Health Canada Santé Canada

Canada

Pest Management Regulatory Agency

Guidance and Requirements for Confidential Business Information

PMRA Guidance Document

Protecting the health and environment of Canadians

Protéger la santé des Canadiens et l'environnement

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Document history (revision/update)

Updated	*Update/Rationale:*
June 2022	Changes were made by the merging of CBI Part 1 and Part 2 into one comprehensive guidance document that is up-to-date with current day processes and practices.
June 2006	*Initial issuance of DIR2006-03:* Confidential Business Information Designation and Segregation Part 1: Submission of Test Data.
June 2006	*Initial issuance of DIR2006-04:* Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data.

Disclaimer

This document does not constitute part of the *Pest Control Products Act* or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

Note: This guidance update is not a result of the work performed for PMRA's current transformation as communicated in April 2022.

This guidance is a reflection of the current process. If changes are required as a result of PMRA Transformation, updates to this document will take place a later time.

Table of contents

1. Introduction

Under the authority of the *Pest Control Products Act*, the public may inspect test data in support of a decision made under the Act to:

- register a pest control product
- amend a registration
- continue a registration following a re-evaluation or special review
- cancel a registration following a re-evaluation or special review

The *Pest Control Products Act* also requires that **Confidential Business Information (CBI)**, as defined in the Act, be protected from all forms of public access. To allow for the protection of CBI within test data submitted to the PMRA, they 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 *Pest Control Products Act*.

This guidance document replaces *DIR2006-03: Confidential Business Information Designation and Segregation Part 1: Submission of Test Data*. This document also addresses the need to define the procedures for designation and segregation of CBI in test data received by the PMRA prior to the *Pest Control Products Act* coming into force. These requirements are found in DIR2006-04: Part 2 *Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data* but have been included in this document.

2. Definitions

2.1 *Pest Control Products Act*

The *Pest Control Products Act* is an Act to protect human health and safety and the environment by regulating pest control products.

2.2 Confidential business information

Confidential Business Information as defined by the *Pest Control Products Act*, is information that:

- Is designated as CBI by the information provider; 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
    - The monetary value of sales of pest control products and other financial or commercial information provided pursuant to the *Pest Control Products Act* 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.

Additionally, CBI as defined by the *Pest Control Products Act*, means:

- Information to which access may be refused under the *Access to Information Act*.

2.3 The Public Registry of Pest Control Products

One of the mandates of the *Pest Control Products Act* is to increase transparency in the pesticide registration system. A key mechanism for meeting this mandate is the Pesticide Public Registry.

The **Public Registry** is a collection of non-confidential information on pesticides and the pesticide regulatory system. The Public Registry is made up of the following components:

- Pesticide Product Information Database
- Regulatory and Policy Documents
- Public Involvement

The **Register of Pest Control Products** (*Register*) is a body of pest control product information to which the rules of access of the *Pest Control Products Act* apply. The information the Register must contain is prescribed in subsection 42(2) of the *Pest Control Products Act* and the Regulations. The registrant means a person in whose name a pest control product is registered.

2.4 Test data

"Test Data" as defined by the *Pest Control Products Act*, are: scientific or technical information respecting the health or environmental risks or the value of a pest control product.

"Pest" as defined by the *Pest Control Products Act*, means: An animal, a 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.

"Pest Control Product" as defined by the *Pest Control Products Act*, means:

a. a product, an organism or a substance, including a product, an organism or a substance derived through biotechnology, that consists of its active ingredient, formulants and contaminants, and that is manufactured, represented, distributed or used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects;
b. an active ingredient that is used to manufacture anything described in paragraph (a); or
c. any other thing that is prescribed to be a pest control product.

2.5 Confidential test data

"Confidential test data" (CTD) as defined by the *Pest Control Products Act*, are test data that may be protected from disclosure under the *Access to Information Act*.

Before a pesticide can be registered for use in Canada, the PMRA reviews available scientific test data to determine whether there are concerns for human health or safety, or the environment, when the product is used according to the label. Some of the data reviewed by the PMRA scientists includes confidential test data. Confidential test data does not include scientific data that is publicly available (for example, has been published in a scientific journal).

The PMRA scientists evaluate confidential test data when conducting risk and value assessments. These assessments are an important part of the decision on whether or not the pesticide can be used in Canada, and under what conditions.

The *Pest Control Products Act - Access to Information* Section 43(1) - provides the following description regarding confidential test data:

A person who wishes to inspect confidential test data in the Register must submit to the Minister:

(a) an application in the form and manner directed by the Minister; and

(b) 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

  (i) the purpose of the inspection, and

  (ii) 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.

2.6 The XML e-Index

The XML e-index is a list, in XML (Extensible Mark-up Language) format, that is an index of test data submitted to the PMRA. An XML e-Index must accompany all instances where test data are submitted to the PMRA. The XML e-Index can be compiled by using the e-Index Builder Application (available on the Pesticides portion of the Canada.ca website). CBI designations of the relevant test data are made in this XML e-Index file.

Completion of the XML e-Index CBI Field is mandatory for each document; the e-Index Builder Application will not allow you to finalize the XML e-Index without this setting. When returned to the PMRA, CBI designations are loaded directly into the PMRA document management system. For more details and guidance on the XML e-Index, see Regulatory Directive *Requirements for Submitting Data Index, Documents and Forms*.

3. Background

3.1 Overview

Increased transparency of the pesticide regulatory system is a fundamental principle of the *Pest Control Products Act*.

Transparency 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 *Pest Control Products Act* 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 *Pest Control Products Act*). The test data supporting the registration decision are placed in the Register following the registration decision. Once confidential test data are placed in the Register, they may be made electronically available for public inspection under specific settings. The conditions set out in the *Pest Control Products Act* include the submission of an application to inspect the CTD 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 CTD apply include those concerning new and amended registrations and proposed and final decisions made in relation to re-evaluations and special reviews.

The *Pest Control Products Act* also requires protection of CBI, as defined in the Act, from all forms of public access and third-party stakeholders. For the purpose of protecting CBI, new test data submitted to the PMRA must be designated as CBI by the information provider and accepted as meeting the definition of CBI by the PMRA before it is placed in the Register.

If the PMRA determines that information designated as CBI does not meet the definition of CBI as defined in the *Pest Control Products Act*, then it is not CBI. The PMRA is required by the *Pest Control Products Act* to give written notice to the information provider stating the reasons why the information is not CBI.

3.2 Relevant Statutory Provisions

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

A copy of the *Pest Control Products Act* (Bill C-8) can be accessed at the Parliament of Canada website.

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.info-arla@hc-sc.gc.ca.

Table 2.2.1 *Pest Control Products Act* Reference to Requirements

***Pest Control Products Act* Requirement**	***Pest Control Products Act* Reference**
The PMRA has the authority to determine the form and manner in which information is provided.	7(1)
All registered pest control products must eventually be subject to re-evaluation.	16(2)
Public consultation on pest control products registered prior to the *Pest Control Products Act* 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)
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 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 *Pest Control Products Act* apply to all applications for the registration of a pest control product or for an amendment to its registration received before the *Pest Control Products Act* comes into force if no decision to grant or deny the application has been made before the day the *Pest Control Products Act* 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 *Pest Control Products Act* will be delayed until the public has been consulted on its registration under section 28 of the *Pest Control Products Act*.	81(2)

4. Scope

This policy applies to test data relevant to a registration decision under the *Pest Control Products Act*, including test data submitted in support of the following:

- Data submitted previous to the Act coming into force in 2006;
- 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.

Note: Data reviews and study summaries are considered test data and will be treated like other test data in accordance with this directive.

5. Designation and segregation of CBI

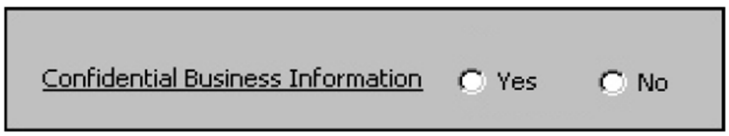
For CBI to be protected from public access, the information provider must designate and segregate CBI in the manner described hereafter. The CBI must also be accepted by the PMRA as meeting the definition of CBI in the *Pest Control Products Act*.

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

- Mandatory use of the CBI field in an accompanying XML e-Index to flag those documents that are CBI;
- Segregation of CBI into a separate CBI Reference document, where a document contains some CBI, but the entire document is not CBI (see Appendix 1 for example); and
- Document data in the XML e-Index for the parent document and its corresponding CBI Reference document must be identical except for the CBI field (in other words, parent document marked CBI "No" and CBI Reference document marked CBI "Yes").

The PMRA will verify that all documents claimed as CBI (for which the XML e-Index CBI field is set to "Yes") meet the definition of CBI in the *Pest Control Products Act* and that CBI has been segregated appropriately.

For each document in the XML e-Index, check off one of the following in the Confidential Business Information field:

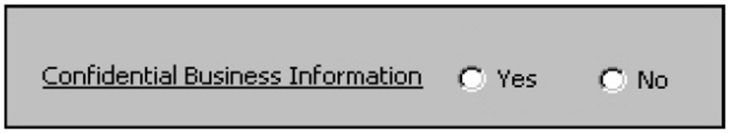


- **Yes** means: I, on behalf of my company, have authority, and the document contains CBI, or
- **No** means: I, on behalf of my company, have authority, and the document contains no CBI.

5.1 Designation and segregation of pre-2006 data

For test data received prior to when the *Pest Control Products Act* came into force for which CBI (as defined in the *Pest Control Products Act*) has not been addressed in the required form and manner, the PMRA will contact the registrants, prior to the registration decision on the evaluation of the test data, to allow an opportunity to address CBI. This will provide registrants and applicants the opportunity to complete the **CBI designation** before a registration decision is reached with respect to the evaluation of test data that are relevant to a decision. The process and requirements for designating CBI in the test data are outlined as follows:

- For pre-2006 data the PMRA will send the applicant/registrant a CBI Notice for Previously Submitted Test Data and an electronic file 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 1. A brief overview is provided hereafter.
- For each document identified in the PMRA generated XML e-Index, indicate in the Confidential Business Information field one of the following:



- **Yes** means: I, on behalf of my company, have authority, and the document contains CBI; Segregation Notice applies or
- **No** means: I, on behalf of my company, have authority, and the document contains no CBI

For data received before the act came into force, 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.

- CBI must be designated, accepted by the PMRA as CBI, and segregated from the test data prior to a registration decision being made. Registration, re-evaluation and special review decisions will not be delayed pending CBI designation, and CTD must be made available for public inspection if requested via the Reading Room.
- The CBI Notice for Previously Submitted Test Data will not be treated as a data deficiency.
- If **no response** is received within the specified timeline, the PMRA will conclude that there is no CBI within the documents listed in the PMRA generated XML e-Index, and designate said data as not CBI.

5.2 Segregation of CBI of pre-2006 data (exceptions)

Segregation of CBI is **not required** for all data that was already submitted prior to 2006. However, if it is required under exceptional circumstances for a document that contains some CBI [for example, 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 (see example in Appendix 1).
- The cover page must be titled: CBI Reference document.
- The cover page must also include identifying information identical to the parent document so that both documents can be linked. For example, the same laboratory report number, DACO satisfied, author(s), title and report date must be indicated.
- Each piece of segregated CBI in the parent document must be replaced by a reference code. The reference code may be determined by the information provider; however, it must be in a format that facilitates identification of excised CBI information with a clear and logical linkage between the parent document and the CBI Reference document.
- A separate CBI Reference document must be provided for each parent document from which CBI was excised.

Note: The two documents; the parent document and the CBI Reference document, must have identical XML e-Index entries except for the CBI field value (that is, parent document marked CBI "No" and CBI Reference document marked CBI "Yes").

It is only acceptable to segregate information that meets the definition of CBI in the *Pest Control Products Act*. Do not remove whole pages unless the entire page is CBI.

5.3 Summary of requirements for each document

Mandatory			Optional
Document		**e-Index CBI flag**	**Statement of CBI page**
Contains no CBI		No	No claim of CBI is made for any information contained in this document on the basis of the definition of CBI under the Pest Control Products Act.
Entire document is CBI		Yes	The entire document is claimed as CBI on the basis of the definition of CBI under the Pest Control Products Act.
Contains some CBI	Parent	No	Information claimed as CBI, as per the definition of CBI under the Pest Control Products Act, has been removed to a CBI Reference document.
	CBI reference	Yes	None

5.4 PMRA verification

The *Pest Control Products Act* requires that the PMRA verify the information designated as CBI meets the definition of CBI in the *Act*. The PMRA will verify CBI has been addressed in the form and manner required, and that the designated CBI meets the definition of CBI as defined by the *Pest Control Products Act*.

If the PMRA is satisfied that information designated as CBI meets the definition of CBI in the *Pest Control Products Act* and is segregated in accordance with Section 4.2 of this Regulatory Directive, it will be protected from public inspection and the PMRA will acknowledge acceptance of the designated information to the information provider. A data index will be included indicating the CBI setting in the PMRA document management system for each document provided.

- The PMRA will acknowledge acceptance of the designated information to the information provider.

It the PMRA is not satisfied that CBI designation and segregation have been completed in accordance with this Regulatory Directive, the Agency will send a written CBI Notice to the information provider indicating that:

- The information designated as CBI does not meet the definition of CBI in the PCPA;
- The CBI is not segregated in accordance with Section 4.2 of this Regulatory Directive;

If the PMRA determines that the designated information does not meet the definition of CBI in the *Pest Control Products Act*, 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 information after the registration decision is made under the *Pest Control Products Act*.

If the CBI Notice requires the information provider to make CBI designations, clarify CBI designations or segregate the CBI in accordance with Section 4.2 of this Regulatory Directive, the PMRA will expect a response to the CBI Notice within 30 days.

- 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.
- The CBI Notice will not be treated as a deficiency.
- If CBI has not been addressed satisfactorily by the information provider prior to the registration, re-evaluation and special review decisions under the *Pest Control Products Act*, the test data will be placed in the Register and be subject to public inspection as it was provided.

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.

6. List of abbreviations

CTD	*Confidential Test data*
CBI	*Confidential Business Information*

7. References

CUSMA: Canada-United States-Mexico Agreement. *https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cusma-aceum/index.aspx?lang=eng*

Access to Information Act (R.S.C., 1985, c. A-1)

Pest Control Products Act

Appendix I : CBI Reference Document Example

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: 2020

25 April 2021

CBI reference

Title: Short-term Oral Toxicity Study in Rats

CBI reference code Examples	CBI information excised	Page number (line)	Reason for CBI claim
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