



## **Notification to the Classification and Labelling Inventory**

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# Outline

- Basic facts about C&L notification under CLP
  - Practical steps for the notification
  - Details of the notification tools
  - Practical manuals for the IT tools
  - Principle and practices of the HelpNet service
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## ECHA's role under CLP

- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging - 20 January 2009
    - Managing proposals for harmonised C&L
    - Handling requests for use of alternative names
    - **Developing and managing C&L inventory**
    - Providing guidance and support
  - C&L awareness
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## C&L Notification – Who?

- *“Any manufacturer or importer, or group of manufacturers or importers ... who place on the market a substance ... shall notify to the Agency ...” (CLP, Art. 40(1))*
  - **Group of Manufacturers / Importers**
    - *Corporate company with different legal entities*
    - *Several companies with no specific links*
    - *SIEF*
    - *Joint Submission ...  
that agree on a common C&L for the same substance*
  - **C&L for a same substance should be agreed (Art. 41)**
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## Only Representatives (OR)?

- **Only Representatives under REACH**
    - ORs of non-EU manufacturers can fulfil all obligations of importers under REACH, incl. register substances
    - Importers are then relieved from their obligation to register the substances imported
  - **Only Representatives under CLP?**
    - ORs have no role under CLP, and are not entitled to notify C&L on behalf of importers
    - Importers need not notify the C&L, if the substance has been registered by OR
    - If OR is also importer, he can notify C&L on behalf of “Group of Manufacturers / Importers”
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# C&L Notification - What and When?

- Which substances? (CLP, Art. 39)
    - Substances subject to registration under REACH and placed on the market
    - Other substances meeting classification criteria and placed on the market on their own or in a mixture above concentration limit  
→ Note! No tonnage trigger!
  - Exemptions
    - No notification is required, if the same information has already been submitted as part of a registration dossier
  - Deadline for C&L notification
    - Within 1 month after placing on market on or after 1/12 2010
    - First deadline: 3 January 2011
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## Practical steps for the notification (I)

- **Practical guide 7: How to notify substances to the Classification & Labelling Inventory**
    - Will be available on the CLP section of ECHA web site in mid April
  - **Basic information on C&L notification, e.g.**
    - Helps to identify industry obligations
    - Provides general information on notification and the Inventory
    - Advises how to prepare for C&L notification
    - Describes basic features of the different notification tools (incl. limitations)
    - Includes useful links to related guidance and other documents
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## Practical steps for the notification (II)

- What information?
    - Name and contact details of the notifier
    - Identity of the substance (sections 2.1 to 2.3.4 of Annex VI of REACH)
    - Classification of the substance according to CLP
    - “Reason for no classification”
    - Label elements (hazard pictograms, signal words, hazard statements and supplemental hazard statements)
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## How to prepare for notification (I)

1. List the substances and mixtures you manufacture or import
  2. Clarify if any are exempted from CLP (cf. Art 1)
  3. Check if any are subject to REACH registration
  4. Collect all information on your substances' identity and composition
  5. Name your substances in line with the guidance on SID
  6. Check if your substances are listed in Annex VI to CLP
  7. Gather all available and reliable information on the hazardous properties of your substance if the C&L is not harmonised
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## How to prepare for notification (II)

8. Classify your substances by comparing the available information with the classification criteria
  9. Prepare a scientific justification if you specify a M-factor or set a specific concentration limit (SCL)
  10. Decide if you want to establish or join a group of manufacturers and/or importers
  11. Create your C&L notification in the appropriate format
  12. Create your REACH-IT account (if not done already) and submit your notification
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# Group of Manufacturers/Importers

- REACH-IT Industry User Manual, Part 15
  - Stepwise guide on managing your group
  - Several screenshots on REACH-IT
  - Clear indication of possible actions in creation, management and group/member details pages
- Content
  - Introduction and concept of group of MI
  - Navigation overview of the module
  - Step by step instructions to manage and create new groups;
  - Common error messages



# Group of MI - Example (I)

REACH-IT Industry User Manual  
Part 15 - Manage your group of manufacturers or importers



## 4.1.2 Overview of your groups


The group of MI overview screen can be accessed from the Classification & Labelling menu by selecting the "Manage Groups of Manufacturer(s)/Importer(s)" menu item.

The "Manage the Groups of Manufacturer(s)/Importer(s)" page opens (Figure 3).

From this page, you have an overview of all the groups you have created, and can perform several actions.

Figure 3: Manage the groups of MI



If you hover with your mouse pointer over the appropriate  symbol you will find further information on each functionality of this page.

You can either start the creation of a new group by clicking on the link <create a new group of Manufacturer(s)/Importer(s)>, or update the composition of a group by selecting a group and clicking on the link <view/update group> or delete one group.

Table 1: Actions that can be performed on the "Manage the Groups of MI" page

You want to...	Action that must be performed	Result
Start the creation of a new group	Click the link <create a new group of Manufacturer(s)/Importer(s)>	Navigate to Figure 5 where the user will select the creation method.
Delete a Group	Select a group from the table using the radio button and click the <Delete Group> button.	Navigate to Figure 13 where the user will be asked to confirm the deletion.
View/Edit a Group	Select a group using the radio button and click the <view/update group> button.	Navigate to Figure 9 where the selected group details will be displayed.
View the C&L notified by a group	This functionality is not yet available.	



## Details of the notification tools

- Different tools for preparing C&L notifications
    - IUCLID 5
    - XML creation and Bulk Submission (for companies with many notifications)
    - Online creation and submission via REACH-IT (for companies with few notifications, e.g. SMEs)
  - ECHA manuals will be available
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# Notification tools: IUCLID 5.2

- REACH-IT Industry User Manual, Part 12
  - Stepwise guide on C&L notification creation and submission
  - More than 90 screenshots
  - Active links to other parts of REACH-IT and ECHA guidance
- Content
  - Introduction, creation of Legal entity
  - Creation of a reference substance and a substance dataset
  - **Details of IUCLID 5.2 sections to be completed**
  - Creation of a dossier using the “CLP notification” template
  - Export of the notification dossier
  - Update of a C&L notification dossier
  - **Submission in REACH-IT**



# IUCLID 5.2 - Example (I)

## 5.7.2.1. Classification - Physical hazards

For all endpoints indicated in the block "Physical hazards", either the two first fields (i.e. the field "Hazard category" (e.g. expl. Div. 1.1) and the field "Hazard statement" (e.g. explosive; mass explosion hazard)) shall be filled in, or the field "Reason for no classification" shall be filled in. (Figure 57)

Figure 57: Specify hazard category and hazard statement for the Physical hazards

Physical hazards	Hazard statement	Reason for no classification
Explosive		data lacking
Flammable gases		data lacking
Flammable aerosols		data lacking
Oxidizing gases		data lacking
Gases under pressure		data lacking
Highly flammable liquids		data lacking
Flammable liquids		data lacking
Self-heating substances and mixtures		data lacking
Pyrophoric liquids		data lacking
Pyrophoric solids		data lacking
Self-heating substances and mixtures which in contact with water emit flammable gases		data lacking
Oxidizing liquids		data lacking
Oxidizing solids		data lacking
Organic peroxides		data lacking
Corrosive to metals		data lacking

✘ The following hazard category and hazard statement do not exist in the CLP regulation and shall not be used in your C&L notification:

Classification endpoint	Hazard category	Hazard statement
Flammable liquids	Flammable liquid 4	H227: Combustible liquid



# IUCLID 5.2 - Example (II)

## Data Submission Manual

### Part 12 - How to Prepare and Submit a Classification and Labelling Notification Using IUCLID



### 9.3 Step 3: Starting a C&L notification submission

To start the dossier submission, go to the <Classification and Labelling> menu, and click on <Notify a C&L using IUCLID> (Figure 90)

Figure 90: Starting a notification submission







## Notification tools: Bulk submission

- Objectives:
    - Submit in one shot many notifications
    - Dump C&L from centralised data base
    - Reduce the number of submissions
  - **xml file** submitted via REACH-IT
  - ECHA will provide an **Excel tool** for data creation and transfer to xml
    - Will be available in mid April
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## Bulk submission tool - Limitations

- The xml bulk submission can be used **only** under the following strict conditions:
    - Substances notified must be identified by CAS or EC number,
    - Only one composition for each substance,
    - Not usable if the notifier wants to set an M factor (if not already in Annex VI to CLP)
    - Not usable if the notifier wants to specify a SCL for other hazard classes than the one already given in Annex VI to CLP regulation
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# Bulk submission – Example



You are connected as **SandL007** on

[Home](#) > [C&L Bulk Notification](#) > [Select Manufacturer\(s\)/Importer\(s\) group](#) > [Submit External Dossier](#)

**Company**

- Pre-registration
- Pre-SIEF
- Online dossiers
- Phase-in Information
- Registration / notification
- Joint submission
- Classification and Labelling
- Message box
- User account
- Inventories
- Legal entity change
- Invoices
- Search


### Bulk Classification and Labelling (C&L) notification

Please pick here using the "Browse" button the file which contains your dossier (your file should have an "xml" extension)

\* File name:  [Browse...](#)

\* Enter the text shown:  [?](#)

Can't read the text below? [Try another](#)



### Access code for large files

For the submission of a file larger than 20 MB, please [request a large file access code](#) before submission.

If you have an access code for a large dossier, please, enter it here

Large file access code:

[Submit dossier](#)

## Notification tools: On-line notification

- SMEs... but not only
  - No need to use IUCLID 5
  - C&L notification **prepared directly in REACH-IT**
  - Pragmatic approach :
    - ⇒ Reduced fields
    - ⇒ On-line help and guide along the wizard
    - ⇒ Compulsory fields
    - ⇒ Link with the C&L inventory (incl. Annex VI)
    - ⇒ “I agree” concept
    - ⇒ Generate a IUCLID 5 dataset that you can reuse later
  - Available in June 2010
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# On-line notification - Example

Substance identity
  Optical information
  C&L
  Production site
  Contact
  Validation

Please find below the Harmonised Classification and Labelling related to the substance you want to notify.

Check it and indicate if you want to continue your notification with this C&L or if you want to include further information.

Fields marked with an asterisk (\*) are mandatory.

## General information

Dossier name:	My new dossier name that I gave in the previous screen
Type of notification:	Respect harmonised classification
Substance type:	Mono-constituent substance

## Substance identity

Index number	EC number	CAS number	International Chemical Identification
200-010-010-7	200-010-7	50-10-2	oxyphenonium bromide

## Classification

Physical hazards	Hazard statement
Explosives <input type="text" value="unst. expl."/> ▼	explosive; severe projection hazard <input type="text" value="explosive; severe projection hazard"/> ▼
Self-reactive substances and mixtures <input type="text" value="self react. type D"/> ▼	heating may cause a fire or explosion <input type="text" value="heating may cause a fire or explosion"/> ▼

Health hazards	Hazard statement
Acute toxicity - oral <input type="text" value="acute tox. cat. 3"/> ▼	harmful if swallowed <input type="text" value="harmful if swallowed"/> ▼
Acute toxicity - dermal <input type="text" value="acute tox. cat. 2"/> ▼	may be harmful in contact with skin <input type="text" value="may be harmful in contact with skin"/> ▼
Acute toxicity - inhalation <input type="text" value="acute tox. cat. 2"/> ▼	fatal if inhaled <input type="text" value="fatal if inhaled"/> ▼

To be continued

## Labelling

Signal word:  ▼

- I want to notify the same classification and labelling as the one Harmonised in Annex VI of the CLP  
 I want to notify further classification and labelling information [?](#)

## HelpNet – Principles and Practices

- Voluntary network of national REACH and CLP helpdesks
  - ECHA acts as focal point
  - Successor of former REHCORN since October 2009
  - Main objectives
    - Ensure consistent and harmonised advice on REACH and CLP for industry (FAQs on ECHA web site)
    - Forum for discussion and exchange of information relevant for helpdesks
    - Training / workshops for national helpdesks
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## HelpNet – Tools (I)

- **HelpNet Steering Group:**
    - REACH helpdesk of 27 EU Member States + Norway + Iceland
    - CLP helpdesk of 27 EU Member States
    - Associated members of European Commission
    - ECHA
    - Observers from Turkey and Croatia and CLP helpdesks of Norway and Iceland
    - Observers of stakeholder helpdesks (A.I.S.E, Cefic, CEPE, CONCAWE, EuPC, IMA-Europe)
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## HelpNet – Tools (II)

- HelpNet Exchange (HELPEX)
  - Web-based IT tool for discussing question and answers by national helpdesks, ECHA and COM
  - Observers do not have access to HELPEX, but contribute to FAQ update

Note: List of national REACH and national CLP helpdesks available on ECHA website:

[http://echa.europa.eu/reach/helpdesk/nationalhelp\\_contact\\_en.asp](http://echa.europa.eu/reach/helpdesk/nationalhelp_contact_en.asp)

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## Guide available

- All relevant guides and manuals will be available on the CLP section of ECHA web site in mid April
  - “Practical steps” guide No 7
  - Industry User Manual Part 6 on dossier submission updated
  - Industry User Manual Part 12 on C&L notification using IUCLID
  - Industry User Manual Part 15 on managing groups
  - Industry User Manual Part 16 on on-line C&L notification
  - Other CLP guidance and FAQs
- C&L session at the 4<sup>th</sup> Stakeholders’ Day on 19 May

# Conclusions

- IUCLID 5.2 available since **15 February 2010**
- Bulk submission and Management of groups of manufacturers/importers in REACH-IT since **March 2010**
- On-line notification will be available **in June 2010**
- All notification tools compatible with each other
- Start preparing your C&L Notifications **NOW**



**“Don’t wait until the last minute”**