

## Weeding Out the Edible, Extracts and Topical Appeal

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### Introduction

On December 20, 2018, Health Canada launched a 60-day public consultation on draft regulations to amend Schedule 4 (the "Schedule") to the *Cannabis Act* (the "Act") to include the following classes of cannabis that can be legally sold in Canada: "edible cannabis", "cannabis extracts" and "cannabis topicals". The draft regulations also propose that an Order be made to remove "cannabis oil", which is currently listed in Schedule 4 of the Act, from the Schedule six (6) months after the amended Regulations come into force. Following this 6-month transition period, cannabis oil would be subsumed under the new product classes.

The draft regulations also seek to address public health and safety risks associated with the new classes of cannabis, including its appeal to youth and the risks of accidental consumption, overconsumption and foodborne illness, among others.

### Public Health and Safety

The proposed amendments to the legislation will put in place new manufacturing controls for the production of edible cannabis products to improve cleanliness and reduce the risk of foodborne illness. For example, the legislation proposes:

- that requirements pertaining to cleanliness of equipment used with cannabis or ingredients be expanded to also include conveyances, which refers to anything that is used within the licensed facility to transport cannabis or ingredients used in the production of cannabis products (e.g., a forklift or hand lift) (requirement would apply to licensed cultivators and processors);
- a new ventilation requirement that provides clean air and removes unclear air that may have a negative impact on cannabis or ingredients (requirement would apply to both licensed cultivators and processors);
- an expansion of the sanitation requirements to explicitly require hand cleaning / sanitizing stations and lavatories in buildings where cannabis is produced (requirement would apply to licensed cultivators and processors);
- protective coverings for employee clothing and footwear (for licensed processors only);
- that licensed processors who produce edible cannabis or cannabis extracts would be required to prepare, retain, maintain and implement a written Preventive Control Plan

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("PCP") to identify and address, through effective control measures, any potential hazards that pose a risk to the production of these products;

- that all licensed processors would need to take steps to ensure that animals and pests are not able to enter into any building or part of a building where cannabis is being processed; and
- a requirement that any water, including ice or steam used in the production of a cannabis product, coming into contact with cannabis or an ingredient be potable, unless the water does not present a risk of contamination.

### **Packaging and Labelling**

Part 7 of the Cannabis Regulations identifies the mandatory requirements that currently apply to the packaging and labelling of all marijuana products. The proposed regulations would expand on the information that is required for each product depending on its type.

Currently, Part 7 requires that packaging and labelling of all products include:

- a standardized cannabis symbol;
- health warning messages;
- the identification of THC and CBD content; and
- child-resistant packaging.

The proposed regulations would also restrict packaging for all classes of cannabis products from including any representation of a health benefit, as well as prohibit against any representation that associates a cannabis product, its package, or its labelling with an alcoholic beverage.

It is also proposed that an exception be made to allow the use of containers that contain metal (such as beverage cans) and that the exterior of a container in which a cannabis product package no longer need to have a matte finish.

### **Edible Cannabis (solid and beverage)**

A cannabis edible includes products containing cannabis intended to be consumed in the same manner as food (*i.e.*, eaten or drunk). The proposed regulations seek to limit the amount of THC per package or container to 10 milligrams and will not permit any vitamins, minerals or alcohol to be added to products.

All edible cannabis products also would need to be shelf-stable (*i.e.*, not require refrigeration or freezing), and not contain any product that is considered to be unsafe or would cause the sale of a food regulated under the *Food and Drugs Act* ("FDA") to be unsaleable.

In addition to the current labeling requirements listed above, the draft regulations propose that edible cannabis products also include the following on their labels:

- 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 "best before date" if the product is expected to deteriorate over a period of ninety (90) days or less; and
- a cannabis-specific nutrition facts table ("NFT").

Further, any nutrient content representation that goes beyond those permitted on the list of ingredients and cannabis-specific NFT (including those that are currently permitted on food such as "low fat") or mention of additional vitamin or mineral content of the product is prohibited. There would also be a new requirement to use "food-grade packaging" for the immediate container of edible cannabis and for any wrappers.

### **Cannabis Extracts (ingested, inhaled or concentrated)**

The cannabis extracts class in the proposed regulations will include products that are produced by using extraction processing methods or by synthesizing phytocannabinoids. As is the case for cannabis oil, the draft regulations would limit the amount of THC per package to 1,000 milligrams and there would be a limit of 10 milligrams of THC per discrete unit that is intended to be ingested or per use (such as in a capsule). Additionally, the proposed regulations seek to restrict any ingredients that include either nicotine or caffeine, as well as prohibits against any added vitamins or minerals. As well, to ensure consistency with the objective of limiting the appeal of marijuana products to children, no sugars, colours or sweeteners are permitted to be included in cannabis extracts.

In addition to the current packaging requirements discussed above, it is proposed that cannabis extract products will also be required to include the following on its packaging:

- a list of ingredients;
- the identity of the cannabis product in terms of its common name or function;
- a list of allergens; and
- the intended use of the product (*i.e.*, for "vaping").

The container of extracts will also require a design such that it could not be easily poured or drunk directly from the container.

### **Cannabis Topical**

A cannabis topical is proposed to include products that use cannabis as an ingredient and which is intended to be used on external body surfaces (*i.e.*, skin, hair, and nails). The proposed regulations would limit the maximum amount of THC that can be dispensed per activation of a product at 10 milligrams, and permit a maximum of 1,000 milligrams per package.

In addition to the packaging requirements for all other marijuana products, it is proposed that the labelling for topical products include:

- a list of ingredients;
- intended use of the product (*i.e.*, "apply to skin");
- directions for use (but the content would not be prescribed); and
- the following warning statement: "**Do not swallow or apply internally to broken, irritated, or itching skin**".

Products also are not permitted to make any cosmetic benefit claim, such as "**reduces the appearance of wrinkles**" or "**soften skins**".

### **Conclusion**

For further information please refer to the proposed regulations which was published in the Canada Gazette, Part I, on or about December 22, 2018.

The consultation period for the proposed regulations ended February 20, 2019.