



An overview of quality requirements for cannabis products in Canada

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Cannabis products in Canada

There are two paths to bring cannabis to market in Canada

1. Cannabis products

- Subject to the *Cannabis Act* and its regulations
- Not considered health products (not allowed to make health claims), no pre-market approval
- Quality framework is Good Production Practices (GPPs) under the *Cannabis Regulations*

2. Drugs containing cannabis (for human or vet use)

- Subject to both the *Cannabis Act* and its regulations in addition to the *Food and Drugs Act* and its regulations
- These are health (and veterinary) products, subject to pre-market approval
- Quality framework is Good Manufacturing Practices (GMPs) under the *Food and Drugs Regulations*

The *Cannabis Act*: An overview

Taking a public health approach, the *Cannabis Act* creates a control framework for cannabis that:

- Restricts youth from accessing cannabis
- Controls access for adults of legal age
- Provides oversight for the operation of the legal cannabis industry
- **Strictly regulates the supply chain**
- Establishes strong penalties to protect public health and safety

Cannabis Regulations health and safety measures

- Good production practices
 - Preventative control plans
 - Contamination limits
 - Analytical testing requirements (on every lot/batch)
- Product compositional requirements
- Adverse reaction reporting
- Product recall procedures
- 60-day notification period for new cannabis products
- Health Canada published guidance documents
- Health warning messages
- Packaging (plain packaging that is childproof)
- Standardized cannabis symbol
- Among others...

Classes of cannabis products

Dried cannabis

Cannabis extracts, including inhaled forms

Cannabis topicals

Edible cannabis

Fresh cannabis

Cannabis plants

Cannabis seeds



General quality control requirements for all products include

Accurate testing and labeling of THC and CBD (finished product testing)

Chemical and microbial contaminants specifications within established limits taking into account how the product is consumed

- *Cannabis Regulations* leverage standards in pharmacopoeias

Accessories must not contaminate the cannabis

Testing must occur at or after the last step when contamination is likely to be introduced or concentrated

- Finished product testing is not strictly mandatory for contaminants (unlike THC and CBD)

Mandatory cannabis testing for pesticide active ingredients*



Cannabis contaminant testing

Typical contaminant tests

- Mycotoxins (aflatoxins)
- Elemental impurities
- Microbial contaminants
- Foreign matter
- Residual solvents (when used)
- Pesticides*

Timing of testing

- At or after last step in which contamination could occur or be concentrated, except...
 - Edible cannabis – Must be on input cannabis

*Mandatory cannabis testing for pesticide active ingredients

List of 96 pesticides

To ensure no unauthorized use of pest control products

Timing of testing

- Has to occur on all harvested cannabis (fresh or dried), prior to becoming a dried cannabis product or being processed to make other product classes

<https://www.canada.ca/en/public-health/services/publications/drugs-health-products/cannabis-testing-pesticide-requirements.html>

Key takeaways

Requirements for contaminants are general

- Designed in a way that is applicable to **any and all** chemical or microbial contaminants, on a case-by-case basis
- It is necessary to understand production processes in place and inherent risks of contamination present for each product
- Health Canada has issued guidance *ad hoc* where requirements may be unclear to licence holders

Leverage or align with existing frameworks where appropriate

- E.g., edibles align with food requirements, topicals align with cosmetics requirements
- Case-by-case, leverage or apply existing standards (e.g., pharmacopoeias, others)
- Align with existing Health Canada frameworks for evaluating risk (e.g., conduct health risk assessments to support the need for product recalls)

Questions/Comments?

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Health Canada guidance on Good Production Practices

<https://www.canada.ca/en/health-canada/services/cannabis-regulations-licensed-producers/good-production-practices-guide/guidance-document.html>