Regulatory Proposal PRO2021-01

Labelling of formulation preservatives

(publié aussi en français)

16 February 2021

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

ISSN: 1197-740X (print)
1925-122X (online)

Catalogue number: H113-8/2021-1E (print)
H113-8/2021-1E-PDF (PDF version)

Canada

Executive summary

The Pest Management Regulatory Agency (PMRA) is proposing to remove the requirement for labelling of formulation preservatives as described in Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*. This Proposal is being distributed for information and for public comment. After consideration of comments received, an amendment to DIR2006-02 will be published and the policy will be implemented.

Background and issue

Regulatory Directive DIR2006-02 outlines Health Canada's PMRA policy on the regulation of formulants contained in pest control products. The PMRA ensures that information on formulations and identification of formulants are accurate and meet current standards. Since the implementation of the policy, the PMRA has ensured that many toxic formulants in registered pesticides have been eliminated or replaced with less hazardous alternatives. This outcome is aligned with the Minister of Health's primary objective under the *Pest Control Products Act* to prevent unacceptable risks from the use of pest control products to human health and the environment.

As part of its comprehensive review of the Pest Control Product Regulations, Health Canada strives for efficiencies to ensure that regulations continue to meet program objectives while minimizing administrative burden on regulated parties and government. Where necessary, it recommends policy, program or regulatory amendment to ensure alignment between regulations and operations.

Labelling requirements for formulation preservatives

A formulation preservative is added to another pest control product to protect the formulation from degradation or denaturation by pests. Examples include material preservatives added to agricultural formulations or insecticides added to rodenticide baits. DIR2006-02 currently requires that preservatives that are pesticide active ingredients be listed on the product label.

Preservatives that function by killing pests are "pest control products" under the *Pest Control Products Act*. The active ingredients that they contain are required to be registered, unless they are otherwise authorized (see paragraphs (a) and (b) of the definition of "pest control product" and subsection 6(1) of the *Pest Control Products Act*). **The end-use products derived from these active ingredients must similarly be registered with the PMRA and approved for use as preservatives in other pest control products.**

While the preservatives are intentionally added to another pest control product to preserve its quality, they are not responsible for that product's intended primary effects. An example is the addition of an insecticide at 0.1% to a rodenticide bait to prevent spoilage by insects. The function of the preservative in this context is not consistent with the *Pest Control Products Act*, where "active ingredient" is defined as "that ingredient to which effects of the control product are attributed". These preservatives are added to other pest control products as a formulant to protect the formulation from degradation or denaturation by pests.

Therefore, they meet the definition of "formulant" rather than "active ingredient". Formulants are not required to be listed on the principal display panel of the pest control product to which they are added.

The PMRA is proposing to no longer require label identification of active ingredients that are present in another pest control product as a formulation preservative. This policy change is the result of a review of the overall benefits and risks related to the use of the preservatives in that context. The PMRA has determined that preservatives do not fit within the definition of "active ingredient" when used in another pest control product, as they are not a component to which the intended effects of the product are attributed and are not primarily responsible for the product's effects. Label disclosure is still required for allergens and List 1 formulants of toxicological concern.

The removal of the labelling requirement for preservatives would not lead to any change in risk to human health and the environment, as the pest control product – like all pesticide products registered at the PMRA – would still be assessed for health and environmental concerns: label statements related to directions of use, precautions and protective equipment requirements would not change.

When this policy is in effect, registrants may amend their labels at the next opportunity to remove the preservative statement, but will not be required to do so.

Amendments to Regulatory Directive DIR2006-02

Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document* specifies requirements for formulation preservatives used in pest control products. It states that formulation preservatives must be identified on the Statement of Product Specifications Form (SPSF) under "purpose" and on the pest control product label (Part II Guidance on How to Comply with the Formulants Policy, Section 6.3.1 of DIR2006-02). It mandates that a letter of confirmation of source of supply be provided for preservatives (Part II, Section 6.3.2 of DIR2006-02), and states that formulation preservatives are subject to registration under the *Pest Control Products Act* (Part II, Section 6.3.3 of DIR2006-02).

For end-use products formulated from various source products, the preservative statements can become cumbersome, particularly when there are multiple possible combinations of preservatives at varying levels. With the proposed change, preservatives will still be identified on the SPSF for both new and amended product submissions, but they would no longer appear on the product label.

Removing the label requirement would simplify the labelling process resulting in cost savings for regulated parties and the government while ensuring that program objectives are met with reduced administrative burden. Registrants would still have to identify the formulants and their functions on the SPSF, as only registered formulation preservatives can be used.

The following Sections of DIR2006-02 would be affected when this change in policy is in effect:

Part I

4.13 Labelling Requirements for Formulation Preservatives

The label requirement outlined under this section would no longer apply. The PMRA has determined that preservatives do not fit within the definition of “active ingredient” when used in other pest control products as they are not a component to which the intended effects of the product are attributed and are not primarily responsible for the product's effects.

SPSF revisions related to formulation changes (for example, change in preservative identity, concentration or source of supply) and provision of associated letters of confirmation of source of supply would continue to be required under an amendment submission.

Part II Guidance on How to Comply with the Formulants Policy

4.1 Labelling Disclosure Deadlines for Allergens and Formulation Preservatives

The label requirement outlined under this section would no longer apply. Requirements related to allergen disclosure in DIR2006-02 remain unchanged.

6.3 Formulation Preservatives
6.3.1 Formulation Preservative Disclosure on the SPSF and Label
6.3.2 Label and SPSF Amendment Submission Timelines
6.3.3 Registration of Preservatives

The PMRA has determined that preservatives do not fit within the definition of “active ingredient” when used in other pest control products as they are not a component to which the intended effects of the product are attributed and are not primarily responsible for the product’s effects. Therefore, for this scenario, they would be considered as formulants and would require listing only on the SPSF, not on the label.

6.6.3 Label Disclosure for Products with Multiple Formulations

The label requirement outlined under this section would no longer apply. Requirements related to allergen disclosure in DIR2006-02 remain unchanged.

Next steps

Health Canada's PMRA is inviting interested Canadians to submit their views on the amendment of DIR2006-02, related to the labelling requirement of formulation preservatives.

Health Canada will consider all comments received before finalizing its position. **Please provide your comments and include the following information:** your full name and organization, telephone number, and complete mailing address or email address.

Written comments on this proposal will be accepted up to **60 days from the date of publication**. Please forward all comments to PMRA Publications. (Contact information can be found on the cover page of this document.)