Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Directive DIR2001-01

User Requested Minor Use Label Expansion

The purpose of this document is to inform provinces and territories, registrants, user groups and other stakeholders about the Pest Management Regulatory Agency's (PMRA) policy concerning User Requested Minor Use Label Expansion (URMULE). This document describes the criteria, data requirements and process for the consideration of additional minor uses to end-use products (EPs) registered in Canada.

This document replaces Regulatory Directive DIR93-23, *User Requested Minor Use Label Expansion*, and was preceded by the URMULE Regulatory Proposal PRO2000-02, issued for public comment on April 25, 2000. Comments received were considered in the final version of this regulatory directive.

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1.0 Introduction

The projected sales of some pest control products in Canada may be so low that manufacturers conclude that they cannot justify the costs to support Canadian registrations. For commercial reasons, therefore, such products may not be available for use in this country; however, many of these “minor use” products are regarded as essential to cost-effective pest control and the competitiveness and sustainability of agriculture, forestry, aquaculture and other sectors.

The URMULE program considers the expansion of a label for a new minor use of a pesticide for which the active ingredient(s) and the EP are currently registered in Canada. The use expansion is considered only if the product is efficacious and the risks are considered acceptable.

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

2.0 Definitions

Candidate product
A candidate product is a pesticide that has both the active ingredient(s) and the EP registered in Canada but for which the potential market volume for the minor use is not sufficient to persuade the registrant to develop the data required to register that minor use in Canada. EPs containing active ingredients under re-evaluation by the PMRA are not eligible.

Crop groups
Crop groups are primarily comprised of botanically related commodities subject to comparable cultural practices. Grouping is intended to simplify the establishment of maximum residue limits (MRLs) for a set of crops based upon residue data for crops deemed representative of the group. Section 15 of Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*, provides a thorough description of each crop group.

Minor use
A minor use is defined as a necessary use of a pest control product for which the anticipated volume of sales is not sufficient to persuade a manufacturer to register and sell the product in Canada.

The definition 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 on a major crop because the use may be needed only occasionally or is limited to a small percentage of the total area of the crop. Restrictions on volume of use or area are considered on a case-by-case basis.

Presubmission
A presubmission consists of a "Proposal for an URMULE" form, a letter of support from the registrant and any information available to support the proposed use.

Provincial or forestry minor use coordinator
The provincial and forestry minor use coordinators (Appendix I) are the contacts for minor use issues within their jurisdictions.

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

Sponsor
A sponsor is an individual or an organization representing a user or a user group and is responsible for identifying candidate products that should satisfy user needs.

Submission
A complete submission includes all items of a presubmission plus any further information requested by the PMRA as a result of the presubmission consultation.

User group
A user group is a group of persons needing and planning to use a candidate minor use pest control product (e.g., greenhouse growers, forest nursery managers).

3.0 Criteria for an URMULE registration

Proposals that meet the following criteria are evaluated under the URMULE program:

(*i*) the active ingredients and the EP must be registered in Canada;

(*ii*) the registrant must be willing to add the new use to the EP label; and,

(*iii*) there must be sufficient information to assess the safety, merit and value of the proposed new use.

4.0 Data requirements

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* (PCPA) and Regulations, taking into account the relatively small sales volume, use volumes and areas of use, as well as the need to protect human health and the environment.

Sponsors are advised to obtain and read the registered Canadian product label carefully, as the presence or absence of the pest or crop on the label or deviations from the registered use pattern influence data requirements.

Information needed to support an URMULE registration involves mainly efficacy, crop tolerance and residue data. Other data may also be required, however, on a case-by-case basis as determined during the presubmission consultation (PSC). In an effort to reduce the need for additional data generation in Canada, the PMRA considers U.S. Interregional Research Project Number 4 (IR-4) data from equivalent field trial regions or relevant data from other countries that is submitted in the assessment of URMULE presubmissions. Refer to Section 9.6 of DIR98-02 for descriptions of field trial regions.

Data required to support greenhouse uses need not be generated in specific field trial regions.

4.1 Efficacy and crop tolerance

Data requirements are determined on the basis of the information provided on the "Proposal for an URMULE" form. As a general rule, pests or crops not on the Canadian label require efficacy and crop tolerance data. Proposed use patterns that deviate from the registered use pattern (rate of application, number of applications, frequency and intervals between applications, crop and pest growth stages and preharvest interval) may also require efficacy and crop tolerance data. Bridging data from crops within the same crop grouping (see Section 15 of DIR98-02) are considered when supported by scientific rationale.

4.2 Residues

The *Food and Drugs Act* (FDA) prohibits the sale of food containing pesticide residues at levels exceeding MRLs that are established under that Act. MRLs for specific pesticides (active ingredients and metabolites or derivatives) on specific foods are listed in Table II to Division 15 of the Food and Drugs Regulations (FDR). By virtue of subsection B.15.002(1) of the FDR, the MRL for any pesticide and food combination not listed in Table II is 0.1 ppm.

The data requirements to support the use of a pesticide on food commodities proposed under the URMULE program are similar to those required to support other new use registrations. If residue data are required to establish an MRL, the PMRA provides an "URMULE Residue Trial Specification" form outlining the data to be provided. Available data from other crops within the same crop grouping are considered in determining these requirements. Flexibility on data requirements may be considered in certain cases when a waiver request in the form of a scientific rationale is provided and considered adequate. Residue trials must be conducted in accordance with Regulatory Directives DIR98-01, *Good Laboratory Practice*, and DIR98-02.

5.0 URMULE process

An overview of the URMULE registration process is provided below and depicted in the flow chart included as Appendix III.

5.1 Proposal (sponsor and provincial or forestry minor use coordinator)

Sponsor
The first step in any URMULE proposal is the identification of a need by the sponsor or user group. In proposing a candidate product, the sponsor must ensure that the proposed use of the product meets the criteria for URMULE registration as outlined in Section 3.0 of this document. The sponsor then proceeds with a proposal in the following manner:

(*i*) Obtain a letter of support from the registrant of the pest control product for the proposed use. The letter of support must be signed by the registrant's Regulatory Affairs Section and be specific to the proposed use, including the product name, Pest Control Product (PCP) number, crop and rates of application. The letter should also indicate whether the company intends to use the assumption of risk statement (Appendix II) for efficacy and crop tolerance in conjunction with this registration, although this intent may be influenced by the data generated in support of the minor use and can be reversed by the registrant when submitting the supplemental label. Any added statement must be acceptable to both the registrant and the sponsor.

(*ii*) Complete the "Proposal for an URMULE" form. The form is available electronically on the PMRA Internet site and hard copies are available from the Agency upon request. The proposed uses must be described in detail in the proposal. Attach all available supporting efficacy, crop tolerance and residue data for the proposed use, as applicable. If the "Proposal for an URMULE" form is modified in any way, the presubmission will be returned to the sponsor.

(*iii*) Send all documentation to the corresponding provincial minor use coordinator for signature, except for forestry minor use applications, which are sent to the forestry minor use coordinator (Appendix I).

Provincial and forestry minor use coordinators
It is the responsibility of the provincial and forestry minor use coordinators to review the presubmission, sign the "Proposal for an URMULE" form attesting that this is a legitimate need of the sponsor or user group and forward the package to the PMRA. Provincial and forestry minor use coordinators are also responsible for any additional provincial liaison, including notifying provincial regulatory agencies of the minor use proposal.

5.2 Presubmission consultation (PMRA)

Any initial URMULE proposal is considered a presubmission consultation. Upon receiving a presubmission, the PMRA verifies that the program criteria are met and the proposal is complete. If further data are required, the PMRA notifies the sponsor in writing of the data requirements for registration, which may consist of efficacy, crop tolerance and residue studies or any other data specified by the Agency. The performance

standard for presubmission consultation is 97 calendar days from the date of receipt by the Agency.

A copy of the sponsor's "Proposal for an URMULE" form and a copy of the PMRA's Presubmission Consultation Response, communicating the outcome of the PSC, is sent to all provincial and forestry minor use coordinators to facilitate coordination across Canada.

5.3 Data provision (sponsor)

If more data or information are required as a result of the presubmission consultation, the sponsor is responsible for their acquisition and submission as a single package to the PMRA. The data package must include a cover letter clearly referencing the corresponding presubmission consultation number assigned by the Agency in Section 5.2 and listing the studies and data included in the package.

5.4 Submission (PMRA)

The initial PSC package and data received in response to the presubmission consultation are considered a submission which is handled in accordance with the Agency's *Management of Submissions Policy*. The performance standard for submission review is 60–180 days, depending on the use site category and the amount and complexity of data to be reviewed.

5.5 Decision on acceptability for registration (PMRA)

The PMRA proposes a regulatory decision based upon the review of submitted information. If the risks and value are considered acceptable for the proposed use expansion, the PMRA notifies the sponsor and registrant in writing of the acceptability for registration and the letter is copied to all provincial and forestry minor use coordinators. The notification also includes a request for the registrant to submit an "Application for New or Amended Registration" along with the corresponding supplemental label.

In addition, if the expansion involves a food or feed use and if it is necessary to establish a new MRL, the PMRA initiates the process to amend the FDR. This regulatory amendment process takes from 12 to 18 months. If the proposed new MRL is higher than the existing one for that residue and food combination (i.e., 0.1 ppm or a level listed in Table II to Division 15 of the FDR), it would be expected that the new food use might result in residues exceeding the existing MRL and, therefore, sale of the food may be in violation of the FDA. In this case, provided there is at least one MRL for the pesticide listed in Table II to Division 15 of the FDR for any food, an Interim Marketing Authorization (IMA) may be issued. An IMA, which is typically processed within six weeks, permits the sale of food containing residues up to the proposed MRL while the regulatory process for the establishment of the new MRL is being completed.

An IMA is issued upon written request from the registrant. The request may be submitted with the initial URMULE proposal in anticipation of the potential need for an IMA. Alternatively, the request may be made by the registrant upon notification by the Agency that the proposed use is acceptable and that it is possible to issue an IMA. The former approach permits a more timely processing of the IMA, however, as the request would already be on file. An IMA request template is attached as Appendix IV.

If the risks and value are not considered acceptable for the use expansion, the PMRA notifies the sponsor and registrant in writing of the negative decision and copies the letter to all provincial and forestry minor use coordinators.

5.6 Supplemental label (registrant and the PMRA)

The registrant prepares and submits an "Application for New or Amended Registration" (Category C submission) with a fee form, fees and copies of a supplemental label specifically for the accepted minor use. An assumption of risk statement for performance and crop tolerance, as described in Appendix II, may be placed on the supplemental label by the registrant. Upon successful review of the label by the PMRA, a "Certificate of Registration" is issued to the registrant based on the supplemental label and the accepted supplemental label is copied to the sponsor and provincial and forestry minor use coordinators. The URMULE registration process is now complete and the product can be used for this use.

At this point, provincial and territorial authorities, in publishing recommendations on the use of pest control products, may incorporate such acceptable uses in the knowledge that they meet the requirements of the PCPA. As noted in Section 5.5, however, unless the existing MRL (0.1 ppm or a level listed in Table II to Division 15 of the FDR) covers potential residues or an IMA has been issued, the sale of food containing residues of this pesticide may be in violation of the FDA.

5.7 Full label (registrant and the PMRA)

The registrant is required to add the URMULE registration to the full label at its next printing by submitting an "Application for New or Amended Registration," which is handled in accordance with the Agency's *Management of Submissions Policy* for Category C submissions. Only those uses accepted for registration with the assumption of risk statement on the supplemental label may use the assumption of risk statement on the full label and enclosed within a box.

List of abbreviations

EP	end-use product
FDA	*Food and Drugs Act*
FDR	Food and Drug Regulations
GAP	good agricultural practices
IMA	Interim Marketing Authorization
IR-4	Interregional Research Project Number 4
MRL	maximum residue limit
PCP	pest control product
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
ppm	parts per million
PSC	presubmission consultation
URMULE	User Requested Minor Use Label Expansion

Appendix I Provincial and Forestry Minor Use Coordinators

The list is accurate as of the publication date of this regulatory directive.

Newfoundland Ms. Goldie Porter Department of Forest Resources and Agri-Foods P.O. Box 4895 Manuels, NF A1W 1T2 Telephone: (709) 729-0022 Facsimile: (709) 729-0205 E-mail: gporter@agric.dffa.gov.nf.ca	**Prince Edward Island** Mr. Don Reeves PEI Department of Agriculture and Forestry P.O. Box 306 Kensington, PE C0B 1M0 Telephone: (902) 836-8925 Facsimile: (902) 836-8921 E-mail: dreeves@agric.gov.pe.ca
Nova Scotia Mr. Lorne Crozier NS Department of Agriculture and Marketing P.O. Box 550 Truro, NS B2N 5E3 Telephone: (902) 893-6548 Facsimile: (902) 893-0244 E-mail: lcrozier@nsdam.gov.ns.ca	**New Brunswick** Mr. Kelvin Lynch Agriculture and Rural Development P.O. Box 6000 Fredericton, NB E3B 5H1 Telephone: (506) 453-3478 Facsimile: (506) 453-7978 E-mail: klynch@gov.nb.ca
Quebec M. Michel Letendre M.A.P.A.Q. Direction des services technologiques 200, chemin Sainte-Foy, 9ième étage Québec, QC G1R 4X6 Telephone: (418) 380-2100, ext. 3577 Facsimile: (418) 380-2181 E-mail: michel.letendre@agr.gouv.qc.ca	**Ontario** Mr. Jim Chaput Ontario Ministry of Agriculture, Food & Rural Affairs Agriculture & Rural Division Crop Technology 1 Stone Road West Guelph, ON N1G 4Y2 Telephone: (519) 826-3539 Facsimile: (519) 826-4964 E-mail: jim.chaput@omafra.gov.on.ca
Manitoba Ms. Rhonda Kurtz Pesticide Licensing Manitoba Agriculture Room 204, 545 University Crescent Winnipeg, MB R3T 2N7 Telephone: (204) 945-7706 Facsimile: (204) 945-4327 E-mail: rkurtz@agr.gov.mb.ca	**Saskatchewan** Mr. Doug Billett Sustainable Production Branch Saskatchewan Agriculture and Food Room 125, 3085 Albert Street Regina, SK S4S 0B1 Telephone: (306) 787-8061 Facsimile: (306) 787-0428 E-mail: dbillett@agr.gov.sk.ca

Alberta Mr. Shaffeek Ali Pest Prevention and Management Unit Alberta Agriculture, Food and Rural Development Room 304, J.G. O'Donoghue Building 7000 - 113th Street Edmonton, AB T6H 5T6 Telephone: (780) 422-4909 Facsimile: (780) 422-0783 E-mail: shaffeek.ali@agric.gov.ab.ca	**British Columbia** (Staffing action underway) Ms. Madeline Waring Plant Industry Branch B.C. Ministry of Agriculture and Food Abbotsford Agriculture Centre 1767 Angus Campbell Road Abbotsford, BC V3G 2M3 Telephone: (604) 556-3027 Facsimile: (604) 556-3030 E-mail: Madeline.Waring@gems5.gov.bc.ca
Forestry Mr. Michael Irvine Forest Health & Silviculture Ontario Ministry of Natural Resources Roberta Bondar Place Suite 400, 70 Foster Drive Sault Ste. Marie, ON P6A 6V5 Telephone: (705) 945-5724 Facsimile: (705) 945-6667 E-mail: Michael.irvine@mnr.gov.on.ca	

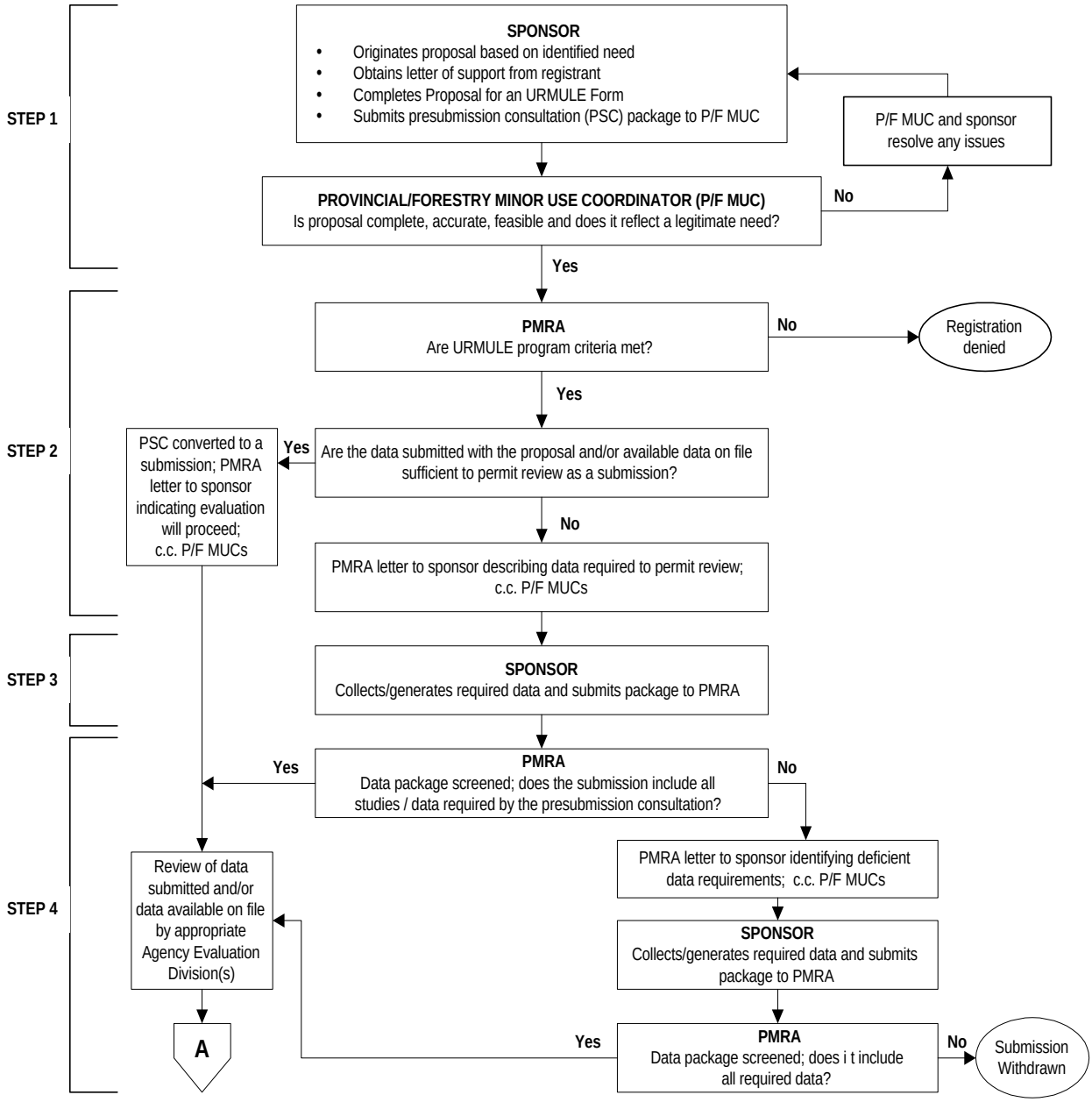
Appendix II Assumption of risk statement for performance and crop tolerance

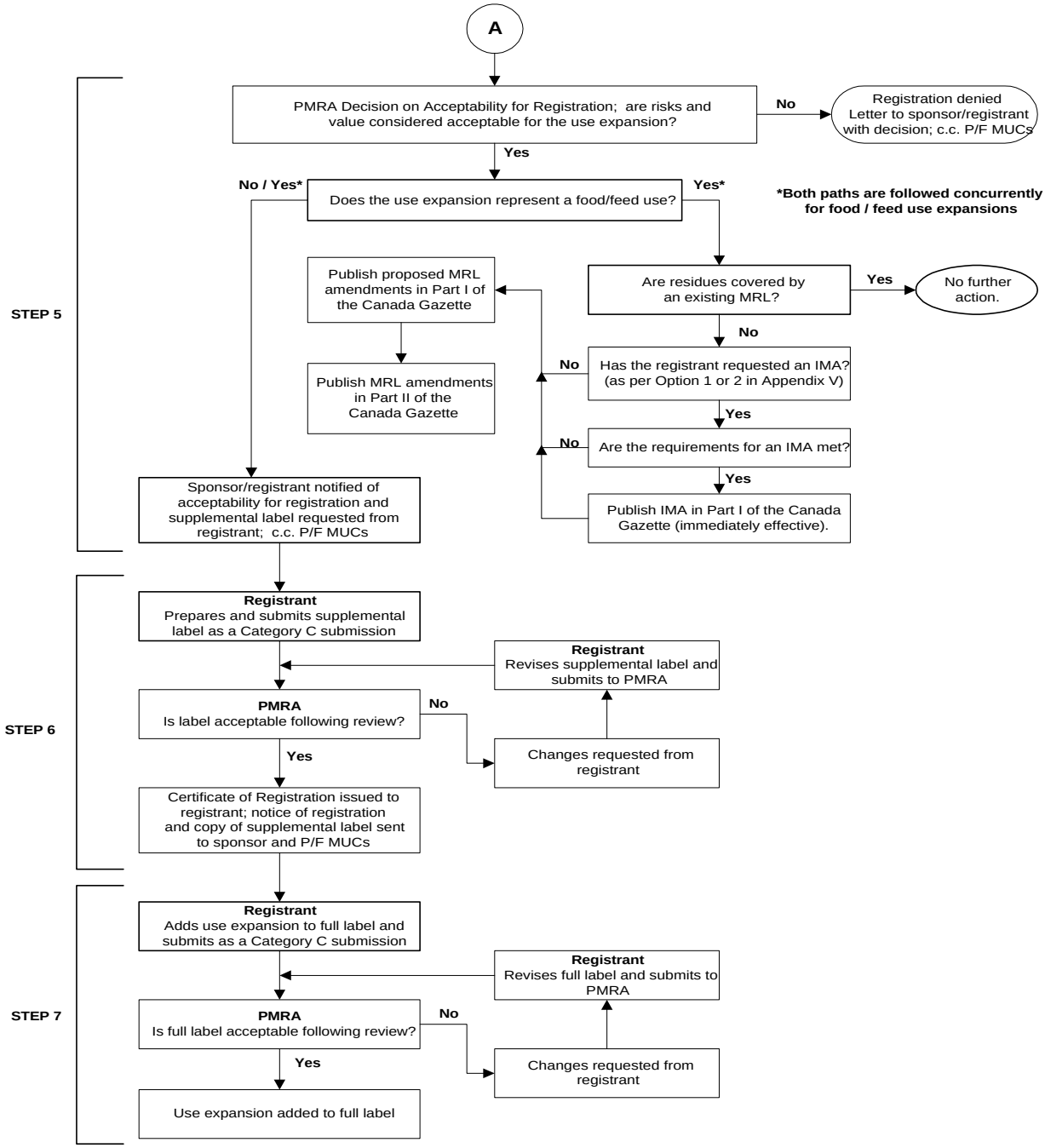
The assumption of risk statement provides for the user of the product to accept responsibility for any problems that may arise relating to performance and crop tolerance. The assumption of risk statement does not relieve the registrant of any liability, however, in relation to health and environmental risks.

An assumption of risk statement for performance and crop tolerance may be placed on the supplemental label that is developed for the minor use expansion. The statement must be acceptable to both the registrant and the sponsor or user group. An example of such a statement follows:

> NOTE TO USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR THE INDICATED SPECIAL USE APPLICATIONS:
>
> The DIRECTIONS FOR USE for this product for the use(s) described on this Supplemental Label were developed by persons other than (COMPANY NAME) and accepted for registration by Health Canada under the User Requested Minor Use Label Expansion program. (COMPANY NAME) itself makes no representation or warranty with respect to performance (efficacy) or crop tolerance (phytotoxicity) claims for this product when used on the crop(s) listed on this Supplemental Label.
>
> Accordingly, the Buyer and User assume all risks related to performance and crop tolerance arising, and agree to hold (COMPANY NAME) harmless from any claims based on efficacy or phytotoxicity in connection with the use(s) described on this Supplemental Label.

Appendix III URMULE process for registration




A
PMRA Decision on Acceptability for Registration; are risks and value considered acceptable for the use expansion?
No
Registration denied Letter to sponsor/registrant with decision; c.c. P/F MUCs
Yes
No / Yes*
Does the use expansion represent a food/feed use?
Yes*
*Both paths are followed concurrently for food / feed use expansions
Publish proposed MRL amendments in Part I of the Canada Gazette
Are residues covered by an existing MRL?
Yes
No further action.
STEP 5
No
Publish MRL amendments in Part II of the Canada Gazette
No
Has the registrant requested an IMA? (as per Option 1 or 2 in Appendix V)
Yes
No
Are the requirements for an IMA met?
Yes
Sponsor/registrant notified of acceptability for registration and supplemental label requested from registrant; c.c. P/F MUCs
Publish IMA in Part I of the Canada Gazette (immediately effective).
Registrant
Prepares and submits supplemental label as a Category C submission
Registrant
Revises supplemental label and submits to PMRA
PMRA
Is label acceptable following review?
No
STEP 6
Changes requested from registrant
Yes
Certificate of Registration issued to registrant; notice of registration and copy of supplemental label sent to sponsor and P/F MUCs
Registrant
Adds use expansion to full label and submits as a Category C submission
Registrant
Revises full label and submits to PMRA
PMRA
Is full label acceptable following review?
No
STEP 7
Changes requested from registrant
Yes
Use expansion added to full label

Appendix IV IMA Request Template

<Date>

Minor Use Coordinator
Compliance, Laboratory Services and Regional Operations Division
Pest Management Regulatory Agency
2720 Riverside Drive
Address Locator: 6605D
Ottawa ON K1A 0K9
Canada

Subject: *[Name of product and active ingredient(s)]* — Request for an Interim Marketing Authorization (IMA) for *[name of crop(s) or livestock]*

Dear *[name of Minor Use Coordinator]*:

SELECT EITHER OPTION 1 OR 2 AS THE IMA REQUEST TEMPLATE, AS APPROPRIATE:

Option 1. Anticipatory IMA request made with the initial URMULE proposal

[Name of sponsor] has made a proposal to the Pest Management Regulatory Agency (PMRA) to amend the registration of *[name of product and active ingredient(s)]* to allow its use on *[names of crops or livestock]* under the URMULE program. Should the proposed use be accepted and if a new maximum residue limit (MRL) needs to be established in Table II, Division 15, of the Food and Drug Regulations to permit the sale of *[names of crops or livestock]* treated with *[name of product and active ingredient(s)]*, I would like to request an IMA to allow the sale of *[names of crops or livestock]* containing residues at a level less than or equal to the proposed MRL while the regulatory process to amend the Regulations is undertaken, if the conditions for issuing an IMA are met.

Option 2. IMA request made following approval of the minor use registration

[Name of registrant] has been informed that the application to amend the registration of *[name of product and active ingredient(s)]* to allow its use on *[names of crops or livestock]* has been approved by the Pest Management Regulatory Agency (PMRA) under the URMULE program. We have also been informed that a new maximum residue limit (MRL) of *[XX]* ppm needs to be established in Table II, Division 15, of the Food and Drug Regulations to permit the sale of *[names of crops or livestock]* treated with *[name of product and active ingredient(s)]*. I would like to request an IMA to allow the sale of *[names of crops or livestock]* containing residues at a

level less than or equal to the proposed MRL while the regulatory process to amend the Regulations is undertaken.

If you have any questions, please contact me at (###) ###-####.

Sincerely,

[Name/Title/Affiliation/Address of requester]