Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Directive DIR2006-04

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

This Regulatory Directive defines the requirements and procedures for the designation of confidential business information (CBI) in test data received by Health Canada's Pest Management Regulatory Agency (PMRA) prior to the new *Pest Control Products Act* (PCPA 2002) coming into force and for which the CBI designation requirement has not already been addressed.

It replaces Regulatory Proposal PRO2005-05, *Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data*, published for comment in October 2005. Comments received were taken into consideration in finalizing the procedures described in this Regulatory Directive.

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Foreword

Under the authority of the PCPA 2002, the public may inspect test data submitted by registrants in support of a decision made under the Act to register a pest control product, to amend a registration or to continue a registration following a re-evaluation or special review.

However, the PCPA 2002 also requires that CBI, as defined in the Act, be protected from all forms of public access. To allow for the protection of CBI within test data previously submitted to the PMRA, it must be designated as CBI by the information provider and accepted as meeting the definition of CBI by the PMRA prior to the registration decision being rendered under the PCPA 2002. This Regulatory Directive addresses the need to define the procedures for the designation of CBI in the test data received by the PMRA prior to the PCPA 2002 coming into force.

When submitting test data under the PCPA 2002, the requirements for designation and segregation of CBI can be found in Regulatory Directive DIR2006-03, *Confidential Business Information Designation and Segregation Part 1: Submission of Test Data*.

Table of Contents

1.0 Definitions

1.1 *Pest Control Products Act* 2002 (PCPA 2002)

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

1.2 Confidential business information (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; 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 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]

1.3 Test data, as defined by the PCPA 2002, are:

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

1.4 Confidential test data (CTD), as defined by the PCPA 2002, are:

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

1.5 The **Register of Pest Control Products (Register)** is:

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

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[1] 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.

1.6 The **PMRA Generated XML e-Index** is:

- a list, in XML format, of test data relevant to a registration and is generated from the PMRA document management system. The PMRA generated XML e-Index can be opened using the e-Index Builder Application (available on the PMRA website). CBI designations of the relevant test data are made in this XML e-Index file. When returned to the PMRA, CBI designations are loaded directly into the PMRA document management system.

2.0 Background

2.1 Overview

Increased transparency of the pesticide regulatory system is a fundamental principle of the PCPA 2002. It allows the public to have access to reports on the evaluation of pesticide products and to inspect the test data on which the evaluations were based.

The PCPA 2002 also requires that a Register of Pest Control Products be established. The Act specifies what information about pest control products is to be placed in the Register, at what time the information is to be placed in the Register, and how access to the information is to be granted to the public. (See subsection 42(2) of the PCPA 2002). The test data supporting the registration decision are placed in the Register following the registration decision. Once test data are placed in the Register, they are to be made accessible for public inspection under controlled conditions. The conditions set out in the PCPA 2002 include the submission of an application to inspect the test data and a signed affidavit made under oath or statutory declaration made under the *Canada Evidence Act*, stating the purpose of the inspection and that the person does not intend to use the test data or make them available to others in order to register or amend a pest control product in Canada or elsewhere.

The registration decisions to which the provisions for public inspection of test data apply include those concerning new and amended registrations and decisions made upon completion of re-evaluations and special reviews.

The PCPA 2002 also requires protection of CBI, as defined in the Act, from all forms of public access. For the purpose of protecting CBI from public inspection, CBI within relevant test data previously submitted to the PMRA must be designated as CBI by the information provider and accepted as meeting the definition of CBI by the PMRA prior to issuing the registration decision under the PCPA 2002. If the PMRA determines that information designated as CBI does not meet the definition of CBI as defined in the PCPA 2002, then it is not CBI. The PMRA is required by the Act to give written notice to the information provider stating the reasons why the information is not CBI.

2.2 Relevant Statutory Provisions

The provisions relevant to this document are detailed in Table 2.2.1.

A copy of the PCPA 2002 (Bill C-8) can be accessed at the following address: www.pmra-arla.gc.ca/english/legis/pcpa-e.html. Requests for assistance can 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 2.2.1 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 applications for the registration of a pest control product or for an amendment to its registration received before the PCPA 2002 comes into force 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 (test data and evaluation reports) on pest control products that are registered before the coming into force of the PCPA 2002 will be delayed until the public has been consulted on its registration under section 28 the PCPA 2002.	81(2)

PCPA 2002 Requirement	PCPA Reference
Public consultation on pest control products registered prior to the PCPA 2002 coming into force 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)

3.0 Scope

This policy applies to test data, relevant to a registration decision under the PCPA 2002 that were submitted before the coming into force of the PCPA 2002, including test data submitted in support of the following:

- applications to register or amend a pest control product, including joint reviews;
- maximum residue limit (MRL) submissions;
- re-evaluations;
- special reviews; or
- responses to deficiency requests or other requests for information.

4.0 Designation of CBI

The PMRA will work with registrants and applicants to complete the CBI designation before a registration decision is reached with respect to the evaluation of test data that are relevant to a registration decision. The process and requirements for designating CBI in the test data are outlined as follows.

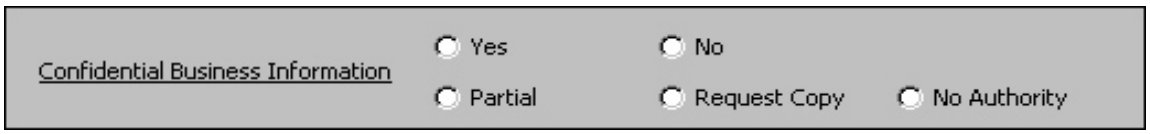
- The PMRA will automatically consider test data that were submitted under Part 2 and Part 3 (DACO[2] 2.1–2.16, DACO 3.1–3.7) to be CBI, and protect it from public inspection.

- The PMRA will send the applicant/registrant a **CBI Notice for Previously Submitted Test Data** and a CD/DVD containing a PMRA generated XML e-Index listing the relevant test data to facilitate the designation of CBI.

- The registrant/applicant must complete the designation for each document identified within the PMRA generated XML e-Index and return the file to the PMRA. Complete instructions for designating CBI are provided in Appendix I. A brief overview is provided hereafter.

[2] DACO: Data code

- For each document identified in the PMRA generated XML e-Index, indicate in the Confidential Business Information field one of the following:



  - **No Authority** means: The company to which the CBI Notice was addressed does NOT have authority to make a CBI declaration for the document, or
  - **Yes** means: I, on behalf of my company, have authority, and the document is completely CBI, or
  - **No** means: I, on behalf of my company, have authority, and the document contains no CBI, or
  - **Partial** means: I, on behalf of my company, have authority, and the document contains some CBI, or
  - **Request Copy** means: I, on behalf of my company, have authority, but do not have record of this file and I request that the PMRA provide a copy of the document.

For each document claimed as **No Authority**, indicate in the Comments field the contact information identifying the company holding the authority. If the contact information of the company having the authority to designate CBI applies to a large proportion of the documents listed in the PMRA Generated XML e-Index, that information can be attached as a separate document to the XML e-Index under DACO 0.8.12—CBI Designation Authority.

For each document claimed as **Partial**, provide a separate CBI Reference Document for each document using the template provided in Appendix II.

A response to the CBI Notice for Previously Submitted Test Data is due within 30 days of the date of issue of the CBI Notice for Previously Submitted Test Data.

- Timeframes may be longer, but CBI must be designated, accepted by the PMRA as CBI and segregated from the test data prior to a registration decision being made. Registration decisions will not be delayed pending CBI designation, and CTD must be made available for public inspection following a registration decision.

- The CBI Notice for Previously Submitted Test Data will not be treated as a deficiency.

- If **No response** is received, the PMRA will conclude that there is no CBI within the documents listed in the PMRA generated XML e-Index.

4.1 Content of CBI Designation Response for Previously Submitted Test Data

When returning the completed XML e-Index file to the PMRA on a CD or DVD, it should be clearly labelled **For CBI Designation Response** and be accompanied by a copy of the applicable CBI Notice for Previously Submitted Test Data.

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

For each document marked as **No Authority** in the CBI field, the name and address of the authority must be provided. This can be in the Comments Field for each applicable document or if it applies to many documents, a separate file indicating the authority can be attached to the XML e-Index under DACO 0.8.12—CBI Designation Authority. The PMRA will communicate directly with the authority identified in the same manner.

For each document marked as **Partial** in the CBI field, a separate CBI Reference Document *must* be associated with it.

- It is critical that the association between the document marked as **Partial** and its CBI Reference Document is made in the XML e-Index by using the copy row function of the e-Index Builder Application (see Appendix I).

Each CBI Reference Document (See Appendix II) must state the following:

1. The title of the document to which it pertains.
2. The location (page number and line) of the CBI.
3. The CBI content.
4. The reason for the claim of CBI.

4.2 PMRA Validation

The PCPA 2002 requires that the PMRA verify if the information designated as CBI meets the definition of CBI in the Act. The PMRA will verify that CBI has been addressed in the form and manner required and that the designated CBI meets the definition of CBI as defined by the PCPA 2002.

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

- 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, then that designated information is not CBI. The PMRA will:

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

If CBI has not been designated and accepted as CBI prior to a registration decision, the test data (other than DACOs 2.1–2.16 and 3.1–3.7) will be placed in the Register as they were provided.

5.0 Implementation

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

The order in which the PMRA will issue these notices will be based on the dates of the expected registration decision on the evaluation of the test data.

Once CBI in test data has been designated and accepted as such by the PMRA, it will not be subject to future re-designation.

Appendix I Supplemental Instruction on Using the PMRA Generated XML e-Index

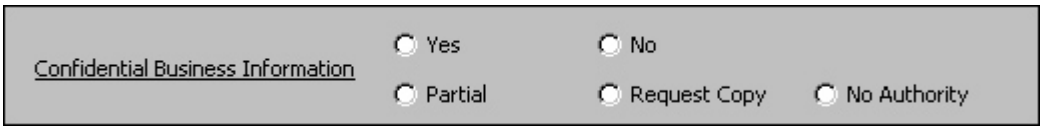
To open the PMRA generated XML e-Index from the CD/DVD provided, you must first download the e-Index Builder Application from the PMRA website. The e-Index Builder Application and the e-Index Builder User Guide can be found at the following link: http://www.pmra-arla.gc.ca/english/appregis/e-indexbuilder-e.html.

When you open the e-Index Builder Application, if a prompt indicates that a newer version exists, you must download and use the latest version for the PMRA generated XML e-Index.

To open the PMRA generated XML e-Index, click the **open e-Index** button and select the XML e-Index file provided.

When you open the PMRA generated XML e-Index, the rows highlighted in yellow in the **List of Documents** section are the individual documents requiring a CBI declaration.

For each document, select the yellow highlighted row in the **List of Documents** section. The **Confidential Business Information** field will change from two to five options. All remaining fields, except **Comments**, will be locked.



For each document listed, you must pick one of the five options in the Confidential Business Information field.

- **No Authority** means: The company to which the CBI Notice was addressed does NOT have authority to make a CBI declaration for the document, or
- **Yes** means: I, on behalf of my company, have authority, and the document is completely CBI, or
- **No** means: I, on behalf of my company, have authority, and the document contains no CBI, or
- **Partial** means: I, on behalf of my company, have authority, and the document contains some CBI, or
- **Request Copy** means: I, on behalf of my company, have authority, but do not have record of this file and I request that the PMRA provide a copy of the document.

Adding Contact Information for Authority to Designate CBI

For each document claimed as **No Authority**, indicate in the Comments field the contact information identifying the company that has the authority. The contact information of the company having the authority to designate CBI can be attached as a separate document to the XML e-Index under DACO 0.8.12—CBI Designation Authority if that information applies to a large proportion of the documents listed in the PMRA Generated XML e-Index.

Adding CBI Reference Documents to the XML e-Index

For each document claimed as "**Partial**", it is necessary to send to the PMRA a CBI Reference Document (See Appendix II for template) that identifies the title of the document to which the CBI pertains, the CBI claimed, the reason for the claim and the coordinates (page and line) within the original document.

The CBI Reference Document must be added directly into the XML e-Index file:

1. Select the document row (highlighted yellow) to which the CBI Reference Document pertains, and from the **EDIT** menu, the main toolbar or the right mouse button, click the **Copy Row** option. This will automatically create a new entry for the CBI Reference Document and set a relationship between the two documents that will be recognized by the PMRA document management system when the XML e- Index is returned to the PMRA.

   Note: **DO NOT** use the **Create New row** option as this will not create a relationship between the two documents when it is returned to the PMRA document management system.

2. You must select **Yes** in the CBI field for the new row representing the CBI Reference Document.

3. Attach the CBI Reference Document to the new row using the "Browse" option located in the Document Details section.

   Note: **DO NOT** change any other fields in the XML e-Index file for the CBI Reference Document.

To add a document that is **NOT** related to any specific document in the XML e-Index (e.g., the name of the authority to claim CBI on a group of documents), choose the **Add New Row** option (green +) on the main toolbar to add the document as described in the e-Index Builder User Guide.

Note: This is not to be used for the CBI Reference Document that is to accompany each partial declaration of CBI.

Finalizing the XML File

Once all of the CBI declarations have been made, validate and finalize the XML e-Index (see e-Index Builder User Guide). Copy the .PRZ file to a CD or DVD and return it to the PMRA along with a copy of the original CBI Notice for Previously Submitted Data. Label your disk as follows: **For CBI Designation Response**.

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 April 2006

CBI Reference Document
Title: Short-term Oral Toxicity Study in Rats

CBI Information Excised	Page Number (line)	Reason for CBI Claim
Propylene glycol	60 (line 20)	Formulant name
Propylene glycol	71 (line 2)	Formulant name
Sodium chloride	Throughout document	Formulant name
Wording for entire paragraph	97	Discloses monetary value