Regulatory Directive DIR99-05

User Requested Minor Use Registration (URMUR)

The purpose of this regulatory directive is to inform registrants, user groups and other interested stakeholders about the Pest Management Regulatory Agency's (PMRA) policy concerning User Requested Minor Use Registration (URMUR).

This document was preceded by Regulatory Proposal Pro97-04 on URMUR, issued for public comments in September 1997. Comments received were considered in the development of this Regulatory Directive.

The purpose of the URMUR policy is to:

- encourage registrants to apply for the registration of products, including biopesticides such as microbials and pheromones, that are registered in the United States or other Organisation for Economic Co-operation and Development (OECD) countries, that due to potential low volume of sales might never be registered;
- ensure that by making use of acceptable foreign reviews completed in other countries, the procedures for the technical review of URMUR applications are as efficient as possible; and
- ensure that registration standards for URMUR applications are appropriate to the use, recognizing the relatively small sales volumes, use volumes and areas of use, as well as the need to maintain Canadian standards of health and environmental protection.

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Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2250 Riverside Drive
A.L. 6606D1
Ottawa, Ontario
K1A 0K9

Internet: **pmra_publications@hc-sc.gc.ca**
www.hc-sc.gc.ca
Facsimile: **(613) 736-3798**
Information Service:
1-800-267-6315 or (613) 736-3799

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1.0 Introduction

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

2.0 Definitions

Candidate Product
A pesticide that is registered in an OECD country, and for which the potential market volume in Canada is not sufficient to persuade the registrant to develop the data required for a Canadian registration.

Foreign Reviews
Foreign reviews are documents written by a regulatory body of a country (e.g., U.S., Australia, Germany, United Kingdom), other than Canada, providing an evaluation of data submitted by registrants in support of registration of a pesticide.

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

Minor Use Coordinator
The minor use coordinator (see Appendix I) is the contact for minor use issues in either a federal or provincial role.

OECD
The OECD is the Organisation for Economic Co-operation and Development in which developed countries participate (e.g., European Union, U.S., Canada).

Registrant
A registrant is the company to which a candidate product is registered.

Sponsor
A sponsor is an individual or an organization representing a user or a user group, and is responsible for identifying a candidate product that should satisfy the user’s need.

Submission
A complete submission consists of application forms, supporting documents, studies/data, and foreign reviews. Submissions for both a technical grade active ingredient (TGAI) and an end-use product (EP) are required for an URMUR.

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

User Requested Minor Use Registration (URMUR)
A User Requested Minor Use Registration of a pesticide is for a use in a use site (for example, in agriculture, forestry, aquaculture or other sectors), such that the potential market volume of the product for that use is not sufficient to persuade the registrant to carry out the additional research required for registration.

3.0 Criteria for Eligibility for URMUR Candidates

All types of products, including traditional chemical products and biopesticides (e.g., pheromones, microbials, etc.) may be eligible for the URMUR program, provided the following criteria are met:

- The pest control product must be intended to meet an identified need, supported by a sponsor/user group.

- The pest control product must comply with the URMUR definition.

- The pest control product must contain an active ingredient that is registered in an OECD country but is not registered in Canada. (Canadian registered pesticides for which minor uses are requested are eligible for the present User-Requested Minor Use Label Expansion Program [URMULE]. Consult Regulatory Directive Dir93-23, *User Requested Minor Use Label Expansion.*)

- Registration of the pest control product in an OECD country must be less than five years old at the time of application, to ensure adequacy of the data base and availability of foreign reviews.

- The registration of the pest control product must not have been previously suspended, cancelled or voluntarily withdrawn in Canada because of health and environmental concerns, or, the pest control product must not have been previously assessed for registration and found to be unacceptable because of health or environmental concerns in Canada and other countries.

- The registrant will submit an URMUR application to the Pest Management Regulatory Agency (PMRA) and serves as the liaison point between the PMRA and the sponsor/user group for registration-related information. The sponsor/user group will work directly with the registrant.

- The registrant will supply foreign reviews from OECD countries along with supporting data/studies.

- The proposed area (i.e., hectarage) and volume of use must be identified.

4.0 Requirements for URMUR Submissions

The PMRA has published various documents containing guidance for preparing submissions and outlining data requirements. Applicants should contact the Pest Management Information Service, PMRA, at 1-800-267-6315 or (613) 736-3799, for these documents. These guidelines are also available on the PMRA web site as downloadable documents at http://www.hc-sc.gc.ca/pmra-arla/qpubs2-e.html. Applicants are encouraged to consult with the Agency prior to making submissions.

Similar to other regular registrations involving a new active ingredient, submissions for the technical grade active ingredient (TGAI) and at least one end-use product (EP) are required. See Appendix II for the elements of a complete URMUR submission. The efficiency of this process depends on the validity, completeness, and availability of foreign reviews and data submitted in support of registration.

The data requirements for an URMUR shall be determined by the Minister in accordance with the *Pest Control Products Act* 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. Where Canadian field studies (field dissipation) are needed to confirm environmental fate and effects, a registration may be approved for a period up to five years, with the sponsor/user group being required to generate the studies during the registration period. Aquatic biotransformation studies will be required only if relevant concerns are identified during the submission review. If required, they may be undertaken and submitted during the registration period. The need to generate additional data to satisfy the requirements of this program will be considered.

In addition, because the PMRA is committed to facilitating the integration of pest management with sustainability and the introduction of new pest management technology, the PMRA will be interested in the potential contributions to sustainability of candidate products.

Following a decision to register an URMUR product for other than a full registration, the sponsor/user group and the registrant will be responsible for the generation of any required supplementary data.

URMUR submissions are also subject to the applicable fees. The registrant may apply for fee exemptions or reduced fees however, based on the nature of the products and the volume of sale. Please refer to the PMRA's *Guidance Document on Pest Control Product Cost Recovery Fees*.

5.0 Procedures for URMUR Submissions

5.1 Proposal by Sponsor/User Group

The first step in any URMUR initiative is the identification of a need by the sponsor/user group. In consultation with the Provincial/Forestry (P/F) Minor Use Coordinator (Appendix I), the sponsor/user group will identify a candidate product and take this concern forward to the manufacturer of the product, the ultimate registrant. The sponsor/user group must provide the registrant with a letter of support indicating the need of such a product and their commitment to contribute to the development of information that may be required for registration. The letter of support should be endorsed by the P/F Minor Use Coordinator. Alternatively, the P/F Minor Use Coordinator may write a separate letter of support attesting that this is a legitimate need of the sponsor/user group. The P/F Minor Use Coordinators are responsible for any additional provincial liaison, e.g., notification of application to provincial regulatory agencies.

5.2 Application for Registration

The registrant will review the proposal of the sponsor/user group and determine whether the candidate product meets the criteria for the URMUR program.

The registrant will submit the registration application to PMRA. The application must include all required elements specified above, including a letter of support provided by the sponsor/user group and the P/F Minor Use Coordinator.

5.3 Assumption of Risk Statement

An assumption of risk statement for performance and crop tolerance should be placed on the EP label. The statement must be acceptable to both the registrant and the sponsor/user group. The assumption of risk statement does not relieve the registrant of any liability in relation to health and environmental risks. An example of such a statement follows:

> **Note to User: Read the Following Before Using this Product:**
>
> The DIRECTIONS FOR USE for this product for the use(s) described on the label were developed by persons other than (**Company Name**) and accepted for registration by Health Canada under the User Requested Minor Use Registration program. (**Company Name**) itself makes no representation or warranty with respect to

performance (efficacy) and/or crop tolerance (phytotoxicity) claims for this product when used in accordance with this label.

Accordingly, the user assumes risk of damage or loss resulting from such use(s), and agrees to hold (**Company Name**) harmless from any claims based on efficacy and/or phytotoxicity in connection with the use(s) described on this supplementary label.

5.4 Processing of URMUR Submissions

Upon receiving a submission for an URMUR, the PMRA will screen the submission to ensure completeness and to verify that the criteria are met.

The duration of the evaluation process for an URMUR product is expected to be approximately one year (see Regulatory Proposal Pro96-01, *Management of Submission Policy*) unless additional data are required to evaluate health risks, environmental risks, or value. The PMRA will propose a regulatory decision based on the review of foreign reviews and/or submitted data. Restrictions on volume of use/area will be considered on a case-by-case basis.

URMUR products will only be eligible for full registration for the specific minor use, amendments, or URMULEs if they conform to the conditions set forth by the registration, including the provision of supplementary data as required.

6.0 Summary

This User Requested Minor Use Registration Policy is designed to:

- encourage registrants to apply for the registration of products, including biopesticides such as microbials and pheromones, that are registered in the U.S. or other OECD countries for which they would not normally be prepared to apply, with sponsor/user groups taking on the responsibility for the generation of any required and supporting information;

- ensure that registration standards for URMUR applications are appropriate to the use, recognizing the relatively small sales volumes, use volumes and areas of use, as well as the need to maintain Canadian standards of health and environmental protection; and

- ensure that the procedures for the technical review of URMUR applications are as efficient as possible by making use of foreign reviews completed by reliable regulators in other countries.

Acronyms

EP	End-Use Product
MAPAQ	Ministère de l'agriculture, des pêcheries et de l'alimentation du Québec
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
TGAI	Technical Grade Active Ingredient
URMULE	User Requested Minor Use Label Expansion
URMUR	User Requested Minor Use Registration

Appendix I Minor Use Registration - Provincial/Forestry Coordinators

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, PEI C0B 1M0 Telephone: (902) 836-8925 Facsimile: (902) 836-8921 E-mail: dreeves@pei.sympatico.ca
Nova Scotia Mr. Lorne Crozier NS Department of Agriculture and Marketing P.O. Box 550 Truro, NS B2N 5E3 Telephone: (902) 893-6545 Facsimile: (902) 893-0244 E-mail: lcrozier@gov.ns.ca Dr. Klaus Jensen Research Station Agriculture and Agri-Food Canada Kentville, NS B4N 1J5 Telephone: (902) 679-5333 Facsimile: (902) 679-2311	**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) 644-4689 Facsimile: (418) 646-0832	**Ontario** Mr. Craig Hunter Ontario Ministry of Agriculture, Food and Rural Affairs 1 Stone Road West Guelph, ON N1G 4Y2 Telephone: (519) 826-3293 Facsimile: (519) 826-3259 E-mail: chunter@omafra.gov.on.ca
Manitoba Ms. Rhonda Kurtz Crop Diagnostic Centre Room 201 - 545 University Crescent Winnipeg, MB R3T 5S6 Telephone: (204) 945-7706 Facsimile: (204) 945-4327	**Saskatchewan** Mr. Doug Billett Sustainable Production Branch Saskatchewan Agriculture and Food Room 133, 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: (403) 422-4909 Facsimile: (403) 422-0783 E-mail: shaffeek.ali@agric.gov.ab.ca	**British Columbia** Ms. Madeline Waring Plant Industry Branch B.C. Ministry of Agriculture, Fisheries 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 Renewal Section 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: irvinem@gov.on.ca	

Appendix II Elements of a Complete Submission to Register an URMUR Pest Control Product

Required Elements include:

- **Covering letter** outlining the purpose and contents of the submission should be included with each submission. It should include the product name, relevant use-site categories, related submissions, and relevant history if applicable. Data or waiver requests should not be included as part of the covering letter.
- **Letter of support** from sponsor/user group, including commitment from sponsor/user group indicating that they are prepared to contribute to the development of the following information that may be required for registration:
    - collecting samples of treated crops/animals for residue determination,
    - providing data on tolerance of crop to proposed treatment,
    - providing laboratory facilities for analysis of samples,
    - development of environmental chemistry and fate laboratory data,
    - development of environmental toxicology laboratory data,
    - development of Canadian field data on dissipation/accumulation, and
    - an assessment of occupational and/or bystander exposure.
- **Letter of support** from provincial/forestry minor use coordinator (by endorsing the letter of support from the sponsor/user group or using a separate letter).
- **Application form** completed, signed and dated.
- **Fee Form** completed, signed and dated, and a cheque payable to the Receiver General for Canada.
- **Product specification form** completed, signed and dated.
- **Letter(s) of authorization** designating agent, formulator, consultant, etc.
- **Letter(s) of authorization** to share data reviews with other countries.
- **Draft label**.

- **Index** of supporting data.

- **Scientific data or studies** supporting the safety and effectiveness of the proposed product, citing previously submitted data or requests for waivers. Supporting data must be organized and numbered according to the PMRA DACO Table or following the OECD format. Data organized in the original format submitted to the OECD countries where the product is registered and the foreign reviews are produced will also be considered if a DACO Table cross-referencing the studies in the original format is provided. If the PMRA format is to be followed, readers should refer to the regulatory document on *Organizing and Formatting Complete Submissions for Pest Control Products* (Pro98-02) or subsequent regulatory directive.

- **Foreign reviews** of the submitted scientific data or studies.

- **Comprehensive data summary** (Tiers II and III) in accordance with the European Commission or OECD guidelines, where available. Refer to Regulatory Directives Dir96-05 and Dir97-01, *Comprehensive Data Summaries*.

Conditionally Required Elements may include:

- **Letter(s) of authorization** to cite data previously submitted by another company.

Note: Submissions for a TGAI product and at least one EP are required for each URMUR.

All supporting information must be submitted in specified electronic and/or paper formats acceptable to PMRA.