Regulatory Directive DIR2001-04

Notification/Non-notification

This regulatory directive defines certain minor changes to control products registered under the *Pest Control Products Act* (PCP Act). It proposes to expand upon, and will supercede the existing notification or non-notification process as described in Regulatory Directive DIR94-01, *Notification/Non-Notification*. This directive has modifications in response to comments on the Regulatory Proposal PRO2000-01, *Notification/Non-notification*. The United States Environmental Protection Agency (EPA) published Pesticides Registration (PR) Notice 98-10, *Notifications, Non-Notifications and Minor Formulation Amendments*, October 22, 1998, which describes an expanded notification or non-notification process. This is a directive to adopt many of the items currently accepted either by notification or non-notification, as detailed in the EPA's PR Notice 98-10. Possible expansion of this process to include additional EPA items will be given future consideration. The development of a similar approach to notification or non-notification is considered to be consistent with the goals and objectives of the North American Initiative under the North American Free Trade Agreement.

This directive delineates 16 types of changes that will be given similar or identical treatment as they are given by the EPA; 5 that will be reviewed in more depth; 4 that will be reviewed in less depth than by the EPA and 2 for which there is no corresponding EPA reference point.

This directive will come into effect six months from the date of publication, with the exception of Sections 3.10–3.13 inclusive, which will come into effect upon publication of the regulatory directive on Formulants Policy.

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1.0 Introduction

This regulatory directive defines certain minor changes to control products registered under the PCP Act. It proposes to modify and expand upon, and will supercede the existing notification or non-notification process as described in DIR94-01, *Notification/Non-notification*. This directive also includes modifications in response to comments provided to the earlier PRO2000-01, *Notification/Non-notification*. The EPA published PR Notice 98-10, October 22, 1998, which describes an expanded notification or non-notification process.

For changes to registration not identified in Section 3.0 or 4.0 of this regulatory directive, registrants must continue to submit an "Application for Amended Registration." As before, amendments require review and approval by the Pest Management Regulatory Agency (PMRA) before sale of the product. Any changes to product registrations through notification or non-notification will be audited during subsequent amendments and renewals.

NOTE: Registrants are advised that it is an offense to make changes to a control product that do not conform to provisions of this regulatory directive. Changes made to products inconsistent with the provisions of this directive do not alter any applicable law respecting a registrant's liability for injury or loss attributable to labelling errors. Registrants will be required to take immediate corrective action to address problems or concerns resulting from such errors. Options for corrective action include, but are not limited to, correcting and resubmitting the label at the next printing, over-stickering, relabelling and recalling the product.

This directive delineates an Agency decision regarding 27 types of changes for either notification or non-notification. Of the total, 16 types of changes will be given similar or identical treatment as they are given by the EPA; 5 will be reviewed in more depth; 4 will be reviewed with less depth than by the EPA and 2 have no corresponding EPA reference point. The differences in approach between the PMRA and the EPA for the various types of changes are summarized in the tables attached at the end of this document. For five types of changes, the PMRA has decided to undertake a more in-depth review, e.g., notification instead of non-notification, based on the potential hazard, process differences or policy considerations associated with the proposed change. The proposed process is based on Agency experience and expertise in reviewing these types of changes under the current amendment process. For four other types of changes, e.g., corrections to typographical errors, the PMRA has proposed to allow registrants to make these changes without notification, where a similar change would require notification by the EPA.

The notification or non-notification process is described in the following three parts:

Notification (Section 3.0): changes that are acceptable when the PMRA has been notified by the submittal of a notification letter.

Non-notification (Section 4.0): changes where the PMRA does not need to be informed.

Changes that require amended registration (Section 5.0): changes that require review and approval through an amendment. This is NOT meant to be an all-inclusive list of changes requiring amendment. It is in reference to types of changes, identified in a 1998 EPA PR Notice, which the PMRA will continue to review as amendments to registration.

Registrants are encouraged to contact the Pest Management Information Service at the numbers given on the front page for advice about proposed changes that may or may not be accommodated through notification or non-notification.

2.0 Background

DIR94-01 was published in 1994 as a result of the Pesticide Registration Review Team's recommendation to facilitate minor changes to registrations without compromising human health, safety or the environment. The PMRA is proposing expanding the existing notification or non-notification process to include other types of changes that can be made without prior PMRA review and approval.

Notification and non-notification procedures accepted by the EPA have been considered for implementation in Canada. Expanding notification and non-notification in Canada represents another effort toward international harmonization.

3.0 Notification

Changes that can be made to registered products upon submission of a notification letter

Certain changes may be made to a registered product by submitting a letter in which registrants must clearly identify the type of notification and list the name and registration number of each product affected by that change. However, in the future, an electronic notification form will be available on the PMRA web site. It is intended that this form will be available by September 2001. Registrants will be advised of its availability. Registrants are encouraged to contact the Pest Management Information Service prior to submitting a notification.

For all labelling changes, two hard copies of the revised label (either draft or final printed) with the changes highlighted must be submitted. The label may be submitted electronically in the Portable Document Format (PDF). It is the responsibility of the registrant to ensure that all changes are declared on the notification letter.

NOTE: The documents contained in the PMRA's Product Register, accompanying the most recent Certificate of Registration, are considered legal documents. Any deviations from the current version of the label or forms, not provided for through the notification or non-notification process, may

be considered a violation of the PCP Act and Regulations. The label submitted by notification will be stamped "NOT REVIEWED — RECEIVED UNDER NOTIFICATION." Changes made that do not qualify for the notification process will not be accepted. Where the PMRA finds that identified changes do not qualify for notification, the PMRA will attempt to contact the registrant and request that an "Application for Amended Registration" be submitted.

The following changes may be made by notification.

3.1 Change in either the name or address of the registrant or Canadian agent

Registrants must keep the PMRA informed as to their current address. Address changes may be made to the product label as soon as they occur.

3.2 Formulator name or address addition or change for end-use products (EP) and manufacturing concentrates (MA) only

The site of formulation for an EP or an MA may be changed by notification letter. Changes to formulation sites for a microbial (biological) pest control product require an application for amended registration.

NOTE: An amendment is required to obtain approval for changes to the manufacturing site for a technical grade active ingredient (TGAI) or an integrated system product (ISP).

3.3 Certain Label Improvement Programs (LIP) where the PMRA has specified exact label changes

The PMRA may request that registrants upgrade or revise product labels to incorporate (verbatim) specific standardized label statements. Certain label upgrades may be appropriate for the notification process and do not require a formal amendment. The PMRA will inform registrants, as part of the Label Improvement Program, whether an amendment is required or if notification of the change would be sufficient. In appropriate cases, the registrant would submit a notification letter referencing the name and registration number of the product that had come into compliance with the criteria and conditions of the LIP.

If labels are found to be lacking the required changes during a subsequent amendment or inspection, or at renewal, then routine enforcement procedures could be implemented.

3.4 Changes in packaging and related labelling statements

Changes in the shape, colour or composition of packaging and in related labelling statements are permitted by notification only if all of the following criteria are met:

i. the rate, concentration, frequency or methods of application do not change;

ii. exposure is not increased, for example, changing from a paper bag to plastic jug or foil lined mylar bag. Note: adding non water-soluble packaging to a product, which is only registered in a water-soluble package, is considered an increase in exposure. Changes that result in new or additional protective clothing or equipment requirements are unacceptable;

iii. the product is not a rodenticide, where packaging is especially important in safe use of the product;

iv. no precautionary statements, directions for use, or other required labelling statements are changed;

v. no changes are made to bait stations, control stations, attractant stations or other packaging that houses the pesticide during its use;

vi. the package size is not reduced to the point that the net contents of the package are smaller than the amount required by directions for use; and

vii. the package size or other characteristics are not changed in a way that violates PMRA-mandated restrictions imposed on a product (e.g., size limitations may be imposed on a product to limit its use to homeowners only).

NOTE: Registrants are required to attest, in a covering letter, that all the above criteria for notification have been met. Additional package sizes, within the range approved on the Product Specification Form, do not require notification.

3.5 Product name change

The name of a registered product may be changed by notification provided that the registration number and the registrant do not change. The new name should be specific to the product and be descriptive of its physical form and purpose. It may include a distinctive brand or trademark. Product names that are confusing, misleading or make exaggerated claims will be rejected.

3.6 Deleting a pest(s)

A pest may be deleted from a product label by notification provided that the reason for deletion is stated on the notification letter.

3.7 Disposal statements

Registrants may revise outdated disposal statements through notification by choosing the appropriate statement verbatim from the PMRA Registration Handbook and DIR99-04, *Disposal Statements for Control Product Labels*, is applicable. However, a request for variation in the wording of those statements must be submitted as an amendment.

3.8 Trade label statement (refer to Regulatory Note REG2001-05, *Residue Level Label Statement*)

Registrants, as outlined in REG2001-05, may add the following statement to labels through notification:

"If this pest control product is to be used on a commodity that may be exported to the U.S. and you required information on acceptable residue levels in the U.S., contact 1-888-375-4648 or www.cropro.org."

This statement is required on all labels of products registered for use on food, including seed treatment products.

3.9 Transfer of ownership

Transferring ownership of registration(s) is proposed as a two-step process: an optional notification followed by a mandatory amendment to registration(s). An application for amended registration is required to document the change of ownership of a registered product on the Agency's Product Register.

Step 1: Notification of mailing address additions or changes, at time of sale, is encouraged prior to application for amendment. A notification will provide important information so that the Agency may continue to correspond with the appropriate persons and address. This is to ensure that all affected parties receive required correspondence and publications, until the transfer of registrations via the amendment process is completed (see step 2).

The notification should include the following information:

- the name and address of the new applicant;
- phone and fax number of the new applicant;
- an attached list of the affected products and their names and registration numbers;
- an attached list of affected submissions, for both registered and unregistered products;

- indicate amendment applications to document the transfer will be submitted to the Agency; and
- relevant background information such as the parties involved and the date of sale.

Step 2: An application for amended registration, to be provided by the new applicant, is required for each affected product.

3.10 Change in formulation process

Please refer, when released, to the regulatory directive on Formulants Policy.

3.11 Nominal concentration of formulant

Please refer, when released, to the regulatory directive on Formulants Policy.

3.12 Certified limits of formulant

Please refer, when released, to the regulatory directive on Formulants Policy.

3.13 Change of the supplier of a formulant

Please refer, when released, to the regulatory directive on Formulants Policy.

4.0 Non-notification

Changes that can be made to a registered product without informing the PMRA

The following changes may be made to product labelling, packaging or specifications without notifying the PMRA.

4.1 Correction of typographical or print errors

4.2 Changes in net contents

Changes in the net contents of products that are necessary to accommodate changing package sizes or contents variability, provided such changes would not require wording changes in use directions, mixing instructions, precautionary statements, package type, class designation or other requirements pertaining to size. Changes to net contents are acceptable where the change falls within the range currently found on the Product Specification form on the Agency's Product Register.

Registrants are encouraged to contact Pest Management Information Service if they are considering adding package sizes that do not fall within the range of sizes currently on the Product Specification form. Package size changes to products, designated as "RESTRICTED" class, require an amendment.

4.3 Revision, addition or deletion of the following non-mandatory (with respect to the PCP Act or Regulations) label elements:

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

4.4 Label format

Changes, to label format design, that do not modify approved label text and are consistent with the format requirements of the Pest Control Products Regulations (PCP 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. Changes in colour or type size must not reduce the legibility of the labelling text or minimize the precautionary symbols. Particular care must be taken when revising crack-and-peel labels, or label and booklet and product data sheet combinations to ensure the integrity of the label is maintained until the end of the line.

4.5 Warranty statements

When a registrant wishes to include a limitation of a warranty statement on the label of a control product, it should be exactly as follows, under the heading "NOTICE TO BUYER," as per Section 37 of the PCP Regulations:

"Seller's guarantee shall be limited to the terms set out on the label and, subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product and accepts the product on that condition."

« La garantie du vendeur est limitée et soumise aux conditions exprimées sur l'étiquette de sorte que l'acheteur assume les risques corporels ou matériels que l'utilisateur ou la manipulation du produit peuvent entraîner et accepte celui-ci à cette condition. »

4.6 Symbols or graphics consistent with label text

Illustrations that portray how the container should be opened or where the product should be used may be added to the product label without notification, provided that they accurately represent and do not conflict with the instructions on the approved label, or are not false or misleading.

4.7 Redundant (i.e., when the same statements appear numerous times on a label) labelling statements

Registrants may remove redundant labelling without notification provided that:

- the removal does not contravene labelling requirements stated in the PCP Regulations;
- the precautionary symbol(s) and statement(s) are retained and all other requirements of the PCP Regulations are met; and
- statements specifically required by the PMRA are not removed. For example, crop specific statements like grazing limitation statements and aerial application limitation statements.

4.8 Change in a source of starting materials for TGAIs or ISPs

Changes to the starting materials for technical products covered by PMRA DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product* may be made without notification if the TGAI or ISP remains in accordance with the specifications upon which registration was granted. Non-notification is acceptable, therefore, if:

- the nominal guarantee or 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; and
- impurities of toxicological significance, as described in clause 2.13.4 of DIR98-04 are not introduced, or the upper certified level of such impurities currently listed in the product specifications are not exceeded.

Otherwise, a submission to amend the registration is required.

5.0 Changes that require a submission to amend the registration

The following changes are not permissible under notification or non-notification, but continue to require an application to amend the product registration. This is NOT meant to be an all-inclusive list of changes requiring amendment. It is in reference to types of changes, identified in a 1995 EPA PR Notice on notification, which the PMRA will continue to review as amendments to registration.

5.1 Transfer of product registration from one registrant to another (change of ownership)

To document the change of ownership on the product register, the new owner of the registration must submit an application for amendment with the following for each product to be transferred:

- a letter indicating the sale or transfer of listed products, current submissions and all supporting data from the old registrant to the new applicant (this letter must come from the old registrant);
- an application form indicating the new registrant and signed by the new registrant. The electronic forms process may be used (see REG2001-01, *Electronic Forms*);
- a Product Specification form indicating the new registrant and the complete address of the formulating plant, registration number of the TGAI or ISP, and Chemical Abstracts Service numbers for the formulants. The electronic forms process may be used (see REG2001-01);
- four copies of the draft label (indicating the new registrant name and address). The label may be submitted electronically in the PDF format;
- a letter of confirmation of the source of supply from the basic manufacturer for each active ingredient used in the control products being transferred;
- a fee form and a total of $154 per product. The electronic forms process may be used (see REG2001-01); and
- if the transfer involves a TGAI, an update of chemistry information for the active ingredients as specified in Parts 2.1–2.2, Appendix I, DIR98-04, as well as any information in Parts 2.3–2.9 that has changed.

5.2 Bilingual labelling

The addition of French and English label text is not permitted by notification. The PMRA is proposing amendments to the PCP Regulations that will require bilingual labelling for most pesticide labels (see Discussion Paper DIS99-01, *Preliminary Consultation on a Regulatory Amendment for Bilingual Labelling of Pest Control Products*).

Until this requirement is in effect, the review of translated text is necessary to ensure that the labelling statements are consistent in both official languages. Submit an application forms, fee form with the $154 fee, four copies of a draft label in both English and French, and electronic PDF labels in English and French. The electronic forms process may be used (see REG2001-01).

5.3 Addition of pest(s)

This type of change requires an application for amended registration to allow for the review of efficacy data to ensure that recommended rates are both safe and at the lowest effective level.

5.4 Additional master copies of private labels (EPA equivalent to additional brand name)

This type of change requires an application for new or amended registration. Under the current PCP Act, each product label with its own product name or brand name requires a separate registration number. Additional registrations of either an identical product or similar products with different brand names are possible under the PMRA's private label or master copy registration processes respectively.

5.5 Advisory statements

Due to the potential ambiguity of language and misinterpretation of the intent of the statement, advisory statements will continue to be reviewed under the amendment process. The EPA recently issued PR Notice 2000-05, *Notice on Guidance for Mandatory and Advisory Labelling Statements*, stating that these types of additions to the label must now be approved via the amendment process.

5.6 Changing the supplier of the TGAI or ISP for a registered EP or MA

A decision on whether this is suitable for notification is delayed pending the conclusion of Agency–industry discussions on a revised Product Specific Registration (PSR) policy. An amendment to registration is required, for this change to a registration, until this is complete.

6.0 Next steps

There are several other specific items that are identified in EPA PR Notice 98-10 that can either be changed by notification or non-notification. These items will be further studied by the PMRA and consideration given to further expanding the list of items that can be accommodated in this process. The PMRA is planning to continue working with the pesticide manufacturing industry and other interested and affected stakeholders to expand this program where possible.

Table 1 Summary of changes to the PMRA notification or non-notification process

Type of change	Previous PMRA process	EPA process	New PMRA process
Changes by notification (refer to Section 3.0)			
3.1 Registrant or agent name or address	Notification	Notification	Notification
3.2 Formulator name and address for EP and MA	Notification	N/A	Notification (except for microbial or biological pest control products)
3.3 LIPs requested by the PMRA	Amended registration	Amendment or notification	Amendment or notification: LIP directives will state whether an amendment or notification is required to document the label update
3.4 Packaging and related labelling statements	Amended registration	Notification of changes to shape, colour or composition of packaging and related labelling statements	Notification of changes to shape, colour or composition of packaging and related labelling statements Limitations and conditions are specified in this regulatory directive
3.5 Product name change	Amended registration	Notification (includes brand name)	Notification, provided registrant and registration number remain unchanged
3.6 Delete pest	Amended registration	Notification (except public-health pests and termites)	Notification of deleted pests with reason for deletion
3.7 Disposal statements	Amended registration	Notification of changes as per EPA PR Notices 83-3, *Label Improvement Program — Storage and Disposal Statements* and 84-1, *Clarification of Label Improvement Program*	Notification for changes that correspond to the standard statements in the Registration Handbook and DIR99-04
3.8 Trade label statement	Amended registration	N/A	Notification, if limited to this label change
3.9 Transfer of ownership (see 5.1, Amendment section)	Amended registration	Notification followed by amended registration	Notification followed by amended registration
3.10 Formulation process	Non-notification	Notification	Deferred until release of directive on Formulants Policy
3.11 Nominal concentration of formulant*	Amended registration	Notification	

Type of change	Previous PMRA process	EPA process	New PMRA process
3.12 Certified limits of formulant*	Amended registration	Notification	
3.13 New or alternate source of formulant*	Amended registration	Notification (source info required by the EPA)	
Changes by non-notification (refer to Section 4.0)			
4.1 Typographical errors	Non-notification	Non-notification	Non-notification
4.2 Net contents and package size	Non-notification (except "RESTRICTED" class products)	Non-notification	Non-notification ("RESTRICTED" class products require amended registration)
4.3 Non-mandatory label statements (e.g., TDG symbols, lot or batch numbers)	Non-notification	Non-notification (non *Federal Insecticide, Fungicide and Rodenticide Act* [U.S. FIFRA] related elements)	Non-notification for addition or deletion of non-mandatory label statement Changes are limited to those specified in this regulatory directive
4.4 Label format (i.e., colour, type size, placement)	Non-notification	Non-notification	Non-notification
4.5 Warranty statements	Amended registration	Notification	Non-notification when adding Section 37, PCP Regulations, "Notice to Buyer" statement
4.6 Symbols or graphics consistent with label text	Amended registration	Notification	Non-notification for diagrams showing how to open container, and pictures of where the product can be used
4.7 Removal of redundant labelling statements	Amended registration	Notification	Non-notification Conditions are specified in this regulatory directive
4.8 Source of starting materials for ISP or TGAI	Information on change to source not presently required UNLESS chemical specifications are affected	Notification	Non-notification
Changes by amendment (refer to Section 5.0)			
5.1 Transfer of ownership (see 3.9, Notification section)	Amended registration	Notification followed by amended registration	Notification followed by amended registration.

Type of change	Previous PMRA process	EPA process	New PMRA process
5.2 Bilingual labelling	Amended registration	Non-notification	Amended registration See DIS99-01
5.3 Addition of pest(s)	Amended registration	Notification	Amended registration
5.4 Additional master copy or private label	Separate (new) registration	Notification	Separate (new) registration One registration number per product name This item will be considered by the Submission Category Working Group
5.5 Advisory statements	Amended registration	Amended registration (ref. EPA PR Notice 2000-05, *Guidance for Mandatory and Advisory Labelling Statements*)	Amended registration
5.6 Changing supplier of the registered ISP or TGAI in an EP or MA	Amended registration	Notification (active must be registered for same uses as end-use product, and be similar to current source)	Amendment A decision on whether this is suitable for notification is delayed pending the conclusion of Agency–industry discussions on a revised Product Specific Registration (PSR) policy

* Called an inert by the EPA

Table 2 Comparison of EPA PR Notice 98-10 and PMRA notification or non-notification process

Type of change	U.S. EPA (PR98-10)	Similar or identical to or different from the EPA process and explanation	PMRA process
Labelling			
1. Brand name change (equivalent to master copy or private label)	Notification	different	Separate (new) registration One registration number per product name
2. Product name change	Notification	identical	Notification provided registrant and registration number stay the same
3. Add pest _____ 4. Delete pest	Notification (except public health pests and termites)	different _____ identical	Amended registration _____ Notification of deleted pests
5. Packaging and related labelling statements	Notification of changes to shape, colour or composition of packaging and related labelling statements	similar	Notification
6. Disposal statements	Notification of changes as per PR Notices 83-3 and 84-1	identical	Notification
7. Bilingual labelling	Non-notification	different	Amended registration See DIS99-01
8. Symbols or graphics consistent with label text	Notification	different	Non-notification
9. Removal of redundant labelling statements	Notification	different	Non-notification
10. Warranty statements	Notification	different	Non-notification
11. Typographical errors	Non-notification	similar	Non-notification
12. Package size and net contents	Non-notification	similar	Non-notification
13. Registrant or agent name and address	Notification	identical	Notification

Type of change	U.S. EPA (PR98-10)	Similar or identical to or different from the EPA process and explanation	PMRA process
14. Formulator (end-use) name and address	N/A	different	Notification (except for microbial or biological pest control products)
15. Label format (i.e., colour, type size, placement)	Non-notification	similar	Non-notification
16. Non-mandatory label statements (e.g., TDG symbols, lot or batch numbers)	Non-notification (non-FIFRA related elements)	similar	Non-notification
17. Transfer of ownership	Notification followed by amended registration	identical	Notification, followed by amended registration
18. Label improvement programs requested by the PMRA	Amendment and notification	similar	Notification and amended registration
19. Advisory statements	Amendment (ref. EPA PR Notice 2000-05)	identical	Amendment
20. Trade label statement	N/A	different	Notification, if the only label change
Chemistry			
21. Changing supplier of the registered TGAI in an EP	Notification	different	Amendment, pending consideration of PSR implications
22. New or alternate source of formulant*	Non-notification	different	Deferred until release of directive on Formulants Policy
23. Source of proprietary inerts: undisclosed composition	Amended registration	identical	Amended registration
24. Nominal concentration of inert (within the certified limits on the accepted Confidential Statement of Formula)	Notification	similar	Deferred until release of directive on Formulants Policy
25. Certified limits of inert: within the standard certified limits in 40CFR 158.175(*b*)(2)	Notification	similar	Deferred until release of directive on Formulants Policy

Type of change	U.S. EPA (PR98-10)	Similar or identical to or different from the EPA process and explanation	PMRA process
26. Formulation Process (i.e., diluting, drying, mixing, blending)	Notification	similar	Deferred until release of directive on Formulants Policy
27. Source of starting materials for integrated system products	Notification	different	Non-notification

* Called an inert by the EPA

List of abbreviations

EPA	Environmental Protection Agency
EP	end-use product
FIFRA	*Federal Insecticide, Fungicide and Rodenticide Act* (U.S.)
ISP	integrated system product
LIP	Label Improvement Program
MA	manufacturing concentrate
PCP Act	*Pest Control Products Act*
PDF	portable document format
PMRA	Pest Management Regulatory Agency
PR	pesticides registration
TDG	transportation of dangerous goods
TGAI	technical grade active ingredient
U.S.	United States