

PMRA Verification of CBI Designations

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PCPA 2002 Requirements

- ▶ PMRA is required to verify that the information designated as CBI meets the definition of CBI in the Act.
 - ◆ If not met, the designated info. is NOT CBI.
 - the PMRA must give written notice to the provider that the information is NOT CBI.
 - the PMRA will also provide written notice of acceptance of CBI designations to the information provider.
- ▶ PMRA must place in the Register info. not designated or that does not meet the definition of CBI.

Reminder:

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.

Recall for New Test Data: 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

New Test Data

- ▶ Use of the XML e-Index is a data requirement.
- ▶ CBI screening in parallel with submission screening and the PMRA will verify:
 1. DACO 0.8.11 CBI Designation Methodology
 2. Statement of CBI Pages (if DACO 0.8.11 specifies used)
 3. that each document marked as CBI “Yes” meets the definition of CBI as per PCPA 2002.
 4. that for each CBI Reference document verify that it matches one parent document and that CBI has been excised and cross-referenced from the parent document appropriately.

1. DACO 0.8.11 CBI Designation Methodology

- ▶ If not submitted
 - ◆ PMRA will notify the information provider that CBI screening will be based on the XML e-Index CBI Field.
- ▶ If CBI designations done using only the XML e-Index
 - ◆ PMRA will check documents marked as CBI “yes”
- ▶ If DACO 0.8.11 indicates that Statement of CBI pages have been inserted in addition to the XML e-Index CBI field
 - ◆ PMRA will verify the CBI Statement Pages

2. Optional Statement of CBI Page Within Each Document

If specified as used on the DACO 0.8.11 CBI Designation Methodology document PMRA will:

- ◆ Check that each document has an appropriate Statement of CBI page.
- ◆ Verify that the CBI field XML e-Index submitted matches the Statement of CBI pages.
- ◆ Any clarification will be requested from the information provider via a CBI Notice (see slide xx).

3. Verifications of CBI “Yes”

PMRA will verify for every documents marked as CBI “Yes” that the entire document meets the definition of CBI as per the PCPA 2002.

- ◆ PMRA will send a written notification confirming acceptance of CBI designations.
- ◆ If PMRA decides that the document does not meet the definition then it is not CBI and the PMRA is required to provide written notice to the person who provided the information
- ◆ If segregation of CBI is required PMRA will send a written CBI Notice which may require CBI to be segregated (see Slide XXX).

4. CBI Reference Documents

- ▶ Must have the CBI XML e-Index field set as “Yes”
 - ◆ As per previous slide PMRA will only be screening documents marked as CBI “Yes”
- ▶ PMRA will verify that:
 - ◆ all information claimed as CBI meets the definition as per PCPA 2002.
 - ◆ a link can be made between the CBI Reference document and the parent document
 - ◆ CBI has been extracted from the document parent document and replaced with a CBI reference code.
- ▶ A written CBI Notice will be sent to the information provider if segregation has not been completed as per DIR2006-03

DIR2006-04 CBI verification

- ▶ If PMRA agrees, designated information is CBI (per PCPA 2002)
 - ◆ PMRA will segregate CBI from the test data & protect the CBI from access under the PCPA 2002.
- ▶ If PMRA disagrees with designation a written notice will be given to the registrant
 - ◆ There is no formal appeal process however registrants can always express concerns to the PMRA

Recall For Previously Submitted Test Data

- ▶ **No Authority:** company does not have authority to designate CBI for this document
- ▶ **Yes:** I, on behalf of my company have authority and the entire document is CBI.
- ▶ **No:** I, on behalf of my company have authority and the document contains no CBI
- ▶ **Partial:** I, on behalf of my company have authority and the document does contain some CBI.
- ▶ **Request Copy:** 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 to facilitate CBI designation.

Verification of response to Previously submitted CBI Notice

1. XML index returned will be loaded directly into PMRA's data management system.
2. For all claims of CBI "No", PMRA will automatically accept claim.
3. For all documents marked of "No Authority" PMRA will send a CBI Notice to the authority identified.
4. For requests for copies of the test data, PMRA will send a new CBI Notice with the requested files on CD/DVD
5. For all documents marked "Partial" PMRA will verify the CBI Reference documents and segregate CBI
6. For all claims of CBI "Yes", PMRA will verify that the entire document meets the definition of CBI as per PCPA 2002.

CBI Notices New & Previously Submitted Test Data

Issued when:

- ▶ CBI has not been designated as per directives
- ▶ designated CBI does not meet the definition of CBI in the PCPA 2002
- ▶ CBI has not been segregated as per directives
- ▶ CBI Statement pages if used do not match the XML e-Index

Specifies:

- ▶ issues,
- ▶ action PMRA will take or
- ▶ what response is required to resolve issues.

CBI Notices New & Previously Submitted Test Data

- ▶ Not a deficiency, review will not be delayed.
- ▶ A response, if required, is due within 30 days of the date of issue.
 - ◆ Timeframes may be longer BUT
 - ◆ For PMRA to be able to protect CBI, it must be verified, accepted, and segregated by the time a registration decision is reached.
- ▶ **No response = no claim of CBI**
 - ◆ i.e. test data will be released to the Reading Room if requested.

CBI Summary

- ▶ CBI can only be protected if it is designated as CBI as per PCPA 2002
 - ◆ The onus is on the registrant to designate CBI.
 - ◆ PMRA required to verify that designated information meets the definition of CBI.
 - ◆ decisions will not be delayed due to CBI.
 - ◆ CBI Notices are not data deficiencies.
- ▶ Transition: PCPA 2002 applies to all decisions made after June 28th regardless of when data was received
 - ◆ will be challenging for both PMRA and industry.