MANDATORY CANNABIS TESTING FOR PESTICIDE ACTIVE INGREDIENTS

Requirements

Government of Canada Gouvernement du Canada

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Disclaimer: This document must be used in conjunction with the Mandatory cannabis testing for pesticide active ingredients - List and limits, which lists pesticide active ingredients subject to the mandatory testing and their limits of quantification.

This document and the List and limits have been updated to align with the amended *Cannabis Regulations*.

Date published: August 30, 2019

Effective date: December 2, 2019

Également disponible en français sous le titre :

Analyse obligatoire du cannabis pour les résidus de principes actifs de pesticides—Exigences

Cat.: H14-270/2-2019E-PDF
ISBN: 978-0-660-32255-1
Pub.: 190303

Contents

1.0 Purpose

This document outlines the requirements for mandatory testing for pesticide active ingredients in cannabis. The objective of the mandatory testing is to assist licence holders under the *Cannabis Regulations* to ensure that:

- The requirements of the *Pest Control Products Act* and the *Cannabis Act* related to the use of pest control products (PCPs) are met
- Individuals have access to quality-controlled cannabis products that have not been treated or contaminated with unauthorized PCPs
- Individuals have accessible and accurate information so they can make informed decisions

To meet the mandatory testing requirements, licence holders under the *Cannabis Regulations* must demonstrate that none of the unauthorized pesticide active ingredients, as listed in the Mandatory cannabis testing for pesticide active ingredients - List and limits published by Health Canada, are used to treat cannabis or have contaminated it.

This document details the regulatory requirements under the *Cannabis Regulations;* additional requirements related to pesticide testing, reporting and record keeping; and provisions for the transition between the requirements in this document and the requirements in the previous version. It also includes frequently asked questions in section 10 and best practices related to pest management and the use of PCPs in Appendix A.

Health Canada's Controlled Substances and Cannabis Branch is the authority responsible for licensing and compliance monitoring under the *Cannabis Act* and its Regulations. The Cannabis Directorate of Health Canada's Regulatory Operations and Enforcement Branch delivers on a compliance and enforcement mandate that supports the Controlled Substances and Cannabis Branch and conducts inspections and compliance verifications to enforce the *Cannabis Act*.

Health Canada's Pest Management Regulatory Agency is the authority responsible for regulating PCPs under the *Pest Control Products Act* and associated Regulations. Promoting, monitoring and enforcing compliance under the *Pest Control Products Act* is the responsibility of the pesticide compliance program of the Regulatory Operations and Enforcement Branch.

Health Canada will use this document to assess licence holders' compliance with the requirements of the *Cannabis Act* and the *Cannabis Regulations*, and with any conditions on their licence. This document should be read in conjunction with the requirements set out in the *Cannabis Act* and the *Cannabis Regulations* and those shown on individual licences.

2.0 Background

In February 2017, following three recalls of cannabis for medical purposes related to the unauthorized use of PCPs, Health Canada announced that it would begin a series of unannounced inspections and targeted testing of cannabis products from licence holders under

the *Access to Cannabis for Medical Purposes Regulations* to ensure that only authorized PCPs were used during the production of cannabis. Test results from samples collected during these inspections demonstrated that certain licence holders used unauthorized PCPs. Health Canada recognized the need to introduce additional measures to strengthen the monitoring of the use of PCPs and reduce the potential risk to public health.

In May 2017, Health Canada announced that mandatory testing for the presence of pesticide active ingredients in all cannabis products would be required before the products could be sold or provided to individuals. In instances where the use of unauthorized PCPs was detected, conditions were added to the licences of the implicated licence holders to require mandatory testing on all of their cannabis products and to report the test results to Health Canada before the products could be sold or provided to individuals.

Health Canada also announced it would continue to carry out targeted testing of product samples collected during its regular and unannounced inspections of licence holders.

Health Canada undertook the development of the mandatory testing requirements and consulted with regulated parties and stakeholders in 2017 and 2018. In April 2018, the peer-reviewed methodology for analyzing pesticide active ingredients in cannabis developed by the Pest Management Regulatory Agency was distributed to laboratories to support their preparation for implementation of the mandatory testing. The method was published in an article by Moulins et al entitled Multiresidue Method of Analysis of Pesticides in Medical Cannabis.

Mandatory testing for the presence of pesticide active ingredients became effective on January 2, 2019. This testing is in addition to the existing analytical testing requirements under the *Cannabis Regulations*, such as testing for microbial and chemical contaminants; for dissolution and disintegration; and for quantity or concentration of delta-9-tetrahydrocannabinol, delta-9-tetrahydrocannabinolic acid, cannabidiol and cannabidiolic acid.

3.0 Scope

The requirements in this document apply to holders of licences for cultivation, processing, and analytical testing under the *Cannabis Regulations*. For the purpose of this document, “licence holders” refers to holders of a licence for cultivation, processing or analytical testing.

Holders of a licence for cultivation and processing are responsible for ensuring mandatory testing for pesticide active ingredients is completed as specified in section 5 of this document.

For the purpose of this document, all references to cannabis include industrial hemp used in the production of cannabis.

4.0 Regulatory requirements

The *Cannabis Regulations* outline regulatory requirements that licence holders are required to follow when conducting activities with cannabis.

4.1 Licence conditions

Holders of a licence for cultivation and/or a licence for processing have the following condition on their licence:

> [NAME OF HOLDER] must meet the requirements set out in the Health Canada document entitled Mandatory cannabis testing for pesticide active ingredients–Requirements. / [NOM DU TITULAIRE] doit respecter les exigences énoncées dans le document de Santé Canada intitulé Analyse obligatoire du cannabis pour les résidus de principes actifs de pesticides—Exigences.

Holders of a licence for analytical testing have the following condition on their licence:

> Any pesticide testing activities conducted under the scope of Health Canada's Mandatory cannabis testing for pesticide active ingredients–Requirements must meet the requirements set out in that document. / Toutes les activités d'analyse de pesticides menées dans le cadre de l'Analyse obligatoire du cannabis pour les résidus de principes actifs de pesticides—Exigences de Santé Canada doivent respecter les exigences énoncées dans ce document.

Holders of a licence for industrial hemp under the *Industrial Hemp Regulations* are not required to conduct this testing as a result of a condition on their licence. However, any industrial hemp (e.g., heads, leaves, branches, etc.) that is used in the production of cannabis products will be subject to the mandatory pesticide testing requirements by virtue of the conditions noted above on the other licences.

4.2 Good production practices

Part 5 of the *Cannabis Regulations* lists the good production practices (GPP) related to cannabis.

Section 79 of the *Cannabis Regulations* prohibits the sale, distribution or export of cannabis unless the applicable requirements set out in sections 80 to 88.94 of the *Cannabis Regulations* have been met.

Section 81 of the *Cannabis Regulations* prohibits treating cannabis with a PCP unless the PCP is registered or otherwise authorized for that use under the *Pest Control Products Act*.

The Good Production Practices Guide for Cannabis published on the Health Canada website should be consulted for further guidance on how licence holders can meet the requirements of Part 5 of the *Cannabis Regulations*.

The Pest Management Regulatory Agency's online pesticide label search tool can be used to determine which PCPs are registered or authorized for use on cannabis. All other PCPs are prohibited from being used on cannabis or industrial hemp.

The *Pest Control Products Act* prohibits the use of unauthorized PCPs on cannabis or industrial hemp, and requires that authorized PCPs be used in accordance with label directions.

4.3 Cannabis products

Part 6 of the *Cannabis Regulations* lists the general provisions for cannabis products. It sets limits on the residues of PCPs for cannabis plants, cannabis plant seeds, fresh cannabis and dried cannabis. For cannabis extracts, cannabis topicals and edible cannabis, the limits on the residues of PCPs are set for the cannabis used to make cannabis products.

Additionally, the requirements in Part 6 of the *Cannabis Regulations* establish acceptable limits for microbial and chemical contaminants in cannabis products and in cannabis that is used in the production of edible cannabis. Applicable tolerance limits have been established in publications referred to in Schedule B of the Food and Drugs Act, and they may include limits on certain pesticide active ingredients. The tolerance limits for the pesticide active ingredient must be appropriate for the intended use and any reasonably foreseeable use of the cannabis product.

4.4 Record keeping

Part 11 of the *Cannabis Regulations* lists the requirements for the retention of documents and information.

Section 231 of the *Cannabis Regulations* requires licence holders to maintain records demonstrating their adherence with the applicable provisions of Part 5 and 6 of the *Cannabis Regulations*. Licence holders must be able to demonstrate that the activities they conduct are compliant, using records available at the licensed site.

5.0 Testing, reporting, and record keeping requirements

5.1 General requirements

A holder of a licence for cultivation under the *Cannabis Regulations* must not sell, distribute or export a lot or batch of cannabis plants or cannabis plant seeds that is a cannabis product unless the requirements outlined in section 5.0 of this document have been met. This means testing cannabis in accordance with section 5.2, reporting any positive results in accordance with section 5.3, and maintaining records in accordance with section 5.4 of this document.

A holder of a licence for cultivation under the *Cannabis Regulations* may choose (but is not obliged) to conduct the mandatory testing requirements in section 5.0 of this document for the dried cannabis and fresh cannabis that they produce.

A holder of a licence for processing must ensure that a lot or batch of cannabis meets the requirements outlined in section 5.0 of this document before using that lot or batch of cannabis for any activity authorized by its licence for processing (e.g., extraction, formulation, or packaging and labelling). This means, in accordance with section 5.2 of this document, ensuring that the cannabis has been tested, or testing it after it is received from a holder of a licence for cultivation, processing or industrial hemp, or, in the case of a holder of a licence for both processing and cultivation, after it is harvested and/or dried. This also means ensuring that a positive result has been reported, or reporting it to Health Canada, in accordance with section 5.3 of this document. Finally, all holders of a licence for processing must maintain records in accordance with section 5.4 of this document.

Cannabis must be produced, distributed, stored, sampled and tested for pesticide active ingredients in accordance with standard operating procedures designed to ensure that those activities are conducted in accordance with this document and the *Cannabis Act* and its Regulations.

The requirements outlined in section 5.0 of this document are in addition to the other requirements set out under Part 5 and Part 6 of the *Cannabis Regulations*.

5.2 Testing requirements

Testing must be conducted on a representative sample of each lot or batch of cannabis. A licence holder that requests an analysis must retain a portion of the sample for at least one year after the date of the last sale of any portion of the tested cannabis lot or batch. The retained portion of the sample must be of sufficient quantity to enable a retest of the sample for pesticide analysis.

Holders of a licence for processing that receive cannabis from a holder of an industrial hemp licence must retain a representative sample of the lot or batch of cannabis.

Health Canada has set limits of quantification (LoQ) for pesticide active ingredients in fresh cannabis, cannabis plants, and dried cannabis. These limits are based on the identification and quantification of the molecule using current chemical analytical methods and equipment.

The pesticide active ingredients and their LoQs are listed in the Mandatory cannabis testing for pesticide active ingredients - List and limits document published by Health Canada. Testing must be conducted, at minimum, for all pesticide active ingredients with a LoQ. Health Canada reviews the Mandatory cannabis testing for pesticide active ingredients - List and limits document periodically and amends it if necessary.

5.2.1 Laboratory testing

The mandatory testing must be conducted by a third-party laboratory ("the laboratory") that holds a licence for analytical testing under the *Cannabis Regulations*. The laboratory must be a distinct entity that functions and reports independently of the person requesting the analysis.

This independence is important; although the person requesting the analysis and the laboratory may share a common goal of assuring that quality-controlled cannabis is produced, their interests may sometimes conflict as the report from the laboratory may impact the output of the person requesting the analysis.

Similar to good manufacturing practices that apply to licensed drug manufacturing establishments, the laboratory must have access to adequate and separate facilities, equipment and trained personnel to fulfill its duties and responsibilities.

For quality assurance purposes, the person requesting the analysis is responsible for:

- Ensuring the laboratory is licensed under the *Cannabis Regulations* to possess and conduct analytical testing of cannabis
- Assessing the suitability of the laboratory to conduct pesticide detection analysis and maintain records of the assessment
- Ensuring the laboratory uses validated methods for these tests

Laboratories are required to maintain a certificate of analysis for each lot or batch of cannabis that they test. The certificate must contain the following:

- Information about the person requesting the analysis (name, address, contact information)
- Information about the laboratory (name, address, contact information)
- Information about the testing method (name of the method, equipment used, date of last validation)
- Information about the cannabis (lot or batch number, product type)
- The date the lot or batch was sampled
- The list of the pesticide active ingredients for which the cannabis was tested
- The laboratory's LoQ for each pesticide active ingredient
- The result of the analysis for each pesticide active ingredient in the cannabis
- An attestation of the test results by the laboratory (signature of the head or alternate head of laboratory, date the certificate is issued)

5.2.2 Method validation

The laboratory must ensure its methods have been validated before using them. The methods must be able to quantify pesticide active ingredients against the background of the naturally occurring chemicals in the samples. Guidance for validation can be obtained in publications such as the Q2B: Validation of Analytical Procedures: Methodology published by Health Canada or any standard listed in Schedule B of the Food and Drugs Act.

The laboratory's LoQ must be equal to or lower than the LoQ set in the Mandatory cannabis testing for pesticide active ingredients - List and limits document published by Health Canada. The laboratory must produce and maintain records documenting the results of validation studies. Health Canada may verify these records during inspections.

Pesticide active ingredients analysis methods should require the sample extract to be cleaned using common pesticide extraction techniques (e.g., a QuEChERS technique alone or in combination with solid-phase extraction). The extract may then be concentrated or analyzed directly on chromatographic and spectroscopic instruments (e.g., by gas chromatography tandem mass spectrometry [GC-MS/MS] or liquid chromatography tandem mass spectrometry [LC-MS/MS]).

5.3 Reporting requirements

Licence holders that request the analysis must report to Health Canada any test result that equals or exceeds the laboratory's LoQ. All reports, including the certificate of analysis for the affected lots or batches, must be emailed to hc.compliance-cannabis-conformite.sc@canada.ca as soon as possible, but no later than seven calendar days after receipt of the results.

5.3.1 Received lots or batches of cannabis

Licence holders that receive a lot or batch of cannabis that has been previously tested for unauthorized pesticide active ingredients must ensure that any positive pesticide test results have been reported to Health Canada. If not, they must report the test results to Health Canada as soon as possible, but no later than seven calendar days after receipt of the results. Mandatory testing is designed to prevent the need for product recalls related to the unauthorized use of PCPs on cannabis. In the event that a cannabis product that has been treated or contaminated with any unauthorized PCP has been sold or distributed, licence holders must immediately stop the sale of the product and immediately report the test results to Health Canada.

If a cannabis product needs to be recalled, licence holders must submit the information listed under voluntary recall in section 247 of the *Cannabis Regulations*. The Cannabis Voluntary Recall Guide published on the Health Canada website helps licence holders understand their role in a voluntary recall and promotes their compliance with recall requirements.

Health Canada publishes all product recalls on its Recalls and safety alerts website.

5.3.2 Product quarantine and root cause analysis

After reporting a positive pesticide test result to Health Canada, licence holders must quarantine the affected lot or batch of cannabis to avoid cross-contamination until otherwise instructed by Health Canada. They must also immediately begin a root cause analysis to identify the source of contamination. Licence holders must submit their root cause analysis to Health Canada for review by emailing it to hc.compliance-cannabis-conformite.sc@canada.ca.

If the root cause analysis determines that the cannabis was not produced in compliance with the applicable GPP requirements of the *Cannabis Regulations*, Health Canada will not permit the affected lot or batch to be further processed, distributed, sold or exported.

5.3.3 Corrective and preventive action plan

Health Canada may require the licence holder to take corrective actions with regard to the affected lots or batches of cannabis and preventive actions, as applicable. Health Canada may take additional actions necessary to protect the health and safety of Canadians, including compliance and enforcement actions, if warranted.

5.4 Record keeping requirements

All licence holders that requested or conducted the analysis, and all subsequent licence holders that received a previously tested lot or batch of cannabis, must maintain all records relevant to the mandatory testing requirements at the licensed site for a period of two years after the day on which the information is recorded. This includes results that were reported to Health Canada and those that were not, as well as those related to lots or batches of cannabis that were destroyed. These records must be made available for review in a timely manner during inspections.

These record keeping requirements are in addition to those in section 231 of the *Cannabis Regulations*.

6.0 Focus of inspections

Inspections conducted at licence holder sites to ensure compliance with the mandatory testing requirements may include the verification of records and activities. For example, inspectors may ask to review:

- Standard operating procedures to ensure compliance with sections 5.1 to 5.3 of this document for any received lots or batches of cannabis, and related records
- Standard operating procedures related to GPP, sampling, analytical testing, and PCPs (e.g., an integrated pest management program, list of all PCPs used on cannabis)
- The certificate of analysis for all tests conducted
- Root cause analysis and corrective and preventative action plans
- Cannabis release criteria
- Batch records including records related to spray logs, sanitation records, fertigation program (fertilizers + irrigation), rooting products, and anything used on cannabis plants from seed or propagate to point of sale

Inspectors may collect samples of cannabis and cannabis products from the licence holder's site for testing at Health Canada's laboratory. In addition, samples collected may include inputs used at the site, such as soil, fertilizer, carrier oils or PCPs.

Inspectors may also assess compliance with the relevant sections of the *Cannabis Regulations*.

Under Part 5 of the *Cannabis Regulations*, licence holders are expected to assess possible sources of contamination and adopt precautionary measures to prevent the contamination of the cannabis they produce. Sources of contaminants may include:

- Substances used in cultivation of cannabis, including in cultivation of industrial hemp
- Products to control structural pests and other products used as part of a sanitation program
- Fields adjacent to production facilities, which may cause agricultural residues to enter through ventilation intakes, or surface and well waters
- Refurbished facilities and equipment that may have residues from past operations

To help assess these sources, licence holders may consider:

- Testing for other pesticide active ingredients that are not listed in the Mandatory cannabis testing for pesticide active ingredients - List and limits document published by Health Canada
- Taking and retaining samples of material sold or distributed to other licence holders
- Taking samples and analyzing substances used throughout their production process

Health Canada has the authority to take compliance and enforcement actions if an unauthorized PCP is used by a licence holder, whether or not that product is listed in the Mandatory cannabis testing for pesticide active ingredients - List and limits document.

Finally, Health Canada provides an inspection report to the licence holder.

7.0 Transitional provisions

As a result of the amended *Cannabis Regulations* and to account for the addition of the new classes of cannabis (cannabis extracts, cannabis topicals, and edible cannabis), Health Canada has updated the mandatory testing requirements. In addition, certain limits that were previously under development in the Mandatory cannabis testing for pesticide active ingredients - List and limits document have been defined for fresh cannabis and plants, and for dried cannabis.

Sections 7.1 to 7.3 below provide information on general provisions, provisions regarding product types that are not listed in the Mandatory cannabis testing for pesticide active ingredients - List and limits document, and provisions specific to cannabis oil during the transition between the requirements of the previous version of this document and this version.

7.1 General transition

Before December 2, 2019, licence holders may choose to either meet this version of the Mandatory cannabis testing for pesticide active ingredients – Requirements and the Mandatory cannabis testing for pesticide active ingredients - List and limits document or the previous versions published on November 8, 2018.

As of December 2, 2019, a holder of a licence for processing must ensure that a lot or batch of cannabis in their possession meets the requirements in this version of the mandatory testing requirements and the Mandatory cannabis testing for pesticide active ingredients - List and limits document before using it in any activity authorized by their processing licence (e.g., extraction, formulation, or packaging and labelling). To do so, licence holders must do one of the following:

a) Test the lot or batch of cannabis they possess

b) Test all cannabis input used to make the lot or batch they possess

c) Confirm that all cannabis input used to make the lot or batch they possess meets the requirements in this version of the mandatory testing requirements, if the input was received from a holder of a licence for cultivation, processing or industrial hemp

7.2 Product type not listed in the List and limits document

If a lot or batch of cannabis that needs to be tested is not a product type shown in the Mandatory cannabis testing for pesticide active ingredients - List and limits document (e.g., cannabis resin), the testing must be done using a validated method for which the LoQ must not exceed the highest LoQ specified for each pesticide active ingredient in the Mandatory cannabis testing for pesticides active ingredients - List and limits document.

7.3 Cannabis oil transition

The *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)* provide a 12-month transition period, to October 17, 2020, where cannabis oil may continue to be produced by licensed processors and sold by authorized persons with that activity on their licence. After this period, cannabis oil will no longer be listed as a class of cannabis that an authorized person may sell under Schedule 4 to the *Cannabis Act*.

Prior to October 17, 2020, holders of a licence for processing can either:

a) Test the cannabis oil for pesticide active ingredients as per the previous version of the Mandatory cannabis testing for pesticide active ingredients - Requirements and the List and limits documents that were published on November 8, 2018; or
b) Ensure that all lots or batches of cannabis used to produce the cannabis oil comply with this version of the Mandatory cannabis testing for pesticide active ingredients – Requirements and this version of the Mandatory cannabis testing for pesticide active ingredients - List and limits document.

8.0 Disclosure and publication of test results

Health Canada shares the test results of samples taken during inspections with the relevant licence holder. Health Canada also publishes information on all test results of samples taken during inspections on a quarterly basis as part of the Quarterly Compliance and Enforcement Report, Inspection Data Summary.

Licence holders may consider publishing their test results for cannabis to promote transparency and openness.

9.0 Updates to this document

Health Canada updates this document as needed and informs all regulated parties and stakeholders of changes in advance with a sufficient amount of time to allow them to prepare for any new or updated requirements.

10.0 FAQs

1. What is the purpose of the Mandatory cannabis testing for pesticide active ingredients - Requirements?

This document sets out the obligations of licence holders under the *Cannabis Regulations* with regard to testing cannabis for the presence of pesticide active ingredients. These requirements are in addition to the other analytical testing requirements under the *Cannabis Regulations* that have been set out to protect the health and safety of Canadians.

In addition, Health Canada provides a list of best practices related to pest management and the use of pest control products (PCPs) where cannabis is produced. These best practices are included in Appendix A of this document.

2. What are the key changes in this version of the Mandatory cannabis testing for pesticide active ingredients – Requirements document compared to the previous version published in November 2018?

The requirements listed in the previous version of this document required licence holders to test their finished cannabis products for pesticide active ingredients before distribution, sale or export. With the new classes of cannabis being permitted under Schedule 4 of the *Cannabis Act* as of October 17, 2019, the mandatory testing requirements have been updated to clarify that a holder of a licence for processing must test any cannabis before using it (e.g., before transforming it into a cannabis extract).

The updated mandatory testing requirements document provides holders of a licence for processing with the flexibility to use cannabis without having to test it, as long as they have verified that the mandatory testing requirements have been fulfilled by the licence holder from which they purchased the cannabis. This means that all cannabis inputs will be tested early in the production process to prevent the distribution of cannabis that may have been treated or contaminated with unauthorized PCPs during cultivation.

Holders of a licence for cultivation are still responsible for ensuring that each lot or batch of cannabis products (cannabis plants and cannabis plant seeds) that they sell, distribute or export complies with the mandatory testing requirements.

3. What are the key changes in this version of the Mandatory cannabis testing for pesticide active ingredients – List and Limits document compared to the previous version published in November 2018?

Health Canada has updated 71 limits of quantification (LoQ) for pesticide active ingredients that were not determined for fresh, plant and dried cannabis product types at the time of publication in November 2018. For cannabis oil, the LoQs are unchanged for the transition period.

4. Why are the limits for cannabis oil unchanged?

Health Canada is still developing limits of quantification for pesticide active ingredients that most laboratories and analytical techniques can reliably achieve, considering the challenges with analyzing cannabis oil.

During the transition period, licence holders may choose to test the cannabis they used to produce the cannabis oil instead of the final product. This would avoid situations where a positive result for pesticides is a result of the carrier oil, such as olive or grapeseed oil that may contain other pesticides within the established maximum residue limit for this carrier oil.

5. When must cannabis be tested to meet the updated version of the mandatory testing requirements?

To meet the mandatory testing requirements, cannabis needs to be tested as follows:

- All cannabis plants and cannabis plant seeds that are or will become cannabis products need to be tested before sale, distribution or export
- All fresh and dried cannabis that will become cannabis products needs to be tested before using it in any processing activities, such as milling or packaging
- All industrial hemp, fresh and dried cannabis, cannabis plants and cannabis plant seeds that will be used in the production of cannabis extracts, cannabis topicals, or edible cannabis need to be tested before using them in any processing activities, such as extraction or formulation
- Any cannabis that has not been previously tested in accordance with the mandatory testing requirements needs to be tested before it is used in any processing activities

Licence holders that receive cannabis from a holder of a licence for cultivation, processing or industrial hemp are not required to re-test the cannabis as long as they can ensure it has already been tested as per the mandatory testing requirements.

6. How can a licence holder confirm that a lot or a batch of cannabis they have received has been tested as per the mandatory testing requirements?

Holders of a licence for processing that receive a lot or batch of cannabis that was previously tested for pesticide active ingredients must keep a record demonstrating how they ensured that the lot or batch meets all the requirements listed in sections 5.1 to 5.3 of this document.

Previous testing may be confirmed by requesting a copy of the certificate of analysis for the pesticide testing and any other related documents, or by obtaining an attestation from the licence holder responsible for the testing.

7. What must licence holders do if they possess cannabis that has not been previously tested according to the updated mandatory testing requirements?

If licence holders cannot ensure that a lot or batch of cannabis in their possession meets this version of the mandatory testing requirements, they must test the lot or batch of cannabis they possess or test all cannabis input used to make the lot or batch they possess.

8. When will the updated version of the mandatory testing requirements come into effect?

The updated mandatory testing requirements will come into effect on December 2, 2019. This provides a period of time for all licence holders to adjust their procedures and prepare to meet the updated Mandatory cannabis testing for pesticide active ingredients - List and limits document. After this date, licence holders will need to meet the updated mandatory testing requirements, as indicated on their licence, in addition to the requirements of the *Cannabis Act* and its Regulations.

Before this date, licence holders should refer to section 7 of this document to understand how they should test their cannabis under the transitional provisions.

9. What pesticide active ingredients are licence holders required to test for?

Before December 2, 2019, licence holders may test for all of the pesticide active ingredients with a limit of quantification in the updated version of the Mandatory cannabis testing for pesticide active ingredients - List and limits or in the previous version of the List and limits published on November 8, 2018.

After December 2, 2019, licence holders are required to test for all of the pesticide active ingredients on the updated version of the Mandatory cannabis testing for pesticide active ingredients - List and limits that have limits of quantification.

The list is expected to evolve as laboratory capabilities, product information and availability, and risks change over time. Health Canada reviews the list periodically and updates it as needed, based on Health Canada's monitoring of the industry and as laboratory technology advances. Changes to the list will be communicated in advance of its publication to regulated parties and stakeholders.

10. How did Health Canada determine the list of unauthorized pesticide active ingredients that are to be tested by laboratories?

The Pest Management Regulatory Agency maintains a list of historical and current pesticide active ingredients approved for use on specific crops in Canada and abroad.

Only certain PCPs have been approved in Canada for use on cannabis. PCPs that are of most concern or most likely to be used on cannabis were added to the Mandatory cannabis testing for pesticide active ingredients - List and limits if they:

- were detected on cannabis in Canada or in U.S. states that have regulated its production
- are used against pests that can be found on cannabis
- were observed by inspectors of Health Canada or the Canada Border Services Agency
- were identified because of their risk to health or because of other factors

11. What can qualify as a representative sample for cannabis plant seeds?

For the purpose of the mandatory testing, a representative sample of cannabis plant seeds may be:

- a sample of the cannabis plants from which the seeds were taken; or
- a sample of the cannabis plants that will be grown from those seeds.

12. What test results must be reported to Health Canada?

Every positive pesticide test result quantified by a laboratory in a sample of a lot or batch of cannabis that has not been previously reported to Health Canada must be reported by the licence holder. If licence holders test cannabis beyond their obligations under the mandatory testing requirements, they must report any positive results to Health Canada.

Holders of a licence for processing must ensure either that the person from which they obtained the cannabis has reported any positive results to Health Canada, or report those results themselves.

Holders of a licence for industrial hemp are not required by a condition on their licence to meet the mandatory testing requirements. However, they may choose to voluntarily test their hemp material prior to sale or distribution to a holder of a cultivation or processing licence and report any positive results to Health Canada as per the mandatory testing requirements.

13. What limit of quantification must laboratories use and how should this be reported on the certificate of analysis?

The laboratory must use a method that can reliably measure pesticide active ingredients in cannabis at concentrations equal to or below the LoQs set by Health Canada.

The certificate of analysis must clearly indicate the laboratory LoQ and whether the results are below or above this LoQ.

14. Why do the limits of quantification for each pesticide active ingredient vary?

Limits of quantification are based on the identification and quantification of the molecule using current chemical analytical methods and equipment. They vary because each pesticide active ingredient has specific properties that affect the limit at which laboratories can quantify them with precision and accuracy. The limits were developed in collaboration with the analytical laboratory of the Pest Management Regulatory Agency and are set to a level at which most laboratories and analytical techniques can reliably measure their presence in cannabis.

It is expected that the limits established by Health Canada will be adjusted over time as laboratory technology advances. Changes to the limits will be communicated in advance to regulated parties and stakeholders.

15. What are potential sources of pesticide active ingredients in cannabis?

Potential sources of pesticide active ingredients in cannabis include substances used in the cultivation of cannabis; products for controlling structural pests and other products used as part of a sanitation program; fields adjacent to production facilities, which may cause agricultural residues to enter through ventilation intakes, or surface and well waters; refurbished facilities and equipment that may have residues from past operations; or carrier oils that may have residues from the source crop cultivation.

Under good production practices, licence holders are expected to assess possible sources of contamination and adopt precautionary measures to prevent the contamination of the cannabis they produce.

16. Are licence holders allowed to sell, distribute or export cannabis that has been treated with unauthorized PCPs, if the levels are below the limit of quantification set by Health Canada?

No. Under the *Cannabis Regulations*, licence holders must not sell, distribute or export cannabis treated with an unauthorized PCP, regardless of the concentration of the pesticide active ingredients in the finished product. All PCPs used must be registered or authorized for use on cannabis under the *Pest Control Products Act*.

17. What constitutes a third-party laboratory for mandatory testing?

The laboratory must be a distinct entity that functions and reports independently of the person requesting the analysis. Similar to the requirements that apply to licensed drug manufacturing establishments subject to good manufacturing practices, the laboratory must have access to adequate and separate facilities, equipment, and trained personnel to fulfill its duties and responsibilities.

In addition, the laboratory must hold a licence for analytical testing under the *Cannabis Regulations*. Licence holders can find laboratories to conduct analytical testing authorized under the Cannabis Act by consulting the list published on the Health Canada website.

18. How will Health Canada know that licence holders are meeting their obligations regarding mandatory testing?

Licence holders must keep a record of all test results that they request or records demonstrating how the cannabis they receive meets the mandatory testing requirements, as well as root cause analyses and corrective and preventive action plans for a period of two years. These records must be available to Health Canada and will be reviewed as part of the inspection program.

In addition, Health Canada may collect samples for testing at any point during an inspection and unauthorized use of PCPs is subject to compliance and enforcement actions.

19. Why are holders of a licence for processing not always required to test the cannabis they received? Should they not be required to test throughout the production process?

Holders of a licence for processing are not required to re-test a lot or batch of cannabis they received if they can ensure that it already meets all the mandatory testing requirements (e.g., they verified with the supplier that the lot or batch meets the mandatory testing and reporting requirements, and that all parties involved meet the record keeping requirements). Licence holders can share records, signed letters, or other similar documents to demonstrate cannabis meets the mandatory testing requirements. If a holder of a licence for processing is unable to obtain assurance that all requirements have been fulfilled, they will need to retest the cannabis.

A primary goal of mandatory testing is to help give individuals access to quality-controlled products. Testing cannabis at the beginning of the production process will prevent the distribution of cannabis that may have been treated or contaminated with unauthorized PCPs during cultivation. Systematically requiring tests beyond that point in the production process would be redundant.

It is important to note that Health Canada may test a sample at any point in the production process as part of its inspection program. Licence holders that use unauthorized PCPs will be subject to compliance and enforcement actions.

20. What should licence holders do when they receive positive test results from a laboratory?

Licence holders must notify Health Canada of positive test results as soon as possible but no later than seven calendar days after receipt of the results by email to hc.compliance-cannabis-conformite.sc@canada.ca. They must also quarantine the cannabis and begin a root cause analysis to identify the source of contamination.

Results that are reported to Health Canada are used to verify compliance with the *Cannabis Regulations* and the mandatory testing requirements, and to assess the level of risk to health or safety posed by the pesticide active ingredients. Health Canada will initiate compliance and enforcement actions as necessary.

If products that were treated or contaminated with an unauthorized PCP were sold, licence holders must immediately stop selling the products and report the positive test results to Health Canada.

21. Are licence holders required to destroy cannabis products in which unauthorized PCPs have been detected?

Licence holders are not permitted to sell products that were treated or contaminated with unauthorized PCPs. They may choose to voluntarily destroy these products.

Health Canada will assess on a case-by-case basis situations where the cannabis has not been treated or contaminated with unauthorized PCPs but has still tested positive, based on the root cause analysis provided by the licence holder and taking into consideration the risk to health posed by the pesticide active ingredients.

11.0 Contact us

For more information about or to comment on the mandatory testing requirements, mail, fax or email:

Health Canada
Controlled Substances and Cannabis Branch A.L. 0300A
Ottawa, ON K1A 0K9
Fax: 613-941-6840
Email: hc.compliance-cannabis-conformite.sc@canada.ca

Appendix A: Best practices related to pest management and pest control product use for holders of a licence under the *Cannabis Act*

This appendix outlines best practices for pest management, to reduce the need for pest control products (PCPs) in cannabis production, and best practices for PCPs use for holders of a licence under the *Cannabis Act.*

PCPs are important tools to control insect, weed and disease populations. The use of PCPs during the production of cannabis has a direct impact on cannabis plant health and final cannabis products. Pesticides are regulated in Canada through a program of pre-market scientific assessment, enforcement, education and information dissemination. These activities are shared among federal, provincial/territorial and municipal governments and are governed by various acts, regulations, guidelines, directives and by-laws.

The Pest Management Regulatory Agency is the federal authority responsible for pesticide registration and re-evaluation. The Regulatory Operations and Enforcement Branch is responsible for compliance and enforcement of the *Pest Control Product Act* and its Regulations. Provincial and territorial responsibilities may include the regulation of the transportation, sale, use and storage/disposal of pesticides; the training/certification and licensing of applicators and vendors; and compliance and enforcement within their jurisdictions. The role of municipalities is to enact by-laws, which may set further conditions on the use of pesticides.

Best practices

1. Implementing an integrated pest management program to reduce the reliance on PCPs for pest control during cannabis production.

An integrated pest management (IPM) program, as part of good production practices, is an approach to effectively and sustainably reduce pest populations. An IPM program coordinates many measures into a management program for a target pest. These measures could be biological, chemical, cultural or mechanical and may also include pest behavioural methods to reduce pest populations to acceptable levels.

Aspects of an IPM are:

- Prevent the pest problem: This involves proper identification of pest problems and their damage as well as their natural enemies. In addition, the growing environment is planned and managed to prevent the introduction and/or outbreaks of pests, including:
    - Using starting cannabis material that is free of pests
    - Sterilizing growing media before planting
    - Using mechanical control of weeds such as cultivating
    - Sterilizing water and irrigation systems (e.g., using ozone, ultraviolet, or reverse osmosis)

    - Cleaning and sterilizing cultivation tools like secateurs and shears to prevent inoculation of disease
    - Ensuring employees do not introduce pests and that their clothing (e.g., hats, overalls, gloves, shoe covers) is pest free
    - Using filters or mesh in air vents to prevent pests from moving into and within the facility
    - Ensuring waste and/or unusable materials are stored in a way that makes them inaccessible to pests
- Frequent monitoring and record keeping: Frequent monitoring of pest populations, beneficial organisms (when present), pest damage and growing conditions conducive to pest outbreak is an important aspect of IPM, along with maintaining records related to pest monitoring. For insects and mites, trapping and monitoring provides information on pest activity, numbers, emergence and information to optimize spray timing.
- Ongoing assessment of pest control measures: Keeping a log of all measures used during IPM and evaluating the effects and efficacy of these measures

2. *When using PCPs during cannabis production*

- If PCPs are needed to control a pest, use only PCPs that are registered or otherwise authorized for use on cannabis and use them according to the label directions. The Pest Management Regulatory Agency's product label search tool can be used to determine which PCPs are registered and authorized for use on cannabis and industrial hemp in Canada. Pesticide labels are also accessible from a mobile device through the pesticide label search.
- If PCPs are needed to control pests that are not directly on the cannabis (e.g., during sanitation of the premises or the equipment, or for structural pest control):
    - Use only PCPs registered for that specific use
    - Read and carefully follow the instructions listed on its label
    - Prevent cross-contamination of growing areas (e.g., turn off the ventilation systems of an empty grow room during pesticide application)
- Put adequate controls in place in a facility to ensure that unauthorized PCPs are not used, such as:
    - Keeping all PCPs in a separate monitored and restricted area
    - Supervising employees who are preparing and applying PCPs to cannabis
- Put adequate measures in place to reduce the chance that external residues and PCPs will contaminate the cannabis, by:
    - Testing inputs used during cultivation for contaminants (e.g., growing media or soil, water)
    - Establishing barriers to prevent contamination by extraneous pesticide active ingredient (e.g., for indoor cultivation: filtration of the intake air; for outdoor cultivation: buffer zones and windbreaks around the fields)
- Regularly maintain, calibrate and clean equipment used to apply PCPs

- Have all personnel involved in pest control trained on proper application of PCPs and the steps necessary to prevent contamination
- Have an agronomist or a crop specialist who is responsible for pest management