



Regulatory Directive

DIR2001-05

Registration of Pesticides for Emergency Use

The purpose of this document is to inform registrants, user groups, government agencies and other interested stakeholders about the procedure for registering pesticides for emergency control of pest infestations where no other efficacious, registered pest control product or alternative method of control exists.

This regulatory directive replaces Regulatory Directive DIR94-05, *Registration of Pesticides for Emergency Use*, dated March 30, 1994.

(publié aussi en français)

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1.0 Introduction

The process outlined in this document addresses emergency pest situations. It is not intended to serve as a regulatory option in ongoing pest problems or where there is an ongoing need for a registered product to fill a void where no registered product is available.

An emergency is generally deemed to exist when the following criteria are met:

- a pest outbreak or pest situation occurs that can cause significant economic, environmental or health problems;
- there is no effective product or application method registered in Canada for the control of the pest; and
- there is no effective, alternative control method available.

Under the provisions of Section 17(1) of the Pest Control Products Regulations, the Minister may register a control product, **for a period not exceeding one year**, for the emergency control of pest infestations that are seriously detrimental to public health, domestic animals, natural resources or other things.

Special terms and conditions, such as additional precautionary label statements, additional studies or post-use monitoring, may be imposed.

Since emergency registrations require and receive immediate attention, consideration will first be given to products that are already registered in Canada and have previously been subjected to a major review. When no acceptable registered product is available, consideration may be given to products (or uses) that are under evaluation, provided the active ingredient is currently registered in Canada. Those products (or uses) with unacceptable health or environmental risks cannot be considered. The emergency use will be considered only if the product is efficacious and risks deemed acceptable. Active ingredients not registered in Canada will not be considered.

2.0 Sponsorship

Emergency registration must be sponsored by the provincial or federal agency involved in the direct management of the pest problem (e.g., the provincial Ministry of Agriculture). The sponsor is responsible for providing the necessary information to the Pest Management Regulatory Agency (PMRA) to support the proposed registration and for obtaining any additional support letters required (see Section 4.0).

3.0 Application for registration

A complete submission, using form PMRA–ARLA/6005(08/2000), and including all information outlined in Section 4.0 below, must be submitted **by the sponsor** to:

The Director
Efficacy and Sustainability Assessment Division
Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, ON K1A 0K9

A copy of the covering letter accompanying the submission must be faxed to:

The Chief Registrar
Pest Management Regulatory Agency
Fax: (613) 736-3707

To ensure that full and early consideration is given to the request, every effort should be made to ensure the application is complete.

4.0 Information requirements

Requests for emergency registration must include the following:

1. **A covering letter** indicating the purpose of the submission.
2. **A completed application form** PMRA–ARLA/6005(08/2000). Separate submissions outlining the situation in each specific province or region must be made. Only in exceptional circumstances will a single submission, made on behalf of more than one sponsoring province, be accepted.
3. **Letters of provincial support** for the emergency use. For provinces with more than one department or agency responsible for pesticide use or regulation (e.g., environment and agriculture), **a letter of support or letter of no objection from both departments is required**. One purpose of the letter is to indicate that, based on the information available to the sponsoring agency (e.g., agriculture), an emergency situation exists. For provinces with more than one agency responsible for pesticide use and regulation (e.g., an environment ministry), the letter indicates that, based on information available to the provinces at the time of the emergency request and the proposal of the sponsoring agency, no specific local or regional concern with the proposed use has been identified. Although provinces will not know what the PMRA's final decision will be at the time they write this letter, it should be noted that the final emergency use, if accepted, is usually equivalent to or is a more restricted version of the initial proposal.

4. **A letter of support from the company is required.** It is the responsibility of the sponsor to ensure any agreements regarding liability of use (e.g., crop tolerance) are resolved prior to a request for emergency registration.
5. **A draft supplemental label** (usually obtained from the company by the sponsor), indicating the proposed use instructions and precautions, rates and all other label requirements applicable to this proposed additional use in for this emergency registration request.
6. **Appropriate fees:** currently CDN\$262, payable to the Receiver General of Canada, normally provided by the sponsor but may be provided by a grower association or other organization.
7. **A thorough description of the emergency situation** should be provided. It must include the following:
 - nature and scope of the problem;
 - an explanation of why the pest was not previously a problem;
 - explanation of when an emergency exists, e.g., when a specific percent of a crop is affected; and
 - rationale indicating how emergency criteria have been met.
8. **Pesticide(s) proposed for use**
 - Common, trade and chemical (International Union of Pure and Applied Chemistry) names for pesticide(s) proposed;
 - Canadian Registration Number or Research Permit Number (the U.S. Environmental Protection Agency [EPA] registration number, if the proposed pesticide is an EPA-registered product);
 - rate and number of applications;
 - application method(s);
 - quantity of active ingredient or product per application;
 - proposed preharvest interval, if for crop use;

- location of pest infestation and proposed treatment (maps or latitudes and longitudes should be provided);
- total hectares (or other units), which should not be in excess of the need to deal with the emergency;
- length of time that the material must be available to cope with the current problem;
- whether adequate supply or inventory of product is available to meet this need; and
- whether products have to be imported or relabelled.

9. Data

- For pesticides in which a food or feed use is proposed and no maximum residue limit (MRL) exists for that commodity in Canada, residue data must be provided. Supplementary data supporting the establishment of tolerances in other countries may be helpful. Registrants are typically helpful in providing residue data and information. It is the responsibility of the sponsor to request this data from registrants and provide it to the PMRA.

NOTE: Emergency registrations of pest control products may require action under other legislation such as the *Food and Drugs Act* and Regulations and can only proceed when all of the applicable legislation has been satisfied. In certain cases, the time constraints for appropriate evaluation and establishment of MRLs for food uses under the *Food and Drugs Act* and Regulations may preclude the support of the request for emergency registration under the *Pest Control Products Act* and Regulations.

- Data supporting the efficacy of the proposed product(s) and other health or environmental data may be required.

If the sponsor is relying on data previously submitted to the PMRA, the data should be referenced by citation of appropriate Canadian Registration Number or Submission Number.

10. Benefits and losses

Applicants should discuss the anticipated benefits, economic or otherwise, and losses that would occur with and without the emergency registration. For example, the discussion of economics for agricultural uses should include the following:

- the cost of production of crop over the past four years and an estimation for the upcoming crop year;
- the crop yields over the past four years, and a comparison of expected yield with and without the proposed treatment;
- the price received for crop (in appropriate units) over the past four years and an estimation of the price for the upcoming season;
- an estimation of the percentage of the pest controlled with registered pesticides over the past four years;
- an estimation of percentage of the pest expected to be controlled during the upcoming crop year with registered pesticides and with the pesticide proposed for emergency registration; and
- the resulting comparison of expected value of crop, with and without the proposed treatment.

If the information is not available (e.g., in cases of the occurrence of a new pest at an established site), an applicant should explain the lack of availability of information and discuss anticipated economic benefits and losses in other appropriate terms.

For emergency uses other than agriculture, a comparison of expected impact with and without the proposed treatment should be provided.

11. Discussion of currently registered pesticides and alternative control methods

All pesticides currently registered for the stated site and pest combination, as well as all relevant alternative control measures, must be identified. Also, an in-depth explanation must be given explaining why these are ineffective or cannot be used to cope with the emergency. It is important that the explanation fully cover the ineffectiveness or lack of availability of registered pesticides and that, where possible, empirical data supporting ineffectiveness be submitted.

12. Emergency registration in subsequent years

Emergency registrations are not intended as a solution to an ongoing pest management problem. Occasionally, an emergency situation may exist in a subsequent year. In the absence of long-term interest by the registrant, and evidence that users and the sponsoring agencies are actively working towards satisfying the data and information requirements for a long-term solution (i.e., registration), emergency registration for a third year will not normally be considered.