NOTICE OF NEW CANNABIS PRODUCT GUIDE

Requirements under section 244 of the *Cannabis Regulations*

Government of Canada Gouvernement du Canada

Canada

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Disclaimer: This document does not constitute part of the Cannabis Act or its 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 legislation. In the event of discrepancy between the legislation and this document, the legislation shall prevail.

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

This document may be updated from time to time so the reader is encouraged to check back periodically.

Notice of New Cannabis Product Guide

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1.0 Purpose

This document provides guidance to holders of a licence for processing under the *Cannabis Act* ("licence holders") on the application of section 244 of the *Cannabis Regulations* respecting notice of new cannabis products. It is designed to help licence holders understand the requirements and process for providing notice of new cannabis products to be sold in Canada for the first time.

2.0 Background

The *Cannabis Act* (hereafter referred to as "the Act") and its Regulations provide, among other things, the framework for legal access to cannabis and the control and regulation of its production, distribution and sale.

As per section 244 of the *Cannabis Regulations*, licensed processors must notify Health Canada of their intent to sell a cannabis product they have not previously sold in Canada, other than products belonging to the cannabis plants or cannabis plant seeds classes. This Notice of New Cannabis Product (NNCP) must be provided to Health Canada at least 60 calendar days before making the new cannabis product available for sale.

Licence holders are responsible for complying with the Act and Regulations, and other legislation that may apply to them or their activities. Health Canada applies a risk-based approach to compliance and enforcement whereby risk pertains to health, safety and the credibility of the regulatory system, among other factors. The *Compliance and enforcement policy for the Cannabis Act* can be found on Health Canada's website.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. This guide is one of a series of guidance documents written as an accompaniment to the *Cannabis Regulations* under the Act. Health Canada publishes other guidance documents and information on its website that licence holders may use in conjunction with this document to maintain their compliance. For consistency and transparency, this guide and other guidance documents and information are updated as required to reflect changes to policies or operations.

3.0 Scope

This guide outlines the requirements for providing advance notice of new cannabis products that are expected to be made available for sale under section 244 of the *Cannabis Regulations*.

As per section 244 of the *Cannabis Regulations*, the NNCP requirements only apply to holders of a licence for processing.

A cannabis product is defined by subsection 1(2) of the *Cannabis Regulations* and means cannabis of only one of the classes set out in Schedule 4 to the Act — or a cannabis accessory

that contains such cannabis — **after it has been packaged and labelled** for sale to a consumer at the retail level. It does not include cannabis that is intended for an animal, a cannabis accessory that contains cannabis that is intended for an animal or a drug containing cannabis.

Notification under section 244 is not required in respect of cannabis plants or cannabis plant seeds.

The information in this guide is based on the *Cannabis Regulations,* as amended by the *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)* which were published in the Canada Gazette, Part II, on June 26, 2019 and will come into force on October 17, 2019.

Important: Notifying Health Canada of a new cannabis product does not constitute approval for sale by Health Canada, nor does it mean that the product complies with legislative requirements.

It is prohibited to promote, package or label a cannabis product in a manner that is false, misleading or deceptive, such as stating that it has been approved by Health Canada. Contravening this prohibition can lead to compliance and enforcement actions.

Licence holders should not expect any communication from Health Canada after submitting a NNCP. However, Health Canada may contact licence holders for more information or to inform of a potential non-compliance that may be identified.

Licence holders are responsible for making sure their cannabis products meet the requirements of the Act and the *Cannabis Regulations* and that they comply with all applicable legislation.

4.0 Definitions and abbreviations

4.1 Definitions

The *Cannabis Act* and the *Cannabis Regulations* should be referred to for definitions. Some definitions that appear in the Act or in the *Cannabis Regulations* are included in this section for ease of reference, and others appear for the purpose of the guide.

Brand name: The name, whether or not it includes the name of any licence holder, in English or French, that is assigned to the cannabis product, under which the cannabis product is sold or promoted, and that is used to distinguish the cannabis product.

Cannabis: As defined in subsection 2(1) of the Act, means a cannabis plant and anything referred to in Schedule 1 of the Act, but does not include anything referred to in Schedule 2 of the Act.

Cannabis accessory: As defined in subsection 2(1) of the Act, means

(a) a thing, including rolling papers or wraps, holders, pipes, water pipes, bongs and vaporizers, that is represented to be used in the consumption of cannabis; or
(b) a thing that is deemed under subsection 3 to be represented to be used in the consumption of cannabis.

Cannabis extract: As defined in subsection 1(1) of the *Cannabis Regulations,* means

(a) a substance produced by
    (i) subjecting anything referred to in item 1 of Schedule 1 to the Act to extraction processing,
    or
    (ii) synthesizing a substance that is identical to a phytocannabinoid produced by, or found in, a cannabis plant; or
(b) a substance or mixture of substances that contains or has on it a substance produced in a manner referred to in paragraph (a).

It does not include a cannabis topical or edible cannabis.

Cannabis product: As defined in subsection 1(2) of the *Cannabis Regulations,* means cannabis of only one of the classes set out in Schedule 4 to the Act—or a cannabis accessory if that accessory contains such cannabis—after it has been packaged and labelled for sale to a consumer at the retail level. It does not include cannabis intended for an animal, a cannabis accessory that contains cannabis that is intended for an animal, or a drug containing cannabis.

Cannabis topical: As defined in subsection 1(1) of the *Cannabis Regulations,* means a substance or mixture of substances that contains or has on it anything referred to in item 1 or 3 of Schedule 1 to the Act and that is intended for use, directly or indirectly, exclusively on external body surfaces, including hair and nails.

Class of cannabis: Any one of the classes of cannabis in Schedule 4 to the Act. This includes: dried cannabis, fresh cannabis, cannabis plants, cannabis oil (until Oct. 17, 2020), cannabis plant seeds, edible cannabis, cannabis extracts, or cannabis topicals.

Common name, in respect of edible cannabis, has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*.

Discrete unit: Refers to, in the case where a single immediate container contains more than 1 unit of a cannabis product, each of those units. Examples could include multiple pre-rolled joints, capsules, separate edible pieces, etc.

Dried cannabis: As defined in subsection 2(1) of the Act, means any part of a cannabis plant that has been subjected to a drying process, other than seeds.

Edible cannabis: As defined in subsection 1(1) of the *Cannabis Regulations,* means a substance or mixture of a substance that contains or has on it anything referred to in item 1 or 3 of Schedule 1 to the Act and that is intended to be consumed in the same manner as food. It does not include dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds. For clarity, it does not include cannabis extracts and cannabis topicals.

Fresh cannabis: As defined in subsection 1(1) of the *Cannabis Regulations*, means freshly harvested cannabis buds and leaves, but does not include plant material that can be used to propagate cannabis.

Immediate container: As defined in subsection 1(2) of the *Cannabis Regulations*, means a container that is in direct contact with cannabis that is a cannabis product or, if a wrapper is in direct contact with the cannabis, with the wrapper.

Ingredient: As defined in subsection 1(2) of the *Cannabis Regulations,* means

(a) in the case of a cannabis extract or cannabis topical, a substance, other than a substance referred to in item 1 or 3 of Schedule 1 to the Act, that is intended to be present in the final form of the cannabis extract or cannabis topical; and
(b) in the case of edible cannabis,
    (i) a substance, other than a substance referred to in item 1 or 3 of Schedule 1 to the Act,
        (A) that is used to make the edible cannabis where the use results, or may reasonably be expected to result, in the substance or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis, or
        (B) that is part of a mixture of substances referred to in item 2 of the Schedule that is used to make the edible cannabis where the use results, or may reasonably be expected to result, in the substance or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis, or
    (ii) a mixture of substances, other than a mixture of substances that are referred to in item 1 or 3 of Schedule 1 to the Act,
        (A) that is used to produce the edible cannabis if the use of the mixture results, or may reasonably be expected to result, in the mixture or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis, or
        (B) that is part of a mixture of substances referred to in item 2 of the Schedule that is used to make the edible cannabis where the use results, or may reasonably be expected to result, in the first mixture or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis.

Licence holder: The holder of a licence in a class of licence listed in section 8 of the *Cannabis Regulations.*

Produce: As defined in subsection 2(1) of the Act, means to obtain cannabis by any method or process, including by:

- manufacturing;
- synthesis;
- altering its chemical or physical properties by any means; or
- cultivating, propagating or harvesting it or any living thing from which it may be extracted or otherwise obtained.

4.2 Abbreviations

CBD	cannabidiol
CTLS	Cannabis Tracking and Licensing System
NNCP	Notice of New Cannabis Product
THC	delta-9-tetrahydrocannabinol
The Act	the *Cannabis Act*
The Regulations	the *Cannabis Regulations*

4.3 Icons

The following icons are used throughout this guide to highlight information of interest.

Important: Key or cautionary information.

Tip: Supplementary information that could be helpful, including references to external documents.

5.0 Notice – New Cannabis Product

As per section 244 of the *Cannabis Regulations*, licence holders must submit the following information in their notice:

- the cannabis class (as per Schedule 4 of the Act) (e.g., dried cannabis, fresh cannabis, cannabis extract)
- the date on which the cannabis product is expected to be made available for sale
- a description of the product including the brand name

The description could include any of the key information that would distinguish a new cannabis product as noted below. For example, it could include products with a new:

- brand name
- intended use (e.g., inhalation, ingestion, topical)
- cannabis product form (e.g., pre-rolled joint, capsule, spray)
- including an accessory that contains cannabis
- net weight or volume and number of units per immediate container
- THC and CBD concentration and/or quantity per discrete unit, as displayed on the label, and any other cannabinoids, their concentration and/or amount

- ingredients in the cannabis product as listed on the label
- anything else that significantly distinguishes the product (e.g., nano- or biotechnology based, re-introduced terpenes etc.)
- sensory attributes of the product such as the flavour, scent, colour and shape of the product

For the purpose of a NNCP, a new cannabis product is one that is distinct from other cannabis products sold by the processor. If a licence holder changes any of these characteristics, the product may be considered a new cannabis product and a new NNCP could be required. Batch to batch variability in accordance with the *Cannabis Regulations* is not considered a change, and licence holders do not need to notify of these.

Licence holders are invited to contact Health Canada at hc.notice-cannabis-avis.sc@canada.ca if they are uncertain as to when a proposed new product requires notice to Health Canada or for any questions related to NNCPs.

The Cannabis Tracking and Licensing System (CTLS) should be used to notify Health Canada of the intent to sell a new cannabis product. Licensed processors will be able to view the "Notice of New Cannabis Product" section within the CTLS and submit the required information. They will also be able to view certain information for all their previously submitted notices. Changes to a submitted NNCP cannot be made. Alternatively, licence holders may submit the NNCP including a description of the product by requesting a form via email to: hc.notice-cannabis-avis.sc@canada.ca.

There is no fee associated with the NNCP process.

5.1 Submitting a Notice of New Cannabis Product in the CTLS

The CTLS contains fields to provide the required information as part of the NNCP. The fields are divided into 4 sections, as outlined below.

This guide is based on the CTLS release 2.0.

5.1.1 *General Information*

The following fields are found under 'General Information':

- Licence ID: The licence associated with the licence holder who is selling the cannabis product.

- Company product identifiers (if applicable): May be used by the company, if desired, to refer to any identifiers used by the company. For example a Stock Keeping Unit (SKU) or Global Trade Item Number (GTIN), etc.

- Brand name: The brand name under which the cannabis product is proposed to be sold. It should distinguish the product from all others available on the retail market. For

example, a brand name could be “Company X - Milk Chocolate Orange - 50g”. Each brand name is considered a distinct product.

- **Pending licence amendment to authorize for sale:** When a licensed processor has conditions on their licence that do not authorize the processor to sell the class of cannabis being notified, “pending licence amendment to authorize for sale” should be indicated by selecting “yes” in this field.

Important: In the case where a licensed processor is pending authorization to sell a class of cannabis, the licence holder may only sell the product once they are authorized to do so **and** once 60 calendar days have passed since a complete NNCP was submitted to Health Canada.

- **Date of expected sale:** The date of expected sale must be indicated in the CTLS. The date of expected sale must be at least 60 days from the date the NNCP is submitted.

- **Class of cannabis:** Used to identify the class of cannabis as per Schedule 4 of the Act (e.g., dried cannabis, edible cannabis, cannabis extract). A NNCP is not required for cannabis plants or cannabis plant seeds. By definition, a cannabis product can only belong to one class of cannabis. For example, a cannabis product cannot be edible cannabis and a cannabis extract at the same time. The licence holder is responsible for determining the most appropriate class based on the product’s intended use(s), product formulation and packaging/labelling.

5.1.2 *Description*

The following fields are found under ‘Description’:

- **Intended use:** Indicate the intended use of the product. For example, if the product is intended for inhalation, ingestion, or for use on the body or hair. Health Canada has provided a list of possible intended uses within the CTLS. Licence holders have the option to input their own by selecting “other” if the intended use of their product is not reflected in the list provided. The intended use should be consistent with what is on the product label, as this is required information. Refer to the “Packaging and labelling guide for cannabis products” for more information.

- **Cannabis product form:** The identity of the cannabis product in terms of its common name or in terms of its function should be provided. For example, if the product is a joint (pre-rolled), a capsule, a spray, beverage, kief, shatter, etc. Health Canada has provided a list of possible cannabis product forms within the CTLS. Licence holders have the option

to input their own by selecting "other" if the cannabis product form of their product is not reflected in the list provided.

- **Accessory that contains cannabis:** For example, if the cannabis product is composed of an accessory that contains cannabis such as in the case of pre-rolled joints or a vape cartridge, the accessory should be described. The description should include characteristics such as the colour and shape. If the product contains an integrated dispensing mechanism this should also be indicated.

- **Net weight or volume and number of units per immediate container:** Including whether the product is in discrete units or not in discrete units.
    - For cannabis products containing multiple discrete units: The net weight in grams per discrete unit in the immediate container should be provided (e.g., net weight per capsule is 1 g) as well as the number of discrete units in the immediate container (e.g., 20 capsules) and the net weight of the cannabis product in the immediate container (e.g., net weight of the cannabis product in the immediate container is 20 g).
    - For cannabis products not in discrete units (e.g., a vial of cannabis extract): The net weight or volume of cannabis in the container should be provided (e.g., net volume in the immediate container is 5 ml).

- **Cannabinoids:** Including the **THC and CBD** concentration and/or quantity per discrete unit. For dried or fresh cannabis products, the range may be provided. For all other classes, the concentration or quantity that will appear on the label should be provided. If any other cannabinoids are displayed on the product label, their name, concentration and/or amount should also be provided.

- **Ingredients in the cannabis product (as per label)**: For the purpose of a NNCP, the ingredients required to be on the product label under the *Cannabis Regulations* should be submitted. The ingredients provided in the notice should be written as they will appear on the product label (e.g., they may be copied and pasted directly from the label, separated by commas etc.). Changes to the ingredients on the label are very likely to indicate the product is new. Refer to the "Packaging and labelling guide for cannabis products" for more information.
    - **Restricted ingredients:** If any of the ingredients contained in the cannabis product are restricted (e.g., cannabis topical with ingredients found on the Cosmetic Ingredients Hotlist or prohibited/restricted by the *Cannabis Regulations*), they should be identified using the drop-down list provided and their quantity should be included. Refer to the "Guide on composition requirements for cannabis products" for more information.

- **Anything else** that significantly distinguishes the product or makes it novel should be described. This could include a product that is nano-formulated or biotechnology based,

synthetically produced through biotechnological means or otherwise, genetically engineered, a new phytocannabinoid derivative or isomer of cannabis, re-introduced terpenes, among others. For more information on novel products, refer to the "Guide on composition requirements for cannabis products".

- Sensory attributes: Such as flavour, scent, colour or shape of the cannabis product. For example:
    1. Flavour: lemon
    2. Scent: lemon
    3. Colour: yellow
    4. Shape: circular

  The photos provided of the cannabis product should supplement the description of the sensory attributes.

5.1.3 *Documentation*

Photo(s) of the cannabis product should be provided by the licence holder to support the description. The cannabis product includes the packaged/labelled final product. In that respect, photo(s) of the package and of the label should be provided. Photo(s) should also be provided of the cannabis product within the labelled package (e.g., the joint, chocolate, lotion etc.).

As noted earlier, providing this information in the notice does not imply that Health Canada has reviewed and/or approved the product, including the packaging and/or labelling. Licence holders are responsible for making sure their cannabis products meet the requirements of the Act and the *Cannabis Regulations* and that they comply with all applicable legislation.

Tip: Photo(s) should be representative of the cannabis product and be clearly visible.

Some tips:

- Place the product against a white background
- Take photos from multiple angles (e.g., front, back, sides)
- Products such as creams, foams, waxes should be dispensed onto a surface and liquids into a clear container to include a photo of the product contained with the labelled package

The total file size(s) of all photos and supplementary information uploaded into the CTLS cannot exceed 10MB. Thus, for multiple photo(s), low-medium photo resolution should be used so long as it is visible. Should there be information that exceeds this amount, please contact: hc.notice-cannabis-avis.sc@canada.ca.

5.2 Notice of New Cannabis Product – Retention Period

The licence holder must retain a copy of the notice for at least two years after the date on which the cannabis product is expected to be made available for sale, as per subsection 244(2) of the *Cannabis Regulations*.

6.0 Contact us

To receive copies of any guidance documents mentioned above, or if you have questions about cannabis products or the *Cannabis Act* and the *Cannabis Regulations*, email cannabis@canada.ca.

For questions specifically related to NNCPs, email: hc.notice-cannabis-avis.sc@canada.ca.

Alternatively, you can reach Health Canada by phone at 1-866-377-7705.

7.0 Feedback – Help us improve

Health Canada is committed to providing all stakeholders with timely, accurate and reliable information. This includes providing applicants and licence holders with the information they need to comply with the *Cannabis Act* and the *Cannabis Regulations*.

Health Canada appreciates receiving feedback on whether this guide was useful, and welcomes your suggestions for improvement. Email your feedback to cannabis@canada.ca and indicate in the subject line "Feedback on the Notice of New Cannabis Product Guide".

Your comments will help us improve this guide.