Background on Transparency of the New *Pest Control Products Act*

1.0 Introduction

Health Canada's Pest Management Regulatory Agency (PMRA) is preparing to implement the new *Pest Control Products Act* (PCPA 2002), which received Royal Assent in December 2002.

The PCPA 2002 will come into force once supporting Regulations are published in the *Canada Gazette*, Part II.

1.1 Transparency

One of the goals of the PCPA 2002 is to have a more transparent pesticide regulatory system and to increase public participation in regulatory decisions.

The PMRA must establish a register that contains information about pest control products, including information about applications, registrations, re-evaluations and special reviews. This includes, but is not limited to, the following:

- information supplied by applicants and registrants in support of registering or amending the registration of a pest control product or in support of a re-evaluation or special review; and

- PMRA reports on the evaluation of health and environmental risk and value of pest control products.

The PCPA 2002 allows the public to have access to, and a copy of, any information in the Register that is NOT confidential test data (CTD) or is NOT confidential business information (CBI). (See Appendix I for definitions of CTD and CBI.)

- The PMRA must establish an electronic public registry and must include in it all information in the Register that the public can obtain a copy of. This information must be made available to the public "as soon as reasonably practicable"[1].

The public may inspect the CTD that have been provided, when the pest control product for which the data have been evaluated is registered, amended, or the registration is continued following a re-evaluation or special review.

For all submissions for which CTD are submitted to support the registration:

- the CTD will be made available after a decision is rendered, i.e., when the certificate of registration is issued.

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[1] PCPA 2002, section 42(7)

For all re-evaluations and special reviews:

- the CTD will be made available when the final decision to continue the registration is published.

1.2 Public Participation

1.2.1 Public Consultation

Section 28 of the PCPA 2002 requires that the public be consulted before making a final decision:

- to grant or deny the registration of a pest control product containing an unregistered active ingredient;

- to grant or deny the registration or amendment of a pest control product registration if the registration/amendment "may result in significantly increased health or environmental risks"[2]; and/or

- to continue the registration of a pest control product on completion of a re-evaluation or special review.

1.2.2 Reconsideration of Decisions

Any person may file a Notice of Objection to a decision made on which the public is required to be consulted under Section 28 of the PCPA 2002.

The PMRA has the authority to decide whether to establish a review panel to reconsider the decision.

- If the PMRA decides not to establish a review panel, the PCPA 2002 requires that the decision and the reasons for it be communicated in writing to the person who filed the Notice of Objection.

- If the PMRA decides to establish a review panel, the review panel's report will be made public.

- Following reconsideration of a review panel report, the PMRA must publish its decision and include the reasons for it.

[2] PCPA 2002, section 28(1) (a)(ii)

2.0 Inspection of CTD

The public is allowed to have limited, controlled access to inspect the CTD provided by an applicant/registrant when the pest control product supported by the CTD is registered or amended, or when the registration is continued after a re-evaluation or special review.

The principal purpose for allowing the public to inspect CTD is to facilitate public participation in the decision-making process. It is anticipated that a request to inspect CTD will be made by a person after having reviewed the evaluation report supporting the registration decision. The evaluation report will be accessible in the electronic public registry on the PMRA's website. The ability to inspect CTD is particularly important for a person planning to file a Notice of Objection to a registration decision for which there was prior consultation. The Notice of Objection must identify the scientific grounds on which the objection rests; therefore, the PMRA will allow note taking.

Any information designated by the provider as CBI and accepted as CBI by the PMRA must be protected from public access, i.e., only information that has been designated CBI before inspection can be protected.

To protect confidentiality, the PCPA 2002 provides that nothing in the Act prevents the PMRA from refusing to disclose CTD or CBI under the *Access to Information Act*.

- Nothing in the PCPA 2002 entitles a person to make or obtain a copy of CTD.
- Controlled inspection will not put CTD in the public domain in Canada.
- Registrants' rights under data protection programs will not be affected by the public's right to inspect CTD.

If the PMRA permits a person to inspect CTD, the PMRA is required to make a reasonable effort to immediately notify the registrant who provided the data that the PMRA has permitted a person to inspect the data.

A person who wishes to inspect CTD in the Register must submit to the Minister the following:

- an application in the form and manner directed by the Minister; and
- an affidavit made under oath or a statutory declaration under the *Canada Evidence Act* made before a commissioner for oaths or for taking affidavits, stating:

    - the purpose of the inspection; and
    - that the person does not intend to use the test data, or make the test data available to others, in order to register a pest control product in Canada or elsewhere or to amend a registration.

Note: A person who makes a false statement in an affidavit or a statutory declaration is guilty of an offence and is liable:

- on summary convictions, to a fine of not more than $200 000 or to imprisonment for a term of not more than 6 months or to both; or
- on conviction on indictment, to a fine of not more than $500 000 or to imprisonment for a term of not more than 3 years, or to both.

An application to inspect CTD may be denied for the following reasons:

- the PMRA believes the intent of the person is to use or share the data to register a product or to amend a registration; or
- the person has used test data from a prior inspection for such purposes.

2.1 Reading Room

CTD will be available for inspection in the Reading Room at the PMRA's National Office in Ottawa, Ontario. The visitor will be escorted to the Reading Room and monitored during the visit.

CTD will be available in electronic format by using a laptop with disabled ports to prevent the attachment of external copying devices.

Photocopying of the test data will not be permitted.

3.0 Confidential Business Information

To protect CBI from all forms of public access:

- the information provider is required to designate CBI in information provided under the PCPA 2002, in accordance with the definition of CBI (see Appendix I); and
- the PMRA is required to verify that the designated information meets the CBI definition.

If the PMRA is satisfied that information designated as CBI meets the definition of CBI in the PCPA 2002, the PMRA will acknowledge acceptance of the designated information.

If the PMRA determines that the designated information does not meet the definition of CBI in the PCPA 2002, the PMRA is required to:

- give written notice of the decision and the reasons for it to the information provider; and
- allow the public to inspect non-CBI information after the registration decision is made under the PCPA 2002.

The PCPA 2002 provides the authority for the PMRA to specify the "form and manner" in which information is submitted to the PMRA to support an application to register or amend a registration or to provide information in support of a re-evaluation or special review.

To facilitate the protection of CBI, applicants/registrants are required to segregate CBI into separate documents/electronic files upon submission to the PMRA.

If CBI is not addressed prior to a registration decision being made under the PCPA 2002, then the PMRA is obligated to make the relevant CTD available for inspection in the Reading Room as it was provided.

3.1 CBI Designation and Segregation Methodologies and Process

In September 2005, the PMRA published regulatory proposals PRO2005-03 and PRO2005-05, specifying requirements for the information provider to designate and segregate CBI within the CTD. In response to the comments received on the proposals, the PMRA met with industry on 9 March 2006 to discuss options for designation of CBI. These options were taken into consideration in the following regulatory directives, available on the PMRA website:

- *Confidential Business Information Designation and Segregation Part 1: Submission of Test Data* (DIR2006-03): The requirements are designed to minimize the impact on the submission process, while providing the means to ensure that CBI is protected from public disclosure.

- Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data (DIR2006-04): The requirements are designed to improve efficiency, to ensure that CBI is protected from public disclosure and to respect data ownership.

4.0 Transitional Provisions

The PCPA 2002 and the Regulations apply to the following:

- All applications for the registration of a pest control product or for an amendment to its registration **received before** proclamation of the new Act if no decision to grant or deny the application has been made before the day the PCPA 2002 comes into force.

Note: Regardless of when the application was received, the transparency requirements apply to all applications to register or amend the registration of a product for which a decision is rendered under the new Act.

- All **registrations in place prior** to the PCPA 2002 coming into force will be subject to the new Act except that the requirement to place "historical" information supporting those registrations in the Register will be postponed until the registration becomes subject to a decision on which the public has been consulted under section 28 of the PCPA 2002, namely:

    - upon completion of re-evaluation, special review; or
    - an application to amend the registration that may result in a significant increase to health or environmental risk.

    Note: Previously evaluated CTD that are relevant to the decision will become subject to inspection at the time of the registration is amended or is continued following re-evaluation or special review.

Appendix I

Definitions

Confidential test data (CTD) is defined as scientific or technical information respecting the health or environmental risks or the value of a pest control product, to which access may be refused under the *Access to Information Act*.

Confidential business information (CBI), as defined by the PCPA 2002, is information that:

- is designated by the information provider, and
- concerns information regarding:

    - manufacturing or quality control processes relating to a pest control product; or
    - methods for determining the composition of a pest control product; or
    - monetary value of sales of pest control products and other financial or commercial information provided pursuant to the PCPA 2002 or Regulations; or
    - the identity and concentration of the formulants and contaminants in a pest control product, other than those considered to be of health or environmental concern that are identified on a list to be made available to the public.

        Note: The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and Explanatory Note are available in the *Canada Gazette*, Part II, Vol. 139, No. 24, page 2641.