

Health Canada releases final regulations for new classes of cannabis

SEPTEMBER 30, 2019 9 MIN READ

Related Expertise

- [Cannabis](#)
- [Corporate Governance](#)
- [Financial Services](#)
- [Health](#)
- [Mergers and Acquisitions](#)

Authors: [Michael Watts](#), [Susan Newell](#), Marty Putyra

In 2018, Canada legalized the sale of five classes of cannabis. This year will now see the addition of three new permitted classes of cannabis: (a) edible cannabis, (b) cannabis extracts, and (c) cannabis topicals.^[1] Accordingly, Health Canada has released the order and targeted regulations amending the *Cannabis Act* and Cannabis Regulations (collectively, the Amending Regulations) governing these new classes of cannabis, coming into force on October 17, 2019.^[2]

Authorized classes of cannabis

Current	After October 17, 2019
Dried cannabis	Edible cannabis
Cannabis oil	Cannabis extracts*
Fresh cannabis	Cannabis topicals
Cannabis plants	Dried cannabis
Cannabis plant seeds	Fresh cannabis
	Cannabis plants
	Cannabis plant seeds

**Cannabis oil as a separate category will be removed October 17, 2020, to be included under extracts.*

Objectives

The overarching objective of the Amending Regulations is to establish new regulatory controls to address the public health and public safety risks associated with edible cannabis, cannabis extracts, and cannabis topicals.^[3] While permitting the sale of these new classes of cannabis, the Amending Regulations aim to reduce:

- the appeal of cannabis products to youth;
- the risk of accidental consumption or overconsumption;
- potential health and safety risks including the risk of foodborne illness associated with the production and consumption of edible cannabis; and
- the risk of dependence and other negative health outcomes associated with cannabis products.^[4]

To achieve these objectives, the Amending Regulations provide general information about the sale, content and product specifications, packaging and licensing requirements for the new classes of cannabis in general. Please see below for more detailed information regarding the requirements for each new class of cannabis.

Licensing & timelines: implications for licensed producers

As is the case for dried or fresh cannabis and cannabis oil, a processing licence (either standard or micro) will be required in order to produce edible cannabis, cannabis extracts and cannabis topicals, and to package and label these types of cannabis products for sale to consumers. Current holders of processing licences must amend their processing licence once the Amending Regulations take effect before they can begin manufacturing products belonging to the new classes. Although processing licence holders may currently engage in many research and development activities, administering cannabis to a test subject (i.e., for the purposes of palatability testing) requires a specific research licence for each specific project.^[5]

Although the Amending Regulations will come into force on October 17, 2019, since there is a required 60-day notice period before any new cannabis product can be made available for sale, Health Canada has announced that it is expecting that sales of such products will not occur any sooner than mid-December 2019.^[6]

Promotion

As previously discussed in our Osler Update ["Frequently asked questions regarding cannabis promotional materials"](#), it is generally prohibited to promote cannabis, a cannabis accessory, or any service related to cannabis unless authorized by certain limited exceptions. Such restrictions will also apply to the new classes of cannabis. The Amending Regulations will also prohibit certain representations and associations on products, their packages and labels and associated promotional activity, including:

- certain flavours in cannabis extracts, being:^[7]
 - confectionary,
 - dessert,
 - soft drink, and
 - energy drink,
- health or cosmetic benefits,^[8]
- energy value and amount of certain nutrients,^[9]
- statements reasonably likely to create the impression the edible cannabis or accessory is intended to meet particular dietary requirements of a young person or an individual (i) who has a physical or physiological condition caused by a disease, disorder or injury or for whom a particular effect is to be obtained by the controlled intake of food;^[10] and
- promotion that could reasonably associate the cannabis, the cannabis accessory or the service related to cannabis with (a) an alcoholic beverage (precluding branding flavours with terms such as "IPA" or "chardonnay"),^[11] or (b) a tobacco product or a vaping product.^[12]

Packaging & labelling

The Amending Regulations would maintain the core plain packaging and labelling requirements that currently apply to all cannabis products, such as the standardized

cannabis symbol, health warning messages, THC and CBD content, and child-resistant packaging but make additions and adjustments to account for the new classes of cannabis. For example, for edible cannabis, this means that labels must also include:

- a list of ingredients;
- the common name of the cannabis product;
- an indication of the source of an allergen or gluten, or that sulphites have been added to the product;
- a “durable life date” or “best before date” for edible cannabis having a durable life of 90 days or less; and
- a cannabis-specific nutrition facts table or “NFT.”^[13]

Labels for cannabis extracts must also include a list of ingredients, the identity of the cannabis product in terms of its common name or function, and a list of allergens, as well as the intended use of the product (e.g., “for vaping”). For cannabis extracts in a container with an integrated dispensing mechanism, the quantity of THC and CBD per activation (in milligrams) will also be required to appear on the label (in addition to the total concentration of THC and CBD in the container as required for all product classes).^[14]

In addition to the current labelling requirements that apply to all cannabis products, the labels for all cannabis topicals will need to include a list of ingredients, the identity of the cannabis product in terms of its common name or function, as well as the intended use of the product (e.g., “apply to skin”).^[15]

A closer look at the new classes of cannabis

Edible cannabis

Under the Regulations, edible cannabis means a substance or mixture of substances containing any part of a cannabis plant, including the phytocannabinoids produced by or found in such plant and any substance identical to any such phytocannabinoid, 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.^[16]

The Regulations will introduce restrictions on product composition, including limiting tetrahydrocannabinol (THC) to a maximum of 10 milligrams (mg) per immediate container.^[17] Other product restrictions include:

- **Ingredients:** Edible cannabis products must not contain any ingredients other than food and food additives.^[18] Any additives must be used in accordance with the prescribed limits of the *Food and Drug Regulations* under the *Food and Drugs Act*.^[19]
- **Prohibited and unsafe foods:** Edible cannabis must not contain or have on it anything that would cause the sale of the edible cannabis to be prohibited under the *Food and Drugs Act* if the edible cannabis was a food.^[20] Anything that would be considered unsafe and would cause the sale of a food regulated under the *Food and Drugs Act* to be prohibited will also be prohibited under the Regulations.^[21]
- **No vitamins or mineral nutrients:** Edible cannabis must not be fortified with vitamins or

mineral nutrients.^[22] However, a vitamin may be used if it is naturally present in the ingredient used at a level that is not above the naturally occurring level for that ingredient.^[23]

- **Caffeine:** While the use of caffeine as an additive in edible cannabis is prohibited, edible cannabis may contain naturally occurring caffeine in items such as chocolate, tea or coffee, or that has been introduced through the use of ingredients that naturally contain caffeine. However, the total amount of caffeine may not exceed 30 mg.^[24]
- **Shelf stable:** an edible cannabis product that requires storage at or below 4°C to prevent contamination is prohibited.^[25]
- **Production sites:** Licensed producers must not produce, package, label or store edible cannabis at a site set out in the licence if food that is for retail sale is also manufactured at that site unless the food for retail sale is manufactured in a different building.^[26]

Cannabis extracts

Cannabis extracts are products produced by (i) subjecting cannabis to extraction processing; or (ii) synthesizing a substance found in a phytocannabinoid produced by or found in a cannabis plant.^[27]

The Regulation would require that a cannabis extract must not exceed a maximum yield quantity of 1,000 mg of THC per immediate container.^[28] Also, cannabis extracts may not contain more than 10 mg of THC per discrete unit that is intended to be ingested or for nasal, rectal, or vaginal use, such as a capsule.^[29]

Other product composition restrictions include:

- Cannabis extracts may not contain ingredients that are sugars, sweeteners or sweetening agents, nor any ingredient listed in Column 1 of Schedule 2 to the *Tobacco and Vaping Products Act*.^[30]
- Cannabis extracts may not contain any ingredients that may cause injury to the health of the consumer when the product is used as intended.^[31]
- Forms of cannabis extracts that are intended to be used on damaged or broken skin or to penetrate the skin barriers by means other than by absorption (e.g., such as eyedrops or needles) are prohibited.^[32]

Cannabis topicals

Cannabis topicals are substances that are intended for use, directly, or indirectly, exclusively on external bodily surfaces. Cannabis topicals would not be permitted to contain any ingredients that may cause injury to the health of the consumer when the product is used as intended or in a reasonably foreseeable way as is the case for all product classes.^[33]

In addition, the Regulations provide that a cannabis topical must not contain more than 1,000 mg of THC per immediate container.^[34]

[1] *Cannabis Act*, SC 2018, c 16 at s 193.1 and ss 226(2).

[2] *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)*. [Amending Regulations]

[3] Health Canada, *Regulatory Impact Analysis Statement* (June 26, 2019), Canada Gazette, Part II. [RIAS]

[4] *Ibid.*

[5] *Cannabis Regulations*, SOR/2018 144 at s 17 and s 28(4). [Cannabis Regulations]

[6] *Cannabis Regulations*, *supra* note 5 at s 244(1).

[7] *Amending Regulations*, *supra* note 2 at s 29 adding s 104.11 to the *Cannabis Regulations*.

[8] *Amending Regulations*, *supra* note 2 at s 29 adding s 104.12 to the *Cannabis Regulations*.

[9] *Amending Regulations*, *supra* note 2 at s 29 adding s 104.13 to the *Cannabis Regulations*.

[10] *Amending Regulations*, *supra* note 2 at s 29 adding s 104.14 to the *Cannabis Regulations*.

[11] *Amending Regulations*, *supra* note 2 at s 29 adding s 104.15 to the *Cannabis Regulations*.

[12] *Amending Regulations*, *supra* note 2 at s 29 adding s 104.16 to the *Cannabis Regulations*.

[13] *Amending Regulations*, *supra* note 2 at s 46 adding s 132.18 – 132.21 to the *Cannabis Regulations*.

[14] *RIAS*, *supra* note 3; see also *Amending Regulations*, *supra* note 2 at s 46 adding s 132.1, 132.11 and 132.12 to the *Cannabis Regulations*.

[15] *RIAS*, *supra* note 3; see also *Amending Regulations*, *supra* note 2 at s 46 adding s 132.15 – 132.17 to the *Cannabis Regulations*.

[16] *Amending Regulations*, *supra* note 2 at s 1(4) amending ss 1(1) of the *Cannabis Regulations*.

[17] *Amending Regulations*, *supra* note 2 at s 28 adding s 102.7 to the *Cannabis Regulations*. This must also take into account the potential to convert THCA (a non-intoxicating precursor of THC) to THC.

[18] *Amending Regulations*, *supra* note 2 at s 28 adding s 102(1) to the *Cannabis Regulations*.

[19] CRC, c 870.

[20] *Amending Regulations*, *supra* note 2 at s 28 adding s 102.1 to the *Cannabis Regulations*.

[21] *Ibid.*

[22] *Amending Regulations, supra* note 2 at s 28 adding s 102(6) to the *Cannabis Regulations*.

[23] *Amending Regulations, supra* note 2 at s 28 adding s 101.3(4) to the *Cannabis Regulations*

[24] *Amending Regulations, supra* note 2 at s 28 adding s 5.1 to the *Cannabis Regulations*.

[25] *Amending Regulations, supra* note 2 at s 28 adding s 102.4 to the *Cannabis Regulations*.

[26] *Amending Regulations, supra* note 2 at s 25 adding s 88.3(2) to the *Cannabis Regulations*.

[27] *Amending Regulations, supra* note 2 at s 1(4) amending ss 1(1) of the *Cannabis Regulations*.

[28] *Amending Regulations, supra* note 2 at s 28 adding 101.2 to the *Cannabis Regulations*. This maximum yield quantity must take into account the potential to convert THCA into THC.

[29] *Amending Regulations, supra* note 2 at s 1(4) amending ss 96(1) of the *Cannabis Regulations*.

[30] *Amending Regulations, supra* note 2 at s 28 adding s 101.3(2) to the *Cannabis Regulations*. Ingredients listed in Column 1 of Schedule 2 to the *Tobacco and Vaping Products Act* include amino acids, caffeine, colouring agents, essential fatty acids, glucoronolactone, probiotics, taurine, vitamins and mineral nutrients.

[31] *Amending Regulations, supra* note 2 at s 28 adding s 101(1) of the *Cannabis Regulations*.

[32] *Amending Regulations, supra* note 2 at s 27 adding s 98 to the *Cannabis Regulations*.

[33] *Amending Regulations, supra* note 2 at s 1(4) amending ss 1(1) of the *Cannabis Regulations*.

[34] *Amending Regulations, supra* note 2 at s 28 adding s 101.2 to the *Cannabis Regulations*. This maximum yield quantity must take into account the potential to convert THCA into THC.