Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

# Regulatory Proposal PRO2005-03

# Confidential Business Information Designation and Segregation Part 1: Submission of Test Data

*(publié aussi en français)*

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## Foreword

Under the new *Pest Control Products Act* (PCPA 2002), information providers must designate and segregate confidential business information (CBI) as defined in the PCPA 2002.

This regulatory proposal defines the procedures for designation and segregation of CBI when providing test data to the Pest Management Regulatory Agency (PMRA) for any purpose.

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, information providers may use the procedures outlined in this proposal to designate and segregate CBI.

# 1.0 Purpose

The purpose of this document is to communicate to information providers the requirements and procedures for the designation and segregation of CBI when providing test data to the PMRA for any purpose.

For test data previously provided to the PMRA, guidance to address CBI will be provided in a separate document: *Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data.*

# 2.0 Definitions

## 2.1 *Pest Control Products Act* 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 by the information provider, and
- concerns information regarding:
  - 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, 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 defined in paragraph 42 of the PCPA 2002 and the Regulations.

# 3.0 Background

## 3.1 Overview

The PCPA 2002 provides for informed public participation in the pesticide regulatory system. It allows the public to obtain copies of the PMRA's detailed evaluations of health and environmental risks and value, after the pest control product is registered. The PCPA 2002 also allows the public to inspect the CTD on which these evaluations are based. Such access can be provided only after a final registration decision. Under the PCPA 2002, the only information in the Register that can be protected from all forms of public access is CBI.

The PCPA 2002 requires that information providers designate CBI contained in information submitted to the PMRA. The Act also authorizes the PMRA to specify the form and manner in which information is submitted in support of an application or registration. Further, the Act gives the PMRA the authority to decide whether the information designated as CBI, by the provider, meets the definition of CBI as specified in the PCPA 2002. If the designated information does not meet the definition of CBI, the PMRA must give written notice to the information provider. Under the PCPA 2002, provisions for public access apply to all information in the Register, except CBI. This document provides guidance on how to designate and segregate CBI when submitting test data to the PMRA.

### 3.2 Relevant Statutory Provisions

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

A copy of the PCPA 2002, can be accessed at the following address: www.parl.gc.ca. Requests for assistance should be directed to the PMRA 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 any information 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) |

### 3.3 Scope

The requirements described hereafter apply when submitting test data for **any** purpose, 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.

## 4.0 Form and Manner for Designation and Segregation of CBI

For CBI to be protected from public access, the information provider must designate and segregate CBI in the manner described hereafter. CBI must also be accepted by the PMRA as meeting the definition of CBI as defined in the PCPA 2002.

To facilitate the protection of CBI in test data, the PMRA requires the following:

- a Statement of CBI Claim in each document;
- a separation of CBI into a CBI Reference document, where the entire document is not CBI; and
- a mandatory use of a CBI indicator in an accompanying electronic XML e-Index to flag those CBI documents.

## 4.1 Designation of CBI / Statement of CBI

Every document requires a signed Statement of CBI. If the document is electronic, the signature must be incorporated and displayed in the PDF file. This statement must be on a page dedicated for this purpose and located immediately following the title page. If the document has no title page, the CBI Statement must be on the first page.

The Statement of CBI must include one of the following information.

- "No claim of CBI is made for any information contained in this document on the basis of the definition of CBI in the PCPA 2002".

- "The entire document is claimed as CBI on the basis of the definition of CBI in the PCPA 2002".

- "Information claimed as CBI, on the basis of the definition of CBI in the PCPA 2002, has been removed to a CBI Reference Document".

Appendix I shows an example of a CBI Statement.

## 4.2 Segregation

For each document that contains some CBI [e.g., word(s), phrase(s), paragraph(s) or page(s)], the following steps must be taken:

- Extract the CBI from the document (parent), replace it with a reference code and put the excised CBI into a CBI Reference Document.

    - The cover page must be titled "CBI Reference Document".
    - The cover page must include identifying information to link it to the parent document including, where applicable, lab report number, data code (DACO) satisfied, author(s), title and report date.
    - The reference code may be determined by the information provider, but it must be in a format that facilitates identification of CBI with a clear and logical linkage to the parent document.
    - A separate CBI Reference Document is required for each parent document from which CBI was excised.

Appendix II shows an example of a CBI Reference Document.

- The Statement of CBI page (second or cover page) in the **parent** document must contain: "Information claimed as CBI, on the basis of the definition of CBI in the PCPA 2002, has been removed to a CBI Reference Document".

- No Statement of CBI page is required for the **CBI Reference Document**.

### 4.3 XML e-Index

An XML e-Index must accompany all instances where documents are submitted to the PMRA. The XML e-Index CBI indicator is a mandatory flag for each document to indicate whether the entire document is CBI. For more details and guidance on the XML e-Index, see *Requirements for Submitting Data Index, Documents and Forms*, which can be found on the PMRA website at www.pmra-arla.gc.ca.

### 4.4 Summary of Requirements

| Document | | Statement of CBI | e-Index CBI flag |
|---|---|---|---|
| Contains no CBI | | No claim of CBI is made for any information contained in this document on the basis of the definition of CBI in the PCPA 2002. | N |
| Entire document is CBI | | The entire document is claimed as CBI on the basis of the definition of CBI in the PCPA 2002. | Y |
| Contains some CBI | Parent | Information claimed as CBI, on the basis of the definition of CBI under the PCPA 2002, has been removed to a CBI Reference Document. | N |
| | CBI reference | None | Y |

### 4.5 PMRA Verification of CBI

The PMRA will verify that:

- the information provider has addressed CBI in the form and manner required, and
- the designated CBI meets the definition of CBI in PCPA 2002.

If CBI is not designated in accordance with Section 4.1 and not segregated in accordance with Section 4.2:

- the PMRA will send a written CBI notice requesting that CBI be designated and segregated;
- review of the test data will be delayed;
- if there is no response within 45 days, a second CBI notice will be sent, and the test data will move to review provided that all deficiencies (if any) have been addressed; and
- if CBI has not been addressed prior to a regulatory decision, the test data will be placed in the register as it was provided.

If CBI is designated in accordance with Section 4.1, but is not segregated in accordance with Section 4.2:

- the PMRA will send a CBI notice, requesting that CBI be segregated;
- review of the test data will be delayed; and
- if there is no response within 45 days, a second CBI notice will be sent, and the test data will move to review, provided that all deficiencies (if any) have been addressed.

If designated information is determined by the PMRA to not meet the definition of CBI as per PCPA 2002, then that designated information is not CBI:

- the PMRA will give written CBI notice of the decision and reasons for it.
- if changes are required by the CBI notice:
  - review of the test data will be delayed.
  - if there is no response within 45 days, a second CBI notice will be sent and the test data will move to review, provided that all deficiencies (if any) have been addressed.
- all information that is not CBI will be available for public access once a decision has been made under the PCPA 2002.

### 4.6 CBI Designation for Test Data Previously Submitted to the PMRA

For test data received prior to the day the PCPA 2002 comes into force, for which CBI (as defined in PCPA 2002) has not been addressed in the required form and manner, the PMRA will contact the information providers prior to disclosure to allow for an opportunity to address CBI.

A separate guidance document regarding the requirements and process for addressing CBI for information previously submitted to the PMRA will be published as *Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data.*

# 5.0 Implementation

## 5.1 Upon Publication of this Document

CBI designation and segregation should be addressed in the manner specified in this document for any test data provided to the PMRA. This will avoid having to designate and segregate the CBI at a later date per the requirements and process described in *Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data.*

Prior to the list of formulants and contaminants of health concern being published, information providers should consider that it will include Track 1 substances under the Toxic Substances Management Policy and formulants classified as List 1 or allergens.

## 5.2 Upon Coming into Force of the PCPA 2002

CBI must be addressed in the manner specified for all test data provided to the PMRA.

# Appendix I

**Example Statement of Confidential Information**

Information claimed as CBI, on the basis of the definition of CBI in the PCPA 2002, has been removed to a CBI Reference Document

**Signature**
*If document is electronic, signature must be incorporated and displayed in the PDF file.*

John Doe, Owner
ABC Chemicals

12 March 2005

**Appendix II**

Example—CBI Reference Document

# CONFIDENTIAL BUSINESS INFORMATION REFERENCE

Parent Document:
Lab. Report No.: 3.141592654
DACO: 4.3.1
Author(s): John Doe, Jane Doe, and Bob Doe
Title: Short Term Oral Toxicity Study in Rats
Report Date: 1999

# 25 February 2005

# CBI Reference
## Title: Short Term Oral Toxicity Study in Rats

| CBI Reference Code | CBI Information Excised | Page Number (Line) | Reason for CBI Claim |
|---|---|---|---|
| Examples | | | |
| CBI 0001 | Propylene glycol | 60 (line 20) | Formulant name |
| CBI 0001 | Propylene glycol | 71 (line 2) | Formulant name |
| CBI 0002 | Sodium chloride | Throughout document | Formulant name |
| CBI 0003 | Wording for entire paragraph | 97 | Discloses monetary value |

CBI verified by the PMRA

_____ _____

Date Signature