

# Health Canada Issues Proposed Regulations for Edible Cannabis, Cannabis Extracts, and Cannabis Topicals

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Section 193.1 of the [Cannabis Act\[1\]](#) will authorize the legal sale of “edibles containing cannabis” and “cannabis concentrates.” Although Section 193.1 is not currently in force, it will become effective no later than October 17, 2019.

On December 22, 2018, Health Canada [published draft regulations](#) (the “Draft Regulations”) in the *Canada Gazette*, which will regulate the following new classes of cannabis:

- a. Edible Cannabis: Products containing cannabis that are intended to be consumed in the same manner as food (i.e. eaten or drunk);
- b. Cannabis Extracts: Products that are produced using extraction processing methods or by synthesizing phytocannabinoids; and
- c. Cannabis Topicals: Products that include cannabis as an ingredient and that are intended to be used on external body surfaces (i.e. skin, hair, and nails).

Health Canada has launched a sixty-day public comment period for the Draft Regulations, which will end on February 20, 2019. Health Canada will consider these public comments before issuing final regulations.

## Licensing

Part 2 of the current [Cannabis Regulations\[2\]](#) establishes the classes (i.e. cultivation, processing, sale) and subclasses (i.e., standard/micro-cultivation, standard/micro-processing) of licences that authorize activities with cannabis at the federal level. A processing licence (either standard or micro) will be required in order to manufacture, package and label edible cannabis,

cannabis extracts and cannabis topicals for sale to consumers. The following additional requirements will also apply to licenced processors:

- a. A past conviction for an offence under the [Safe Food for Canadians Act](#)<sup>[3]</sup> (“SFCA”), or any of the Acts that will be repealed when the SFCA comes into force, will be a ground for refusal or revocation of a processing licence, if the conviction occurred within the preceding 10 years.
- b. The *Cannabis Regulations* currently state that a licensed processor must retain the services of an individual with the necessary training, experience and technical knowledge to act as a Quality Assurance Person (“QAP”). The Draft Regulations specify that the QAP must have the necessary qualifications to oversee the production of all classes of cannabis that the licensed processor is authorized to produce (including training, experience, and technical knowledge of both good production practices and product rules). However, if the QAP does not have the requisite knowledge and training with respect to edible cannabis, the licence holder must retain the services of another individual with the necessary qualifications.
- c. The *Cannabis Regulations* currently require licence holders to establish and maintain a system of control to support efficient product recalls. The Draft Regulations will require licence holders to conduct a recall simulation at least once every 12 months and retain the documentation for at least two years.

### Production Practices

Part 5 of the *Cannabis Regulations* currently impose requirements on federal licence holders relating to the production, distribution and storage of cannabis to control the quality of cannabis produced by federal licence holders. The *Draft Regulations* would impose additional rules to prevent contamination of cannabis products and to address the risk of foodborne illness associated with edible cannabis. For example:

- a. Current requirements relating to the cleanliness of equipment used with cannabis or ingredients will be expanded to also include anything that is used within the licensed facility to transport cannabis or ingredients used in the production of cannabis products (e.g., forklift, hand lifts, etc.).
- b. Licenced cultivators and processors will be required to have a ventilation system that provides clean air and removes unclean air that may have a negative impact on the cannabis or ingredients.
- c. Existing controls designed to prevent the contamination of cannabis would be expanded, at least in the case of licenced processors, to also cover ingredients intended to form

part of a cannabis product.

- d. Licensed processors of edible cannabis or cannabis extracts will be required to prepare, retain, maintain, and implement a written Preventive Control Plan to identify and address, through effective control measures, any potential hazards that pose a risk to the production of these products.
- e. The QAP will be required to proactively conduct an investigation (not merely when a complaint is made if they suspect that cannabis (or an ingredient) may present a risk of injury to human health or does not meet requirements in Part 5 or Part 6 of the *Cannabis Regulations*, and, if necessary, take immediate measures to mitigate any risk.
- f. All licensed processors (not just those processing edible cannabis) will need to ensure that animals and pests are not able to enter into any building or part of a building where cannabis is being processed.
- g. Any water (including ice or steam used in the production of a cannabis product) coming into contact with cannabis (or an ingredient) will need to be potable, unless the water does not present a risk of contamination.
- h. Licensed processors will be required to separate incompatible activities and ensure that contaminated waste is disposed of properly. Licensed processors producing edible cannabis would also be required to identify and place contaminated ingredients in a designated area.
- i. If the production of edible cannabis occurs at a site where conventional food products are also being manufactured for sale, the edible cannabis will need to be produced in another building within the licensed site.

### Testing Procedures

The Draft Regulations will make minor revisions to rules governing the sampling and testing of cannabis. For example:

- a. When conducting microbial and chemical contaminant testing, the licensed processor will now have the option of conducting testing on either the final form of the cannabis product or at the final step in the production process during which the contaminants could be concentrated. For example, if a cannabis extract is used in the production of a cannabis topical, the licensed processor would have the option of conducting testing on

the cannabis extract or on the final form of the cannabis topical.

- b. The current *Cannabis Regulations* state that levels of microbial and chemical contaminants must be within established limits for herbal medicines. Under the Draft Regulations, microbial and chemical limits will need to be within limits that are appropriate for the intended use of the product (e.g. ingestion, inhalation, etc.).

## Product Rules for New Cannabis Classes

### Product Composition and Ingredients

#### Certain Product Forms Prohibited

Product forms that pose a greater risk to human health, such as those intended to be used in or around the human eye (for example, eye drops) or products that are intended to be used on damaged or broken skin or to penetrate the skin barrier by means other than by absorption (i.e. through the use of abrasives or needles) will continue to be prohibited.

#### Limits on Tetrahydrocannabinol (“THC”) and Cannabidiol (“CBD”)

The Draft Regulations will establish THC and CBD limits:

- a. For edible cannabis, there will be a limit of 10 mg of THC per discrete unit (i.e. individual serving) and per immediate container (the container that is in direct contact with cannabis, not including any wrapper). For example, an immediate container could contain one discrete unit of edible cannabis that contains 10 mg of THC. It also could contain two discrete units, which each contain 5 mg of THC.
- b. For cannabis extracts, there will be a limit of 10 mg of THC per discrete unit that is intended to be ingested or for nasal, rectal, or vaginal use (e.g., a capsule). In addition, there will be a limit of 1,000 mg of THC per immediate container. For example, an immediate container could contain 100 capsules of an extract that each contain 10 mg of THC, or 200 capsules of an extract that each contain 5 mg of THC.
- c. For cannabis topicals, there will be a limit of no more than 1,000 mg of THC per immediate container.
- d. For a cannabis accessory that contains cannabis, there will be a limit of 1,000 mg of THC per immediate container.

A lower possession limit and smaller package sizes would also apply to any cannabis product that contains more than 3% THC by weight (these products are considered “concentrates” for

the purposes of Schedule 4 to the *Cannabis Act*). The maximum package size and public possession limit of 7.5 grams (equivalent to 30 grams of dried cannabis) would apply to edible cannabis, cannabis extracts, or cannabis topicals that contain more than 3% w/w THC.

#### Variability Limits for THC and CBD

The Draft Regulations also establish “variability limits” on the amount of THC and CBD permitted in the new classes of cannabis:

- a. The following variability limits will apply to edible cannabis:
  1. If the total quantity of THC or CBD that is displayed on the label exceeds 5 mg, the product cannot contain less than 85% of that amount, or more than 115% of that amount.
  2. If the quantity of THC or CBD that is displayed on the label is more than 2 mg but less than 5 mg, the product cannot be less than 80% of that amount or more than 120% of that amount.
  3. If the quantity of THC or CBD that is displayed on the label is less than 2 mg, the product cannot be less than 75% of that amount or more than 125% of the amount displayed on the label.
- b. Cannabis extracts and cannabis topicals cannot contain less than 85% of the amount displayed on the label, or more than 115% of that amount.
- c. If a cannabis product that is not divided into discrete units but is represented as being divisible into discrete units, or is divided into discrete units that are represented as being divisible into discrete sub-units, each represented unit/sub-unit must not contain:
  1. A quantity of THC that is less than 75% or more than 125% of the quantity of THC in each of the other represented units/sub-units; and
  2. A quantity of CBD that is less than 75% or more than 125% of the quantity of CBD in each of the other represented units/sub-units.

#### Edible Cannabis

The following rules will apply to edible cannabis:

- a. Only food and food additives may be used as ingredients in edible cannabis. In addition, the use of food additives must be in accordance with the limits and purposes that are

prescribed for foods in the [Food and Drug Regulations](#)[4] (“FDR”).

- b. Edible cannabis may not be fortified with vitamins or mineral nutrients.
- c. Edible cannabis must not contain caffeine unless it has been introduced through the use of ingredients that naturally contain caffeine (i.e., chocolate, tea, or coffee). In addition, the total amount of caffeine in the immediate container must not exceed 30 mg.
- d. Edible cannabis must not contain ethyl alcohol, although a small concentration of ethyl alcohol that does not exceed 0.5% w/w of the edible cannabis will be permitted, since ethyl alcohol is often present as a by-product in fermented ingredients or products (e.g., vinegar).
- e. Any temporarily marked food described in a Temporary Marketing Authorization Letter issued under the FDR may not be used as an ingredient (or a constituent element of such an ingredient).
- f. If the edible cannabis product contains anything that would be considered unsafe and would cause the sale of a food regulated under the [Food and Drugs Act](#) [5] (“FDA”) to be prohibited, then its sale would also be prohibited under the *Cannabis Act*.
- g. The use of meat products, poultry products and fish as ingredients would be prohibited, except for dried meats, poultry or fish that are obtained from someone authorized to produce such products under provincial or territorial laws or the SFCA. Such ingredients must also have a water activity of 0.85 or less at the time they are obtained.
- h. The sale of edible cannabis in a hermetically sealed container will be prohibited if any constituent of the edible cannabis has a pH above 4.6 and a water activity higher than 0.85.
- i. Edible cannabis products must not require refrigeration or freezing to prevent it from becoming contaminated.

### Cannabis Extract

The following rules will apply to cannabis extracts:

- a. Cannabis extracts must not contain any ingredients other than: (1) carrier substances, (2) flavouring agents, or (3) substances that are necessary to maintain the quality or stability

of the cannabis product. For example, adding nicotine to cannabis extracts will be prohibited.

- b. Cannabis extracts cannot contain sugars, sweeteners or sweetening agents.
- c. Cannabis extracts cannot contain ingredients that are listed in Column 2 of [Schedule 2 to the Tobacco and Vaping Products Act\[6\]](#). For example, the addition of vitamins, mineral nutrients, and probiotics will be prohibited.
- d. Any ingredient, other than a flavouring agent, used in the preparation of a cannabis extract that is intended to be inhaled will need to comply with a standard set out in one of the publications referred to in [Schedule B to the FDA](#).
- e. The use of ethyl alcohol will be permitted in cannabis extracts that are intended to be ingested (for example, tinctures) but there will be a maximum package size of 7.5 g per immediate container, for all cannabis extracts that contain ethyl alcohol; this limit will apply regardless of the THC content of the product.
- f. A cannabis extract must not contain any ingredient that may cause injury to the health of the consumer when the product is used as intended, or in a reasonably foreseeable way. However, in respect of a cannabis extract that is intended to be combusted and inhaled (i.e. smoked), this does not prohibit something that may cause injury as a result of the intended combustion and inhalation.

### Cannabis Topicals

A cannabis topical must also not contain any ingredient that may cause injury to the health of the consumer when the product is used as intended, or in a reasonably foreseeable way.

### Cannabis Accessories

The Draft Regulations include amendments designed to ensure that cannabis accessories do not increase the potential for harm associated with cannabis products, and to establish dispensing limits for accessories containing certain cannabis extracts. For example:

- a. A cannabis accessory must not, through chemical means other than heating or combustion, alter or enhance the effects of the product, increase the potential for physical dependence on the product, or increase the toxicity of the cannabis product when used as intended.

- b. A cannabis accessory that dispenses a cannabis extract intended for ingestion or nasal/rectal/vaginal use must not dispense a maximum yield quantity that exceeds 10 mg of THC.

### Packaging and Labelling Requirements

The packaging and labelling requirements that currently apply to all cannabis products (e.g., the standardized cannabis symbol, health warning messages, THC and CBD content, and child-resistant packaging) will apply to the new classes of cannabis. However, the Draft Regulations provide for specific additions and adjustments to account for the new classes of cannabis and to address the public health risks associated with these new classes (i.e. risk of accidental consumption and overconsumption).

### Labelling Requirements

The Draft Regulations impose the following labelling requirements on the new classes of cannabis and to cannabis accessories containing those classes of cannabis:

- a. In addition to the current labelling requirements that apply to all cannabis products, the following information will be required on the label of all edible cannabis: (1) a list of ingredients; (2) the common name of the cannabis product; (3) an indication of the source of an allergen or gluten, or that sulphites have been added to the product (alternatively, this information could appear as part of the ingredient list); (4) a “best-before date,” which will apply to edible cannabis products that are expected to deteriorate over a period of 90 days or less; and (5) a cannabis-specific nutrition facts table.
- b. In addition to the current labelling requirements that apply to all cannabis products, the following information will be required on the label of all cannabis extracts: (1) a list of ingredients, (2) the identity of the cannabis product in terms of its common name or function, (3) a list of allergens, and (4) the intended use of the product (e.g., “for vaping”).
- c. In addition to the current labelling requirements that apply to all cannabis products, the following information will be required on the label of all cannabis topicals: (1) a list of ingredients, (2) the intended use of the product (e.g., “apply to skin”), (3) directions for use (although the exact language is not prescribed in the Draft Regulations), and (4) a warning statement (i.e., “Do not swallow or apply internally or to broken, irritated, or itching skin.”).
- d. The standardized cannabis symbol will need to be displayed on any cannabis accessory that contains a cannabis extract intended to be inhaled, and which contains more than 10 ppm of THC. This would require vaping devices or vaping cartridges that contain a cannabis extract with THC to have the symbol directly on the device or cartridge. In



addition, the standardized cannabis symbol will need to be displayed on the exterior surface of any wrapper that is in direct contact with edible cannabis, a cannabis extract, or cannabis topical that contains more than 10 ppm of THC.

### Packaging Requirements

The Draft Regulations also make the following changes to the existing packaging requirements:

- a. There will be an exception to the current prohibition on the use of a naturally-occurring metallic colour on the external surface of an immediate container that is made of metal, which will allow for the use of metal beverage cans.
- b. The exterior surface of any container in which a cannabis product is packaged will no longer need to have a matte finish.
- c. The immediate container for cannabis extracts will need to be designed in such a way that the extract cannot be easily poured, or drunk directly from the container. For extracts in liquid form that are not intended to be inhaled, and which contain at least 10 mg of THC, the container will need to include an integrated dispensing mechanism that dispenses no more than 10 mg of THC, unless the extract is in the form of discrete units (e.g., a capsule).
- d. In the case of edible cannabis, there will be a requirement to use “food-grade” packaging (i.e., packaging that meets requirements set out in the FDR and the [Safe Food for Canadians Regulations \[7\]](#) (“SFCR”) for food for the immediate container and for any wrappers.
- e. The co-packaging of edible cannabis and a food will be prohibited, as will the co-packaging of more than one class of cannabis in the same exterior container.
- f. An exterior container may not contain more than one immediate container (which will prevent the sale of sampler packs).
- g. The immediate container of a cannabis product cannot be pressurized, although an exception is provided for edible cannabis in liquid form, such as carbonated beverages.
- h. The use of expanded panels and alternative display formats for certain required information will be permitted when the immediate container is too small to otherwise

accommodate all required information on the exterior display surface. However, tags and package inserts would still not be permitted.

In addition to the THC limits already described above, the following new maximum package sizes will also apply:

- a. As mentioned above, the maximum package size for all cannabis extracts that contain ethyl alcohol and are intended to be ingested is 7.5 g, irrespective of the concentration of THC in that product; and
- b. The maximum package size for all liquid cannabis extracts is 90 mL.

This is in addition to the maximum package size of 7.5 g that will apply to all “cannabis concentrates.”

### Prohibitions on Representations

The Draft Regulations will prohibit the following representations on all product packages and labels:

- a. It will prohibit representations regarding health benefits, including those that are currently permitted on food (applies to all classes of cannabis).
- b. It will prohibit nutrient content representations that go beyond those permitted in the list of ingredients and cannabis-specific nutrition facts table, including those that are currently permitted on food (applies to edible cannabis only).
- c. It will prohibit representations regarding cosmetic benefits (applies to all classes of cannabis).
- d. It will prohibit all representations that associate a cannabis product, its packaging or its labelling (including its brand element) with an alcoholic beverage. For example, it will not be possible to use terms related to alcoholic beverages (e.g. beer, wine, etc.) for cannabis products. In addition, it will not be possible to use the name or logo of a company that manufactures alcoholic beverages on a cannabis product.
- e. It will prohibit the representation of certain flavours, which are appealing to youth, on the packaging and labelling of cannabis extracts. Other than cannabis flavour, the flavours that are set out in Column 1 of [Schedule 3 to the Tobacco and Vaping Products Act](#) are prohibited.

- f. It will prohibit the representation of edible cannabis as being a suitable means of meeting dietary requirements. For example, it would be prohibited to say that edible cannabis is suitable for people with diabetes, or as part of a low-calorie diet.

These prohibitions will be in addition to the existing prohibitions set out in the Cannabis Act.

### Transitional Provisions

The Draft Regulations provide that an order will be made to remove “cannabis oil” from [Schedule 4 of the Cannabis Act](#) six months after they come into force, in order to provide for an appropriate transition period. Following the six-month transition period, cannabis oil would be subsumed under the new product classes.

During this proposed six-month transition period, cannabis oil could continue to be sold as a class of cannabis (by federal licence holders and provincially and territorially authorized distributors and retailers), subject to the current rules as they apply to cannabis oil. For example, cannabis oil would continue to be subject to the limit of 10 mg of THC per discrete unit, but the new limit of 1,000 milligrams of THC per immediate container would not apply to cannabis oil during the transition period.

A six-month transition period for dried or fresh cannabis will also be provided in relation to microbial and chemical contaminants. During the six-month period, microbial and chemical contaminants could remain within established limits for herbal medicines, rather than within limits appropriate for the intended use of the product.

### Areas of Potential Concern

One concern is that the Draft Regulations will result in wasteful excessive packaging in the case of edible cannabis. The limit of 10 mg of THC per discrete unit (i.e. individual serving) of edible cannabis is reasonable enough but to impose the same limit on the immediate container goes too far. If alcohol does not need to be sold in packages containing only one serving (for example, one shot of whiskey or one bottle of beer), it makes little sense to require edible cannabis to be sold in single serving packages.

The prohibition on representations that associate cannabis product with an alcoholic beverage may also be a concern for some licenced processors. The justification for this prohibition is that it will help to address the risks associated with the co-use of alcohol and cannabis. However, prohibiting the use of terms such as “beer” or “wine” or the use of names/logos normally associated with alcohol, in connection with cannabis products, may not actually discourage such co-use.

The requirement that the production of edible cannabis take place within another building, if conventional food products are also manufactured at that site, may result in significant infrastructure costs. Although avoiding cross-contamination or accidental mislabeling/packaging is a valid objective, one wonders if a less costly option might be available.

### Conclusion

The Draft Regulations, which will regulate edible cannabis, cannabis extracts, and cannabis topicals, may be considered unduly restrictive on some issues. However, as the public comment period is still open, Health Canada may address these issues before the final regulations are published.

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[1] S.C. 2018, c. 16.

[2] SOR/2018-144.

[3] S.C. 2012, c. 24.

[4] C.R.C., c. 870.

[5] R.S.C., 1985, c. F-27.

[6] S.C. 1997, c. 13.

[7] SOR/2018-108.