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Regulatory Proposal

PRO2014-01

# Phase II: Notification/ Non-notification

*(publié aussi en français)*

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## **1.0 Introduction**

### **1.1 Purpose**

As mentioned in the Notification/Non-notification Regulatory Directive (DIR2013-02), the Pest Management Regulatory Agency (PMRA) is committed to ongoing review and analysis of its submission policies. As the Agency identifies further product changes appropriate for notification or non-notification, the PMRA will strive to keep the policy current.

The PMRA invites the public to submit written comments on these proposed revisions to the Notification/Non-Notification Directive for up to 30 days from the publication of this document. Please forward all comments to PMRA Publications. Before making a final decision, the PMRA will consider all comments received in response to this consultation document.

### **1.2 Background**

On 15 April 2013, DIR2013-02, *Notification/Non-notification*, revised and superseded the previous Regulatory Directive (DIR2001-04) by expanding the previous directive and clarifying the process for changes that could be made through either a notification or non-notification (the PMRA does not need to be notified) process. This latest revision (Phase II) further expands the changes that can be made through notification.

The PMRA is confident that the changes in this proposal will improve efficiencies for registrants and the Agency, while maintaining the Agency's mandate to protect human health and the environment.

### **1.3 Highlights of changes**

Changes that are reflected in this proposal include:

- addition of a tank mix;
- changes to rotational crops (addition or removal) and plant-back intervals (increase or removal);
- changes to application rate, when based on a precedent with identical formulation;
- changes to application timing, when based on a precedent with identical formulation;
- changes to application number or frequency, when based on a precedent with identical formulation;
- changes to application method, when based on a precedent with identical formulation;
- certain changes to precautionary statements; and
- changes in source of starting materials that are not commodity chemicals.

## 1.4 Provisos

This document includes only those sections of the 2013-02 Regulatory Directive (i.e. under Section 3.0, Notifiable Label Changes, and Section 4.0, Formulation/Specification-related Changes) for which the PMRA proposes additions or amendments. For a full description of the currently established Notification/Non-notification changes, including documentation requirements and implementation instructions, consult DIR2013-02.

## 2.0 Notification

Notifiable changes are those that may be made to registered pest control products upon submission to the PMRA of a completed notification form.

## 3.0 Notifiable label changes

The following label changes are being proposed for notification.

### 3.1 Addition of tank mixes to product labels

This revision applies to Section 3.11, **Addition of a tank mix that is currently labelled on the tank mix partner**, which appears in the current Directive, DIR2013-02. Addition of tank mixes to product labels through notification will no longer be restricted to those that are currently listed on one of the tank mix partner labels.

A registrant may add through notification a tank-mix for crop production or vegetation management to a registered product label provided that the following conditions are met.

- Each tank mix partner is registered for use in Canada on the crop of interest, including genetically modified crops.
- Tank mix partners must be clearly indicated, by product name, on the product labels being changed. Specific directions regarding use of the tank mix, or a reference to the tank mix partner label, must be included. A general reference that “this product can be tank mixed with other products” would not be acceptable.
- The tank mix only includes an adjuvant when specifically required by one of the tank mix partner labels. If an adjuvant is not required on the label of any tank mix partner, then no adjuvant may be added to the tank mix.
- As per the tank mix partner labels, the application timings of all tank mix partners are compatible with regards to crop and pest staging.
- Each tank mix partner is applied in accordance with its registered product label (for example, Directions for Use, Precautions, Buffer Zones). In cases where information on the tank mix partner labels differs between them, the most restrictive directions must be followed. The following statement must be included on the label: “Follow the most conservative use precautions of all tank mix partners.”
- The tank mix is not specifically excluded or contraindicated on either tank mix partner label.

- The use of the tank mix provides additional value to the user (for example, increased scope of pests controlled [relative to those controlled by one of the tank mix partner products alone], contributes to resistance management or integrated pest management, cost- or time-savings).

When a tank mix is listed on the label of a master product, this tank mix may be added to the related master copy products through notification provided the master copy label contains the uses to which the tank mix applies.

### 3.2 Rotational crops and plant-back intervals

Changes to rotational crops (addition or removal) and plant-back intervals (addition or removal) may be made through notification when they are based on a precedent with identical formulation, which has been previously assessed by the PMRA. The following conditions apply:

- The precedent product must have the same (i.e. identical) formulation or differ only in aspects that would qualify as notifiable changes.
- Only one precedent product can be used for each notifiable change. All labeled information for each combination of use site/crop/pest/rate/frequency/and method of application must be identical to that on the registered precedent product label.
- The applicant for the submission must also be the registrant for the precedent product being cited.
- The applicant must use the most recent, approved, registered label and attest that no other changes have been made other than those identified on the label submitted for notification.
- For deletions of information, the full context of the information being deleted needs to be considered. Therefore, any other information on the label which relates or refers to the information being deleted, and does not relate to anything else on the label, must also be removed.

An **increase** in plant-back interval or **removal** of a rotational crop may be submitted through notification, which is not based on a precedent, under the following conditions:

- The applicant must use the most recent, approved, registered label and attest that no other changes have been made other than those identified on the label submitted for notification.
- For deletions of information, the full context of the information being deleted needs to be considered. Therefore, any other information on the label which relates or refers to the information being deleted, and does not relate to anything else on the label, must also be removed.
- The notification process **does not** apply to a decrease in plant-back interval or addition of a plant-back interval when a precedent cannot be cited. In this case, an amendment application for the change must be submitted.

### **3.3 Changes to application rate (increase or decrease), application timing, application number or frequency, or application method when based on a precedent**

Registrants may make these specified changes (addition or removal) to a product label through notification when they are based on a precedent and the precedent product has been previously assessed by the PMRA. The following conditions apply:

- The precedent product must have the same (i.e. identical) formulation or differ only in aspects that would qualify as notifiable changes.
- Only one precedent product can be used for each notifiable change. All labeled information for each combination of use site/crop/pest/rate/frequency/and method of application must be identical to that on the registered precedent product label.
- The applicant for the submission must also be the registrant for the precedent product being cited.
- The applicant must use the most recent, approved, registered label and attest that no other changes have been made other than those identified on the label submitted for notification.
- For deletions of information, the full context of the information being deleted needs to be considered. Therefore, any other information on the label which relates or refers to the information being deleted, and does not relate to anything else on the label, must also be removed.

### **3.4 Precautions**

Where precautionary statements have been changed or modified for a precedent product with identical formulation, based on an assessment of data for a submission subsequent to that of the original review, these changes may be requested by notification for products that were based on the precedent product provided there are no implications regarding data protection.

For example, Product B was based on precedent Product A. Subsequent to the registration of Product A, new data were submitted and reviewed which supported changes to the label of Product A regarding related hazard symbols and precautionary statements. The applicant would now like to apply these same changes to Product B which has the identical formulation and uses.

As Product B was based on precedent Product A, both Product A and B must have the identical formulation and be registered for the same uses. The precautionary statements (i.e. precaution section) and hazard symbols must be copied in their entirety from the precedent label.

The applicant must use the most recent, approved, registered label and attest that no other changes have been made other than those identified on the label submitted for notification.

For deletions of information, the full context of the information being deleted needs to be considered. Therefore, any other information on the label which relates or refers to the information being deleted, and does not relate to anything else on the label, must also be removed.

### **3.5 Changes in source of starting materials that are not commodity chemicals**

This change is in addition to what is currently described in **Section 4.0 Formulation/ Specification-related Changes** of DIR2013-02.

For technical products covered by PMRA Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product* (or most recent version), changes in the source of starting materials that are not commodity chemicals may be made by notification if the technical grade active ingredient or integrated system product remains in accordance with the specifications upon which registration was granted and the specifications for the starting material do not change. (Changes in source of starting materials that are commodity chemicals are non-notifiable changes as outlined in Section 7.8 of DIR2013-02.) Registrants must attest on the notification form that the specifications of the starting material have not changed. Notification is acceptable, therefore, if:

- the nominal guarantee and certified limits of the active ingredient(s) are not changed;
- the upper certified limit of any existing impurity is not exceeded;
- there are no new impurities found at a level equal to or greater than 0.1% by weight;
- impurities of toxicological significance as described in clause 2.13.4 of DIR98-04 are not introduced, or the current upper certified limits of such impurities currently listed in the product specifications are not exceeded; and
- the specifications of the starting material are not changed

Otherwise, a submission to amend the registration is required.

### **4.0 Next Steps**

The PMRA invites the public to submit written comments on these proposed revisions to the Notification/Non-Notification Directive for up to 30 days from the publication of this document. Please forward all comments to PMRA Publications. Before making a final decision, the PMRA will consider all comments received in response to this consultation document.





## Appendix I

**Table A Product Changes Described in this Regulatory Proposal (Applicable Section of this Proposal in Parenthesis)**

Type of Change	Notification	Non-notification	Application for New or Amended Registration
Label Changes			
Addition of tank mixes to product labels	Criteria are met (3.1)		Neither notification nor non-notification criteria are met or other tank mixes or variations in label text
Rotational crops and plant-back intervals	Criteria are met (3.2)		Neither notification nor non-notification criteria are met
Changes to application rate (increase or decrease), application timing, application number or frequency, or application method when based on a precedent	Criteria are met (3.3)		Neither notification nor non-notification criteria are met
Precautions	Criteria are met (3.4)		Neither notification nor non-notification criteria are met
Changes in source of starting materials that are not commodity chemicals	Criteria are met (3.5)		Neither notification nor non-notification criteria are met