

Désignation et triage des renseignements commerciaux confidentiels (RCC)

Démonstration en direct à l'aide de captures d'écran

Le 27 juin 2006

Jamie Munro



Health Canada Santé
Canada 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

Triage de RCC hypothétiques à partir de la page 50 du traité intitulé *The Art of War*

CBI.0002 said: “CBI.0001 good fighters of old first put CBI.0001 mselves 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

Exemple de document référence RCC

page 2

Titre : *The Art of War*

Code de référence RCC	RCC extrait	Page et ligne	Raison de la désignation RCC
CBI 0001	<i>The</i>	Dans tout le document	Nom du produit de formulation
CBI 0002	<i>Sun Tzu</i>	50 (ligne 1)	Nom du produit de formulation
CBI 0003	<i>“Standing on the defensive indicates insufficient strength; attacking, a superabundance of strength.”</i>	50	Divulgence de valeurs pécuniaires

Partie 2 :

Données d'essai déjà fournies

Rappel étape 3.1 de l'index électronique XML généré par l'ARLA

- ▶ S'ouvre avec la version la plus récente du générateur de l'index électronique → site Web de l'ARLA.
- ▶ Permet la mise en forme des champs RCC et commentaires.
- ▶ Autorise l'ajout de documents de référence RCC par le titulaire d'homologation correspondant à chaque dossier de l'index électronique XML.
 - ◆ Exige l'application de la fonction **copie de ligne** du générateur de l'index électronique.
- ▶ Permet l'ajout de fichiers reliés à plusieurs dossiers ou à la liste de données entière.
 - ◆ p. ex. un énoncé général concernant l'autorité responsable des désignations RCC.

- **Sans autorité** : l'entreprise n'a pas le pouvoir de désigner des RCC pour ce document.
- **Oui** : Au nom de mon entreprise, je suis le responsable des désignations RCC et j'atteste que ce document en entier est désigné RCC.
- **Non** : Au nom de mon entreprise, je suis le responsable des désignations RCC et j'atteste que ce document ne contient aucun RCC.
- **En partie** : Au nom de mon entreprise, je suis le responsable des désignations RCC et ce document contient certaines RCC.
- **Demande de copie** : Au nom de mon entreprise, je suis le responsable des désignations RCC. Comme aucun dossier ne correspond à ce fichier, j'en demande une copie à l'ARLA afin de simplifier le processus de désignation des RCC.



#	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 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

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

e-File Name

Browse

Clear

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