

DIR2006-03: Confidential Business Information Designation and Segregation Part 1: Submission of Test Data

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Confidential Business Information

PCPA 2002 defines CBI as information designated as CBI by the information provider and concerns:

- ◆ Manufacturing or quality control processes
- ◆ Methods for determining the composition
- ◆ Monetary value of sales and other financial or commercial information
- ◆ **Identity & concentration of formulants & contaminants other than those considered to be of health or environmental concern**
 - Published in 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.

DIR2006-03 Applies To All Test Data For:

- ▶ Applications to register or amend
 - ◆ Including Joint review submissions
- ▶ Import Maximum Residue Limits (MRL)
- ▶ Re-evaluation / Special reviews
- ▶ Responses to PMRA requests for test data.

Note: Data reviews and study summaries are considered test data.

CBI Designation Requirements

1. Mandatory CBI field in the XML e-Index.
2. DACO 0.8.11 CBI Designation Methodology
 - ▶ Specifies method used to designated CBI
3. For each document that contains some CBI, but entire document is not CBI
 - ▶ Segregation of CBI to separate CBI Reference document for each parent document

1. CBI Field

- ▶ XML e-Index required to accompany all instances where test data are submitted.
- ▶ CBI Field is mandatory for each document.
 - ◆ CBI “Yes” indicates that entire document is CBI as per the PCPA 2002.
 - ◆ CBI “No” indicates that there is no CBI in the document

2. DACO 0.8.11 CBI Designation Methodology

- ▶ Single signed page accompanying the data submission.
- ▶ Listed in XML e-Index as DACO 0.8.11

States one of the following:

“CBI designation has been completed by inserting a signed Statement of CBI page in each document submitted and by using the XML e-Index”.

OR

“CBI designation has been completed using only the XML e-Index CBI field. No verification of any Statement of CBI page is required by the PMRA”.

CBI Designation Methodology Document

DACO 0.8.11

Check one of the following:

“CBI designation has been completed by inserting a signed Statement of CBI page in each document submitted and by using the XML e-Index CBI field.”

OR

“CBI designation has been completed using only the XML e-Index CBI field. No verification of any Statement of CBI page is required by the PMRA.”

Signature

If the document is electronic, the signature must be incorporated and displayed in the PDF file, including, but not limited to, graphic representations of cursive signatures, typed free text and digital signatures.

Name, title

Company

Date dd-Month-yyyy

2. DACO 0.8.11 CBI Designation Methodology - Summary

	DACO 0.8.11 Option 1	DACO 0.8.11 Option 2
Designation methods used by registrant	The CBI field in the XML e- Index & Optional Statement of CBI pages for each documents	Only the CBI field in the XML e-Index
PMRA Verification	Check that Statements of CBI match the CBI designations in the XML e-Index	Statements of CBI will not be looked at.
Release for inspection in the reading room	Managed by final PMRA verified CBI field	Managed by final PMRA verified CBI field

Optional Statement of CBI Page Within Each Document

- ▶ If it is not indicated that the optional Statement of CBI page is used in the CBI Designation Methodology document, CBI screeners will not open documents looking for Statement of CBI pages.
- ▶ If the optional Statement of CBI pages are indicated as used in the CBI Designation Methodology document:
 - ◆ Signed Statement of CBI page required in each document
 - ◆ Can use EPA CBI pages provided includes one of the Canadian specific statements.
 - ◆ Statement of CBI page must be either immediately after the cover page or the first page if no cover page exists.

Optional Statement of CBI Page Within Each Document

Must include one of the following statements:

- ▶ “No claim of CBI is made for any information contained in this document on the basis of the definition of CBI under the PCPA 2002.”
- ▶ “The entire document is claimed as CBI on the basis of the definition of CBI under the PCPA 2002”.
- ▶ “Information claimed as CBI, as per the definition of CBI under the PCPA 2002, has been removed to a CBI Reference document”.

Appendix I: Example Statement of CBI Page

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 the document is electronic, the signature must be incorporated and displayed in the PDF file, including, but not limited to, graphic representations of cursive signatures, typed free text and digital signatures.

Name, title

Company

Date dd-Month-yyyy

3. Segregation of CBI: For each document that contains some CBI

Extract CBI from the document (parent)

- Replace the CBI with a reference code
- Place excised CBI into a CBI Reference document

CBI Reference Document

- ▶ Provide separate CBI Reference document for each parent document.
 - ◆ Identifying document information in XML e-Index identical to parent document except CBI field.

- ▶ Cover page titled: CBI Reference document
 - ◆ On cover page include identifying document information of parent document.

- ▶ Reference code must be in a format that facilitates logical linkage between the parent and the CBI Reference document.

Appendix II: Example CBI Reference Document

Title: Short-term Oral Toxicity Study in Rats

CBI Reference Code	CBI information Excised	page # and line	Reason for CBI Claim
CBI 0001	Propylene glycol	60 (line 20)	Formulant name
CBI 0001	Propylene glycol	71 (line 15)	Formulant name
CBI 0002	Sodium Chloride	Throughout document	Formulant name
CBI 0003	Wording for entire paragraph	97	Discloses monetary value

Summary of DIR2006-03

Mandatory		Optional	
Document	e-Index CBI flag	Statement of CBI Page	
Contains No CBI		"N"	No claim of CBI is made for any information contained in this document on the basis of the definition of CBI under the <i>PCPA 2002</i> .
Entire Document is CBI		"Y"	The entire document is claimed as CBI on the basis of the definition of CBI under the <i>PCPA 2002</i> .
Contains Some CBI	Parent	"N"	Information claimed as CBI, on the basis of the definition of CBI under the <i>PCPA 2002</i> , has been <u>removed</u> to a CBI Reference Document".
	CBI Reference	"Y"	None
DACO 0.8.11 CBI Designation Methodology		N	None

Summary

PMRA will be able to protect CBI in evaluation reports & CTD provided:

- ▶ CBI is designated per PCPA 2002 definition, &
- ▶ CBI is segregated into separate document(s).