Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Proposal

PRO2005-05

Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data

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Foreword

Confidential business information (CBI), as defined in the new *Pest Control Products Act* (PCPA 2002), must be addressed for all test data prior to a decision being made by the Pest Management Regulatory Agency (PMRA) under the PCPA 2002.

This regulatory proposal defines the procedures for the designation of CBI in test data received by the PMRA prior to the PCPA 2002 coming into force, for which CBI had not previously been addressed.

This proposal is being distributed for information and comment. Please provide your written comments to the Publications Section within 45 days of the date of this regulatory proposal. In the interim, the PMRA will begin to work with applicants and registrants regarding designation of CBI in previously provided test data.

1.0 Purpose

The purpose of this document is to communicate the procedures for the designation of CBI for test data that was submitted to the PMRA prior to the PCPA 2002 coming into force. This applies to all relevant test data for which CBI had not been designated previously and for which a decision will be made under the PCPA 2002.

Guidance on designation and segregation of CBI when submitting test data under the PCPA 2002 is found in *Confidential Business Information Designation and Segregation Part 1: Submission of Test Data.*

2.0 Definitions

2.1 PCPA 2002

The PCPA 2002 is an Act to protect human health and safety and the environment by regulating products used for the control of pests and replaces the *Pest Control Products Act*, chapter P-9 of the Revised Statutes of Canada, 1985.

The PCPA 2002 was given Royal Assent on 12 December 2002. It will be brought into force by an Order that will be made by the government once key regulations to support the Act are in place.

2.2 CBI, as defined by the PCPA 2002, is information that:

- is designated as CBI; and
- concerns information related to the following:
    - manufacturing or quality control processes relating to a pest control product;
    - 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 new PCPA or the 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.[1]

[1] The list of formulants and contaminants of health or environmental concern will be published in the *Canada Gazette*, and it is anticipated that it will include Track 1 substances under the Toxic Substances Management Policy and formulants classified as List 1 or allergens.

2.3 **Test data**, as defined by the PCPA 2002, is:

- scientific or technical information respecting the health or environmental risks or the value of a pest control product.

2.4 **Confidential Test Data (CTD)**, as defined by the PCPA 2002, is:

- test data or information that may be protected from disclosure under the *Access to Information Act*.

2.5 The **Register**, as defined by the PCPA 2002, is:

- a body of pest control product information to which the rules of access of the PCPA 2002 apply. The information the Register contains is prescribed in subsection 42(2) of the PCPA 2002 and the Regulations.

3.0 Background

3.1 Overview

The Register established under the new Act will contain information concerning registered products, including the test data supporting the registrations. The public will have the right to inspect the test data in the Register. However, that right will not permit inspection of CBI as defined in the Act. Accordingly, it will be necessary to segregate CBI contained in the test data to protect it from public inspection.

Test data provided prior to the coming into force of the new Act will be placed in the Register when it is used in the making of a registration decision under the new Act. Such decisions will include new and amended registrations and decisions made upon completion of re-evaluations and special reviews. The CBI contained in the test data will have to be identified and segregated when test data are placed in the Register.

For test data submitted prior to the new Act coming into force, the PMRA will treat test data submitted under parts 2 and 3 (DACOs[2] 2.1–2.16, DACOs 3.1–3.7) as CBI. Applicants and registrants will be provided an opportunity to designate additional information as CBI in accordance with the process described hereafter. When the PMRA is satisfied that additional information so designated is within the definition noted above, it will be segregated and protected from public inspection.

[2] DACO: data code

3.2 Relevant Statutory Provisions

The provisions relevant to this document are detailed in Table 3.2.1.

A copy of the PCPA 2002 (Bill C-8) can be accessed at the following address: www.parl.gc.ca. Requests for assistance should be directed to the Pest Management Information Service at 1 800 267-6315 within Canada, at 1 613 736-3799 outside Canada, or via e-mail at pmra_infoserv@hc-sc.gc.ca.

Table 3.2.1 PCPA Reference to Requirements

PCPA 2002 Requirement	PCPA Reference
The PMRA shall allow the public access to, and copies, of any information in the Register that is not CTD or CBI.	42(4)
Upon meeting certain requirements any person may inspect CTD.	43(1)
Definition of CBI.	43(4) and 43(5)
CBI must be designated by the information provider.	43(4)
The PMRA has the authority to determine the form and manner in which information is provided.	7(1)
The PMRA decides whether designated information meets the definition of CBI.	43(6)
The PMRA must give written notice to the information provider if it is determined that designated information is not CBI and the reasons for it.	43(7)
The requirements of the PCPA 2002 apply to all current applications for the registration of a pest control product or for an amendment to its registration if no decision to grant or deny the application has been made before the day the PCPA 2002 comes into force.	81(1)
Access to information on existing registrations will be delayed until the public has been consulted on its registration under the PCPA 2002.	81(2)
Public consultation on existing registrations of a pest control product will be triggered by the registration of a major new use or upon completion of a re-evaluation or special review.	28(1)
All registered pest control products must eventually be subject to re-evaluation.	16(2)

4.0 Scope

This policy applies to test data relevant to a decision under the PCPA 2002 that was submitted for any purpose prior to the PCPA 2002 coming into force, including test data submitted in support of the following:

- applications to register or amend a pest control product;
- re-evaluations;
- special reviews; or
- responses to deficiency requests or other requests for information.

5.0 Designation of CBI

The PMRA will work with registrants and applicants in the following manner to attain a CBI designation before a regulatory decision is reached with respect to the evaluation of test data that is relevant to a decision made under the PCPA 2002:

- The PMRA will automatically consider test data that were submitted under parts 2 and 3 (DACOs 2.1–2.16, DACOs 3.1–3.7) to be CBI, and protect it accordingly.

- The PMRA will send a **CBI Notice for Previously Submitted Test Data** and an index of the relevant test data requesting that the registrant/applicant:

    - confirm that the registrant/applicant has the authority to designate CBI; and
    - identify and provide coordinates for any **additional** CBI contained in the test data; or
    - provide the name of the company that has the authority to designate CBI in the test data.

    Note: The company identified as having authority to designate CBI may request an electronic copy of the test data listed in the index provided by the PMRA.

- The registrant/applicant must respond to the **CBI Notice for Previously Submitted Test Data** within the timeframe specified in the notice.

    Note: A separate CBI Designation Response for Previously Submitted Test Data is required for each CBI Notice for Previously Submitted Test Data.

    - If no response is received, the PMRA will conclude that the test data contains no additional CBI.

    - If the response indicates that the test data contains no additional CBI, no further action is required.

- If the response indicates that a different company has the authority to designate CBI, in the whole package or subset, the PMRA will communicate in the same manner as above with the authority identified in the registrant/applicant response.

- If the test data contains additional CBI, the response must identify and provide the coordinates for the CBI, using the reporting method identified in section 5.1 and in accordance with Appendix I.

5.1 Content of CBI Designation Response for Previously Submitted Test Data

The response must quote the PMRA reference number for the CBI Notice for Previously Submitted Test Data and must clearly indicate in the subject line: **CBI Designation Response for Previously Submitted Test Data**. A template is provided in Appendix I.

Clearly state the name and title of the company authorized to designate CBI and have the response signed and dated.

List documents containing CBI in the same sequence as the index provided by the PMRA.

For each study containing CBI, state the following:

1. The PMRA document identifier number as shown on the index.
2. The location (page number and line) of the CBI.
3. The CBI content.

CBI items in the same document must be numbered consecutively.

5.2 PMRA Validation

The PMRA will verify that:

- the CBI has been addressed in the form and manner required; and
- the designated CBI meets the definition of CBI in the PCPA 2002.

If the PMRA is satisfied that information designated as CBI is within the definition of CBI in the PCPA 2002, it will be segregated and protected from public inspection.

If designated information is determined by the PMRA to not meet the definition of CBI in the PCPA 2002, then that designated information is not CBI. The PMRA will then do the following:

- give a written CBI notice of the decision and reasons for it; and
- provide public access to all non-CBI information once a decision has been made under the PCPA 2002.

If CBI has not been addressed prior to a regulatory decision, the test data (other than DACOs 2.1–2.16 and 3.1–3.7) will be placed in the register as it was provided.

6.0 Implementation

Upon publication of this document, the PMRA will commence issuing CBI notices for previously provided test data.

Appendix I Template—CBI Designation Response for Previously Submitted Test Data

Name, title
Address

RE: CBI Designation Response for Previously Submitted Test Data, PMRA notice number: _____

Check Appropriate Boxes

☐ I have the authority to designate CBI for all test data indexed:

- ☐ Designations are listed in Table 1.1; or
- ☐ I require a copy of the test data before I can designate CBI. (Return a copy of the indexed test data with checks beside those required studies.)

OR

☐ I have the authority to designate CBI for part of the test data indexed:

- ☐ The name of the authority to designate the remaining test data is listed in Table 1.2; and
- ☐ Designations for which I have the authority are listed in Table 1.1; or
- ☐ I require a copy of the test data before I can designate CBI. (Return a copy of the indexed test data with checks beside those required studies.)

OR

☐ I do not have the authority to designate CBI for any of the test data indexed.

Table 1.1			
PMRA Document Identifier	**Page # and Line**	**CBI Information**	**Reason for Deletion**
Examples			
1	60 (line 20)	Formulant: propylene glycol	Formulant name
1	71 (line 15)	Formulant: propylene glycol	Formulant name
6	10 (Line 40)	Formulant: propylene glycol	Formulant name

Table 1.2	
PMRA Document Identifier	**Authority to Designate CBI**
Examples	
1	ABC Chemicals; contact name and address
2	ABC Chemicals; contact name and address
6	XYZ Chemicals; contact name and address

Name, title
Signature

Date: yyyy/mm/dd