance.

While the ISO 20714 method is used by Health Canada's laboratories in the determination of nicotine concentrations to establish compliance with the NCVPR, regulated parties may use any other method which is suitable and fully validated for their own quality assurance purposes. Regulated parties should discuss method validation requirements with their laboratory.

Note that while the conditions of the ISO 20714 standard method are clearly defined in the ISO standard, minor method modifications to improve the performance of this method are permitted. Such modifications are made by Health Canada within the scope of permitted modifications as specified in the ISO 20714 standard.

Health Canada's methodology for assessing a vaping product's compliance with the VPLPR

Vaping products sampled by inspectors to establish compliance with the nicotine concentration requirements of the VPLPR (i.e. "nicotine-free") will be tested in Health Canada's laboratories using a method developed by Health Canada. Samples will be tested in triplicate. Any result obtained which is in excess of the limit of quantitation will be reported as a mean value and will include an uncertainty range representative of a 95% confidence interval.

Limit of quantitation means the smallest amount or the lowest concentration of a substance that may be measured by means of a given analytical procedure with the established accuracy, precision, and uncertainty.

The upper and lower uncertainty boundary will be used to determine a potential result range. Results obtained in which the lower uncertainty boundary value is below the regulatory limit will be assessed as demonstrating no evidence of non-compliance. An example is shown in the following table:

Table 2: Determining nicotine concentration

Mean reported result	Result uncertainty (95 % confidence interval)	Corresponding Potential Result Range
0.14 mg/mL Nicotine	± 0.05 mg/mL	0.09 mg/mL – 0.19 mg/mL

The sample result presented above would be interpreted as demonstrating no evidence of non-compliance.

Enforcement actions may be taken for any result in which the lower uncertainty boundary value is greater than or equal to 0.1 mg/mL of nicotine in a vaping product declared or otherwise marketed to be “nicotine-free”.

The VPLPR does not prescribe an analytical method for use in the determination of nicotine concentrations. A regulated party may use any suitable method which is fully validated to determine the concentration of nicotine at the VPLPR limit of 0.1 mg/mL

Ongoing Compliance Monitoring

Health Canada will continue to monitor compliance with the TVPA, CCPSA and their associated regulations. Non-compliant products will be subject to the enforcement actions available to Health Canada inspectors under the appropriate powers of either the TVPA or CCPSA.

Contact Us

For more information about the compliance and enforcement of the TVPA and its regulations, you can send an e-mail to Health Canada at: tcp.questions-plt@hc-sc.gc.ca