

### OVERVIEW

- The updates to the Cannabis Act and Regulations to legalize the production, sale, and distribution of Cannabis edibles, extracts, and topicals came into force on October 17, 2019.
- This QuickNote focuses on the updates made to the regulations, which set the requirements that must be met in order to sell and distribute these new classes of cannabis product.

### WHO DOES THIS APPLY TO?

- Existing licence holders of cannabis in its various forms interested in, or actively seeking to enter, new extensions of the market (i.e., edible cannabis, cannabis extracts, cannabis topicals).
- Current cannabis licence applicants interested in, or actively seeking to enter, new extensions of the market (i.e., edible cannabis, cannabis extracts, cannabis topicals).
- Those who are currently, or seeking to, provide goods and services to the Cannabis Industry (e.g., security firms, packaging, and labelling component suppliers, device manufacturers, etc.).
- Prospective new applicants who want to:
  - Grow cannabis
  - Make cannabis products
  - Sell cannabis for medical and/or recreational purposes
  - Perform testing of cannabis
  - Perform research with cannabis



## KEY POINTS

### New Cannabis Classes

- Health Canada regulates cannabis products under the Cannabis Act and the Cannabis Regulation.
- As time passes, **expect further amendments to be made** to maintain the original intent of the provisions by integrating new research.

### Edible Cannabis (e.g., gummies, chocolates):

- Limit of 10mg of THC per package.
- Limits on added vitamins, added minerals, nicotine, alcohol, and caffeine.
- Plain and child-resistant packaging. The product must **not** be appealing to youth nor make health claims.
- Packaging/labelling follows food guidelines (ingredient list, allergens, nutritional facts table), as well as guidelines specific for cannabis (e.g., THC symbol, Health warning message).

### Cannabis Extract for Ingestion (e.g., oil)

- Limit of 10mg of THC per unit (such as a capsule) or dispensed amount.
- Limits on added vitamins, added minerals, nicotine, alcohol, and caffeine. **No** added sugars, sweeteners, or colours.
- Plain and child-resistant packaging. The product must **not** be appealing to youth nor make health claims.
- Package size limits depending on percent THC content. Must include dispensing device for liquids not in unit form.
- Packaging/labelling guidelines include ingredient list, allergens, and nutritional facts table, as well as guidelines specific for cannabis (e.g., THC symbol, Health warning message).



## Cannabis Extract for Inhalation (e.g., rosin)

- Limit of 1000mg of THC per package.
- Limits on added vitamins, added minerals, nicotine, alcohol, and caffeine. **No** added sugars, sweeteners, or colours.
- Plain and child-resistant packaging. The product must **not** be appealing to youth nor make health claims.
- Package size limits depending on percent THC content.
- Packaging/labelling guidelines including ingredient list, allergens, and nutritional facts table, as well as guidelines specific for cannabis (e.g., THC symbol, Health warning message).

## Cannabis Topical (e.g., creams)

- Limit of 1000mg of THC per package.
- Limits on nicotine and alcohol. **For use only** on skin, hair, and nails. Cannot be used in eyes or on damaged skin.
- Plain and child-resistant packaging. The product must **not** be appealing to youth nor make health claims.
- Packaging/labelling guidelines include ingredient list, allergens and nutritional facts table, as well as guidelines specific for cannabis (e.g., THC symbol, Health warning message).

All new cannabis class products must display on their outer packaging the following THC symbol:



At least 1.27 cm x 1.27 cm in size with at least 2 points of white border on all sides.



## Preventative Control

The update to the cannabis regulations in October 2019 for new cannabis classes also introduced updates to the Good Production Practices (GPPs) captured in section 5. Many changes were related to the introduction of new cannabis classes, and thus the updates brought GPPs in-line with the Safe Food for Canadians Regulations (SFCR).

### Key amendments:

- Holders of licences for processing edible cannabis and/or cannabis extracts will require a **Preventative Control Plan (PCP)**. The PCP identifies, addresses, controls, and maintains the mitigation of potential hazards that pose the risk of contaminating products.
- The **Quality Assurance Person (QAP)** will be required to conduct preventative investigations on cannabis and/or cannabis product ingredients if they suspect potential issues with the product.

### Preventative Control Plan (PCP)

- A document that highlights the **hazards** present in a process. Hazards are split into the following categories:
  - **Biological:** Microorganisms such as bacteria, fungus, and parasites.
  - **Chemical:** chemical concerns present along the process, such as pesticides, cleaning agents, and lubricants.
  - **Physical:** debris and/or foreign material such as stones and metal, or even rodents and other pests.
- These hazards are then evaluated for their risk, and those with significant risk must be controlled for through **Critical Control Points (CCPs)** and **Critical Limits**.



- **12 steps to Create a PCP:**
  - 1) Assemble PCP team: consisting of QAP and Subject Matter Experts (SMEs) (including floor workers)
  - 2) Describe your product: what is it, what is it made of, how is it packaged/distributed, storage conditions, etc.
  - 3) Identify the consumer and the product's intended use
  - 4) Construct a plant schematic as well as process and traffic flow diagrams
  - 5) Confirm the diagrams against your finalized processing line
  - 6) Conduct hazard Analysis based off the product description and diagrams
  - 7) Determine your Critical Control Points (CCPs) by evaluating hazard risk
  - 8) Establish your Critical Limits for each CCP: how is the significant hazard going to be mitigated?
  - 9) Establish a monitoring system for each CCP
  - 10) Establish corrective actions in case of non-conformance
  - 11) Establish verification procedures
  - 12) Establish documentation and recordkeeping
- **Implementation:** PCP effectiveness verification is performed through trial process runs. The PCP is then implemented, and subsequent staff training is conducted.
- **Maintenance:** The PCP is maintained by routine improvement checks. Changes are mandatory if introducing a new process step or if an existing process step has changed.



## WHAT DO I NEED TO DO?

- Develop your business strategy
- Apply for the applicable Health Canada cannabis licences, or amend already existing licences
- Design, build, and qualify your facility
- Establish and maintain a compliant GPP quality system
- Prepare a PCP for each proposed product line
- Prepare for your Health Canada inspections

## DEFINITIONS

CCP	Critical Control Points
CFIA	Canadian Food Inspection Agency
GPP	Good Production Practices. The quality system required by the Cannabis Regulations
HACCP	Hazard Analysis and Critical Control Points – a food safety system that has been adapted into the cannabis industry as the Preventative Control Plan (PCP)
Holder of a Licence for Processing	The holder of a licence that permits possession, production, sale/provision, shipping, transportation, delivery, and destruction of cannabis
PCP	Preventative Control Plan
QAP	Quality Assurance Person
SFCR	Safe Food for Canadian Regulations
SME	Subject Matter Expert
THC	Tetrahydrocannabinol - a main cannabinoid present in cannabis

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## RELATED DOCUMENTS

- [Cannabis Regulations](#)
- [Final regulations: Edible cannabis, cannabis extracts, cannabis topicals](#)
- [Guidance document: Good Production Practices guide for cannabis](#)
- [CFIA - Reference Database for Hazard Identification](#)

## FAQ

### 1. If I produce a new class of cannabis, which regulations do I follow?

- Licence:** Cannabis Guide (Cannabis Act) as a Processor
- Final regulations:** Edible Cannabis, Cannabis Extracts, Cannabis Topicals
- Cannabis Act** (Good Production Practices)
- Cannabis Regulations:** PCP requirements (for extracts and edibles only)

### 2. What foods am I allowed to infuse with Cannabis?

Nearly any food or drink product can be infused with cannabis, except products already prohibited under the Food and Drug Act. The following products are **prohibited** unless certain criteria are met:

- Meat, poultry or fish products
- Caffeine products
- Ethyl alcohol products
- Products that require refrigeration
- Products within hermetically sealed (airtight) containers





- f. Irradiated food product
- g. Foods which have been given a temporary marketing authorization

In addition, food additives (e.g., vitamins, minerals, emulsifiers, etc.) must meet certain criteria to be used as ingredients in edible cannabis products, such as:

- I) The edible cannabis product does not contain parts of the cannabis plant referred to in schedule 1 and schedule 2 of the Cannabis Act.
- II) The edible cannabis product has received a marketing authorization which permits the food additive to be in or on the food product.
- III) The food additive is **not** caffeine/caffeine citrate.

**3. Are there different food classifications (liquid foods vs. solid foods) and, if so, how do they differ?**

Food classification of edible cannabis products generally adhere to the same guidelines as regular food product. There are certain prohibitions with regards to cannabis as an ingredient that can affect the promotion/labelling of the product. For example, Cannabis as an ingredient cannot be advertised to meet dietary requirements.

**4. What does a current holder of a licence for processing need to do with their licence in order to start producing and selling new cannabis classes?**

Currently licensed producers may go through the licence amendment process to add the possession, production, and distribution of edible cannabis, extracts and/or topicals to their licensable activities. Please contact [Cannabis@canada.ca](mailto:Cannabis@canada.ca) for the updated guidelines on how to amend your licences.

**5. I want to make the following edible cannabis products: chocolate brownies, cherry-flavored gummies, and lemon-flavored gummies. Is one PCP sufficient for this?**

No, one PCP will not be sufficient as there are two different kinds of proposed products: brownies and gummies. Cherry-flavored gummies and lemon-flavored gummies can potentially be captured under the same PCP. If significant differences are noted between the processing of the two gummy flavors, then separate PCPs may be required.





**6. Can I produce non-cannabis foods alongside cannabis foods?**

Cannabis food processing **cannot** occur in the same facility as regular food processing. Separate facilities will be required.

**7. How am I able to determine all the hazards associated with my edible cannabis food product?**

A solid understanding of your ingredients and process is required. The Canadian Food Inspection Agency (CFIA) has created a database utilized in the food industry to assist with hazard identification of common food ingredients and processes. A link to the database can be found in the references section. Note that this database cannot be the only source of information for your hazard analysis – further research will be required to complete a comprehensive hazard assessment. In addition, cannabis hazard research is ongoing, and thus more hazards associated with cannabis ingredients may be identified in the future.

**Do you need more information?**

If you need help navigating the requirements that **must be met** in order to sell and distribute these new classes of cannabis products, **contact us today!**

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or visit  
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