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Regulatory Proposal

PRO2020-01

Streamlined Category B Submissions and Tank Mix Labelling

(publié aussi en français)

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1.0 Introduction

On 31 July 2002, Health Canada's Pest Management Regulatory Agency (PMRA) published Regulatory Note REG2002-04, *Category C Submission Efficacy Reviews*. The purpose of this new Regulatory Proposal is to clarify the eligibility and conditions for Streamlined Category B Submissions, which have replaced Category C Submission efficacy reviews. This Regulatory Proposal will also clarify and consolidate guidance related to tank mix labelling, and proposes consequential amendments to other documents published by the PMRA.

2.0 Streamlined Category B Submissions

With the publication of Regulatory Directive DIR2017-01, *Management of Submissions Policy* (8 March 2017), new terminology was introduced for submissions with a limited number of amendments, and requiring only a value assessment: Streamlined Category B Submissions. These types of submissions were formerly termed Category C Efficacy Reviews.

Based on review capacity and experience evaluating these types of submissions since the publication of REG2002-04, the PMRA is proposing to increase the number of label amendments permitted within one of these submissions to six (6).

The nature of the types of label amendments that are eligible for a Streamlined Category B Submission has not changed from REG2002-04. However, a new standard label statement related to tank mixing, further to the addition of specific tank mix combinations, is being proposed as being an eligible amendment (see Section 3).

Appendix I of this document presents the proposed eligibility and conditions for Streamlined Category B submissions. In addition, the PMRA is proposing to make the corresponding amendments to guidance related to tank mixing in other published documents.

3.0 Tank Mixes

3.1 Tank Mix Labelling

Historically, each specific permitted tank mix combination was added to a product label, following review and approval by the PMRA. On 27 October 2009, the Memorandum to all applicants, registrants and their regulatory representatives regarding the use of unlabelled tank mixes of commercial class pest control products used for crop production or vegetation management was published. In that document, it was indicated that users of commercial class products used for crop production or vegetation management were permitted to use unlabelled tank mixes, subject to certain conditions. Those conditions ensured that the tank mix use was consistent with the directions for use for each of the tank mix partners, when used alone. The memorandum generated several questions from stakeholders, and a frequently asked questions document was published on 3 November 2010 to provide clarifications.

Updated guidance related to tank mixing was next published in Regulatory Directive DIR2016-02, *Notification/Non-notification*, on 16 May 2016. This directive provides guidance on the addition of tank mixes to a product label via notification (Section 3.10). Essentially, the same tank mixes within the scope of the 2009 memo could be added to a label as a notifiable change. In addition to this, DIR2016-02 provides for the addition of a general label statement related to unlabelled tank mixes as a non-notifiable change (Section 7.11).

3.2 Tank Mix Policy – Clarification

Paragraph 6(5)(b) of the *Pest Control Products Act* states that no person shall use a pest control product in a way that is inconsistent with the directions on the label. As a result, if a label contains no guidance related to tank mixing, then tank mixes are not permitted.

In order to clarify and consolidate guidance related to tank mix labelling, the PMRA proposes the following changes to relevant documents:

- Rescind the 27 October 2009 Memorandum on unlabelled tank mixes;
- Rescind the 3 November 2010 frequently asked questions document on unlabelled tank mixes;
- Revise Section 2.4.5 of the *Value Guidelines for New Plant Protection Products and Label Amendments* (14 April 2016) to remove reference to the 27 October 2009 memorandum;
- Revise Section 3.10 of DIR2016-02, *Notification/Non-notification* to delete the portion of the section related to tank mixes for crop production or vegetation management not labelled on any product;
- Delete Section 7.11 of DIR2016-02, *Notification/Non-notification* to remove the standard label statement that is currently a non-notifiable label change. This statement is as follows:

“In some cases, tank mixing a pest control product with another pest control product or a fertilizer can result in biological effects that could include, but are not limited to: reduced pest efficacy or increased host crop injury. The user should contact [*insert registrant name*] at [*insert contact information*] for information before mixing any pesticide or fertilizer that is not specifically recommended on this label. The user assumes the risk of losses that result from the use of tank mixes that do not appear on this label or that are not specifically recommended by [*insert registrant name*].”; and

- Update REG2002-04, *Category C Submission Efficacy Reviews*, as presented in Appendix I of this document, noting the introduction of the following new general label statement related to tank mixing:

“This product may be tank mixed with a fertilizer, or with registered pest control products, whose labels also allow tank

mixing, provided the entirety of both labels, including Directions For Use, Precautions, Restrictions, Environmental Precautions, and Buffer Zones are followed for each product. In cases where these requirements differ between the tank mix partner labels, the most restrictive label must be followed. Do not tank mix products containing the same active ingredient or mode of action unless specifically listed on this label.

In some cases, tank mixing pest control products can result in reduced pesticide efficacy or increased host crop injury. The user should contact [*insert registrant name*] at [*insert contact information*] for information before mixing any pesticide that is not specifically recommended on this label.”

These changes will ensure consistency in the guidance to stakeholders regarding labelling requirements for tank mixes. The removal and amendment of the above documents will take place after this consultation, in consideration of any comments received.

Once implemented, specific tank mix combinations or the new general label statement related to tank mixing could be added to a label through existing application processes (for example, as a standard or a streamlined Category B submission), with supporting information as required. Any labels containing the tank mix statement from Section 7.11 of DIR2016-02 would need to be amended to remove that statement in the next submission for that product, or at next label printing. Registrants would be permitted to provide more detailed guidance to users of pest control products for tank mixes that include only products whose labels contain the new general label statement related to tank mixing. Any additional guidance would need to be consistent with the provisions of Regulatory Directive 2016-01, *Guidelines for the Advertising of Pest Control Products*.

Users of pest control products would have the option of applying tank mixes that are specifically identified on product labels, as well as applying tank mixes of products where each tank mix partner label contains the new general label statement related to tank mixing, provided all requirements (for example, conditions, restrictions and directions for use) on the labels are followed.

4.0 Next Steps

The PMRA invites the public to submit written comments on this proposal up to 60 calendar days from publication. The PMRA will consider all comments received during the 60-day consultation period. Please forward all comments to PMRA Publications with the following information:

- your full name and organization,
- telephone number, and
- complete mailing or e-mail address.

Appendix I – Proposed Eligibility and Conditions for Streamlined Category B Submissions

1.0 Eligibility:

Category B submissions that require only value (Part 10) information are eligible for review as Category B Streamlined submissions, provided that the request concerns:

- a decrease in the use rate;
- an increase in the level of control (for example, upgrading to control from suppression);
- the addition of a pest;
- the addition of a tank-mix; or
- the addition of the general label statement related to tank mixing found below.

2.0 Conditions:

- The total amount of product applied to the crop does not increase as a result of the amendments (for example, no increase in application rate and/or number of applications per year).
- Products proposed for use in tank-mixes must each be registered for the specific use site/crop when applied individually; the application rate when applied as a tank mix partner cannot exceed the application rate when the product is used alone.
- All tank-mix partners must already be registered for the timing (for example, pre-emergent, post-bloom) and method of application (for example, soil drench, foliar, aerial) proposed in the tank-mix directions.
- The following general label statement related to tank mixing may be proposed:

“This product may be tank mixed with a fertilizer, or with registered pest control products, whose labels also allow tank mixing, provided the entirety of both labels, including Directions For Use, Precautions, Restrictions, Environmental Precautions, and Buffer Zones are followed for each product. In cases where these requirements differ between the tank mix partner labels, the most restrictive label must be followed. Do not tank mix products containing the same active ingredient or mode of action unless specifically listed on this label.

In some cases, tank mixing pest control products can result in reduced pesticide efficacy or increased host crop injury. The user should contact [*insert registrant name*] at [*insert contact information*] for information before mixing any pesticide that is not specifically recommended on this label.”

- A maximum of six (6) label amendments are allowed within one submission. For example:
 - The addition of six (6) new pests; or
 - a decrease in the application rate for three (3) pests already on the label and the addition of three (3) new pests; or
 - the addition of one (1) tank mix that is proposed to control five (5) pests that do not already appear on either tank mix partner label, etc.