



Regulatory Proposal

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Consultation on Revised Procedures for the Registration of Pesticides for Emergency Use

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Table of Contents

Consultation foreword	1
1.0 Introduction	1
2.0 Sponsorship	3
3.0 Organizing an emergency registration application	3
3.1 Administrative and regulatory requirements	4
3.2 Labels.....	4
3.3 Value information.....	5
3.4 Other information	7
4.0 Emergency registration in subsequent years.....	7
5.0 Multi-year emergency registrations to manage pests of environmental concern	8
6.0 Application submission	8
Appendix I	10
Table 1 Checklist of the information required for an emergency registration application...	10

Consultation foreword

This document contains proposed guidance for registering pesticides or amending registrations for emergency control of seriously detrimental pest infestations. Where currently registered pesticides and non-chemical control methods or practices are insufficient to address the pest outbreak, the Pest Management Regulatory Agency (PMRA) will consider requests for registration of pesticides for emergency use.

The information proposed in this document is intended to replace the current DIR2017-03, *Registration of Pesticides for Emergency Use: Revised Procedures*, dated 31 August 2017.

This document is open for public consultation for 60 days from the publication date. The PMRA will consider all comments received before finalizing the guidance document.

The final guidance is intended to be read in conjunction with the *Pest Control Products Act* and the Pest Control Products Regulations.

Please forward all comments to PMRA Publications, through the Public Engagement Portal (Public Engagement Forms – Consultation Comment), and include:

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

1.0 Introduction

Under section 18 of the Pest Control Products Regulations, the Minister of Health may register a pest control product or amend the registration of a pest control product to permit its use for the emergency control of a seriously detrimental pest infestation. The default validity period for emergency registrations is up to one year. Under conditions described below (see Section 5.0), a validity period of up to three years may be granted for the emergency control of seriously detrimental pests of specific environmental concern.

The process outlined in this document addresses emergency pest situations only. Emergency registrations are not a tool for early or extended access to pest control products (pesticides) not currently registered for that use. For known or ongoing pest problems where no registered product is available, the regular registration processes in place to address such situations are recommended.

Section 18 of the Pest Control Products Regulations permits the emergency registration of a pest control product for the “control of a seriously detrimental infestation.” Health Canada interprets “seriously detrimental infestation” to mean a pest outbreak or situation where the following criteria are met:

- 1) the situation is unmanageable, and
- 2) the situation is expected to cause significant health, environmental or economic impacts.

In determining whether these criteria are met, Health Canada considers all available information, including whether currently registered pest control products, physical control methods, or other pest management practices are insufficient to address the situation.

Examples of emergency pest situations may include but are not limited to:

- invasion by a new pest organism,
- a sudden and significant increase in pest pressures due to environmental or other conditions, or
- the need for an alternative application method due to adverse weather conditions.

When an emergency pest situation persists beyond the expiry date of the original emergency registration, a new emergency use application may be submitted for the same pest. See Section 4.0 for additional information on subsequent requests for emergency registration of the same use.

Emergency registration requests for agricultural uses are typically limited to a single specific crop. In certain scenarios, multiple crops may be considered. For example, in a case where a seriously detrimental infestation affects more than one crop from a recognized crop group in the same way, a single emergency use request may be acceptable provided the use pattern is identical and the added crops do not necessitate additional risk assessments. Applicants are strongly encouraged to consult with the PMRA prior to the submission of any emergency use request when multiple crops are considered.

As a condition of the emergency request, the PMRA may impose special terms or conditions on the emergency use, such as:

- additional precautionary label statements,
- personal protective equipment,
- specific application equipment or engineering controls, or
- the requirement for additional studies or post-use monitoring activities.

Failure to adhere to all applicable conditions of the emergency registration may result in Health Canada taking enforcement action under the *Pest Control Products Act*.

Because emergency registrations require a short turnaround time, consideration will be given first to products that are registered in Canada for which the risks to human health and the environment have been assessed previously. When no Canadian-registered product is available, consideration may be given to products registered in other jurisdictions, provided the active

ingredient is registered in Canada. The emergency use will be considered only if there is evidence that the health and environmental risks are acceptable, and the product has acceptable value in addressing the emergency pest situation.

2.0 Sponsorship

Emergency registrations are generally sponsored by the provincial, territorial or federal authority that supports the management of the pest problem (for example, a provincial Ministry of Agriculture or the Canadian Food Inspection Agency). The individual representing the sponsoring organization, henceforth referred to as the **sponsor**, is responsible for compiling and submitting a complete submission package that includes all the required information described in Section 3.0 of this guidance document. The sponsor serves as the primary contact throughout the application process and are also responsible for discussing the application with all relevant ministries from each participating province and resolving any concerns or issues before submitting to the PMRA.

3.0 Organizing an emergency registration application

The following subsections outline the information required for a complete emergency registration application. In addition to the administrative requirements (letters, forms and labels), all technical information, including the supporting health, environmental and value information, should be organized under the headings listed. Review Appendix I for a submission checklist.

Applicants considering a request for a first-time emergency registration should notify the PMRA prior to submission to discuss the details of the emergency situation to determine if it meets the eligibility criteria and other requirements.

For all emergency registration applications, sponsors should notify the PMRA after completing the electronic submission by sending an email to the PMRA emergency registration central email inbox:

pmra.emergency.registration-arla.homologation.d.urgence@hc-sc.gc.ca

The email should include a copy of the ePRS submission confirmation notice. If the PMRA is not notified of the electronic submission of the emergency registration application, there may be delays in processing the submission.

For guidance, inquiries or notifications related to an emergency registration application, prospective sponsors (provincial/territorial and federal partners involved in the preparation of emergency registration applications) should also contact the PMRA through the emergency registration central email inbox.

General inquiries related to the emergency registration process should continue to be directed to the PMRA's Information Service.

3.1 Administrative and regulatory requirements

A cover letter, all required forms, letters of support or declaration forms, the processing fee, and draft supplemental labels must be submitted with the emergency registration application. A checklist of the required information can be found in Appendix I.

Letters and declaration forms

All documents described under “1.0 Administrative Requirements” in Appendix I, Table 1 are required for each application. Letters of support from grower groups or associations may also be included as additional supporting information.

The cover letter from the sponsor must explain the purpose of the application. The letter from the registrant must indicate support for the proposed emergency use of their product and confirm that there is sufficient product available to address the emergency for the period required. Any issues from the registrant regarding the liability of use (for example, efficacy or crop tolerance) must be resolved by the sponsor prior to submission of the application.

A signed declaration indicating no-objection from the authority responsible for pesticide regulation (for example, the ministry of environment) must be provided for each province/territory listed on the emergency use application. These declarations ensure that the relevant authorities are informed of the application and are not aware of any issues that would preclude the emergency use as requested. In cases where repeated applications (see Section 4.0) are anticipated, provincial/territorial authorities may indicate their non-objection on declaration forms for a period of up to three years. To reduce unnecessary administrative burden on sponsors of emergency registrations, subsequent applications that are submitted during this three-year period may then refer to the declaration forms submitted as part of the first-time emergency use request, provided no changes are made to the conditions under which the emergency registration was initially granted.

In certain circumstances, additional letters of support or declarations of no-objection may be required by the PMRA and requested following submission.

3.2 Labels

The sponsor must obtain draft emergency use labels in both English and French, in MS Word format, from the registrant and submit them to the PMRA. Only information directly related to the emergency use can appear on the emergency use labels, and reference to all other uses must be deleted. The labels must clearly indicate the proposed directions for use related to the emergency use, including precautions, restrictions and all other label requirements set out in the *Pest Control Products Regulations*.

The front panel of the labels must state “For Emergency Use Only”, indicate the nature of the emergency use, list the participating province(s) or territories, and indicate the requested start and end date of the emergency registration validity period.

Example: “**FOR EMERGENCY USE ONLY.** For sale and use only in British Columbia to suppress cotton ball rot on cranberry, from 1 July 2025 until 30 September 2025.”

Health and Environmental Information

The PMRA will use all available relevant information in its possession to support the health and environmental assessments. In addition, information may be required under the Health and Environmental Information section of the application as specified below.

Human activities associated with the emergency use of the product

Additional information specific to the emergency registration application may be required regarding mixer/loader/applicator and/or post application activities.¹

Crop residue data

For emergency registration requests in which a food or feed use is proposed, relevant residue data (either in PMRA’s possession or provided by the applicant), must demonstrate the level of residues anticipated in the crops when treated according to the proposed use pattern.

During the review of an emergency registration, the agency will determine a residue limit that is specific for the pesticide-commodity combination use within the context of the emergency registration. The PMRA will notify the relevant stakeholders accordingly.

Relevant environmental information

Additional information on environmental exposure specific to the emergency registration request may be required.

3.3 Value information

The following information must be provided under the Value information Section of the application.

Description of emergency situation

In the dossier of information supporting the application, a description of the nature and scope of the pest problem, including geographical distribution of the pest infestation, must be provided.

¹ For additional information, refer to Guidance for Developing Datasets for Conventional Pest Control Product Applications (DACO Part 5.2) <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/guidance-developing-applications-data-codes-parts-1-2-3-4-5-6-7-10.html>

Rationale for emergency use

The sponsor must describe how the application meets both criteria for an emergency use described in Section 1.0 for each participating province. It must include a rationale addressing why the pest outbreak is a seriously detrimental infestation with respect to health or the environment, or why it would result in significant economic loss.

The rationale should also address why the pest was not considered to be a problem in recent years, and why the situation cannot be resolved either with the currently registered alternatives or through registration via the normal regulatory process.

The sponsor must also justify why the emergency use is required for the requested period. If the application proposes a validity period longer than one year, the rationale must explain how the request meets the criteria described in Section 5.0.

Description of proposed product and use pattern

A summary of the proposed product and use pattern must be provided with the following information:

- The common, trade and chemical (International Union of Pure and Applied Chemistry) names for pesticide(s) proposed,
- The *Pest Control Products Act* registration number(s),
- The application rate (of both the product and active ingredient),
- Maximum number of applications per year or crop cycle,
- Number of crop cycles per year (if applicable),
- Initial application timing,
- Application intervals,
- Application method,
- Re-entry interval, and
- Pre-harvest interval (if for crop use).

The applicant is encouraged to provide this information in table format. If the rationale is based on the product being approved for the same use in another country, the foreign registration number and a copy of the foreign label must be provided.

Registered alternatives and cultural control methods

The sponsor should provide the product names, registration numbers, and indicate the type of control measure (for example, conventional or non-conventional pesticide, pheromone) for any alternative end-use products, as well as any cultural control methods and an explanation why these are insufficient to manage the pest outbreak. The sponsor is encouraged to provide this information in table format.

Evidence is required to support any justification for emergency use based on resistance to registered alternatives.

Explanation for choice of product and proposed use pattern

The sponsor should describe what level of pest management is required to mitigate the outbreak and provide evidence that the product will deliver an acceptable level of pest control when applied as proposed. Efficacy data (including foreign data), use history, scientific rationales or other scientific information to address product performance, resistance management and crop tolerance (where applicable) may be provided.

Emergency uses with a realistic prospect of full registration must be prioritized in the choice of product whenever possible. The value assessment for first-time emergency use requests will take into consideration information provided in this section regarding intended actions and anticipated timelines to obtain full registration of the subject use.

Description of social and economic impacts

The sponsor should discuss the anticipated economic, social, and environmental costs that may occur without the emergency registration. For agricultural emergency uses, a description of crop value should be included, as well as the expected percent field loss or percent economic loss of gross or net revenues without the emergency registration. For non-agricultural emergency uses, the impact of not accessing a pest control product should be described, including the potential ecological loss or any impacts on the environment or human health.

3.4 Other information

Other information related to the emergency use may be requested during the assessment period, including information such as if the product must be imported for use, and the need for Canadian labels prior to distribution and use within Canada. Products being imported into Canada must be accompanied by the Canadian emergency label.

Emergency registrations may require additional supporting information or action under other legislation such as the *Food and Drugs Act* or the *Fisheries Act*. The granting of an emergency registration allows a product to be imported, distributed and used under the *Pest Control Products Act*, but it is the responsibility of the registrant or the sponsor to ensure that any other applicable legislation has been satisfied.

4.0 Emergency registration in subsequent years

Where the pest infestation is likely to remain an ongoing issue in future years, the PMRA expects the sponsor and registrant to prioritize the pest issue and pursue full registration of the use through normal regulatory processes as soon as possible. If the pest situation persists beyond the initial emergency registration period, a new emergency registration application with all documentation listed above and an up-to-date information package must be submitted for review. It is requested that the new submission also include a justification for the continued need for the emergency registration, any changes to the emergency situation along with an update on the progress made towards full registration of the use or finding a different long-term solution to the problem. If the process towards registration through regular procedures has not been initiated,

confirmation (for example, a submission number) of a pre-submission request from the product registrant for the subject use should be provided. Additionally, the use should be prioritized at the Minor Use Priority Setting Workshop within the participating province(s) to demonstrate the ongoing need for the registration, where applicable. In order for an emergency use request to be granted, the new emergency application must meet the criteria of an emergency pest situation, as described above.

Similarly to first-time emergency use requests, value assessments of requests for emergency registration for the same use in subsequent years will take into consideration submitted information regarding progress towards full registration.

5.0 Multi-year emergency registrations to manage pests of environmental concern

Under paragraph 18(a) of the Pest Control Products Regulations, validity periods for emergency registrations of up to three years may be granted. Multi-year validity periods will be considered by the PMRA only when the registration is intended to prevent the establishment of a new invasive species (for example, as a component of an Early Detection Rapid Response program) or control a pest posing other environmental concerns (for example, threat to biodiversity, species-at-risk). Exceptions to the default one-year validity period will be considered in these cases on account of the lack of a facilitated regulatory pathway for full registration (for example, not eligible for the User Requested Minor Use Label Expansion program) and regulatory burden that is substantially higher than is typically associated with emergency registrations (for example, lengthy public consultations before use). These uses are expected to be overseen by a governmental or other public organization.

In addition to the requirements for one-year emergency registrations described in Section 3.0 of this guidance document, any sponsor requesting multi-year emergency registrations must include in their application an implementation plan (or Early Detection Rapid Response program) that justifies an extended validity period. This information should be included in the Value Information described in Section 3.3.

The sponsor will be requested to submit annual updates confirming that the pest outbreak continues to meet emergency criteria and detailing on-going efforts for registration through normal regulatory channels. Annual updates can be submitted directly to the PMRA via the contact information provided in the original emergency registration letter. No additional fees are associated with the submission of the annual updates.

6.0 Application submission

All information pertaining to the emergency registration application must be compiled by the sponsor and submitted to the PMRA using the Electronic Pesticide Regulatory System (e-PRS) Secure Web Portal, or sending the PMRA Regulatory Zip (PRZ) file to:

pmra.docs.arla@hc-sc.gc.ca

Information regarding this process can be found on the Electronic Pesticide Regulatory System (e-PRS) page on Canada.ca website.

The review process cannot be completed until all supporting information has been received.

The application is to include the following forms:

- Application for New or Amended Registration form (PMRA/ARLA 6005)
- Fee Estimate form (PMRA/ARLA 6011) for the current fiscal year
- Proposed New Uses and/or Uses to be Withdrawn from the Label form (PMRA/ARLA 6023)
- A Statement of Product Specification form (PMRA/ARLA 6003) is required for the proposed use of any end-use product not currently registered in Canada

Please ensure that the latest version of the forms are used in the emergency registration application.

The application form (PMRA/ARLA 6005) should show that it is for an Emergency Registration by indicating “emergency use” next to “Other:” in section B under Purpose of Application (Section 11). To avoid delays, please ensure the accuracy of the information provided under Submission Contact (in other words, the sponsor’s contact information).

Invoicing

Payments are no longer to be submitted to PMRA at the time of application. Do **not** send payment with the application and fee estimate form. Once both forms are received, Health Canada will send an invoice for payment to the indicated party on the fee form. Payment can only be accepted after the official invoice has been sent out.

Fees and the invoice number will be specified on the invoice issued by Health Canada. These will be required when making payment.

Fees for emergency registrations are normally paid by the sponsoring organization. In instances where a different party (for example, grower association or other stakeholders) intends to pay the fee, 1) they should be identified as the payer on the fee form (PMRA/ARLA 6011) and 2) their complete contact information must be added to the “Submission Contact” section of the application form alongside the sponsor’s information. To avoid confusion and delays in invoicing, please ensure that the payer’s contact information on the application form is easily differentiated from the sponsor’s (for example, marked as “FOR INVOICING”).

Updated information on payment options will be provided with the invoice.

Appendix I

Table 1 Checklist of the information required for an emergency registration application.

1.0 Administrative requirement	<input checked="" type="checkbox"/>
Cover letter from the sponsor. This letter must include the email information for all parties supporting the emergency registration application.	
Letter of registrant support	
Letter of provincial/territorial support from the department ² responsible for pesticide use (for example, Ministry of Agriculture, Ministry of Health)	
Declaration form ² from the department responsible for pesticide regulation (for example, Ministry of Environment)	
Application form (PMRA/ARLA 6005)	
Proposed New Uses form (PMRA/ARLA 6023)	
Fee Form (PMRA/ARLA 6011)	
Statement of Product Specification Form (PMRA/ARLA 6003); applicable only for end-useproducts not currently registered in Canada	
Draft English emergency use label in MS word format	
Draft French emergency use label in MS word format	
2.0 Technical Information	<input checked="" type="checkbox"/>
Health and environmental information	
Human activities associated with emergency use of the product	
Crop Residue Data (if applicable)	
Relevant Environmental Information	
Value information	
Description of emergency	
Rationale for emergency use	
Description of proposed product and use pattern	
Summary of registered alternatives (table format)	
Explanation for choice of product and use pattern	
Description of socio-economic impact	

² For provinces or territories with more than one department responsible for pesticide use, a letter of support and declaration form from each department are required. See section 3.1

Other information	<input checked="" type="checkbox"/>
Requirements for product importation or re-labelling	
Information on progress towards full registration of the use through normal regulatory channels ³	

³ Required for any request for the same emergency use in subsequent years