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Guidance for User Requested Minor Use Label Expansion

PMRA Guidance Document



*Protecting the health and
environment of Canadians*

*Protéger la santé des Canadiens
et l'environnement*



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Updated	Update/Rationale:
10 March 2022	Update to content and requirements.
Previous version dated 14 February 2001	Updated to provide current information and regulations to users.

Disclaimer

This document does not constitute part of the *Pest Control Products Act* or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations, and the applicable administrative policies.

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1.0 User requested minor use label expansion

This document informs the provinces and territories, registrants, user groups, and other stakeholders about the Pest Management Regulatory Agency's (PMRA) policy governing the User Requested Minor Use Label Expansion (URMULE) program. This document describes the criteria, data requirements, and process for the addition of new minor uses to Technical Grade Active Ingredients and end-use products currently registered in Canada.

This document replaces the publication, Regulatory Directive 2001-01 User Requested Minor Use Label Expansion.

2.0 Introduction

The PMRA's policy governing the URMULE program is covered in the sections that follow.

2.1 The URMULE program

"Minor use" pesticides are crop-protection products – typically fungicides, insecticides, and herbicides. Usually, they are applied to low acreage, high-value crops, or where pest control is only required for a small portion of the overall crop acreage. These crops include vegetables, fruits, specialty crops, herbs, and spices, and nursery and landscape plants, and flowers. Often, these crops are of high-value, and are sometimes called "minor crops"; they are grown on significantly smaller areas of land compared to the large acreages of crops like corn, canola, soybeans, and wheat. Specific minor uses of a product lead manufacturers to conclude that projected sales will be too low to justify the support of a Canadian registration. Consequently, these products or use of a product may not be accessible to Canadian growers who consider these uses as essential to cost-effective pest control.

The URMULE program considers the expansion of a label for a new minor use of a pesticide. The technical grade active ingredient and the end-use product must be currently registered in Canada. The label expansion is registered only if the risk to human health and the environment is acceptable, and it has the requisite value. This minor use registration is consistent with all registration decisions made under the *Pest Control Products Act*.

URMULE is a cooperative program that involves the participation of sponsor groups, provincial and forestry minor use coordinators, provincial and federal government agencies, and product registrants.

2.2 Agriculture and Agri-Food Canada and Health Canada roles in the URMULE program

Agriculture and Agri-Food Canada (AAFC) has continued to provide funding and infrastructure support to Canadian growers for their improved access to products that would otherwise not be available to meet their minor use needs. This support helps to

address their evolving crop protection needs and to improve their competitiveness in the global marketplace. This initiative has allowed the development of a collaborative minor use support system between AAFC and Health Canada. Agriculture and Agri-Food Canada's Pest Management Centre (AAFC – PMC) uses these funds to conduct trials for the generation of value and residue data required for the registration of new minor use label expansions. Federal funding allows Health Canada's PMRA to increase its capacity to review minor use applications that are submitted by both PMC, and the provinces.

National minor use research priorities are selected annually by grower representatives at the Canadian Pest Management Priority Setting Workshop. Additionally, close collaboration has been established with the Interregional Research Project #4 (IR-4) in the United States to maximize efficiencies in the generation of data and reports, and also with the United States Environmental Protection Agency in the review of data. These collaborations help to reduce duplication in the registration of new pesticide minor uses.

Information about the PMC and the established priorities and status of specific pesticide/crop projects can be found at the [Pest Management Centre](#) on the Agriculture and Agri-Food Canada website.

3.0 Criteria for an URMULE application

All three of the criteria must be met for review consideration under the URMULE program:

- I. Both the active ingredients and the associated end-use products must be registered in Canada.
- II. The registrant must commit to adding the new use to the end-use product label.
- III. There must be sufficient information to assess the health and environmental risks, and the value of the proposed minor use.

4.0 Definitions

Applicant

An applicant is the individual responsible for submitting an URMULE application package to the PMRA via the ePRS Secure Web Portal. An applicant is either a provincial or forestry minor use coordinator, or the AAFC – PMC.

Application (Category D.3.2 Application)

A complete application (D.3.2 Application) includes all items required for a pre-submission consultation (D.3.1 application). Furthermore, it includes any additional information requested by the PMRA as a result of a pre-submission consultation (Category D.3.1).

Candidate product

A candidate product is a pesticide that has both technical grade active ingredient and end-use product components registered in Canada. However, its potential market

volume for a minor use is insufficient for the registrant to develop the data required to register the minor use in Canada.

Minor use

A minor use is the necessary use of a pest control product for which the anticipated volume of sales is insufficient for a manufacturer to register and sell the product in Canada.

The "minor use" designation emphasizes that it is the projected sales of the pest control product that is minor, and not necessarily the size of the crop. A minor use may be registered for a major crop; the use may be required occasionally, or it is limited to a small percentage of the total area of the crop.

Pest Management Centre of Agriculture and Agri-Food Canada (AAFC – PMC)

The PMC supports Canadian growers of minor crops with their pest management needs by generating data to support the registration of new minor uses for pesticide products. They conduct field, greenhouse, and laboratory trials to generate the required data. These trials include efficacy, crop tolerance (that is, crop injury), and pesticide residue information in the support of regulatory applications to the PMRA.

Pre-submission consultation (Category D.3.1 Application)

A pre-submission consultation application (Category D.3.1 Application) consists of this supporting documentation:

- A cover letter summarizing the purpose of the application
- "Proposal for an URMULE" form
- A letter of support from the registrant
- A proposed label
- Any health, environmental, value information, or available data to support the proposed minor use

The D.3.1 application determines whether there are any outstanding data/information gaps that must be addressed by the applicant in a subsequent minor use application (Submission Category D.3.2).

Provincial or forestry minor use coordinator

The provincial and forestry minor use coordinators are the contacts for minor use issues within their jurisdictions. In addition, they act as the applicant for some minor use applications that are sent to the PMRA:

1. Contact the provincial agriculture ministry to request the identification of a provincial minor use coordinator.

Registrant

A registrant is the company to which the certificate of an amended registration is issued.

Residue Chemistry Crop Groups

Crop groups are botanically or taxonomically related crops. One example of a residue chemistry crop group is Crop Group 9 (cucurbit vegetables): its representative crops are cucumber, muskmelon, and summer squash. Another is Crop Group 14-11 (tree nuts): its representative crops are almond and pecan. Crop groupings allow the maximum residue limits (MRL) to be established for multiple related crops based on residue data from a representative set of crops. Section 15 of Regulatory Directive DIR98-02, Residue Chemistry Guidelines, provides a thorough description of each crop group. Many of these crop groups have been revised since the publication of DIR98-02, and subsequently new crop groups have been established. The original crop groups, and any revisions, can be found in the Pesticides section of Canada.ca.

Sponsor

A sponsor is an individual or an organization that represents a user or a user group. They are responsible for identifying candidate products for potential consideration under the URMULE program.

User group

A user group is a group of persons that require and plan to use a candidate minor use pest control product (for example, greenhouse growers, or forest nursery managers).

5.0 Data Requirements

The data requirements for an URMULE are determined by the PMRA in accordance with the statutory mandate of the Minister of Health, under the *Pest Control Products Act* and Regulations. Sponsors are advised to obtain and carefully read the registered Canadian product label. The presence or absence of the pest and/or crop on the label or deviations from the registered use pattern may influence data requirements.

The information required to support an URMULE registration includes:

- A detailed summary of the proposed use (crop, pest, use pattern)
- Value information to support the proposed use
- Where applicable, occupational exposure data and field trial residue data

Additionally, other data may be required as determined by a pre-submission consultation (D.3.1). The PMRA will consider food residue trials conducted in other regions of North America, on a case-by-case basis, in an effort to reduce the need for Canadian specific trials:

1. Refer to Section 9.6 of *DIR98-02 Residue Chemistry Guidelines* for a description of the field trial regions.
2. Refer to DIR2010-05, "*Revisions to the Residue Chemistry Crop Field Trial Requirements*" for the number and location of trials to support a domestic registration.

The data required to support greenhouse uses is not required to have been generated in specific field trial regions.

5.1 Value information

Value requirements are determined on the basis of the information provided on the "Proposal for an URMULE" form, and the proposed label:

1. Refer to PMRA Guidance Document, Value Assessment of Pest Control Products.
2. Refer to the "*Value Guidelines for New Plant Protection Products and Label Amendments*".

Both of these publications are available on the Pesticides section of Canada.ca.

5.2 Food residues

The *Food and Drugs Act* prohibits the sale of food containing pesticide residues at levels that exceed maximum residue limits (MRLs) established under the *Pest Control Products Act*. The MRLs established in Canada are located in the Maximum Residue Limit Database on the "[Maximum Residue Limits for Pesticides](#)" web page. This database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or food commodities. There might not be an MRL listed for a specific pesticide-crop combination. However, the requirements for pesticide residues that result from agricultural use on the specific crop are established under Subsection B.15.002(2) of the Food and Drug Regulations: the residues must not exceed 0.1 parts per million, commonly referred to as the general maximum residue limit (general MRL).

The residue chemistry data requirements that support the use of a pesticide on food commodities, and proposed under the URMULE program, are consistent with those required to support other new use registrations. If crop field trial residue data is required as a result of the pre-submission consultation, the PMRA provides an "URMULE Residue Trial Specification" form to outline the necessary generated data.

Residue data from representative crops of a crop group may be extended to commodities within the same crop group and these data are considered when determining if additional residue trials are required for a proposed crop. In certain cases, flexibility on data requirements may be considered by a waiver request with the provision

of a thorough scientific rationale. Residue trials must be conducted in accordance with Regulatory Directives DIR98-01, *Good Laboratory Practice*, and DIR2010-05, *Revisions to the Residue Chemistry Crop Field Trial Requirements*.

5.3 Occupational exposure

Mixer/loader/applicator and postapplication exposure assessments are conducted during the review of a minor use submission. The cultivation practices and postapplication worker activities for unique or specialty crops may not be known or readily available. Therefore, the DACO 5.2 "Use Description Information" should be provided. The pre-submission consultation may identify additional occupational exposure data that is required; for example, a dislodgeable foliar residue study.

5.4 Environment

Proposed minor use label expansions are evaluated by the PMRA to determine if the proposed use fits within the currently registered use pattern. However, the proposed use might not align with the registered use pattern. Therefore, an environmental risk assessment may be required to ensure that risks to the environment are acceptable.

6.0 The URMULE process

The URMULE process is explained in the sections below.

6.1 Developing an URMULE proposal and assembling the documentation

The identification of a pest management need is the first step for any URMULE proposal. The proposed use must meet the basic criteria for URMULE registration outlined in [Both the active ingredients and the associated end-use](#) products must be registered in Canada. Applicants can work with a sponsor group to develop the proposal and obtain the required documentation for an URMULE application. The documentation requirements for an URMULE application are described in the sections that follow.

6.1.1 Preparing the proposal form

The URMULE proposal form is available electronically on the Pesticides section of Canada.ca:

1. Complete the "Proposal for an URMULE" form.
2. Provide detailed descriptions of the proposed use(s) in the form.

6.1.2 Obtaining a letter of support from the registrant

A letter of support is required from the end-use product registrant:

1. Obtain a letter from the registrant of the end-use product that indicates their support to add the proposed minor use to the label.
 - a. The letter of support must be signed by the registrant and be specific to the proposed use.
 - b. Includes the product name, Pest Control Product number, crop, pest, and details regarding the use pattern (for example, rates, number of applications, and application interval).

6.1.3 Obtaining the proposed label

The registrant of the end-use product must supply a proposed label to the applicant:

1. Obtain a proposed label from the registrant of the end-use product.

This label should consist of the registered label, plus the directions for use specific to the proposed minor use expansion. As relevant, these directions should include crop, pest, application rate, re-application interval, pre-harvest interval, number of applications, timing of application, and any other relevant directions or restrictions.

In addition, registrants may include the minor use statement on their label. This statement may be placed on the label directly preceding the uses added through the URMULE program. The statement is:

The DIRECTIONS FOR USE for the uses described in this section of the label were developed by persons other than [registrant name] under the User Requested Minor Use Label Expansion program. For these uses, [Registrant name] has not fully assessed performance (efficacy) and/or crop tolerance (phytotoxicity) under all environmental conditions or for all crop varieties when used in accordance with the label. The user should test the product on a small area first, under local conditions and using standard practices, to confirm the product is suitable for widespread application.

6.1.4 Preparing the application cover letter

Each application must be accompanied by a cover letter:

1. State the purpose of the application (that is, Category D.3.1 or D.3.2.). This detail ensures that the application is coded correctly at the time of submission set-up.
2. Provide a brief description of the proposed minor use in the letter.
3. Outline any additional information or data that accompanies the application.
4. Provide additional details that may be relevant for a review of the application.

6.1.5 Additional information

Additional information that may support the URMULE application:

1. Provide additional supporting information for the proposed use, like value and occupational exposure information, and residue data, as applicable.

6.2 Submitting the application to the PMRA

It is the responsibility and initiative of the applicant to submit the application to the PMRA (that is, the provincial and forestry minor use coordinators, or the AAFC – PMC) to. Prior to sending the application, applicants should:

1. Review the application package.
2. Sign the "Proposal for an URMULE" form attesting and verifying that this submission is a legitimate need of the user group.
3. Submit documentation electronically to the PMRA via the e-PRS Secure Web Portal.

Subsequently, provincial and forestry minor use coordinators are responsible for any additional provincial liaison, including the notification of provincial regulatory agencies of the minor use proposal.

The registration of a new minor use label expansion can encompass three submission categories that are completed sequentially. These submission categories are discussed separately below. Applicants are not required to initiate the minor use process through the submission of a Category D.3.1 pre-submission consultation application. However, they are encouraged to submit this application category if they want the PMRA to confirm the data requirements related to the proposed minor use, or as requested by PMRA to the applicant. Applicants who believe their application is complete (that is, no data gaps) can submit their minor use as a Category D.3.2 application directly to the PMRA. In this case, the application must contain the required documentation in Section 6.1.

The minor use submission categories listed below and the processes for the three submission categories are illustrated in Appendix A ([Figure 1](#)).

6.2.1 D.3.1 Pre-submission consultation

A category D.3.1 application is a pre-submission consultation. After receiving a D.3.1 application, the PMRA:

1. Verifies that the program criteria have been met.
2. Determines that the proposal is complete and includes the required documentation (6.1.1 Preparing the proposal form).
3. Determines that the details of the proposed use are consistent across the documentation.

The appropriate PMRA science directorates review the application.

Any data deficiencies identified during the science review are sent to the applicant in writing. These deficiencies can consist of value (including efficacy), crop tolerance, and residue studies, or any other data and information specified by the PMRA.

6.2.2 D.3.2 Application

The required documentation consists of the items listed in 6.1.1 Preparing the proposal form, plus any data or information to address the deficiencies identified in the Category D.3.1 pre-submission consultation application (if this category of application was completed).

1. The PMRA verifies that the program criteria are met; determines the completeness of the proposal; verifies the inclusion of the required documentation; and, determines that details about the proposed use are consistent across all documentation.
2. The PMRA evaluates the risk and value of the proposed minor use.
3. The PMRA proposes a regulatory decision based upon a review of the submitted information:
 - a. If the risks and value are considered acceptable for the proposed use expansion, the PMRA notifies the registrant in writing of the acceptability for registration. The letter is copied to all provincial and forestry minor use coordinators, the sponsor, and AAFC – PMC. In addition, this notification includes a request for the registrant to submit an “Application for New or Amended Registration (
 - b. 6.2.3 C.6.3 Application – Registration of a Minor Use)”.
 - c. If a review of the proposed use expansion has not demonstrated acceptable risks or value, the PMRA notifies the registrant in writing of the negative decision, and copies the applicant and all provincial and forestry minor use coordinators, the sponsor, and AAFC – PMC.

6.2.3 C.6.3 Application – Registration of a Minor Use

The registrant prepares and submits an “Application for New or Amended Registration” (Category C.6.3 application). It contains:

1. An application form (application for new or amended registration – form 6005).
2. A fee estimate form (form 6011).
3. English and French labels in Word format with the approved minor use incorporated (with the track changes feature enabled).

A “Certificate of Registration” is issued to the registrant and the approved French and English labels are copied to the provincial and forestry minor use coordinators, AAFC – PMC, and the sponsor.

Now, the URMULE registration process is complete and the product is acceptable to use as of the date of approval.

If the expansion of use involves a food or feed use and it is necessary to establish or revise an existing MRL, PMRA initiates the promulgation process once the C.6.3 application is complete. A proposed maximum residue limit (PMRL) document is published for consultation on the proposed MRL(s). Once the consultation process is complete, the MRL is established and entered into the MRL database, typically 14 days after the consultation process has closed.

At this point, provincial and territorial authorities may communicate the acceptable new use in the knowledge that they meet the requirements of the *Pest Control Products Act*.

List of document abbreviations

AAFC	Agriculture and Agri-Food Canada
IR-4	Interregional Research Project Number 4
MRL	maximum residue limit
PCP	pest control product
PMRA	Pest Management Regulatory Agency
PMRL	Proposed maximum residue limit
URMULE	User Requested Minor Use Label Expansion

Appendix A URMULE process at PMRA

The minor use submission process is illustrated in Figure 1.

Figure 1: Minor Use Submission Process

