



Regulatory Proposal

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Consultation on the Proposed Approach for Registering Pesticide Uses on Cannabis and Industrial Hemp: Use-site Categories, Data Requirements and Label Statements

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Consultation Foreword

Health Canada's Pest Management Regulatory Agency (PMRA) invites stakeholders to comment on the *Consultation on the Proposed Approach for Registering Pesticide Uses on Cannabis and Industrial Hemp: Use-site Categories, Data Requirements and Label Statements*.

The Government of Canada has committed to ensuring that the PMRA makes timely, science-based decisions to support the safe and sustainable use of effective pesticide products in Canada. This involves establishing scientific data requirements to assess risks associated with pesticide use in the production of cannabis and industrial hemp as well as pest control product label statements to prevent uses that may pose unacceptable risk.

The PMRA will accept written comments on the *Consultation on the Proposed Approach for Registering Pesticide Uses on Cannabis and Industrial Hemp: Use-site Categories, Data Requirements and Label Statements* up to 60 days from the publication of this document.

Please forward all comments to the PMRA Publications section (contact information on the cover page of this document) Comments should include:

- Title of this consultation document;
- Your full name and organization;
- Your phone number; and
- Your complete mailing address or email address.

1.0 Executive summary

This document describes the Health Canada Pest Management Regulatory Agency's (PMRA) approach to the classification of cannabis and industrial hemp crops into use-site categories, as well as associated data requirements and label amendments. It describes information needed to support an application for proposed pesticide uses based on the intended end-uses of the crops.

Previously, pesticide registrations for cannabis focused on microbial products and non-conventional pesticides (biopesticides). Pesticide use on industrial hemp concentrated on industrial or food uses of the crop. This document identifies data requirements to assess additional potential risks, including risks from ingestion or from inhalation due to smoking or vaping of products/commodities derived from these crops that have been treated with either a biopesticide or conventional pesticide. Where these risks have not been assessed or if a risk assessment has been completed and the risks are unacceptable, label statements will be added to communicate when the pesticide may not be used on cannabis or industrial hemp crops.

This proposed approach is intended to inform the data generation and evaluation to support the registration of pesticide uses on cannabis and industrial hemp crops. The PMRA is now seeking feedback from all stakeholders on this proposed approach.

2.0 Introduction

This document identifies the unique aspects of cannabis and industrial hemp crops with respect to end-uses and the assessment of associated risks. The purpose of this document is to communicate to stakeholders about the appropriate use-site category classification(s) for cannabis and industrial hemp crops and related data requirements for the assessment of risk, as well as label statements for these crops based on the intended end-uses.

3.0 Background

Growth of the cannabis industry has steadily increased since the recreational use of cannabis was legalized in Canada in 2018. Cannabis products have become more accessible through online availability and brick and mortar retail access. Industrial hemp growers have also extended their market access by harvesting flowers for smoking, vaping, and cannabinoid extraction.

Cannabis use carries its own health risks. Risk assessments conducted by the PMRA consider risks associated with the application of pesticides to cannabis. More information regarding the health effects of cannabis use is available on the webpage on Cannabis use effects and risks on Canada.ca (<https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/health-effects/effects.html>).

The PMRA conducts risk assessments to ensure that pesticides do not pose unacceptable risks to human health or the environment when applied according to label directions. As part of the health evaluation, the PMRA conducts risk assessments for the dietary, occupational and residential exposure to pesticides. As there is the potential that dried or fresh cannabis and industrial hemp (flowers) treated with pesticides can be smoked or vaped, the PMRA must also assess the exposure to pesticide residues from the inhalation of products derived from these crops. Therefore, pyrolysis studies are required for pesticides intended for use on cannabis and industrial hemp crops grown for smoking and vaping of the flowers/buds. These studies are required to identify potential pyrolytic by-products that may be formed when pesticide residues that remain on treated cannabis or industrial hemp are combusted.

To date, mostly biopesticides have been registered for use on cannabis and industrial hemp crops grown for flowers and extracts for consumption. However, as the industry expands, producers of cannabis and industrial hemp crops could face serious disease, insect and weed pressures, which may require the use of conventional chemical pesticides for adequate control. Additional data requirements for cannabis and industrial hemp crops grown for flowers or extracts are required for both biopesticides and conventional pesticides.

4.0 Purpose and scope

The assessment of inhalation and dietary risks is necessary for the registration of pesticides to evaluate the human health risks associated with consuming cannabis and industrial hemp products/commodities that have been treated with pesticides. While the same data requirements that apply to pesticides used on agricultural crops also apply to pesticides applied to cannabis and industrial hemp crops, the assessment of inhalation risks are unique to the

products/commodities derived from these crops. The development of scientific methods for generating the requested data are not within the scope of this consultation document.

Data requirements for stored cannabis and industrial hemp commodities and storage areas are not within the scope of this consultation document. Applicants should refer to current data requirements for use-site category 3 (Empty Food and Feed Storage Structures and Areas) and use-site category 12 (Food and Feed Processing and Storage).

5.0 General information on the crops

Cannabis is a genus of flowering plants (*Cannabis sativa*, *C. indica*, *C. ruderalis*). The plant is known as industrial hemp when it, or any part of it, contains a concentration of tetrahydrocannabinol (THC) of 0.3% w/w or less in the flowering heads and leaves. Cannabis refers to varieties that contain concentrations of THC greater than 0.3% w/w.

The word “cannabis” is often interpreted as referring to both industrial hemp and cannabis crops given that they have the same scientific name (*Cannabis sativa*). However, from a regulatory perspective, Health Canada considers industrial hemp and cannabis as two distinct crops.

Health Canada regulates the production of both cannabis and industrial hemp crops through licensing agreements. The production and regulation of cannabis and Industrial hemp crops is governed by legislation, including: the [Cannabis Act](#); the [Cannabis Regulations](#); and, the [Industrial Hemp Regulations](#). Since 2019, Cannabis regulations have undergone amendments (Canada Gazette, Part II, Volume 153, Number 13, <https://gazette.gc.ca/rp-pr/p2/2019/2019-06-26/html/sor-dors206-eng.html>). The PMRA’s data requirements for pesticides used on cannabis and industrial hemp crops have also evolved as outlined below (see Section 7.0 Data requirements).

Cannabis

Cannabis can be used for medical or recreational purposes as a dried or fresh product, edible product, extract, or topical product. It can be grown in both indoor and outdoor production areas. It is not considered a food per se but can be added to food and incorporated into edible products.

Other products made from a mature stalk without any leaf, flower, seed or branch, or fiber derived from a stalk, root or any part of the root of such plants, are excluded from the *Cannabis Act*.

Industrial hemp

Industrial hemp has historically been cultivated for use in the production of a wide range of manufactured and industrial goods, as well as edible seed and oil products. Industrial hemp commodities historically included fiber, non-food products (lubricants, paint, ink, plastics, soap, detergent, and shampoo), seed, and oil (edible and non-edible). Changes to the *Cannabis Act* and Industrial Hemp Regulations now authorize the sale of industrial hemp flowering heads to a Cannabis Processing Licence holder for the extraction of cannabinoids.

Industrial hemp production encompasses selling, cultivating, propagating (in the case of a plant breeder), and harvesting industrial hemp, as well as processing the industrial hemp grain or seed and their derivatives. Other products made from a mature stalk without any leaf, flower, seed or branch, or fiber derived from a stalk, root or any part of the root of such plants, are excluded from the *Cannabis Act*. However, it is important to note that the production of products made from hemp flowering heads and leaves falls outside of the Industrial Hemp Regulations purview and requires a Cannabis Processing Licence under the Cannabis Regulations.

6.0 Use-site category

Identifying the appropriate use-site category allows the classification of pesticide applications according to their purpose and determines data or information requirements to support a pesticide registration. With the legalization of cannabis for medical and recreational use, the potential consumer exposure to pesticides must be considered. For cannabis and industrial hemp crops, consumer exposure can include ingestion of extracts or inhalation by smoking and vaping products/commodities derived from these crops. The need to evaluate dietary and inhalation risks associated with pesticide use on cannabis and industrial hemp crops has resulted in the classification of these crops into multiple use-site categories, depending on the intended use of the harvested crop.

When submitting an application to add pesticide uses for cannabis and industrial hemp crops, the applicant should identify all use-site categories applicable to the end uses of cannabis and industrial hemp proposed for addition to their product label. To aid in the determination of the appropriate use-site category, decision trees have been developed by the PMRA and are attached as Appendix I (Cannabis) and Appendix II (Industrial Hemp) of this document. The decision trees should be used to aid in determining the appropriate use-site category for **each potential end use** of the crop.

The following use-site categories are considered appropriate, depending on the end-uses of the crops.

- Use-site category #5 Food Crops Grown in Greenhouses or other Enclosed Structures
 - Cannabis and industrial hemp crops grown indoors and intended for human consumption (for example, edible seeds, edible oils, cannabinoid production and products vaped or smoked).
 - As there is the potential that products derived from cannabis and industrial hemp crops treated with pesticides can be smoked or vaped, this triggers the need for additional data not typically required for other agricultural crops. (See Section 7.0 Data requirements)
 - Includes applications on mother plants used to produce feminized seed for subsequent planting as a crop grown for human consumption or for cannabinoid production. No other part of the plants used in the seed feminization process will be used for any other purposes.

- Use-site category #6 Non-Food Crops Grown in Greenhouses or other Enclosed Structures
 - Industrial hemp and cannabis grown indoors not for human consumption.
 - Includes seed production for subsequent planting of a crop not intended for human consumption.

- Use-site category #7 Terrestrial Non-food and Non-feed Seed, Fiber, and Industrial Crops
 - Industrial hemp grown outdoors not intended for human or animal consumption such as fiber, biofuel, and lubricants
 - Includes seed production for subsequent planting with a crop not intended for human or animal consumption. No other part of the plant will be used for other purposes.

- Use-site category #10 Seed and Plant Propagation Materials: Food and Feed
 - Seed treatment or treatment of propagation materials of cannabis and industrial hemp crops grown for human or animal consumption.
 - Includes treatment of mother plants grown for feminized seed production for subsequent planting as a crop grown for human consumption or for cannabinoid production. No other part of the plants used in the seed feminization process will be used for any other purposes.

- Use-site category #11 Seed and Plant Propagation Materials: Non-Food and Non-Feed
 - Seed treatment or treatment of propagation materials for industrial hemp crops not grown for human or animal consumption.

- Use-site category #13 Terrestrial Feed Crops
 - Industrial hemp grown outdoors for livestock feed (for example, hemp meal, seeds). Includes seed production for subsequent planting as a livestock feed crop. This does not include the treatment of seed.

- Use-site category #14 Terrestrial Food Crops
 - Cannabis and industrial hemp crops grown outdoors and intended for human consumption (for example, edible seeds, edible oils, cannabinoid production and products vaped or smoked). Includes seed production for subsequent planting as a crop which will have human food uses. This does not include the treatment of seed.

7.0 Data requirements

Each use-site category has a list of required and conditionally required data called data-code (DACO) tables. The proposed use or uses determine the required data for each of the science disciplines to support a pesticide application. If an application seeks to amend a registered pesticide label, it is possible that reduced data requirements will apply.

Applicants are strongly encouraged to request a pre-submission consultation prior to submitting their registration package. During the pre-submission process, the applicant is advised of the need for any additional data or information to support the proposed uses.

To support a Canadian registration of any pesticide on industrial hemp or cannabis crops, the same data requirements as for other agricultural crops are applicable for value, health, and environment. However, additional data/information is required to assess the risks specifically associated with the intended use(s) of the harvested cannabis and industrial hemp crop. The specific data requirements noted below for conventional pesticides and biopesticides consider all routes of potential exposure.

Data requirements in support of an application to register conventional pesticides and biopesticides for use on cannabis or industrial hemp crops

DACO 5.2 (Use Pattern/Exposure Scenario): Required. The specific use pattern for cannabis and/or industrial hemp crops must be described in sufficient detail as well as the intended end use(s) of the harvested cannabis and/or industrial hemp crop.

Use pattern: The use pattern must include the application rate, the maximum number of applications per year/crop cycle, the retreatment interval, and the preharvest interval. In addition, specific information is required about the timing of application to cannabis or industrial hemp crops (for example, only during the vegetative state, when the flowers are not present; or also during flowering stage when the flowers are present).

- a) The Applicant must clearly specify the intended use of the industrial hemp crop, for example, state whether industrial hemp products/commodities will be used for fiber, seed and oil (for human consumption), cannabinoid extraction, or smoking/vaping.
- b) The Applicant must clearly state whether industrial hemp and/or cannabis will be grown indoors in greenhouses or other enclosed structures, or outdoors, or both.

When considering the appropriate data required for the health assessment for pesticides registered for use on cannabis or industrial hemp crops, the different ways these crops can be consumed (including dietary and inhalation) must be considered. Both cannabis and industrial hemp crops can be consumed via smoking or vaping of the fresh/dried commodities.

DACO 7.4.1 (Supervised Residue Trial Study): Required for all agricultural crops and must be submitted for applications to add cannabis or industrial hemp crops to pesticide labels. Information to characterize residues of the active ingredient in the pesticide end-use product is required. Alternatively, an acceptable scientific rationale to waive this data requirement may be provided.

DACO 7.8.1 (Other Studies/Pyrolysis Study): Required for any of the use-site categories where there is the potential for cannabis or industrial hemp products to be consumed through smoking or vaping. A pyrolysis study in the context of this data requirement refers to combustion (burning in the presence of oxygen) and pyrolytic by-products that may form as a result of the combustion of a pesticide. This would be applicable to dried cannabis and industrial hemp where exposure would occur through inhalation during smoking or vaping of cannabis products derived

from these crops. Separate pyrolysis studies on the active ingredient are required at the temperature at which the dried cannabis or industrial hemp product is smoked and at the temperature at which the cannabis or industrial hemp product is vaped. The pyrolysis studies should be conducted with the cannabis/industrial hemp treated with the radiolabelled active ingredient. Alternatively, an acceptable scientific rationale to waive this data requirement may be provided.

If application of biopesticides to cannabis and industrial hemp crops is limited to the pre-flower stage, pyrolysis or combustion data (DACO 7.8.1) are not required. However, DACO 7.4.1 (in other words, Supervised Residue Trial Study) remains conditionally required. Biopesticides proposed for use during the flowering stage of cannabis and industrial hemp crops **must address** the requirements for both DACO 7.4.1 and 7.8.1.

8.0 Label statements

The terms “Cannabis” and “Industrial hemp” will be used for crop protection product labels, as they align with the terminology used in the *Cannabis Act* and Industrial Hemp Regulations.

Industrial hemp has many uses that include both food and non-food commodities. The different products/uses require different risk assessments and will have different data requirements based on the use-site category associated with the product use.

The term “industrial hemp” does not imply only non-food uses, as this crop may also be grown for human consumption. Pesticide labels will reflect which product uses of industrial hemp have been considered by Health Canada during the review of the application. For example, a review may have assessed the use of industrial hemp grown for fiber, seed or oil, but not for smoking and vaping. Statements prohibiting certain uses of these crops will be included on pesticide labels if the risks related to those uses have not been assessed or have resulted in unacceptable risk. Until risks associated with pesticide use on cannabis and industrial hemp have been assessed, label statements are required and should be implemented as applicable.

DO NOT feed industrial hemp treated with this pesticide to livestock.

This statement applies to labels for industrial hemp when risks to livestock resulting from ingestion of industrial hemp treated with a pesticide has not been determined or was found to be unacceptable.

DO NOT harvest any part of the industrial hemp plant treated with this pesticide for the purposes of smoking or vaping or for human consumption.

This statement applies to labels for industrial hemp if the intended use is only for fiber or seed production.

DO NOT harvest the seed for human consumption.

This statement applies to labels for industrial hemp if the intended use is to harvest the flowers and acceptability of the seed for human consumption has not been determined.

DO NOT apply to industrial hemp grown in greenhouses or other enclosed growing structures.

DO NOT apply to cannabis grown in greenhouses or other enclosed growing structures.

This statement applies to labels for industrial hemp and/or cannabis when acceptability of the use in a greenhouse or enclosed structure has not been determined.

These statements may evolve or new statements may be developed in response to changes to production systems or legislative amendments. For example, currently, industrial hemp is not approved as a livestock feed ingredient (for example, hemp meal, hemp seed, hemp oil) in Canada. Therefore, the label amendment related to livestock feed above should be applied to all pesticide labels registered for use on industrial hemp. Contact the Canadian Food Inspection Agency with questions related to registering industrial hemp as livestock feed.

The updated label statements/restrictions will be applied to currently registered pesticide labels as part of label improvements required as a result of a re-evaluation or a special review or incorporated through applications to register new products or to amend the labels of registered products.

9.0 Implementation

Labels with currently registered uses on cannabis or industrial hemp that are inconsistent with the requirements described in this document should be amended. All affected registrants will be requested to submit an application to update their labels within nine months of the publication of a final guidance document. Registrants are advised to make these changes either through submission of a Category C application or in combination with other label changes being proposed under open submissions. Registrants may also submit data to demonstrate that any risk associated with the human consumption of treated cannabis or industrial hemp does not pose unacceptable risk (Category B application).

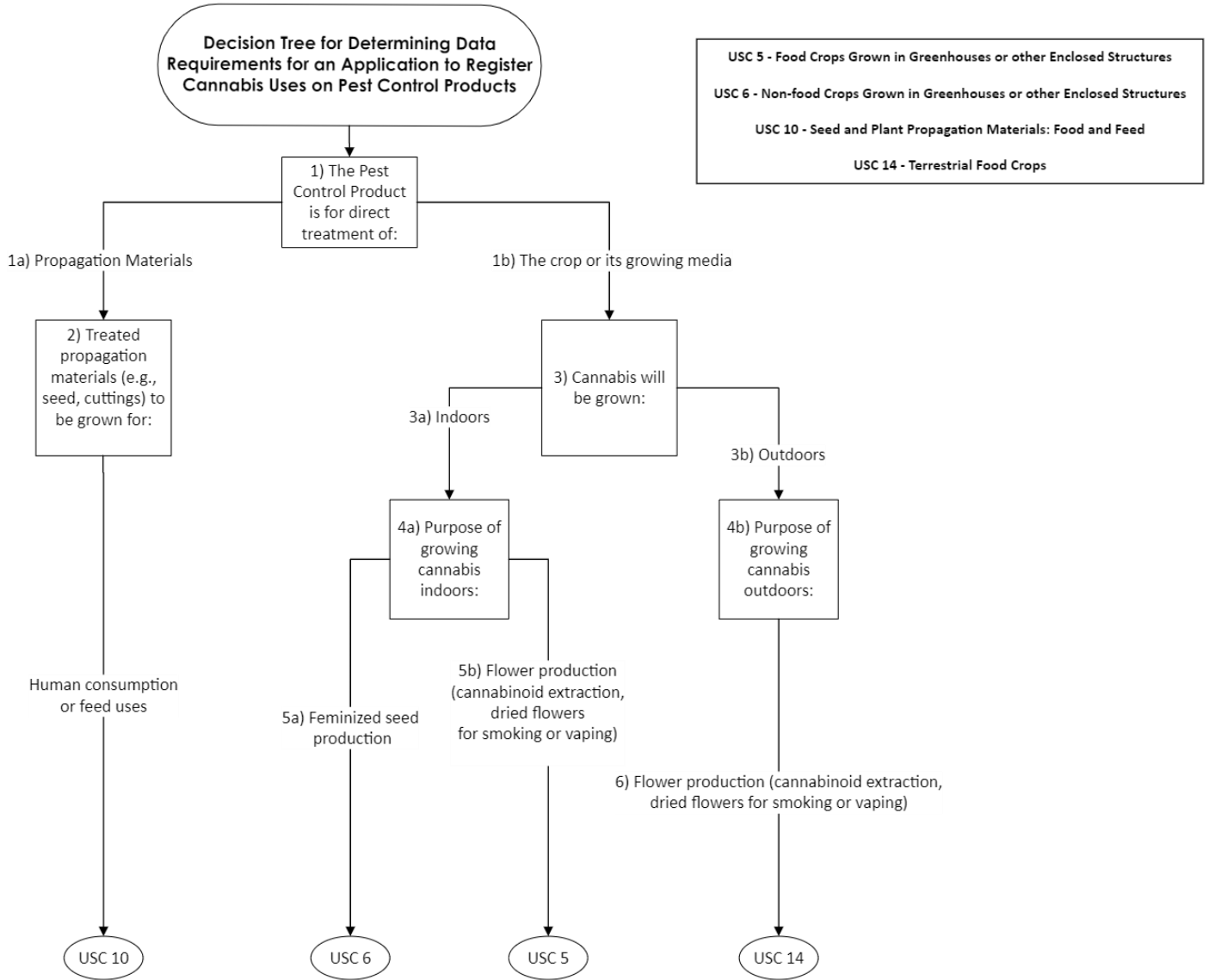
Registrants who do not update their labels are expected to submit data to assess risks associated with pesticide use on cannabis and industrial hemp. Following this nine-month period, any remaining labels that have not been updated will be subject to a notice, issued under Section 12 of the *Pest Control Products Act*, requiring the submission of DACO 7.4.1 residue data and/or DACO 7.8.1 pyrolysis data. Failure to submit the required data will result in the cancellation of the use.

The data requirements and label statements described in this document are currently being implemented in open submissions and for active ingredients under re-evaluation and special review. As noted in section 7.0, applicants are strongly advised to request a pre-submission consultation with Health Canada's PMRA before submitting applications to add cannabis and industrial hemp uses to pesticide labels.

Please note that the cannabis and industrial hemp industries are evolving over time with respect to production methods and locations and the uses of the crops. Guidance will be updated periodically to incorporate any new information that should be considered when registering pesticides for use on these crops.

If there are questions pertaining to this document please contact the Pest Management Information Service at pmra.info-arla@hc-sc.gc.ca.

Appendix I Decision tree for the selection of appropriate use-site categories for cannabis



Appendix II Decision tree for the selection of appropriate use-site categories for industrial hemp

