

How to prepare for EU GHS notification?

PRISM2 Workshop

Promoting Responsibility in SMEs

08 April 2010



L. Heezen

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1- Legal obligations



Title V (chapter 2) to CLP regulation:

- **Obligation for Industry to notify ECHA (article 40-41)**
- **Obligation for ECHA to establish & maintain a C&L Inventory (article 42)**

Which substances you shall notify?



Substance subject to registration under REACH



Also non-classified substances!



If you register under REACH your substance before 3 January 2010 and the registration dossier contains the CLP information, you fulfil your C&L notification obligation, and no notification is required.

Substances classified as hazardous under CLP



No tonnage threshold !

Substances classified as hazardous under CLP and present in a mixture above the concentration limits specified in Annex I to CLP or in Directive 1999/45/EC which results in the classification of the mixture as hazardous

... AND PLACED ON THE MARKET !

2- Who shall notify?



Notification must be performed by:

- Manufacturer,
- Importer, or
- Group of manufacturers/importers

who places a hazardous substance on the market (on its own or in a hazardous mixture),

who places on the market a substance subject to registration under REACH

Note: downstream users, distributors and producers or importers of articles do not need to notify!

When to notify?



General rule: Within one month from placing on the market

Substances on the market on 1 December 2010 have to be notified **by 3 January 2011 (EoB)**

(First working day after 1 January)

Practical examples



Shall I notify, if:

I am manufacturing/importing 100 kg/year of a hazardous substance:

⇒ **Yes, if your substance is placed on the market**

I am manufacturing/importing 500 kg/year of a non-hazardous substance:

⇒ **No !**

I am manufacturing a substance subject to REACH registration, I benefit from the transitional period and intend to register in 2013:

⇒ **Yes, if your substance is placed on the market.**

You have to notify your substance even if this substance is not hazardous !

Practical examples



Shall I notify, if:

I am manufacturing a substance subject to REACH registration, I have already submitted before 3 January 2011 a registration dossier containing C&L according to DSD and CLP criteria:

⇒ **No. You are fine !**

I am manufacturing a substance subject to REACH registration, I have already submitted before 3 January 2011 a registration dossier containing C&L according to DSD criteria only:

⇒ **From 1 December 2010, you shall update your registration dossier without undue delay, as you have to classify according to CLP from that date. (REACH Article 22)**

⇒ **The same applies to the former NONS.**

Practical examples



Shall I notify, if:

I am manufacturing a substance in October 2010 which I leave in stock **for a while** before I place it on the market in February 2011:

⇒ **Yes. you must notify it within 1 month after placing it on the market in 2011.**

I am manufacturing a substance which I supply to a distributor in June 2010 **who** leaves it in stock at first **before he** places it on the market in 2011:

⇒ **No for you and no for the distributor !**

... and what if you do not notify?



You may be subject to enforcement !

Remember that the classification and labelling you present in the Safety Data Sheet of your substance has to be consistent with the information you submit in your C&L notification. The Safety Data Sheets may be inspected by the relevant enforcement authorities in the Member States.

3- Information to be notified



Article 40:

Identity and contact details of the notifier

Identity of the substance(s)

Classification of the substance(s) according to CLP

The reason for “no classification”

SCLs or M-factors and justification

Label elements (hazard pictograms, signal words, hazard statements and any supplemental hazard statements)

→ **about 200 IUCLID fields for one notification!**

Health hazards	Hazard statement	Reason for no classification
Acute toxicity - oral		
Acute toxicity - dermal		
Acute toxicity - inhalation		
Skin corrosion/irritation		
Serious damage/eye irritation		
Respiratory sensitization		
Skin sensitization		
Aspiration hazard		
Germ cell mutagenicity		
Carcinogenicity		
Reproductive toxicity		
Specific effect		
Route of exposure		
Effects on or via lactation		

When updating your notification?



Article 40(2):

Submit an update of your notification when...:

new information available on your substance that has an impact on the C&L,

more details available / changes on your substance composition, change in contact details,

agreement with a classification and labelling already in the public C&L inventory,

specification/update of the group of Manufacturers / Importers, following ECHA request, following an harmonisation procedure...

Special case of substance registered under REACH



If you have already submitted a registration dossier **under REACH** and **if you want to update the C&L information**, you shall update your registration dossier (**REACH-article 22**).

4- Identified challenges of C&L notifications



Deadline : 3 January 2011 !

Huge number of C&L notifications to be submitted

Amount of data requested per notification

Quality of data on substance ID is of highest importance (to identify “same substance” for C&L agreement)

Various profiles of notifiers with different needs:

⇒ The “well-organised” corporate-industry having structured central data-base containing all their C&L

⇒ The SME with few C&L to notify

⇒ And... all the ones not even aware of the need to notify !

5- IT tools to submit your notifications



C&L notifications shall be submitted electronically via the REACH-IT portal on the ECHA website.

=> If not yet done, you need to create your company account in REACH-IT

- Dedicated area in the main REACH-IT menu:

The screenshot shows the ECHA REACH-IT portal interface. The top navigation bar includes the ECHA logo and the text "You are connected". Below the navigation bar, the main content area displays a welcome message: "Welcome Sandrine Lef." and a notification: "You have 7 unread message(s) in your message box." A left-hand menu lists various options, with "Classification and Labelling" highlighted. A callout box points to this menu item, listing the following sub-menu options: "Notify a C&L online", "Notify a C&L using IUCLID", "Notify bulk C&L", "Manage groups of Manufacturer(s) / Importer(s)", "View my submitted C&L notifications", and "Consult the public C&L inventory". Another callout box points to a separate box containing the options "Request for alternative name under CLP art. 24" and "Proposal for Harmonised C&L under CLP art. 37", with the annotation "To be added later 15".

ECHA

Home

Welcome Sandrine Lef.

You have 7 [unread message\(s\) in your message box](#).

- Company
- Pre-registration
- Pre-SIEF
- Online dossiers
- Phase-in Information
- Registration / notification
- Joint submission
- Classification and Labelling**
- Message box
- User account
- Invoices
- Search

Add a new item in the menu

- Notify a C&L online
- Notify a C&L using IUCLID
- Notify bulk C&L
- Manage groups of Manufacturer(s) / Importer(s)
- View my submitted C&L notifications
- Consult the public C&L inventory

With the following sub-menu

- Request for alternative name under CLP art. 24
- Proposal for Harmonised C&L under CLP art. 37

To be added later 15

5- IT tools to submit your notifications



Different submission tools to answer all Industry potential needs related to notification submission:

- ⇒ Creation of C&L using IUCLID 5
- ⇒ Online creation and submission of C&L for SME
- ⇒ XML creation and Bulk submission for company with many notifications to submit

Specification and management of “group of Manufacturers/Importers”

Notification Submission – flexibility



All submission means will be compliant with IUCLID 5.2 and CLP regulation

All submission means will be compatible between each other (including update, submission by a group of MI etc...)

C&L notification with IUCLID 5



The notification is created in IUCLID 5

- Template = “REACH C&L notification” in IUCLID 5.1
- Template = “CLP notification” in IUCLID 5.2

The IUCLID 5 notification is submitted via REACH-IT

User guide on how to fill-in the IUCLID 5 notification will be available at the same time as the tool

The screenshot shows the 'Labelling' section of the IUCLID 5 interface. It includes a 'Signal word' dropdown menu, a 'Hazard pictogram' section with a selected 'Explosive' pictogram (GHS01) and its code, and a 'Hazard statements' section with a selected 'Explosive, mass explosion hazard' (H201) and its code. There is also a field for 'Additional text' and a 'Precautionary statements' section at the bottom.

The screenshot shows the 'Health hazards' section of the IUCLID 5 interface. It contains a table with columns for 'Hazard statement' and 'Reason for no classification'. The rows include: Acute toxicity - oral, Acute toxicity - dermal, Acute toxicity - inhalation, Skin corrosion/irritation, Serious damage/eye irritation, Respiratory sensitization, Skin sensitization, and Aspiration hazard. Below this are sections for 'Germ cell mutagenicity' and 'Carcinogenicity', each with a table for 'Hazard statement' and 'Reason for no classification'.

On-line C&L notification



Target user: SMEs

No need to use IUCLID 5

The C&L notification is prepared directly in REACH-IT

Pragmatic approach to ease the encoding of data in the notification:

- ⇒ Reduce number of fields
- ⇒ Use of default value if possible
- ⇒ On-line help and guide along the wizard
- ⇒ Compulsory fields
- ⇒ Link with the C&L inventory (incl. Annex VI) to ease the encoding of C&L
- ⇒ “agree” concept

⇒ This will not be available in May!!!

Bulk C&L notifications



Objectives:

- Allow to submit in one shot many notifications
- Allow to dump the C&L from industry's centralised DB
- Reduce the amount of submission

Creation of a bulk submission in a **xml file** and then submission of this bulk via REACH-IT

ECHA will provide an **excel tool** for data creation and subsequent transfer to XML

The xml bulk submission can be used **only** under the following strict conditions:

- Each substance you notify must be identified by a CAS number,
- You can not specify more than one composition for each substance,
- You can not notify a substance which is not classified as Hazardous,
- You can not set an M factor (if not given already in Annex VI to CLP)
- You can not specify a different SCL than the one already given in Annex VI to CLP regulation

Group of Manufacturers/Importers



"A group of manufacturers or importers can be one of the following:

- a Corporate company with different LEs*
- several companies that have no specific links between each other*
- a SIEF*
- a Joint Submission ...*

that agree on a common C&L for the same substance."

Objectives :

- **Allow industry to create and manage group(s) of Manufacturers/Importers**
- **Allow industry to submit C&L notification(s) as a group of Manufacturers/Importers (ie 1 notification submitted on behalf of max 499 companies)**
- **Offer to the user an easy solution to update its group(s) of MI without having to submit an update of the C&L notification**
- **Reduce the amount of "agreed" submissions**

Group of Manufacturers/Importers



A group is composed of minimum 2 members.

It is not compulsory for the members to have a REACH-IT account.

The submitted C&L will be considered as agreed by the group.

What the user CAN do in this module:

- create a new group of MI:
 - Outside REACH-IT in an xml format to be uploaded in REACH-IT
 - Inside REACH-IT ahead of the notification
 - Inside REACH-IT during the C&L notification submission (bulk, I5.2, or online).
- delete a group of MI
- update an existing group of MI:
 - add a new member
 - remove a member (only if group contains more than 2 members)
 - update the company details of the member(s)
- Have an overview of the C&L notified by a group

All actions related to the update of the group will be recorded/updated in the C&L inventory.

C&L submission miles-stones



New Notification Submission means will be available in 1st half of 2010 as soon as REACH 2.0 is released:

- ⇒ **IUCLID 5.2 (updated IUCLID according to CLP)**
- ⇒ **bulk notification**
- ⇒ **group of Manufacturers/Importers**

- ⇒ **online C&L notification**

6- How to be prepared ?



The submission tools are not yet available
in REACH-IT,
but
you can already start preparing your notification !

6- How to be prepared ?



- Make an inventory of the products you manufacture in the EU and import,**
- Are those products substances or mixtures classified as hazardous ?**
- Are those substances exempted from CLP?**
- Collect all information to properly identify your substances,**
- Name the substances in line with the SID guidance,**
- Are those substances listed in Part 3 of Annex VI to CLP ?**
- If your substance is not yet HARMONISED, gather all available and reliable information on the hazardous properties of the substances;**
- Prepare a Chemical Safety Report with adequate and reliable information in the case where you want to specify a M-factor, or set a Specific Concentration Limit (article 10-CLP)**
- Classify your substance by evaluating the available information against the classification criteria**
- Create a group of MI if needed, etc...**

Where to find further information?



ECHA web pages http://echa.europa.eu/classification_en.asp :

- Link to the CLP regulation
- Guidance on introduction to CLP, Application of CLP criteria
- Questions & Answers on CLP
- Further explanatory documents under development (IUM on “how to create a C&L notification in IUCLID 5.2”, Q&A on notifications, etc)

CLP awareness campaign :

- ECHA’s third Stakeholders’ Day on 7 December on CLP

If you have questions:

- CLP / REACH helpdesk in your country
- ECHA Helpdesk
- your industry association can be a good source for sector-specific questions

The screenshot shows the ECHA website interface. On the left is a vertical navigation menu with links: HOME, SIEF, REACH, CONSULTATIONS, ECHA CHEM, REACH-IT, CLASSIFICATION (CLP Regulation, Guidance, Harmonised CL), GUIDANCE, HELP, PRESS AND EVENTS, ABOUT ECHA, PUBLICATIONS, WORKING WITH US, and APPEALS. The main content area features a header for 'New classification, labelling and packaging regulation' with a sub-header 'New classification, labelling and packaging regulation'. Below this, there is text about the new EU regulation (EC) No 1272/2008 and its implementation. A 'Guidance' section is highlighted, with a sub-header 'Guidance' and text stating that guidance will be published to support companies. A 'Harmonised classification and labelling' section is also visible, with a sub-header 'Harmonised classification and labelling' and text about proposals for classification. The ECHA logo is visible in the top right corner of the page. The page number '26' is displayed in the bottom right corner.

7. C&L inventory



What will it contain?

The C&L entries of Annex VI to the CLP Regulation
Information submitted by Industry according to Art 40(1):

- Notifier/registrant details including group of MI,
- Substance ID,
- C&L according to CLP

Additional information inserted by ECHA

- Entry in Part 3 of Annex VI
- Joint entry between registrants of the same substance
- Agreed entry between notifiers / registrants
- Difference between other entries for the same substance
- Alternative name (if any)

SEVESO categories

Content of the public C&L inventory



A public version of the C&L inventory will be made available on ECHA's website. It will be the central source on information on classification and labelling for all users of chemicals

According to Article 119(1) of REACH:

- Substance identifier
 - IUPAC for dangerous substances
 - EINECS if available
- C&L, incl. specific concentration limits (SCLs), M-factors and notes

According to Article 42(3) of CLP:

- Entry in part 3 of Annex VI
- Joint entry between registrants of the same substance
- Agreed entry between notifiers or registrant

C&L inventory in a nutshell



**A repository of all C&L information submitted to ECHA
(notifications, registrations) + Annex VI**

A database within the REACH-IT system

A database fully accessible by ECHA and MSCA

**A database used as a background for the online submission of
C&L notifications**

A database used for the dissemination of C&L

=> public C&L inventory end 2010

8. Conclusions



Release of C&L functionalities in REACH-IT in May 2010.

You can already start to prepare your C&L notification by manually compiling the required data, and creating your group of MI (if needed).

Correct information on substance identity is crucial.

We recommend you to start submitting your C&L notification to ECHA when all notification possibilities will be available in REACH-IT:

- ⇒ If you need to notify only a few substances and you are not currently using IUCLID 5, the online notification via REACH-IT could be your preferred option.**
- ⇒ Bulk notification using the XML option may be more practical if you have to notify many chemical substances.**

If you register under REACH before 3 January 2011, include already the C&L according to CLP criteria in your dossier.

Links



- **Cefic website:**

<http://cefic.org/en/reach-for-industries-GHS.html>

- **ECHA website:**

http://echa.europa.eu/home_en.asp

Thanks you
lhe@cefic.be