

# Confidential Business Information Designation and Segregation Live Demo Screen Shots

June 27, 2006

Jamie Munro



Health Canada Santé Canada

**EXAMPLE**  
**CBI Designation Methodology Document**  
**DACO 08.11**

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**

John Doe, Registration Officer  
ABC Company

Date 27-Jun-2006

## **EXAMPLE**

### **Statement of Confidential Business 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**

John Doe, Owner  
ABC Chemicals

12 June 2006

# Hypothetical CBI Segregated from Page 50 of The Art of War

CBI.0002 said: CBI.0001 good fighters of old first put CBI.0001mselves beyond CBI.0001 possibility of defeat, and then waited for an opportunity of defeating CBI.0001 enemy. To secure ourselves against defeat lies in our own hands, but CBI.0001 opportunity of defeating CBI.0001 enemy is provided by CBI.0001 enemy himself. Thus CBI.0001 good fighter is able to secure himself against defeat, but cannot make certain of defeating CBI.0001 enemy. Hence CBI.0001 saying: One may know how to conquer without being able to do it. Security against defeat implies defensive tactics; ability to defeat CBI.0001 enemy means taking CBI.0001 offensive. Standing on the defensive indicates insufficient strength; attacking, a superabundance of strength.

CBI.0003 – (Paragraph)

CBI.0001 general who is skilled in defence hides in CBI.0001 most secret recesses of CBI.0001 earth; he who is skilled in attack flashes forth from CBI.0001 topmost heights of heaven. Thus on CBI.0001 one hand we have ability to protect ourselves; on CBI.0001 other a victory that is complete.

# **CONFIDENTIAL BUSINESS INFORMATION REFERENCE**

Parent document:	12345
Lab. Report No.:	3.141592654
DACO:	4.3.1
Author(s):	Sun Tzu
Title:	The Art of War
Report date:	1910

**25 June 2006**

# Example CBI Reference Document page 2

Title: The Art of War

<b>CBI Reference Code</b>	<b>CBI information Excised</b>	<b>page # and line</b>	<b>Reason for CBI Claim</b>
CBI 0001	The	Throughout document	Formulant name
CBI 0002	Sun Tzu	50 (line 1)	Formulant name
CBI 0003	“Standing on the defensive indicates insufficient strength; attacking, a superabundance of strength.”	50	Discloses monetary value

# Part 2: Previously Provided Test Data



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# Recall Step 3.1 PMRA Generated XML e-Index

- ▶ Open with the most current version of the e-Index Builder Application → PMRA website.
- ▶ Allows editing of CBI field and comments field.
- ▶ CBI reference documents can be added by the registrant associated with each record in the XML e-Index
  - ◆ Must use copy row function of e-Index Builder Application
- ▶ Files that apply to many records or the entire list of data can be added.
  - ◆ e.g. a general statement about who has authority to make CBI designations.



- ▶ **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.



#	Data Numbering Code(s)	Title	Author(s)	Volume No(s)	e-File Name
	2.11.1	Manufacturing Summary	John Doe	1	
	2.11.2	Description of Starting Materials	John Doe	1	
	2.11.3	Detailed Production Process Description	John Doe	1	

2.11.3 DETAILED PRODUCTION PROCESS

Data Numbering  
Code(s)

-- Select Data Numbering Code(s) Here --

Cross Reference Yes  NoPMRA Document No. Application No. Confidential Business Information Yes  No Partial  Request Copy  No AuthorityApplicant DER Yes  No

Company Report No.

NA

Title

Detailed Production Process Description

Author(s)

John Doe

Report Date

2005-12-16

Select

Clear

No. of Pages

2

Volume No(s)

1

EPA MRID No.

NA

Lab Name

NA

Lab City

NA

Lab Country

--- Not Applicable ---

Lab Report No.

NA

Study Carried out under

--- Not Applicable ---

Published

 Yes  NoDocument Group 

Comments

e-File Name

Browse

Clear

e-File Location



#	Data Numbering Code(s)	Title	Author(s)	Volume No(s)	e-File Name
	2.11.1	Manufacturing Summary	John Doe	1	
	2.11.2	Description of Starting Materials	John Doe	1	
	2.11.3	Detailed Production Process Description	John Doe	1	

2.11.3 DETAILED PRODUCTION PROCESS

Data Numbering Code(s)

-- Select Data Numbering Code(s) Here --

Cross Reference

Yes  No

PMRA Document No.

Application No.

Confidential Business Information

Yes  No

Partial  Request Copy  No Authority

Applicant DER

Yes  No

Company Report No.

Title

Author(s)

Report Date




No. of Pages

Volume No(s)

EPA MRID No.

Lab Name

Lab City

Lab Country

Lab Report No.

Study Carried out under

Published

Yes  No

Document Group

Comments

Authority to designate this study is AMC INC; Contact info xyxyxyx

e-File Name




e-File Location



#	Data Numbering Code(s)	Title	Author(s)	Volume No(s)	e-File Name
	2.11.2	Description of Starting Materials	John Doe	1	
	2.11.3	Detailed Production Process Description	John Doe	1	
	2.11.3	Detailed Production Process Description	John Doe	1	Options.wpd

2.11.3 DETAILED PRODUCTION PROCESS DESCRIPTION

Data Numbering Code(s)

-- Select Data Numbering Code(s) Here --

Company Report No. NA

Title Detailed Production Process Description

Author(s) John Doe

Report Date 2005-12-16

No. of Pages 2

Volume No(s) 1

EPA MRID No. NA

Cross Reference  Yes  No

PMRA Document No.

Application No.

Confidential Business Information  Yes  No

Applicant DER  Yes  No

Lab Name NA

Lab City NA

Lab Country --- Not Applicable ---

Lab Report No. NA

Study Carried out under --- Not Applicable ---

Published  Yes  No

Document Group

Comments

CBI attachment for 2.11.3

e-File Name Options.wpd

e-File Location C:\Documents and Settings\PMRAUSER\My Documents\Opti



#	Data Numbering Code(s)	Title	Author(s)	Volume No(s)	e-File Name
	2.11.3	Detailed Production Process Description	John Doe	1	
	2.11.3	Detailed Production Process Description	John Doe	1	Options.wpd
	2.0	CBI reference document for Part 2.0	Jane Doe		dir2003-01-e.pdf

2.0 CHEMISTRY REQUIREMENTS FOR (TGAI) OR (ISP)

Data Numbering Code(s)

-- Select Data Numbering Code(s) Here --

Cross Reference  Yes  No  
 PMRA Document No.   
 Application No.

Confidential Business Information  Yes  No

Applicant DER  Yes  No

Company Report No.

Title

Author(s)

Report Date

No. of Pages

Volume No(s)

EPA MRID No.

Lab Name

Lab City

Lab Country

Lab Report No.

Study Carried out under

Published  Yes  No

Document Group

Comments

e-File Name

e-File Location