How to prepare for EU GHS notification?

PRISM2 Workshop

Promoting Resposibility in SMEs

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L. Heezen

Content

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

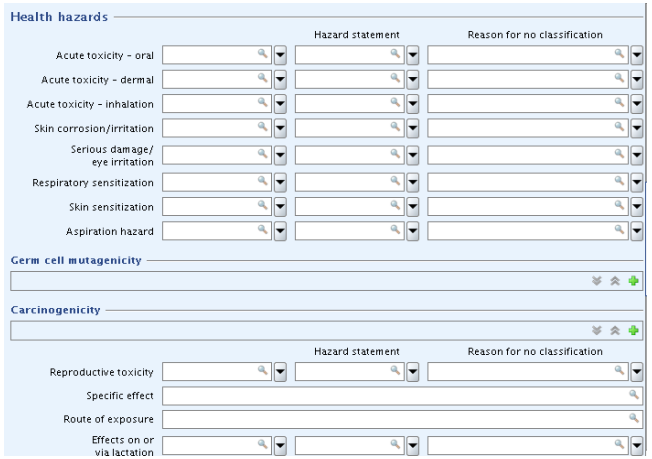
Identity **of the substance(s)**

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 <u>one</u> notification!**

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**

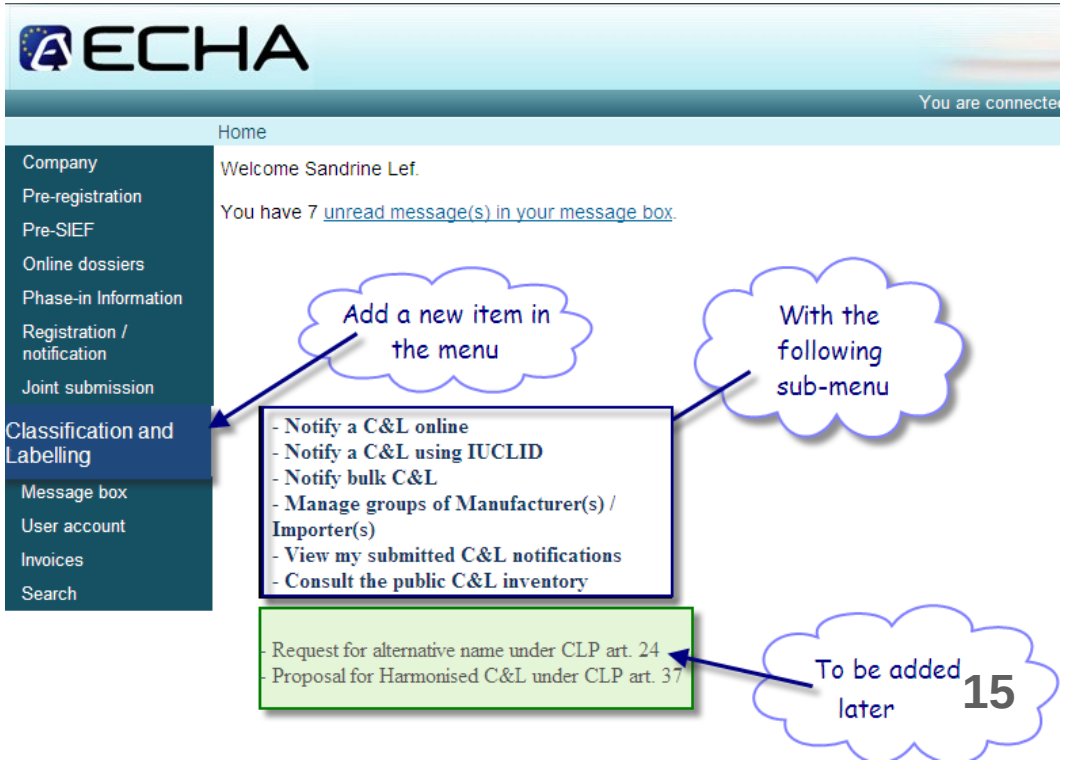
⇒**And… all the ones not even aware of the need to notify !**

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:



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…)

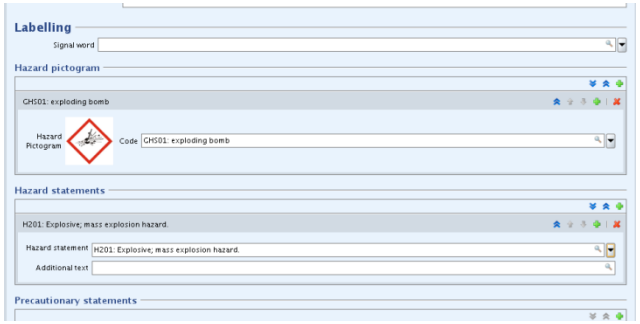
C&L notification with IUCLID 5

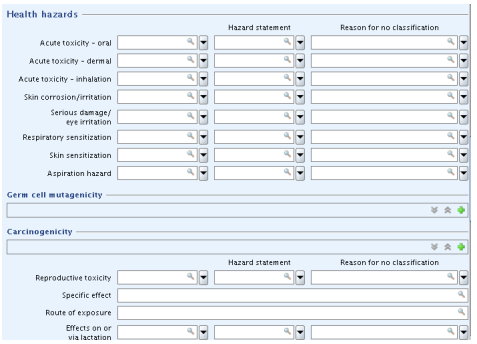
The notification is created in IUCLID 5

- **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**





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 :

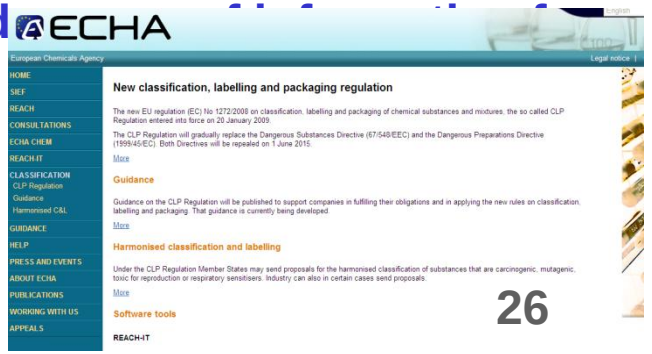
- **Link to the CLP regulation**
- **Guidance on introduction to CLP, Application of CLP criteria**
- **Questions & Answers on CLP**
- **Further explanatory documents under development (IUM on "how to create a C&L notification in IUCLID 5.2", Q&A on notifications, etc)**

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 [illegible] sector-specific questions**



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