

**Classification and Labelling notifications**  
**under the CLP regulation:**

How to be prepared? How to notify?  
C&L inventory creation

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Sandrine Lefèvre-Brévar  
ECHA, Scientific IT tools Unit

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- 3- Information to be notified
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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 my 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 my substance is placed on the market.  
I have to notify my 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 2010 a registration dossier containing C&L according to **DSD and CLP** criteria:
  - ⇒ No. I am fine !
- I am manufacturing a substance **subject to REACH registration**, I have **already** submitted before 3 January 2010 a registration dossier containing C&L according to **DSD criteria only**:
  - ⇒ From 1 December 2010, I shall update my registration dossier without undue delay, as I 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. I 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 me and no for the distributor !

## ... and what if you do not notify?



You may be subject to enforcement !

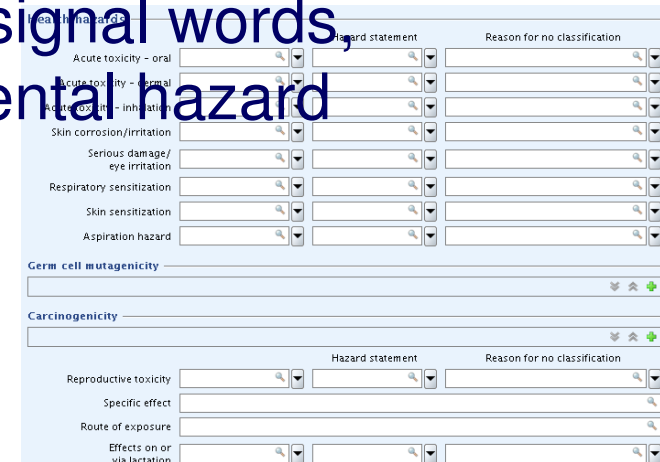
*Remember that the classification and labelling you present in the Safety Data Sheet of your substance has to be consistent with the information you submit in your C&L notification. The Safety Data Sheets may be inspected by the relevant enforcement authorities in the Member States.*

# 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!



The screenshot shows a portion of the IUCLID hazard classification form. It is organized into sections for different hazard categories. The 'Acute toxicity' section includes fields for oral, dermal, and inhalation routes. The 'Skin corrosion/irritation' section includes fields for serious damage/eye irritation. The 'Respiratory sensitization' section includes a field for respiratory sensitization. The 'Skin sensitization' section includes a field for skin sensitization. The 'Aspiration hazard' section includes a field for aspiration hazard. Below these are sections for 'Germ cell mutagenicity' and 'Carcinogenicity'. The 'Reproductive toxicity' section includes fields for reproductive toxicity, specific effect, route of exposure, and effects on or via lactation. Each field has a dropdown menu for selecting a hazard statement and a text box for providing a reason for no classification.

## 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).

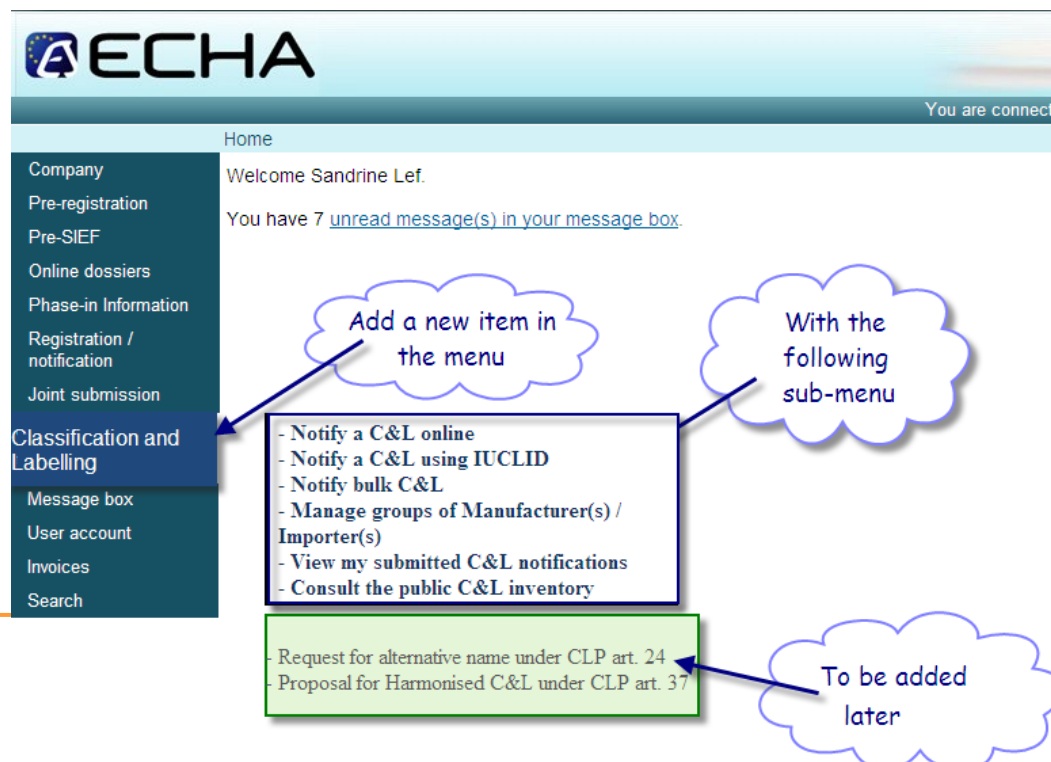
## 4- Identified challenges of C&L notifications



- **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 this, a "Home" section displays a welcome message for "Sandrine Lef." and a notification for 7 unread messages. A dark blue sidebar menu on the left lists various options, with "Classification and Labelling" highlighted. A callout box points to this menu item, listing sub-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 the "Classification and Labelling" menu item, stating "Add a new item in the menu". A third callout box points to the sub-options list, stating "With the following sub-menu". A fourth callout box points to a green box at the bottom of the sub-options list, which contains "Request for alternative name under CLP art. 24" and "Proposal for Harmonised C&L under CLP art. 37", with the text "To be added later".

**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

With the following sub-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

To be added later

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

## 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”



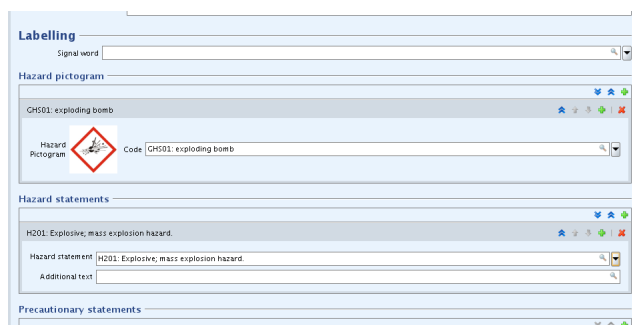
## Notification Submission – flexibility



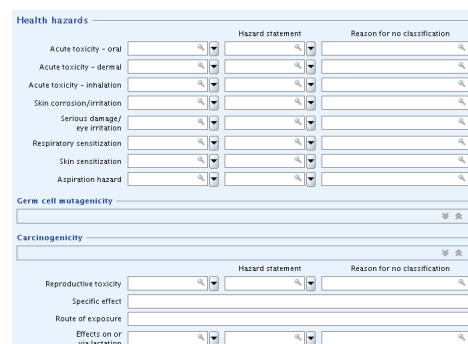
- All submission means will be compliant with IUCLID 5.2 and CLP regulation
  
- All submission means will be compatible between each other (including update, submission by a group of MI etc...)

# 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, a 'Hazard pictogram' section with a selected 'Explosive' pictogram and code 'GHS01: exploding bomb', a 'Hazard statements' section with 'H201: Explosive; mass explosion hazard', and a 'Precautionary statements' section.

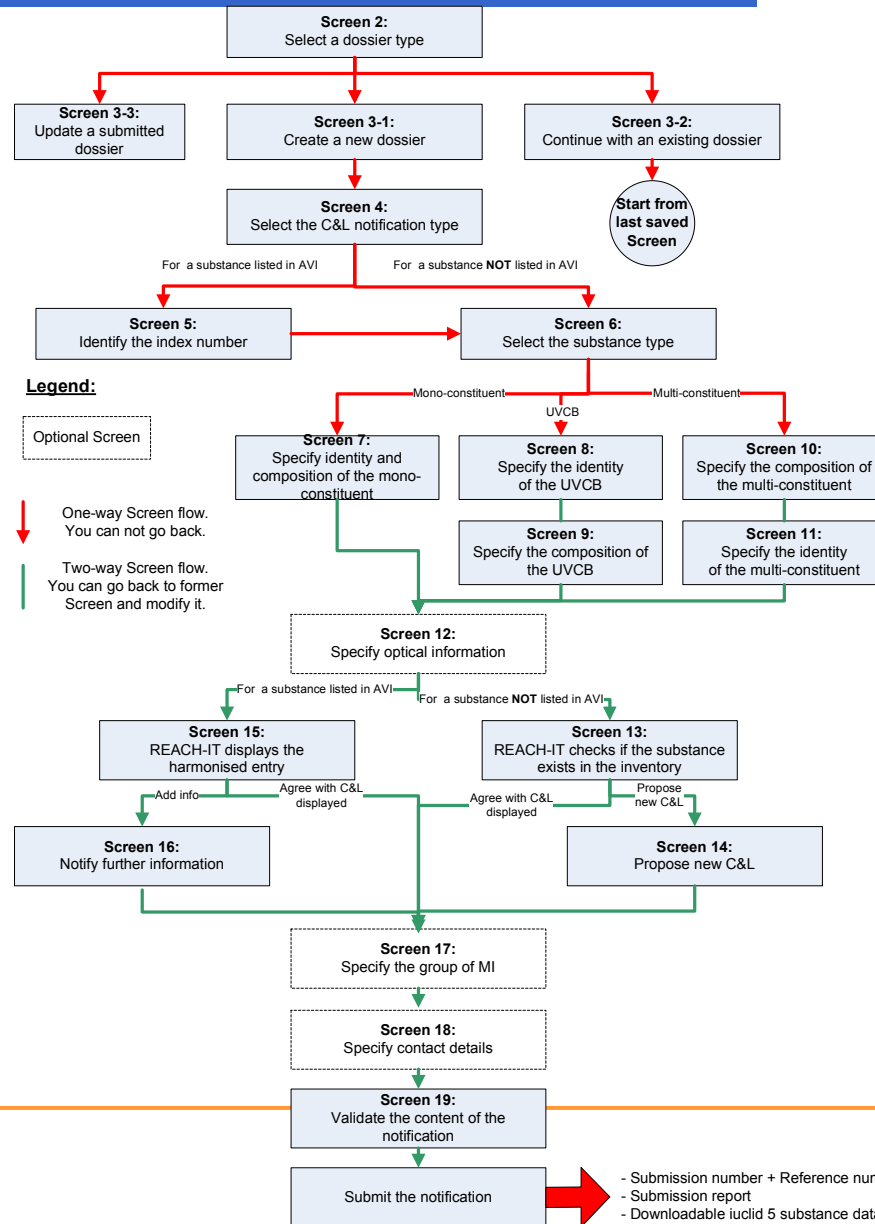


The screenshot shows the 'Health hazards' section of the IUCLID 5 interface. It contains a table with columns for hazard types, hazard statements, and reasons for no classification. The rows include Acute toxicity (oral, dermal, inhalation), Skin corrosion/irritation, Serious damage/eye irritation, Respiratory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

# 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

# On-line dossier - overview



# On-line dossier

**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 toxicity - oral	acute tox. cat. 3 ▼	harmful if swallowed ▼	
Acute toxicity - dermal	acute tox. cat. 2 ▼	may be harmful in contact with skin ▼	
Acute toxicity - inhalation	acute tox. cat. 2 ▼	fatal if inhaled ▼	
To be continued			
Labelling			
Signal word:	no signal word ▼		
<input type="radio"/> I want to notify the same classification and labelling as the one Harmonised in Annex VI of the CLP			
<input type="radio"/> I want to notify further classification and labelling information <a href="#">?</a>			
<< Previous		Save and close	Next >>

# 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, 15.2, 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.**



# Group of Manufacturers/Importers

## ECHA Reach-IT

[Home](#) > ... > ...

### Group of Manufacturer(s)/Importer(s)

If the notifier of this C&L notification is a group of Manufacturer(s)/Importer(s), you shall select it from the list below and click on "next".  
If you do not notify this C&L as a group of Manufacturer(s)/Importer(s), you are invited to specify the quantity for which you notify and click on "next".

You will find below the list of group of Manufacturer(s)/Importer(s) that you have already created in REACH-IT and who can notify to ECHA the C&L under CLP regulation.

If you want to view and/or update the information related to a group (member of the group, member details...), click on the group's name.

You can also [create a new group of Manufacturer\(s\)/Importer\(s\)](#) if needed. ?

	Group Name	Last Update
<input checked="" type="radio"/>	My Group 1	07/10/2009
<input type="radio"/>	My Group 2	07/10/2009
<input type="radio"/>	My Group 3	08/10/2009

## ECHA Reach-IT

[Home](#) > [Manage Groups of Manufacturer\(s\)/Importer\(s\)](#) > Create a new group

\*Group Name:

To create a new group of Manufacturer(s)/Importer(s), you can:

- Upload in REACH-IT a file containing the definition of a group of Manufacturer(s)/Importer(s): ?
- Define the group of Manufacturer(s)/Importer(s) directly in REACH-IT

## C&L submission miles-stones



- Industry can already submit its C&L using **IUCLID 5.1** (notification / registration) (but **not fully in line with the CLP**)
- New Notification Submission means will be available in **1st half of 2010** as soon as IUCLID 5.2 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?



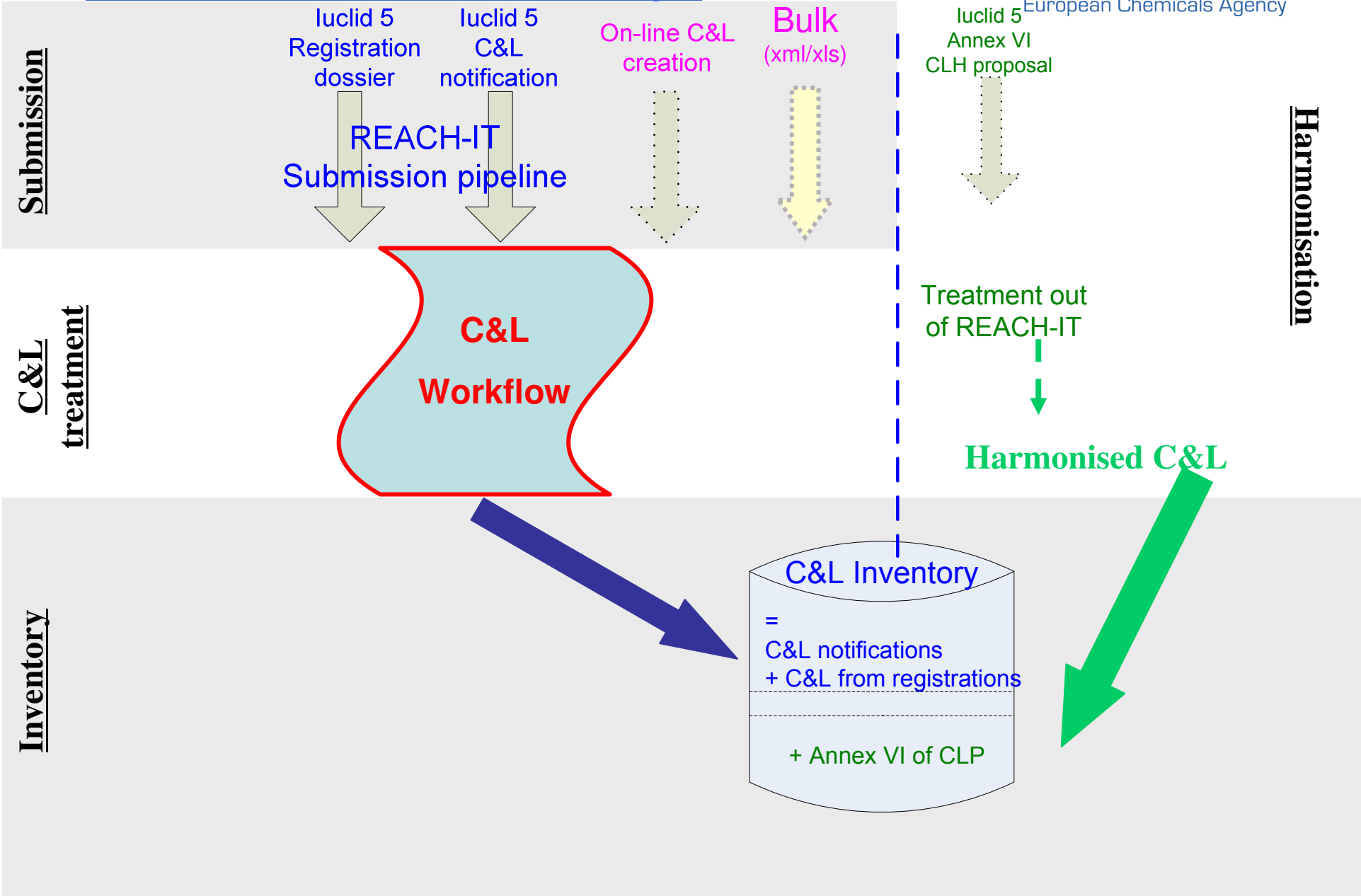
- ECHA web pages [http://echa.europa.eu/classification\\_en.asp](http://echa.europa.eu/classification_en.asp) :
  - Link to the CLP regulation
  - Guidance on introduction to CLP, Application of CLP criteria
  - Questions & Answers on CLP
  - Further explanatory documents under development (IUM on “how to create a C&L notification in IUCLID 5.2”, Q&A on notifications, etc)
- CLP awareness campaign under preparation:
  - 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 of information for sector-specific questions



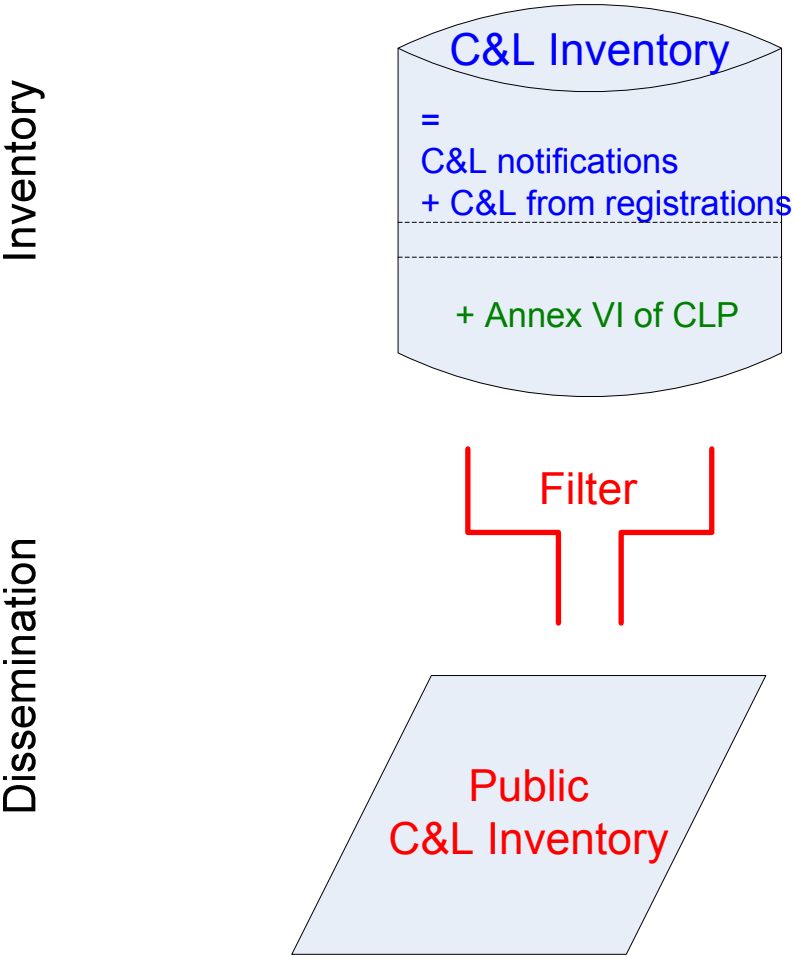
<http://echa.europa.eu>

A screenshot of the ECHA website's navigation menu and main content area. The navigation menu on the left includes links for HOME, REACH, CONSULTATIONS, REACH IT, CLASSIFICATION (CLP Regulation, Guidance, Harmonised C&amp;L), 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 'Guidance'. The text below the sub-header states: 'Guidance on the CLP Regulation will be published to support companies in fulfilling their obligations and in applying the new rules on classification, labelling and packaging. That guidance is currently being developed.' There is also a link for 'Harmonised classification and labelling'.

# 7- How the C&L notifications data will be used: the C&L inventory !



# Overview of the public C&L inventory



# Content of the 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**

# Conclusions

- Release of C&L functionalities in REACH-IT in **1st half of 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 in **Spring 2010** 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 2010**, include already the C&L according to **CLP criteria in your dossier**.

# Thank you for your attention!

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