

### Notification/Non-Notification

The purpose of this Regulatory Directive is to inform registrants of new procedures for handling certain types of minor amendments to existing registered products under the *Pest Control Products Act*. Amendments which meet the criteria outlined will no longer require an application to amend the product registration. Such amendments will be handled through Notification/Non-Notification procedures.

Any amendments not identified in this Regulatory Directive as qualifying for the Notification or Non-Notification procedure **must** continue to be made by means of the formal Application for Amendment process, requiring review and approval before sale of the product.

Any changes made by notification or non-notification will be subject to review during subsequent applications for amendment of registration.

The procedures outlined in this directive will be implemented as a one-year pilot project and will be subject to review and revision at the end of one year.

This document is published under the authority of the Interdepartmental Executive Committee on Pest Management which represents the departments of Agriculture and Agri-Food, Health, Environment, and Natural Resources.

*(publié aussi en français)*

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## Background

One of the recommendations made by the federal Pesticide Registration Review Team was that “the agency develop conditions that will permit a registrant to make specified types of minor changes to end-use product registrations without the need for a formal review by the Agency and without compromising the protection of health, safety and the environment.” (Final Report - Recommendations for a Revised Federal Pest Management Regulatory System, Dec. 1990)

The development of Canadian Notification/Non-Notification procedures represents a further step towards international harmonization (in this case with the United States). A table comparing the procedures used by the U.S. Environmental Protection Agency (U.S. EPA) and Agriculture and Agri-Food Canada for minor changes to registered products is presented in Appendix I.

The implementation of Notification/Non-Notification procedures in Canada will reduce workload for both industry and government. This is consistent with other government initiatives for providing regulatory relief and encouraging industry self-reliance.

The expansion of the pilot project to include additional items in the Notification/Non-Notification process, such as those accepted by the U.S. EPA may occur after further study. In the interim, we would welcome comments on these procedures and how they affect efficiency and client services.

### **Notification: Changes that can be made to registered products which require notification, but not approval.**

Certain changes may be made to a registered product upon notification to the Plant Industry Directorate by a Letter of Notification explaining all changes in detail. It is not necessary to obtain approval of such changes, and the product may be distributed or sold as soon as written notification is submitted. The information will be stored on the product register.

The following changes may be made through a Letter of Notification to the Plant Industry Directorate:

1. Changes in the name and/or address of the registrant, name and/or address of the Canadian agent or change of the mailing address.
2. Formulator name and/or address change for end-use products only. This includes changes to mailing address and site of formulation. Additional formulating sites may be identified by Letter of Notification as well.

A registrant is required to keep the Plant Industry Directorate informed as to his current address of record; however, such changes may be made to labels as soon as they occur. A Letter of Notification must be sent to the Plant Industry Directorate along with a list stating the Canadian registration numbers and all current submission numbers affected. If appropriate, a list of those products and submissions not affected by the change

must also be included along with their relevant numbers. An appropriate number of copies of the letter should be provided for placement on each product and submission file.

Registrants are encouraged to contact the appropriate registration officer prior to submitting a Letter of Notification. A list of registered products and current submissions can be provided to the registrant upon request.

Only the registrant or the authorized Canadian agent may submit a Letter of Notification. Each Letter of Notification must be properly signed and dated.

If the Plant Industry Directorate determines that the change is not consistent with a change allowed under the Notification procedure, an application to amend the product registration will be required. The Plant Industry Directorate will notify the registrant, stating the reasons why a Letter of Notification is not sufficient. If, as a result of this request, an Application is not submitted, the product(s) will become subject to routine enforcement measures.

### **Exceptions**

The following changes **may not** be made by Letter of Notification. An application to amend the product registration form must be submitted for approval.

1. A company transfer (change of ownership)

The following information must be submitted by the new owner for each registered product or current submission:

- a) Application for New or Amended Registration form
- b) Product Specification form
- c) five (5) copies of the draft labels indicating the new company name
- d) Letter of Confirmation of source of supply for the active ingredient(s) signed by the supplier
- e) Letter of Transfer signed by the former registrant
- f) the appropriate fees

2. A formulation site address for technical or manufacturing class products.

The following information is required for each registered product or current submission:

- a) Application for New or Amended Registration form
- b) Product Specification form for manufacturing concentrate; or an update of parts 2.1 - 2.15, Appendix 1 of Regulatory Directive Dir93-03 for technical products
- c) appropriate fees

3. Additional product brand names

In Canada, each product or brand of product is assigned a unique registration number. An Application for New or Amended Registration is required to register additional brand names or to change existing brand names.

**Non-Notification: Changes that can be made to a registered product without notification or approval**

The following changes may be made to product labelling, packaging or specifications without a Letter of Notification or approval by the Plant Industry Directorate:

1. Correction of typographical or printing errors (i.e., label corrections identified by the Plant Industry Directorate).

Typographical errors on labels submitted for Label Text On-Line will be corrected by the Plant Industry Directorate.

2. Changes in the net contents of products which are necessary to accommodate changing package sizes or contents variability, provided such changes would not require wording amendments in use directions, precautionary statements, package type, class designation or other requirements pertaining to size.

Registrants are encouraged to contact the appropriate registration officer if they are considering adding package sizes which do not fall within the range of sizes currently on the official product register. Package size changes may not be made to RESTRICTED class products.

3. Revision, addition or deletion of non-mandatory label elements, such as:

- a) the Transportation of Dangerous Goods (TDG) hazard diamond when a shipping container is also the immediate container offered for sale;
- b) lot or batch codes or other production identifiers;
- c) date of manufacture or label approval;
- d) distributor\*s name and address. The registrant\*s full name and address **must** remain on the primary panel.

4. Label format redesign that does not modify approved label text, consistent with the format requirements of Section 27 of the *Pest Control Products Regulations* and information contained in the Registration Handbook. These may include changes in label colour, company logo, type size or style, use of space, configuration, or placement of label elements. Be particularly careful when using a crack and peel, label and booklet or label and product data sheet formats.

5. Inert Ingredient suppliers.

Many inert ingredients are non-proprietary and available from more than one supplier, each with a different trade name. The identity of such are usually known and the source is not required to be identified. The supplier may be changed freely in such instances without notification to the Plant Industry Directorate. To ensure that the inert ingredient from different sources is the same, verify that the Chemical Abstracts (CAS) number is the same.

If the identity of the source of a specific inert ingredient has been required by the Plant Industry Directorate, or if an inert ingredient has been identified as having toxicological concerns (i.e., if it is included on the U.S. EPA list #1 Formulants of Toxicological Concern), or microcontaminants, an application to amend the product registration is required to document any change of supplier.

These changes are limited to inert ingredients whose identity or specific composition is known, such as specific solvents or common commodity diluents. Changes in proprietary ingredients which generally are composed of a mixture of ingredients and whose composition is not disclosed, **MUST** be made by an application to amend the product registration. Since the composition of such inert ingredients is not known, the Plant Industry Directorate must determine its acceptability based upon information on its composition supplied by the producer.

6. Change in Formulation Process.

A formulating operation (a unit operation such as blending, diluting or drying, as distinguished from a unit process involving a chemical reaction), may be modified without a Letter of Notification, provided the percentages of the active and inert ingredients will not change as a result.

### Exceptions

1. Changes to label text (i.e., use directions, precautions) require an application to amend the product registration.
2. Changes of package size for RESTRICTED class products require an application to amend the product registration.
3. Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government is not acceptable, as per Section 51(c) of the *Pest Control Product Regulations*.
4. The addition of descriptive label text (e.g., “natural”, “safe”, “organic”, “new and improved”) or addition of symbols or pictograms (e.g., representing pests or sites or environmental symbols) to the label requires an application to amend the product registration.
5. Changes in colour or type size **must not** reduce the legibility of the labelling text or minimize the precautionary symbols.

6. Changes to Initial Products and Private Labels will continue to require an application to amend the product registration.
7. Any changes to the active ingredient or source of active ingredient in a formulation must be made by an application to amend the product registration.

## Notification/Non-Notification Procedures

Type of Change (example)	EPA Process	Agriculture and Agri-Food Canada Process
Correcting printing errors (i.e., typographical)	non-notification	non-notification
changes/addition of package sizes (except RESTRICTED class)	non-notification	non-notification
non-mandatory label statements (i.e., TDG symbols, lot/batch numbers)	non-notification	non-notification
label format (i.e., colour, type size, placement)	non-notification	non-notification
source of inert ingredient (no toxicological concerns)	non-notification	non-notification
source of inert ingredient (with toxicological concerns or microcontaminants)	Letter of Notification	application for amended registration
formulation process (i.e., blending, mixing)	notification by form	non-notification
registration/agent name or address	Letter of Notification	Letter of Notification
addition or change of end-use formulator name or address	application for amended registration	Letter of Notification
transfer or ownership of registration	Letter of Notification, followed by application for amended registration with transfer documentation	application for amended registration
label language	notification by form	application for amended registration
addition of brand name	notification by form	application for a new product registration
source of starting material (for Integrated Formulations, Manufacturing Concentrates and Technical Active Ingredients)	notification by form	application for amended registration
source of active ingredient	notification by form	application for amended registration
concentration of inert ingredient	notification by form	application for amended registration

### **Procedures for Non-Notification**

It is no longer necessary to notify the Plant Industry Directorate of amendments that qualify for non-notification. No additional information is required.

### **Procedures for Notification**

For amendments that qualify for notification (company name or address), please submit the following to the Plant Industry Directorate:

1. a letter indicating the company\*s new name or address
2. a list of all affected products (and their registration numbers) and current submissions
3. a list of any products not affected by the change (if applicable)
4. an appropriate number of copies of the letter to place on each product and submission file.

If you have any questions as to whether the change meets the requirements for notification/non-notification, please contact the appropriate registration officer prior to making the change.

### **Transfers**

Transfer of registration of a pesticide product refers to a change in ownership (e.g., purchase) from the current company/registrant to a different company. The transfer is documented through an amendment of registration as described in Section 12.6 of the Registration Handbook (February 1994). Please note that a transfer of registration is not equivalent to a change in the name and/or address of the registrant and accordingly, **cannot** be accomplished by the notification process.