CLP – the implementation of GHS in the EU

Facts and practical advice

Seminar on the latest trend regarding revised CSCL, REACH and CLP
30 March 2010, Tokyo

Gabriele Schöning
ECHA – Classification Unit

Content

- Basis facts about CLP
- Harmonisation of Classification and Labelling (CLH)
- C&L notifications
- Alternative chemical name
- CLP enforcement
- Guidance and Support by ECHA

Basic facts about CLP

- What is CLP?
- Relation to REACH
- ECHA's Role

CLP Regulation

- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging entered into force on 20 January 2009
- Replaces
  - Directive 67/548/EEC (Dangerous Substances Dir., DSD)
  - Directive 1999/45/EC (Dangerous Preparations Dir., DPD)
  - REACH, Title XI (Classification & Labelling)
- Transitional period 2010 – 2015
  - Both classification systems to be used

New hazard pictograms

Physical hazards

Explosive

Flammable

Oxidising

Gases
under pressure

Environmental hazards

Hazardous
to the environment

Health hazards

Acute Toxicity
Category 1-3

Serious
Health hazard

Health hazard

Corrosive

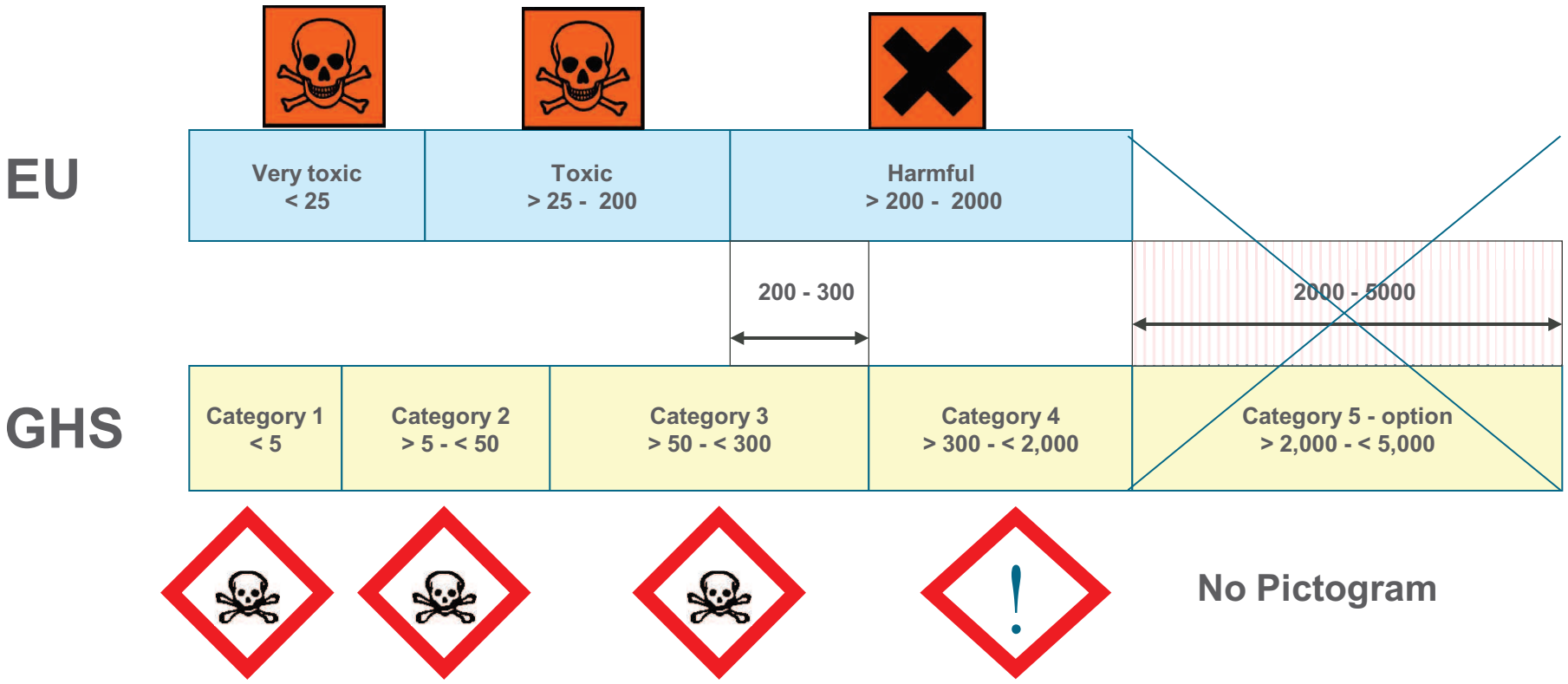
New classification criteria

Different classification criteria and concentration limits

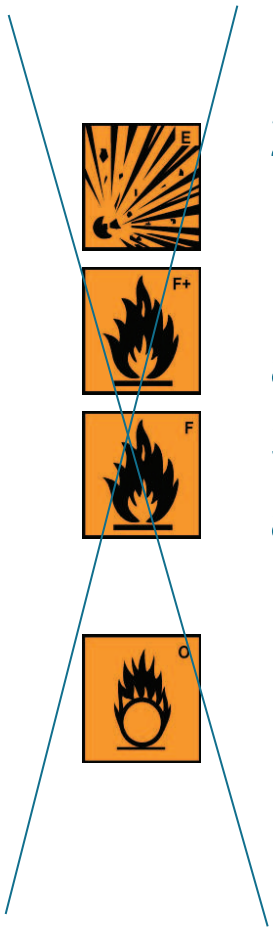
- Explosives (criteria)
- Acute toxicity (criteria: new cut-off limits)
- Reproductive toxicity
  (concentration limits for mixtures)
- Skin corrosion/irritation (criteria for irritation)
- Serious eye damage/eye irritation (criteria for eye irritation)

New classification criteria

Example: Acute toxicity

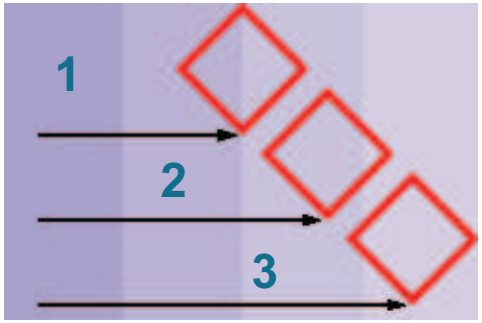


What are the time lines?

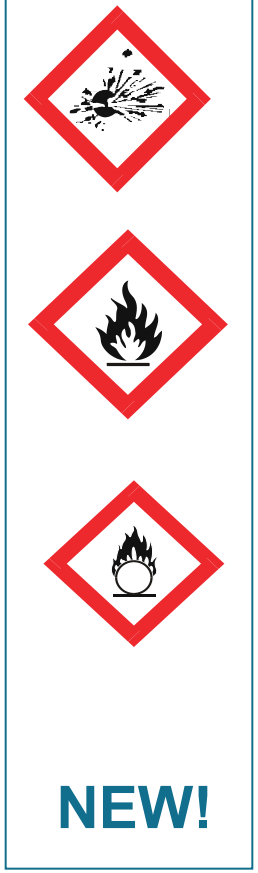


1) CLP entered into force **20 Jan. 2009**.
2) Substances to be classified & labelled according CLP by **1 Dec. 2010** + Notification to C&L inventory **1 month** after placing a substance on the market.
3) Mixtures to be classified & labelled according CLP criteria by **1 June 2015**

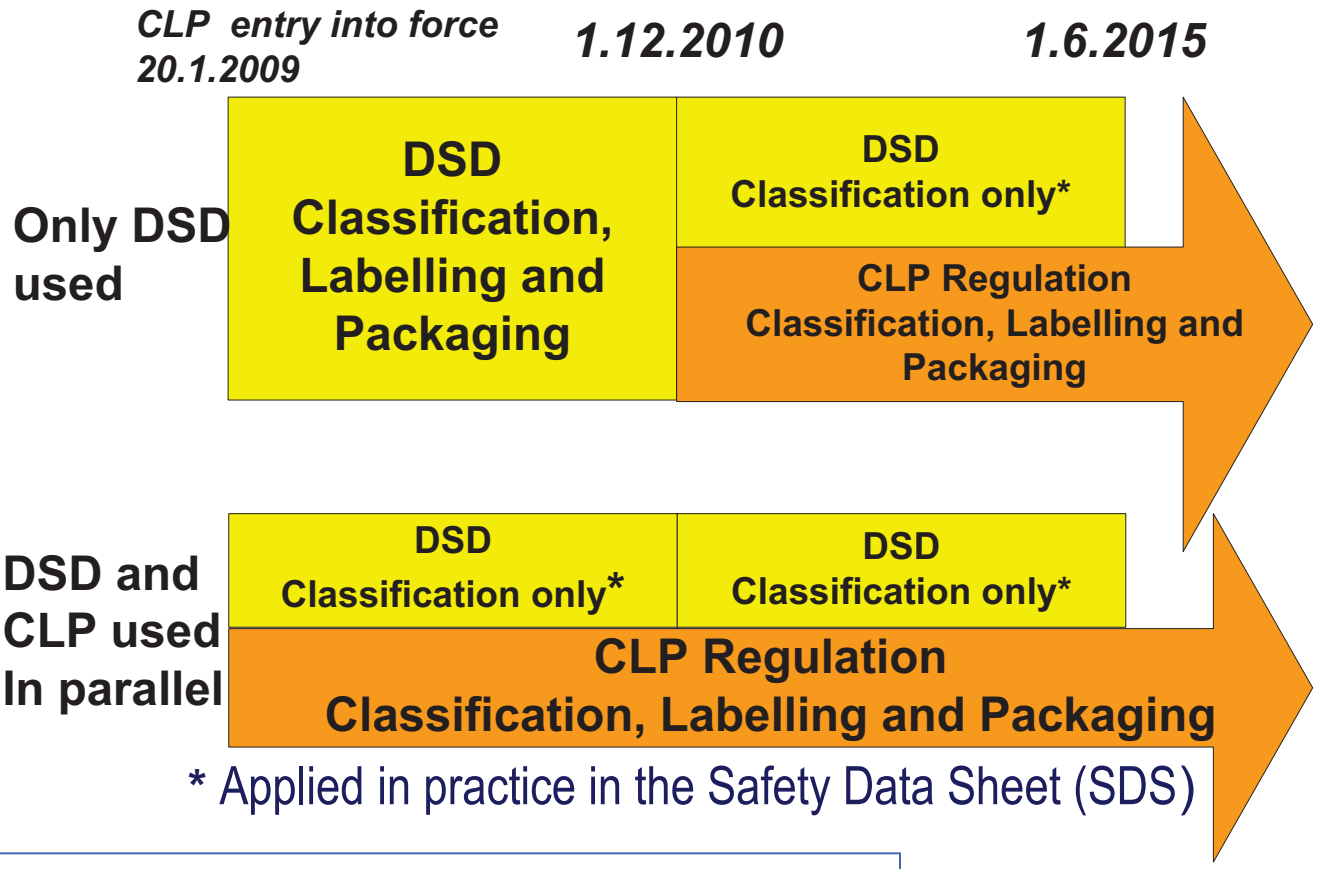
2009



2015

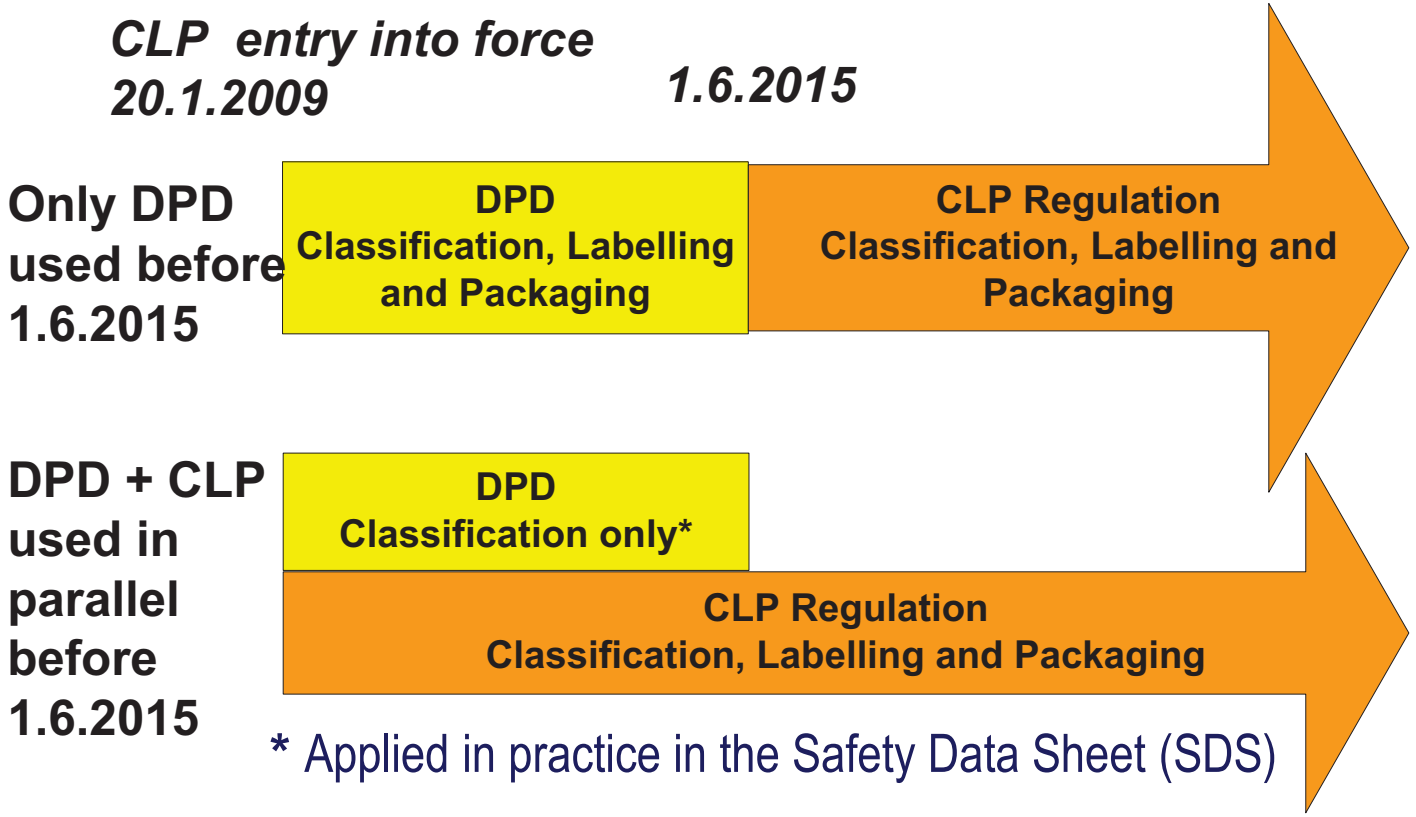


Transitional provisions: *Substances*



CLP = Regulation (EC) No 1272/2008
DSD = Directive 67/548/EEC

Transitional provisions: *Mixtures*



CLP = Regulation (EC) No 1272/2008
DPD = Directive 1999/45/EC

Common objectives of REACH & CLP

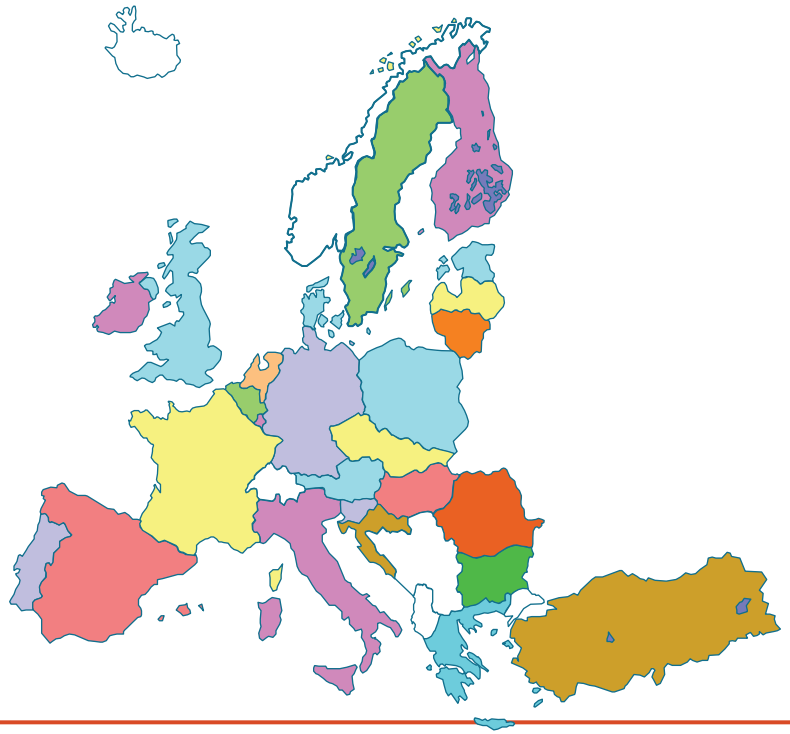
- High level of protection of human health and environment
- Free movement of substances, mixtures and articles on the European market

- Enhance competitiveness and innovation
- Promote alternative methods for assessment of hazards

European Union

Objective of EU Chemicals Legislation (REACH and CLP)

- High level of protection to health and environment
- Prevention of barriers to single European market



27 Member States
3 Candidate countries
23 languages

REACH links to Classification &Labelling

REACH does NOT include CRITERIA for C&L

- It refers to:
  - Substance classification ⇨ Directive 67/548/EEC
  - Preparation classification ⇨ Directive 1999/45/EC
  - Safety Data Sheets ⇨ REACH Annex II
- But has links to C&L
  - Registration
  - Information in the supply chain
  - **C&L Inventory – REACH Title XI → moved to CLP Title V**

REACH vs. CLP – Main processes

- REACH: **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals
  - Registration: Dossiers as the repository of information on substances
  - Evaluation: Dossier evaluation and substance evaluation
  - Authorisation and Restrictions to guarantee safe use of chemicals

- CLP: **C**lassification, **L**abelling and **P**ackaging of Substances and Mixtures
  - Harmonisation of Classification and Labelling
  - Notification of C&L of substances
  - Request for use of an alternative chemical name for a substance in a mixture

ECHA's role under CLP

- Manage proposals for harmonised C&L (CLH)
- Develop and manage the C&L inventory
- Handle requests for use of alternative names
- ECHA Forum co-ordinates enforcement activities
- Receive MS reports on control & enforcement
- Provide guidance and support

- C&L awareness
- Carry out a study on communication of safe use

Main Industry Responsibilities under CLP

- Manufacturers, importers and downstream users shall classify substances and mixtures before placing them on the market
- If a harmonised classification is available, this shall be used
- Suppliers placing a substance or a mixture on the market, shall label and package them in accordance with the classification
- (Group of) manufacturers or importers placing a substance on the market shall notify the Agency

Harmonisation of Classification

C&L Harmonisation

- Agreement at EU level on classification
- List of harmonised C&L (Annex VI, C&L Inventory)
- Suppliers obliged to classify & label accordingly

Harmonisation procedure

- Right of initiative
  - Member State Competent Authorities
  - Manufacturers, Importers, Downstream Users

↓

- ECHA: Scientific opinion by Risk Assessment Committee

↓

- Commission decision via Comitology

Harmonisation of C&L (CLH)

- Proposals may be submitted by
  - MSCAs
  - Industry (Manufacturers/Importers, Downstream Users)
- Which types of substances?
  - Carcinogenic, Mutagenic, Toxic to Reproduction, Respiratory Sensitizers
  - Other hazard classes on case-by-case basis
  - Pesticidal & biocidal active substances
- How many?
  - Estimated 90 proposals per year

CLH: Notification of intention

- MSCAs & industry are requested to notify intentions to propose harmonised C&L
  - Web-form available
- ECHA checks substance ID
- ECHA consults MSCAs via CIRCA
- ECHA publishes Register of Intentions
  - Allows parties concerned to provide information to dossier submitter
  - Allows parties concerned to prepare for commenting

http://echa.europa.eu/chem_data/reg_int_tables/reg_int_curr_int_en.asp

Risk Assessment Committee (RAC) opinion

Proposal received at ECHA

↓

Accordance check (RAC rapporteur)

↓

Publication for comments

↓

RAC evaluation of scientific information

↓

RAC opinion

CLH Proposals

- Notifications of intention*
  - Total No of intentions: 85
  - Proposals submitted: 56
  - Intentions withdrawn: 6
  - Submissions in 2008: 14
  - Submissions in 2009: 33
  - Submissions in 2010: 9
- Harmonisation status
  - Publication of harmonisation proposals:
    Completed: 19 Ongoing: 4
  - Adoption of RAC opinions: 6
  - Commission decision (update of Annex VI): pending (1 ATP/year)

* As of 18 March 2010

C&L Notification

- Basic facts about C&L notification under CLP
- Practical steps for the notification
- Details of the notification tools and practical manuals

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)

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”

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

“Placing on the market”

The moment of “placing in the market” is when the substance/mixture is introduced physically in the customs territory of the Community. So the one month notification "delay" applies from the moment the importer physically introduces the substance/mixture in the customs territory of the Community.

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

Practical steps for the notification (II)

- Which information is required?
  - 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”
  - SCLs or M-factors and justification
  - Label elements (hazard pictograms, signal words, hazard statements and supplemental hazard statements)

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

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

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

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

ECHA http://echa.europa.eu

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.	

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

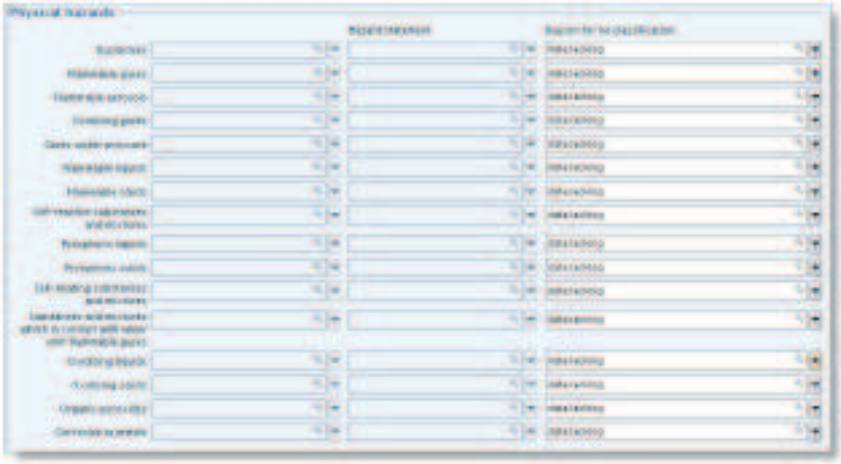
- Content
  - Introduction, creation of Legal entity
  - Creation of a reference substance and a substance dataset
  - **Details of IUCLID 5.2 sections to be completed**
  - Creation of a dossier using the “CLP notification” template
  - Export of the notification dossier
  - Update of a C&L notification 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



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

http://echa.europa.eu

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

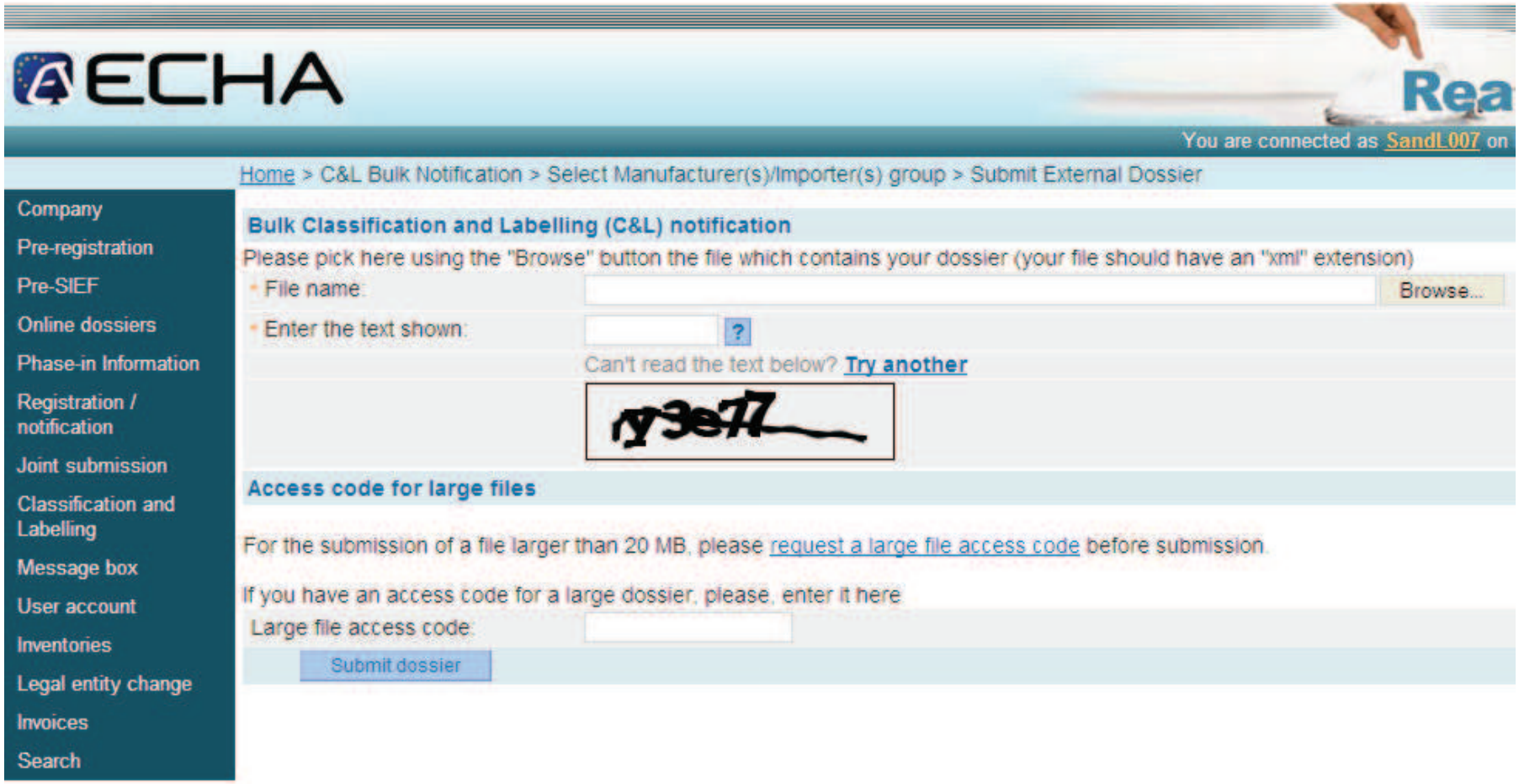
- **xml file** submitted via REACH-IT

- ECHA will provide an **Excel tool** for data creation and transfer to xml
  - Will be available in mid April

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

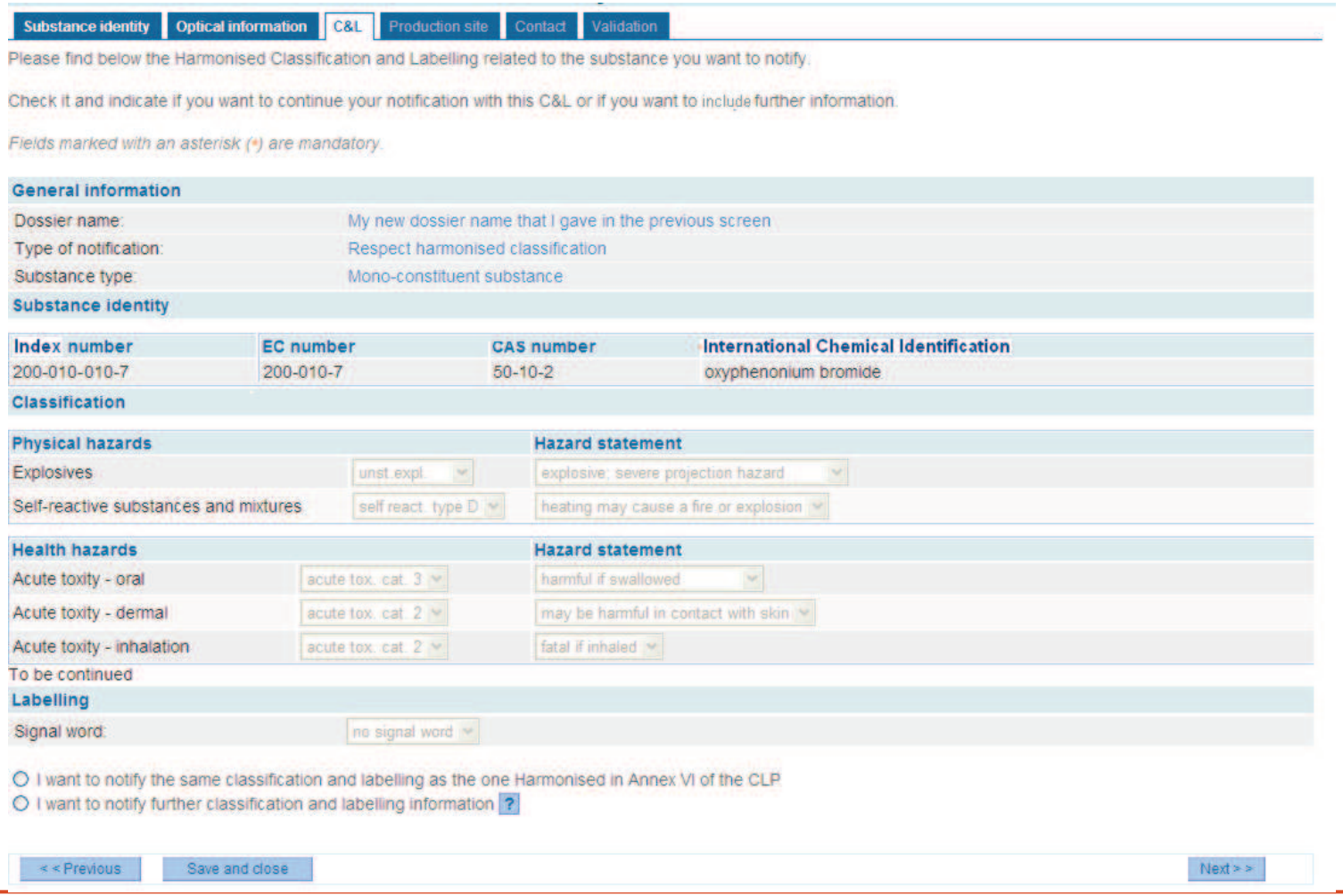
Bulk submission – Example



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

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	unst.expl.	explosive; severe projection hazard
Self-reactive substances and mixtures	self react. type D	heating may cause a fire or explosion

Health hazards		Hazard statement
Acute toxity - oral	acute tox. cat. 3	harmful if swallowed
Acute toxity - dermal	acute tox. cat. 2	may be harmful in contact with skin
Acute toxity - inhalation	acute tox. cat. 2	fatal if inhaled

To be continued

Labelling

Signal word:	no 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 ?

<< Previous | Save and close | Next >>

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”

Alternative chemical name

Alternative chemical name (I)

- Identifier to be used for a substance in a mixture on the label and Safety Data Sheet (Article 24 of CLP)
- Comparable to the process under Article 15 of DPD "Confidentiality of chemical names"
- No major changes in the requirements and criteria for the request in the legal text
- Detailed information on substance identity is needed
- COM Fee Regulation at finalisation stage

Alternative chemical name (II)

- Who can request the use of an alternative name?

  Manufacturer, importer or downstream user of a substance in a mixture

- Who grants the permission?
  - MS CAs: Until 1 June 2015 according to Article 15 of DPD
  - ECHA: From 1 June 2015; before this date only in cases where CLP is fully applied to classification, labelling and packaging of mixtures

Alternative chemical name (III)

- Format
  - IUCLID 5 and relevant annexes (e.g. SDS)
  - On-line application *(development planned*)
- Submission
  - Web form including attachments
  - REACH-IT not before second half of 2011
- ECHA process under development

Alternative chemical name (IV)

- To be assessed by ECHA
  - Substance identity
  - Relevance of the proposed alternative name
  - C&L of the substance
  - Acceptance criteria (Annex I, 1.4)
  - Justification demonstrating that disclosure of the name puts the confidential nature, particularly intellectual property rights, at risk
  - Composition and C&L of the mixture(s)

Acceptance criteria (Annex I, 1.4)

Alternative name may be granted only where

- No Community workplace exposure limit
- Enough information for health and safety precautions in the workplace
- The substance is classified exclusively as one or more of the following hazard categories:
  - Phys-Chem (Part 2 of Annex I),
  - Acute toxicity, Cat. 4,
  - Skin corrosion/irritation Cat. 2,
  - Serious eye damage/irritation Cat. 2
  - Specific target organ toxicity, Single exposure Cat. 2 or 3
  - Specific target organ toxicity, Repeated exposure Cat. 2 or 3
  - Hazardous to the aquatic environment – Chronic Cat. 3 or 4

Acceptance criteria – example

Annex VI
Part 3,
Table 3

International Chemical Identification	Classification		Labelling		
	Hazard class and Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)
	x. 2 x. 2 . 1A	H330 H300 H314	GHS06 GHS05 Dgr	H330 H300 H314	EUH014

Acute Tox. 2
Acute Tox. 2
Skin Corr. 1A

→ Alternative name may not be granted

Safety Data Sheet *

…

Point 2: Hazards Identification

Point 15: Regulatory Information
…
…
..

Boron tribromide
(Index no, EC no or CAS no)

DANGER

Reacts violently with water

Fatal if swallowed. Fatal if inhaled. Causes severe Skin burns and eye damage.

Nme **P statements (≤ 6)** 1 L
Address
Telephone

CLP- Enforcement

CLP Enforcement - Role of Member States (MS)

Article 43 CLP

(1) Member states appoint competent authorities (MSCAs)

(2) MSCAs for enforcement shall co-operate

Article 46 CLP

(1) MS to take measures and maintain a system of official controls, to ensure that substances and mixtures are not placed on the market unless they are classified, labelled and packaged in accordance with CLP.

(2) MS report to ECHA every five years by 1July on results of official controls and other enforcement measures. First time 20 January 2012

The Forum for Information Exchange on Enforcement

Same as under REACH

- Coordinates a **network of Member States' competent authorities** **responsible for enforcement**
- Tasks include:
  - Promotion of best practices & tools (Minimum criteria for inspections adopted)
  - Development of electronic info exchange procedures
  - Identification of enforcement strategies
  - Coordination and evaluation of harmonised enforcement projects
  - Liaison with industry
  - Advising on enforceability of restriction proposals

Guidance and support

- Guidance documents
- HelpNet
- Further information

CLP guidance to industry & CAs

- Module 1: Basic guidance on procedures
- Module 2: Detailed guidance on classification & labelling
  - Part 1: Physico-chemical properties
  - Part 2: Human health properties
  - Part 3: Environmental properties
  - Part 4: General and specific issues

  http://echa.europa.eu/classification/clp_guidance_en.asp
- Guidance on preparing proposal for harmonised C&L (under revision)

Guide available for C&L notification

All relevant guides and manuals will be available on the CLP section of ECHA web site in mid April 2010

- "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

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

HelpNet – Tools

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

Further information

- CLP Regulation
  - http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/index_en.htm#h2-clp-regulation-(ec)-no-1272/2008
- ECHA Guidance
  - http://guidance.echa.europa.eu/docs/guidance_document/clp_en.htm
- ECHA webinar C&L notifications,
  9 April 2010 15-17:00 EET (GMT+2)
  - http://www.echa.europa.eu/news/webinars_en.asp

- C&L session at the 4th Stakeholders' Day on 19 May

Thank you for your attention

http://echa.europa.eu

These slides represent the opinion of the author and do not constitute the official position of ECHA