Guide on composition requirements for cannabis products

Requirements under the *Cannabis Act* and the *Cannabis Regulations*

Government of Canada Gouvernement du Canada

Canada

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

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

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1.0 Purpose

This guide provides guidance and information on the definitions of, and requirements for, cannabis and cannabis products under the *Cannabis Act* (also referred to in this guide as "the Act" and abbreviated to CA for references) and the *Cannabis Regulations* (also referred to in this guide as "the Regulations", and abbreviated to CR for references).

2.0 Background

The *Cannabis Act* and its regulations came into force on October 17, 2018, establishing the legal framework for the production and sale of cannabis products.

As of October 17, 2019, the Regulations will be updated to include rules for the legal production and sale of three new classes of cannabis, namely edible cannabis, cannabis extracts and cannabis topicals. These new requirements will help mitigate the unique public health and public safety risks associated with these new classes of cannabis (e.g., overconsumption, foodborne illness) as outlined in section 5.2 of this guide. Part 6 of the Regulations sets out general requirements pertaining to the formulation, production and composition of cannabis products as well as those specific to all classes of cannabis that are set out in Schedule 4 to the Act.

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.

3.0 Scope

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.

This guide applies to cannabis products sold and distributed in Canada.

This guide outlines the key regulatory requirements relating to the formulation, production and composition of cannabis products as set out in Part 6 of the Regulations.

This guide does not cover broader requirements under the Act and Regulations such as those related to licensing, physical security, packaging and labelling, and good production practices, among others.

On its website, Health Canada publishes other guidance documents and information that licence holders may use in conjunction with this guide to support their compliance with the Act and Regulations. For consistency and transparency, this guide and other guidance documents and information are updated as required to reflect changes to policies and/or operations.

4.0 Definitions and abbreviations

4.1 Definitions

The *Cannabis Act* and the *Cannabis Regulations* should be referred to for a comprehensive list of definitions. The definitions in this section are provided for ease of reference.

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

Cannabis accessory: As defined in the *Cannabis 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 deemed under subsection 2(3) of the Act to be represented to be used in the consumption of cannabis.

Cannabis extract: As defined in 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 cannabis topical or edible cannabis.

Cannabis plant: As defined in the *Cannabis Act*, means a plant that belongs to the genus *Cannabis.*

Cannabis plant seed: Means any seed of a cannabis plant.

Cannabis product: As defined in the *Cannabis Regulations*, 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:

(a) cannabis that is intended for an animal;
(b) a cannabis accessory that contains cannabis that is intended for an animal; or
(c) a drug containing cannabis

Cannabis topical: As defined in 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.

Classes of cannabis: Means the classes of cannabis that an authorized person may sell as per Schedule 4 to the Act.

Contaminated: As defined in the *Cannabis Regulations,* means, in respect of cannabis, a cannabis accessory or an ingredient, containing or having on it anything—including a micro-organism but excluding anything referred to in item 1 or 3 of Schedule 1 to the Act—that may render the cannabis, cannabis accessory or ingredient injurious to human health or unsuitable for human use.

Dried cannabis: As defined in the *Cannabis Act*, means any part of a cannabis plant that has been subjected to a drying process, other than seeds.

Durable life date: As defined in the *Cannabis Regulations,* means the date on which the durable life of a cannabis product ends.

Edible cannabis: As defined in 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 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 also does not include cannabis extracts and cannabis topicals.

Food additive: As defined in the *Cannabis Regulations*, means any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of, or affecting the characteristics of, a food or edible cannabis, but does not include

(a) anything referred to in item 1 or 3 of Schedule 1 to the Act; or

(b) anything that is excluded from the definition food additive in subsection B.01.001(1) of the Food and Drug Regulations

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

Immediate container: As defined in the *Cannabis Regulations*, means a container that is in direct contact with cannabis or a cannabis accessory that is a cannabis product or, if a wrapper is in direct contact with the cannabis or the cannabis accessory, with the wrapper.

Additionally, as per the definitions in the *Cannabis Regulations*, a cannabis accessory that contains edible cannabis in liquid form at the temperature of 22 ± 2°C and that is a cannabis product is deemed to be an immediate container.

Ingredients: As defined in the *Cannabis Regulations*, means:
(a) In the case of a cannabis extract or a cannabis topical, a substance, other than anything referred to in item 1 or 3 of Schedule 1 to the Act, that is used to produce the cannabis extract or cannabis topical, including any substance used in the manufacture of that substance, and that is present in the final form of the cannabis extract or cannabis topical
(b) In the case of edible cannabis,

(i) a substance, other than anything 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 substance 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 that Schedule that is used to produce the edible cannabis if the use of the mixture 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 anything 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 that Schedule that is used to produce the edible cannabis if the use of the latter mixture results, or may reasonably be expected to result, in the former mixture or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis.

Licence holder: For the purpose of this guide, means the holder of a federal licence that has been issued under authority of the *Cannabis Act*, belonging to one of the classes of licences that are listed in section 8 of the *Cannabis Regulations.*

Marketing authorization: As defined in the *Cannabis Regulations*, has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations,* except in subsection (2).

Potential to convert THCA into THC: As defined in the *Cannabis Regulations*, means the maximum amount of THC that would be obtained if THCA was converted into THC with no further degradation of THC.

4.2 Abbreviations

CA	*Cannabis Act*
CBD	cannabidiol
CBG	cannabigerol
CBN	cannabinol
CR	*Cannabis Regulations*
FDA	*Food and Drugs Act*
FDR	*Food and Drug Regulations*
g	gram
mg	milligram
mL	millilitre
s.	section (of an Act or Regulation)
subs.	subsection (of an Act or Regulation)

THC delta-9-tetrahydrocannabinol

THCA delta-9-tetrahydrocannabinolic acid

4.3 Icons

The following icons are used in 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 General restrictions on cannabis products

5.1 Definitions: cannabis, classes of cannabis, cannabis product

5.1.1 Cannabis

Cannabis means a cannabis plant and anything referred to in Schedule 1 to the Act but does not include anything referred to in Schedule 2 to the Act [subs. 2(1), CA].

Schedule 1 refers to:

1. Any part of a cannabis plant, including the phytocannabinoids produced by, or found in, such a plant (e.g., THC, CBD, CBN, CBG) regardless of whether that part has been processed or not, other than a part of the plant referred to in Schedule 2 to the Act
2. Any substance or mixture of substances that contains or has on it any part of such a plant (e.g., when non-cannabis ingredients have been mixed with cannabis, the entire mixture is considered to be cannabis)
3. Any substance that is identical to any phytocannabinoid produced by, or found in, such a plant, regardless of how the substance was obtained (e.g., synthetically derived or of a different biological origin)

Schedule 2 refers to:

1. A non-viable seed of a cannabis plant
2. A mature stalk, without any leaf, flower, seed or branch, of such a plant
3. Fibre derived from a stalk referred to above
4. The root or any part of the root of such a plant

5.1.2 Classes of cannabis

Schedule 4 to the Act refers to the classes of cannabis that an authorized person may sell:

- Dried cannabis

- Fresh cannabis
- Cannabis plants
- Cannabis plant seeds
- Edible cannabis
- Cannabis extracts
- Cannabis topicals

The definition of each class of cannabis can be found in section 4.1 of this guide.

Important: Cannabis oil will no longer exist as a class of cannabis from Schedule 4 to the Act on October 17, 2020. While cannabis oil will cease to exist as a standalone class of cannabis on this date, cannabis oil products will continue to be permitted for sale within the new classes of cannabis (i.e., cannabis extracts, cannabis topicals, and edible cannabis).

5.1.3 Cannabis product

A cannabis product 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 or a cannabis accessory that contains cannabis that is intended for an animal
- A drug containing cannabis [subs. 1(2), CR]

Tip: For more information on drugs containing cannabis, refer to the *Food and Drugs Act* (FDA) and its regulations as well as the Health products containing cannabis or for use with cannabis: Guidance for the Cannabis Act, the Food and Drugs Act, and related regulations.

Cannabis that has been packaged and labelled for sale to a consumer must consist of only one class of cannabis. For example, a cannabis product cannot be edible cannabis and a cannabis extract at the same time. The requirements set out in the Regulations differ depending on the class of cannabis.

Licence holders are expected to determine the most appropriate class based on the product's intended use and formulation. For example, a cannabis product containing cannabis oil could be edible cannabis, a cannabis extract or cannabis topical by virtue of its formulation alone. In this scenario, the licence holder needs to determine what cannabis class they intend their oil-based product to be and to follow the applicable requirements for that class.

5.2 General restrictions (applies to all classes of cannabis)

The Act and Regulations set out the rules and restrictions pertaining to the sale, formulation, production and composition of cannabis products. These requirements aim to reduce the:

- Appeal of such products to young persons;

- Risk of accidental consumption;
- Risk of overconsumption; and
- Risk of foodborne illness.

They are also aimed to minimize the potential for toxicity, addiction, noxious and unintended responses (i.e., adverse reactions) to cannabis products.

The following restrictions apply to all cannabis products:

5.2.1 Appealing to young persons

Unless authorized under the Act, it is prohibited to sell cannabis or a cannabis accessory that has an appearance, shape or other sensory attribute or a function that there are reasonable grounds to believe could be appealing to young persons [s. 31, CA]. The *Policy statement on Cannabis Act prohibitions referring to appeal to young persons* provides more information.

5.2.2 Prohibited sales

Unless authorized under the Act, it is prohibited for a person that is authorized to sell cannabis to sell cannabis of any class that is not referred to in Schedule 4 to the Act [s. 33, CA].

5.2.3 Prohibited substances

Unless authorized under the Act, it is prohibited to sell or distribute any mixture of substances that contains cannabis and any substance that is referred to in column 1 of Schedule 5 to the Act. These are:

- Nicotine
- Caffeine (with some exceptions provided by the Regulations, refer to section 6.5.7 of this guide)
- Ethyl alcohol (with some exceptions provided by the Regulations, refer to section 6.5.8 of this guide) [s. 34, CA].

5.2.4 Prohibited uses

It is prohibited to sell or distribute any cannabis product that is intended to:

- Be used in the area of the human eye (e.g., including the eyebrow area, eyelid, eyelash, eyeball)
- Be used on damaged or broken skin
- Penetrate the skin barrier by means other than by absorption (e.g., through abrasives or needles) [s. 98, CR].

5.2.5 Psychological effects, abuse liability and toxicity

A component of a cannabis product (excluding anything referred to in item 1 or 3 of Schedule 1 to the Act – refer to section 5.1.1 of this guide) or a cannabis accessory that is packaged with a cannabis product must not:

- Alter or enhance the psychological effects derived from the cannabis product in a manner that may cause injury to the health of the user
- Increase the potential for abuse of the cannabis product
- Increase the toxicity of the cannabis product when used as intended or in a reasonably foreseeable way through any means other than heating or combustion [subs. 104(1), CR]

Ethyl alcohol and caffeine are excluded when they meet the conditions set out in the Regulations [s. 104, CR].

5.2.6 THC quantity limits

To reduce the risk(s) associated with overconsumption (including from accidental consumption), the Regulations define limits on the amount of THC that can be present in cannabis products. See section 6 of this guide for a description of specific limits by class of cannabis, which are set for individual servings (or "discrete units") intended for ingestion or nasal, rectal or vaginal use and for single immediate containers.

Important: The Act and Regulations do not set limits on the amount of other cannabinoids, including CBD. However, there are labelling requirements for displaying CBD content.

5.2.7 Other composition and relevant requirements

There are requirements relating to microbial and chemical contaminants, dissolution and disintegration, and residues of pesticides for cannabis products. For more information, refer to sections 93, 94 and 95 of the Regulations, the Good production practices guide for cannabis, and the Mandatory cannabis testing for pesticide active ingredients – Requirements.

Additionally, there are a number of prohibited representations for cannabis products. For example, for edible cannabis, it is prohibited to make an express or implied representation, including by way of a brand element that would:

- Cause reasonable grounds to believe that the representation could create the impression that the cannabis product is intended to meet the particular dietary requirements of an individual who has a physical or psychological condition as a result of a disease, disorder or injury, or for whom a particular effect, including weight loss, is to be obtained by a controlled intake of food, or of individuals who are under 18 years of age [s. 132.3, CR].

For more information, refer to section 132 of the Regulations as well as the Packaging and labelling guide for cannabis products.

6.0 Product requirements by class of cannabis

This section of the guide outlines the requirements that apply to the classes of cannabis. Unless stipulated otherwise, the requirements apply to the cannabis that is a cannabis product or that is, or will be, contained in a cannabis accessory that will become a cannabis product.

Each class of cannabis must meet the terms defined in the Act and Regulations. Refer to section 4.1 of this guide for the definition of each class of cannabis.

6.1 Cannabis seeds or cannabis plant seeds

- A cannabis seed or cannabis plant seed must not contain or have on them residues of a pest control product that is registered for use on cannabis under the *Pest Control Products Act*, or that is otherwise authorized for use under that Act, unless the residues are within any maximum residue limits that are specified in relation to cannabis under section 9 or 10 of that Act [s. 92.2, CR]. Refer to Mandatory cannabis testing for pesticide active ingredients – Requirements for more information.

6.2 Dried or fresh cannabis

6.2.1 Composition

- Dried or fresh cannabis must not contain or have on it anything other than a part of a cannabis plant. It does not include:
    - A non-viable seed of a cannabis plant
    - A mature stalk, without any leaf, flower, seed or branch, of such a plant
    - Fibre derived from a stalk referred to above
    - The root or any part of the root of such a plant [subs. 93(1), CR]

- THC or THCA must not be added to dried or fresh cannabis [s. 99, CR]

6.2.2 Maximum quantities

For dried or fresh cannabis products in discrete units that is intended for ingestion or nasal, rectal or vaginal use, the quantity of THC per discrete unit must not exceed 10 milligram (mg), taking into the account of potential to convert THCA into THC [subs. 96(1), CR].

For dried cannabis products in discrete units that are intended to be inhaled, the net weight of each discrete unit must not exceed 1.0 gram (g) [s. 100, CR].

6.3 Cannabis extracts or cannabis topicals

6.3.1 Things injurious to health

- A cannabis extract or cannabis topical must not contain or have on it anything that may cause injury to the health of the user when the cannabis product is used as intended or in a reasonably foreseeable way. For cannabis extracts that are intended to be combusted

and inhaled, this does not include the thing that may cause injury as a result of the intended combustion and inhalation [subs. 101(1) and (2), CR].

This excludes the cannabis, residues of a pest control product or microbial or chemical contaminants so long as they meet the requirements as noted in subsection 101(3) of the Regulations.

For example, with regards to cannabis topicals, the Cosmetic Ingredient Hotlist is used to communicate that certain substances may not be compliant with requirements of the FDA or the *Cosmetic Regulations*. Some of these ingredients listed may also be considered injurious to the health of the user of cannabis topicals under the Regulations, depending on the quantity or concentration of the ingredient as well as the nature and intended or reasonably foreseeable use of the particular product. This list is not exhaustive and is updated from time to time.

Health Canada strongly encourages licensed processors to make use of the Hotlist when looking to determine whether a particular ingredient could pose a risk of injury to the health of the consumer when used in a cannabis topical product.

6.3.2 Maximum quantities

For all cannabis extracts or cannabis topicals, the THC quantity must not exceed 1,000 mg per immediate container, taking into account the potential to convert THCA into THC [s. 101.2, CR].

6.3.3 Uniform distribution

The cannabinoids and terpenes must be uniformly distributed throughout the cannabis extract or cannabis topical [s. 101.4, CR].

6.3.4 Multiple units

It is prohibited to sell or distribute a cannabis extract or cannabis topical, if the immediate container contains multiple discrete units, unless the properties of each unit, including size but excluding flavour and colour, as applicable, are consistent [s. 98.1, CR].

6.4 Additional requirements for cannabis extracts

In addition to the above, the following requirements also apply to cannabis extracts.

6.4.1 Ingredients

Cannabis extracts must only contain ingredients that are:

- Carrier substances
- Flavouring agents
- Substances that are necessary to maintain the quality or stability of the cannabis product (e.g., binders, disintegrants, preservatives) [subs. 101.3(1), CR]

The following substances are prohibited to be used as ingredients:

- Substances listed in column 1 of the table in Schedule 2 to the *Tobacco and Vaping Products Act* (e.g., amino acids, caffeine, colouring agents, essential fatty acids, glucuronolactone, probiotics, taurine, vitamins, or mineral nutrients). A vitamin may be used as an ingredient to maintain the quality or stability, if it is used in an amount that does not exceed what is necessary to do so [subs. 101.3(2) and (3), CR].
- Sugars, sweeteners or sweetening agents as defined in subsection B.01.001(1) of the *Food and Drug Regulations* (FDR). Specifically, sugars, means all monosaccharides and disaccharides; sweetener means any sweetener that is referred to in section 2 of the *Marketing Authorization for Food Additives That May Be Used as Sweeteners;* and sweetening agent includes any food for which a standard is provided in Division 18 of the FDR, but does not include those food additives listed in the tables to Division 16 of the FDR [subs. 101.3(2), CR].

Any of these prohibited substances may be present in an ingredient that is used to produce the cannabis extract so long as it occurs naturally in that ingredient and is not present above the naturally occurring level for that ingredient [subs. 101.3(4), CR]. Note that nicotine and caffeine are not permitted in cannabis extracts.

For a cannabis extract that is intended to be inhaled, it may only contain ingredients, other than flavouring agents, for which there is a standard in a publication referred to in Schedule B of the FDA, and the ingredients have to comply with the standard (e.g., the United States Pharmacopoeia) [subs. 101.3(5), CR].

For a cannabis extract that is intended to be ingested, it may contain ethyl alcohol at any concentration (e.g., as a carrier substance) if the net weight of the cannabis extract in each immediate container does not exceed 7.5 g [subs. 101.3(6), CR].

6.4.2 Prohibited uses

Cannabis extracts must not be represented for use, directly or indirectly, on external body surfaces, including hair and nails [s. 101.5, CR].

6.4.3 Maximum quantities

For cannabis extract products that are in discrete units, and intended for ingestion or nasal, rectal or vaginal use, the quantity of THC per discrete unit must not exceed 10 mg, taking into the account of potential to convert THCA into THC [subs. 96(1), CR].

The immediate container for cannabis extracts that are not in discrete units and not intended for inhalation are required, among other things, to have an integrated dispensing mechanism (e.g., pump or metered spray for a bottle) that does not dispense more than 10 mg of THC per activation, taking into account the potential to convert THCA into THC [subs. 122.5(1), CR]. This is intended to protect consumers against overconsumption (including from accidental consumption) and provide them with a reliable means to control the dose of a cannabis product.

For cannabis extracts that are in liquid form at room temperature, the immediate container must not contain more than 90 millilitres (mL) of extract [s. 122.3, CR].

6.5 Edible cannabis

6.5.1 Prohibited things

Edible cannabis must not contain or have on it anything in a quantity that would cause the sale of the edible cannabis to be prohibited under any of paragraphs 4(1)(a) to (d) of the FDA if the edible cannabis were a food to which the Act applies [subs. 102.1 (1), CR].

It must not:

- Have in or on it any poisonous or harmful substance;
- Be unfit for human consumption;
- Consist in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; or
- Be adulterated [s. 102.1, CR].

This excludes the cannabis, residues of a pest control product or microbial or chemical contaminants so long as they meet the requirements as noted in subsection 102.1(2) of the Regulations.

6.5.2 Maximum quantities

Subject to the variability limits, the THC quantity for edible cannabis must not exceed 10 mg per immediate container taking into account the potential to convert THCA into THC [subs. 97(2) and s. 102.7, CR].

This means, for example, that a package could contain edible cannabis with two discrete units that each contains 5 mg of total THC or other combinations so long as the overall THC content does not exceed 10 mg of total THC. Each unit must contain the same amount of total THC as every other unit.

6.5.3 Multiple units

It is prohibited to sell or distribute edible cannabis, if the immediate container contains multiple discrete units, unless the properties of each unit, including size but excluding flavour and colour, as applicable, are consistent [s. 98.1, CR].

6.5.4 Ingredients

Edible cannabis must not contain any ingredients other than food and food additives [subs. 102(1), CR].

Food has the same meaning as in section 2 of the FDA which is any article manufactured, sold or represented as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatsoever.

6.5.5 *Food additives*

Food additives may be used as ingredients in edible cannabis if all of the following conditions are met:

- The edible cannabis would be a food that is the subject of a marketing authorization if the edible cannabis did not contain or have on it anything referred to in item 1 or 3 of Schedule 1 to the Act
- The marketing authorization permits the food additive to be in or on the food
- The conditions under which the marketing authorization permits the food additive to be in or on the food, including any maximum levels of use, are complied with, and
- The food additive is not caffeine or caffeine citrate [subs. 102(5), CR].

Tip: Note that permitted food additives are limited to use in or upon foods that are set out in the Lists of Permitted Food Additives at the maximum level of use and conditions of use outlined in those Lists.

Refer to the FDA and its regulations, and Health Canada's Food and Nutrition webpage for more information on foods and food additives.

6.5.6 *Vitamins and mineral nutrients*

Vitamins and mineral nutrients may not be used as ingredients in edible cannabis (i.e., no fortification with added minerals or vitamins) unless they are permitted to be used as food additives and are used according to the relevant rules and limitations for those food additives. For example, the presence of naturally occurring vitamins or minerals in ingredients is permitted, as is the presence of vitamins or minerals because of required fortification of that ingredient under the FDA and its regulations (e.g., thiamine must be added to flour) [subs. 102(6), CR].

6.5.7 *Caffeine*

Edible cannabis must not contain or have on it caffeine unless it has been introduced through the use of ingredients that naturally contain caffeine (e.g., chocolate, tea) and the total amount of caffeine in each immediate container does not exceed 30 mg [s. 5.1 and 102.2, CR]. Note that caffeine cannot be used as a food additive [subs. 101(5)(d), CR].

6.5.8 *Ethyl alcohol*

Edible cannabis must not contain or have on it ethyl alcohol unless the concentration of it does not exceed 0.5% weight-by-weight (w/w) of ethyl alcohol of the edible cannabis [subs. 5.2(2), s. 102.3, CR].

6.5.9 *Meat products, poultry products and fish*

A meat product, poultry product or fish must not be used in edible cannabis unless:

- It is a food additive (e.g., gelatin, when meeting the additive requirements) or

- It has a water activity of 0.85 at a temperature of 22 ± 2°C or less when it is obtained by a licence holder and it has been produced by a person who is authorized to produce it under provincial legislation or the *Safe Food for Canadians Act* or is imported in accordance with that Act (e.g., jerky) [subs. 102(3), CR].

6.5.10 Self-produced food

Licence holders may produce their own food to be used as an ingredient in edible cannabis if the food is not a meat product, poultry product or fish and the sale of the food would not be prohibited under section 4 of the FDA [subs. 102(4), CR].

6.5.11 Foods with temporary marketing authorization

Any foods that have received a Temporary Marketing Authorization Letter (TMAL) issued under the FDR cannot be used as an ingredient or constituent in edible cannabis [subs. 102(2), CR].

Supplemented foods represent a significant category of foods for which TMALs are issued by Health Canada and it includes products such as beverages with added vitamins and minerals, caffeinated energy drinks, energy and granola bars, gums and candies.

Licence holders should review on a regular basis - the Lists of foods that have received Temporary Marketing Authorization Letters given the lists are continuously being updated as TMALs are issued.

6.5.12 Irradiation

Edible cannabis must not be irradiated unless the edible cannabis would be a food that is listed in item 3 or 4, column 1, of the table to Division 26 of Part B of the FDR (i.e., wheat, flour, whole wheat flour, whole or ground spices and dehydrated seasoning preparations) if the edible cannabis did not contain or have on it anything referred to in item 1 or 3 of Schedule 1 to the Act. The relevant FDR requirements must also be met (i.e., paragraphs B.26.003(2)(a) and (b) and subsection B.26.004(1) of the FDR) [s. 102.6, CR].

More information about food irradiation can be found on the Canadian Food Inspection Agency's (CFIA) website: Food Irradiation

6.5.13 Shelf-stable

Edible cannabis may not be sold or distributed if the unopened immediate container requires refrigeration, such as, the edible cannabis must be stored at or below 4°C to prevent the cannabis product from becoming contaminated before its durable life date [s. 102.4, CR].

6.5.14 Hermetically sealed containers

Edible cannabis may not be sold or distributed in a hermetically sealed container if any component of the edible cannabis has a pH that exceeds 4.6 and a water activity that exceeds 0.85 at a temperature of 22 ± 2°C [subs. 102.5(1) CR].

6.6 Cannabis accessory

A cannabis accessory 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 deemed under subsection 2(3) to the Act to be represented to be used in the consumption of cannabis [subs. 2(1), CA].

Other examples of cannabis accessories include a wide variety of things, such as vaping cartridges, droppers, and mechanical pumps.

A cannabis accessory that contains cannabis (within one of the classes set out in Schedule 4 to the Act) that is packaged and labelled for sale to a consumer at the retail level is a cannabis product for the purposes of the Regulations. For greater clarity: the cannabis accessory and the cannabis together are considered the cannabis product and the cannabis accessory is not considered an immediate container.

Besides meeting the general requirements of the Act and Regulations, a cannabis accessory that is a cannabis product (i.e., that contains cannabis) or that is packaged with a cannabis product must:

- Not be contaminated [s. 103, CR]
- Not impart a characterizing flavour to the cannabis [s. 103.1,CR]
- Not dispense more than 10 mg of THC per activation, subject to variability limits and taking into account the potential to convert THCA into THC if the cannabis accessory is a cannabis product intended for ingestion or nasal, rectal or vaginal use; and if the cannabis accessory that is packaged with, and that is intended to dispense, a cannabis extract that is a cannabis product and is intended for ingestion or nasal, rectal or vaginal use [subs. 97(1) and s. 103.2, CR]

Cannabis accessories may be subject to other Acts and Regulations that aim to protect the public, such as the *Canada Consumer Product Safety Act* and its regulations.

6.7 Novel products

As with any other cannabis product, licence holders must ensure that any novel cannabis extracts or cannabis topicals product are not injurious to health and that edible cannabis is not poisonous, harmful or adulterated and otherwise meets the requirements [subs. 101(1) and s. 102.1, CR].

Information about new cannabis products, including novel products, should be provided to Health Canada in a notice of a new cannabis product, as outlined in section 6.8 of this guide.

There are a number of other Acts and Regulations that apply to novel products that licence holders should be aware of, including those mentioned below. The *Cannabis Regulations* do not establish additional rules over and above those that are already established to protect the public.

6.7.1 *Cannabis plants and plants seeds*

Plants with novel traits are regulated under the *Seeds Act* and *Seeds Regulations* as well as the *Plant Protection Act* and *Plant Protection Regulations.* Plants with novel traits include plants into which one or more traits have been intentionally introduced, regardless of method, where

- The trait is new to cultivated populations of the species in Canada, and
- The plant has a potential to have a significant negative environmental effect

These traits can be introduced using biotechnology, mutagenesis or conventional breeding techniques.

Tip: For more information on cannabis with novel traits, including environmental release and import requirements, refer to the Cannabis with novel traits fact sheet.

6.7.2 *Novel food ingredients in edible cannabis*

Edible cannabis must not contain any ingredients other than food and food additives [subs. 102(1), CR]. In addition, edible cannabis products must not contain or have on it anything in a quantity that would cause the sale of the edible cannabis to be prohibited under any of paragraphs 4(1)(a) to (d) of the FDA if the edible cannabis were a food to which that Act applies (refer to section 6.5.1 of this guide).

The FDR defines a novel food under Division 28 of Part B. In summary, novel foods are those that:

- Result from a process not previously used in food
- Do not have a history of safe use as a food
- Have been modified by genetic manipulation (also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology derived foods)

All novel foods must be assessed by Health Canada before they can be sold in Canada.

In that regard, any novel food ingredients should be approved by Health Canada before being used in an edible cannabis product. Failure to secure approval of novel food ingredients could cause the sale of the edible cannabis to be prohibited under any of paragraphs 4(1)(a) to (d) of the FDA (e.g., to be harmful or unfit for human consumption depending on their nature) [subs. 102.1(1), CR].

Refer to Genetically modified foods and other novel foods for more information.

6.7.3 *Nanotechnology and nanomaterials*

To support the regulation of nanotechnology and nanomaterials, Health Canada has adopted the Policy Statement on Health Canada's Working Definition for Nanomaterial. Additionally, more information can be found on Health Canada's Nanotechnology-based health product and food webpage. All nanotechnologies and nanomaterials must comply with all of the relevant provisions in the Act and Regulations.

6.8 Notice of a new cannabis product

As per section 244 of the Regulations, holders of a processing licence must notify Health Canada of their intent to sell a cannabis product, other than a product belonging to the cannabis plants or cannabis plant seeds classes, which have not previously sold in Canada.

New product notifications must be provided to Health Canada in a written notice that contains the information set out in section 244, at least 60 calendar days before the cannabis product is made available for sale. This notification to Health Canada does not constitute approval for sale.

Refer to the Notice of new cannabis product guide for more information.

7.0 Contact us

To receive copies of any guidance documents mentioned above, please contact us at cannabis@canada.ca. If you have questions about cannabis products or the *Cannabis Act* and its regulations, email cannabis@canada.ca. Alternatively, you can reach Health Canada by phone at 1-866-377-7705.

8.0 Feedback— Help us improve

Health Canada is committed to providing all stakeholders with timely, accurate and reliable information. This includes providing information needed to comply with the *Cannabis Act* and its regulations. We would appreciate receiving your feedback on whether this guide was useful, and we welcome your suggestions for improvement. Email your feedback to us at cannabis@canada.ca and indicate in the subject line **Feedback on the Guide on composition requirements for cannabis products.**