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Pest
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1 June 2006

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

Subject/Objet: **Transparency Requirements of the new *Pest Control Products Act*: New Requirements for Applications to Register or Amend a Pest Control Product**

1.0 Purpose

This memo communicates new requirements for applications for new or amended registration as well as the associated revisions to the application form to allow the collection of information on proposed new uses and/or any uses to be withdrawn. These changes will support the transparency requirements of the new *Pest Control Products Act*.

2.0 Background

Increased transparency of the pesticide regulatory system is a fundamental principle of the *Pest Control Products Act* that received Royal Assent in 2002.

The new *Pest Control Products Act* requires that a Register of Pest Control Products (Register) be established. The Act specifies what information about pest control products must be placed in the Register, when the information must be placed there and how access to the information is to be granted to the public (see subsection 42(2) of the Act). The new *Pest Control Products Act* also requires that an electronic public registry be established, into which all information in the Register that is not confidential business information (CBI) and not confidential test data (CTD) must be placed. This information includes, but is not limited to, information about registration applications when they are received, i.e., the name of the active ingredient, the proposed new uses and the uses proposed to be withdrawn.

Section 7(1) of the *Pest Control Products Act* provides the authority for the PMRA to specify the “form and manner” in which information is submitted to the PMRA in support of:

- an application to register a pest control product or amend a product registration;
- a re-evaluation; or
- a special review.

3.0 Updates to the Application Form

3.1 Collection of Proposed New Uses and/or Uses to be Withdrawn Information

For each application to register a new pest control product (including master copies) or to amend a product registration, the applicant must now identify whether they are proposing new uses or withdrawing currently approved uses for the product. Box 14 of the Application for New or Amended Registration (Form 6005) has been introduced for this purpose. If the applicant is proposing new uses for or withdrawing uses from the product, the applicant must now indicate so in Box 14, and Form 6023, **Proposed New Uses and/or Uses to be Withdrawn from the Label**, must accompany the application. This new form (6023) is structured to clearly and easily capture the required information.

For the purpose of fulfilling the requirement to make the proposed new uses and/or uses to be withdrawn public at the time the application is received, “use” is defined as a site/pest combination, namely:

- a) **Site:** means an animal, plant or other organism that is being protected by the product or a location where the product is being used.
- b) **Pest:** means an animal, plant or other organism that is injurious, noxious, or troublesome, whether directly or indirectly, and an injurious, noxious or troublesome condition or organic function of an animal, a plant, or other organism.

This new form (6023), containing the information as received from the applicant, will be posted to the Electronic Public Registry when the application to fulfill this particular transparency requirement as per Section 42(2)(a)(i) of the *Pest Control Products Act* is received.

Note: The Application for New or Amended Registration (Form 6005) will not be posted, only the Proposed New Uses and/or Uses to be Withdrawn from the Label form (6023) will be posted.

3.2 Standardization of Capture of Contact Information

In addition to the revisions described in Section 3.1, the Application for New or Amended Registration (Form 6005) has also been revised to bring the contact information sections in line with the standard introduced two years ago on the Application for Registration Renewal (Form 6000). A submission contact can be identified on the form for the duration of each submission life cycle.

4.0 Reminder Concerning Requirements for Submitting Documents to the PMRA

Applicants are reminded of the changes that took effect on 19 September 2005 with the publication of Regulatory Proposal PRO2005-02, *Requirements for Submitting Data Index, Documents and Forms*.

- a) Application related forms (application, fee and statement of product specification)
 - Only one copy of a form is required. It may be submitted in paper or electronic format; if it is in electronic format, signatures must be incorporated and displayed in the PDF file.
 - Only the most recent version of a form will be accepted, i.e., the one posted on the PMRA website when an application is being prepared.
- b) Only one copy of each electronic or paper document being submitted is required; an additional paper copy is no longer required. Please refer to PRO2005-02 for the conditions under which an electronic or paper document will be accepted.

5.0 Implementation

This memo documents the updates to application forms 6005 and 6023 with respect to uses and contact information and is effective as of the date of publication. Recognizing that Form 6023 is new, the PMRA is prepared to work with registrants to ensure this information is secured for applications, where necessary.

6.0 Other Communication Updates

6.1 Statement of Product Specification Form

A revised Statement of Product Specification form (6003) will be released soon. The revisions are being introduced to support the Formulants Policy (e.g., new approach to numbering product formulations on the form) as well as to standardize data collection and to address some past technical issues with the form.

The Agency recognizes the workload it places on registrants when introducing a new version of the Statement of Product Specification form. The PMRA has developed a “batch” file that will allow registrants that have saved electronic versions of their forms to automatically transfer the content from the current version of the form to the new version.

For more information on this “batch” file, contact the Pest Management Information Service (see contact information in Section 7.0 below).

6.2 Fee Form

A new version of the Fee Form (6011) is being released with a minor revision. The field “Amount of fee enclosed” has been introduced on the Fee Form and removed from the Application for New or Amended Registration (Form 6005).

7.0 Questions

Questions concerning these requirements should be directed to the PMRA via the Pest Management Information Service.

By phone: 1 800 267-6315 (within Canada)
1 613 736-3799 (outside Canada)

By e-mail: pmra_infoserv@hc-sc.gc.ca