



Health
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Pest
Management
Regulatory
Agency

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**Memorandum To/ All Registrants, Applicants and their
Note adressée à: Representatives**

**Subject/Objet: Pest Control Products Containing Active
Ingredients or Sources of Active Ingredients that
are Not Currently Registered in Canada**

Purpose

This memo clarifies the policy established by the Pest Management Regulatory Agency (PMRA) with respect to pest control products (PCPs) that:

- contain an active ingredient that is not registered in Canada or
- are formulated with a source of active ingredient that is not registered in Canada.

It also outlines the procedures to follow for registering the active ingredients or sources of active ingredients contained in these products.

Background

In 1983, the PCP Regulations were amended to require that only registered products that contain registered active ingredients (i.e. source) could be used to formulate new PCPs for registration after 1 January 1984. PCPs registered prior to that date were not subject to this requirement. To retain “exemption” from this requirement, certain conditions are applied to these products.

The PMRA is in the process of fulfilling a commitment to re-evaluate all pesticides, those registered prior to 1995, in light of modern scientific standards and all information available at the time of re-evaluation. The intent is to ensure that continued registration can be supported, and to determine under what conditions continued registration is acceptable. As part of the decision to permit continued registration, the active ingredient itself and the

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product used as the source of active ingredient in all formulated PCPs are expected to be registered. In addition, the new 2002 *Pest Control Products Act* provides for a periodic re-evaluation of all PCPs.

This memo serves to clarify and ensure a common understanding of the conditions that apply to those registered products that:

- contain an active ingredient that is not registered in Canada or
- are formulated with a source of active ingredient that is not registered in Canada.

This memo also outlines the procedures for registrants to register the active ingredients or sources of active ingredients contained in these products.

Conditions for continued exemption from the requirement to use registered active ingredients

For PCPs currently containing active ingredients or sources of active ingredients that are not registered in Canada, the PMRA allows the continued registration, the renewal of registration and the transfer of ownership of these products, if the label uses and product specifications remain unchanged.

The exemption does not apply to the following:

- An application to amend the product specifications or expand or otherwise modify the uses on the label.
- Requests for Master or Initial Product status.

In addition:

- Use of these products as a precedent to support applications to register new products or to support any amendments to existing pest control products is not permitted.
- An exempted product cannot be used as a precedent to support applications to register new products that contain registered sources of the active ingredient.

By obtaining a registration for the active ingredient or source of the active ingredient contained in these PCPs, the restrictions for registration identified above will no longer apply.

Registration of active ingredients

The PMRA is re-evaluating all pesticide active ingredients and associated end uses registered prior to 1 January 1995 to ensure that their continued acceptability is examined using current scientific approaches. Therefore, all active ingredients contained in existing products that were registered prior to 1 January 1984 are also subject to re-evaluation. As an outcome of re-evaluation, if continued registration is determined to be acceptable, all

products will be expected to contain registered active ingredient(s) and registered source(s) of active ingredients. Until that time, the PMRA encourages registrants of existing products containing unregistered active ingredient or an unregistered source of active ingredient to submit an application to register the active ingredients (or sources of active ingredients) based on the requirements applicable to the situation outlined in the next section. Once the active ingredient(s) or source(s) of active ingredients become registered, amendments to the specifications and labels of products containing these active ingredients would be permitted.

Registration procedures

a) For active ingredients that are not currently registered in Canada

The application to register the active ingredient is outlined in Section 8.2.1 of the *Registration Handbook*, which states the following:

“Application in support of registration of a [technical grade of the active ingredient] TGAI or [Integrated System Product] ISP contained in products registered before January 1, 1984, should provide product chemistry data, and an index only of existing data.”

The following is also required:

- an *Application for New or Amended Registration* form,
- a *Statement of Product Specification* form,
- a *Fee Form*,
- the appropriate fees, and
- a label.

Please note that the active ingredient will still be subject to re-evaluation and additional data or information may be requested for re-evaluation purposes.

b) For active ingredients that are registered in Canada, but the source used in the PCP is not

There are 2 options:

i) *Use a currently registered source of the active ingredient.*

For products containing an unregistered source of a registered active ingredient, an application to amend the product by replacing the unregistered source with a currently registered Canadian source of active ingredient would be a Category C.6.2 application. This will require the following:

- an *Application for New or Amended Registration* form,
- a *Statement of Product Specification* form,

- a Letter of Confirmation of Source (from the registrant of the active ingredient),
- a *Fee Form*, and
- the appropriate fees for a Category C.

Please note that the active ingredient will still be subject to re-evaluation and additional data or information may be requested for re-evaluation purposes.

ii) *Register the source of active ingredient.*

To register the source of active ingredient, the following will be required:

- an *Application for New or Amended Registration* form,
- *Statement of Product Specification* form,
- a *Fee Form*,
- the appropriate fees,
- a label,
- the Index and
- Part 2 Chemistry data as outlined in the data code (DACO) table for Category B1.2 application. [This may be subject to Product Specific Registration II (PSRII, Trade Memorandum T-1-249).]

Please note that the active ingredient will still be subject to re-evaluation and additional data or information may be requested for re-evaluation purposes.

All applications must be organized and formatted according to the provisions of Regulatory Directive DIR2003-01, *Organizing and Formatting a Complete Submission for Pest Control Products*. Please contact the PMRA Information Service for more details by email at pmra_infoserv@hc-sc.gc.ca or by calling 1 800 267-6315 (from within Canada) or (613) 736-3799 (from outside Canada).