



Guideline on C&L notification



June 3rd 2010

Introduction : **CLP Regulation 1272/2008 and obligation**
(who ? what ? when ?)

“CLP” or “ the CLP Regulation “ stands for Regulation (EC) N° 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) N° 1907/2006 (REACH). It implements the second edition of the United Nations Globally Harmonised System of Classification and Labelling (GHS) into EU law.

The CLP Regulation came into force on January 2009. It will replace Dangerous Substances Directive 67/548/EEC (DSD) and Dangerous Preparations Directive 1999/45/EC (DPD) in a stepwise approach during a transitional period. On 1 June 2015, both directives will be fully repealed.

One major novelty of the CLP Regulation is the transfer of the Classification and Labelling Inventory from Title XI of REACH to Title V, Chapter 2 of CLP.

CLP requires that information on substance identity and classification and labelling (“C&L”) of a substance should be notified to ECHA, the so called “C&L Notification”. ECHA will include this information in a database, called the Classification and Labelling Inventory.

The notification applies to substances placed on the market on or after 1 December 2010. The deadline for notifying to the inventory is one month after they have been placed on the market.

For substances placed on the market on 1 December 2010 itself, the notification is in practice due on 3 January 2011, because 1 January 2011 will be a Saturday and 2 January a Sunday. It is possible to voluntarily notify before 1 December 2010.

For substances placed on the market after 1 December 2010, the one month period is calculated from the date they are placed on the market after 1 December 2010.

ECHA advises prospective notifiers that the period from 24 December 2010 to 2 January 2011 will be an official holiday for the Agency. ECHA recommends that, where possible, a notification is submitted before 24 December 2010, as this would allow discussions for technical problems with the submission tool to be resolved in a timely manner.

N.B.: proposals for harmonised classification and labelling cannot be done via a C&L notification; therefore, this is not addressed in this Guideline.

I. WHO? (Source: http://echa.europa.eu/reachit/inventory_notification/notification_who_en.asp)

A Legal Entity (“the notifier”) has to notify a substance to the Classification & Labelling (C&L) Inventory in cases where it is **placing the substance on the market** and either:

- **Manufactures** the substance and it is subject to **registration** under the REACH Regulation; or
- **Imports** the substance and it is subject to **registration** under the REACH Regulation; or
- **Manufactures or imports** the substance and it is **classified as hazardous, irrespective of the quantity**; or
- **Imports a mixture which contains the substance** that is **classified as hazardous** and is present above the relevant concentration limit, which results in the classification of the mixture as hazardous according to the CLP Regulation; or
- **Imports** an article containing substances which are subject to registration under Article 7 of the REACH Regulation

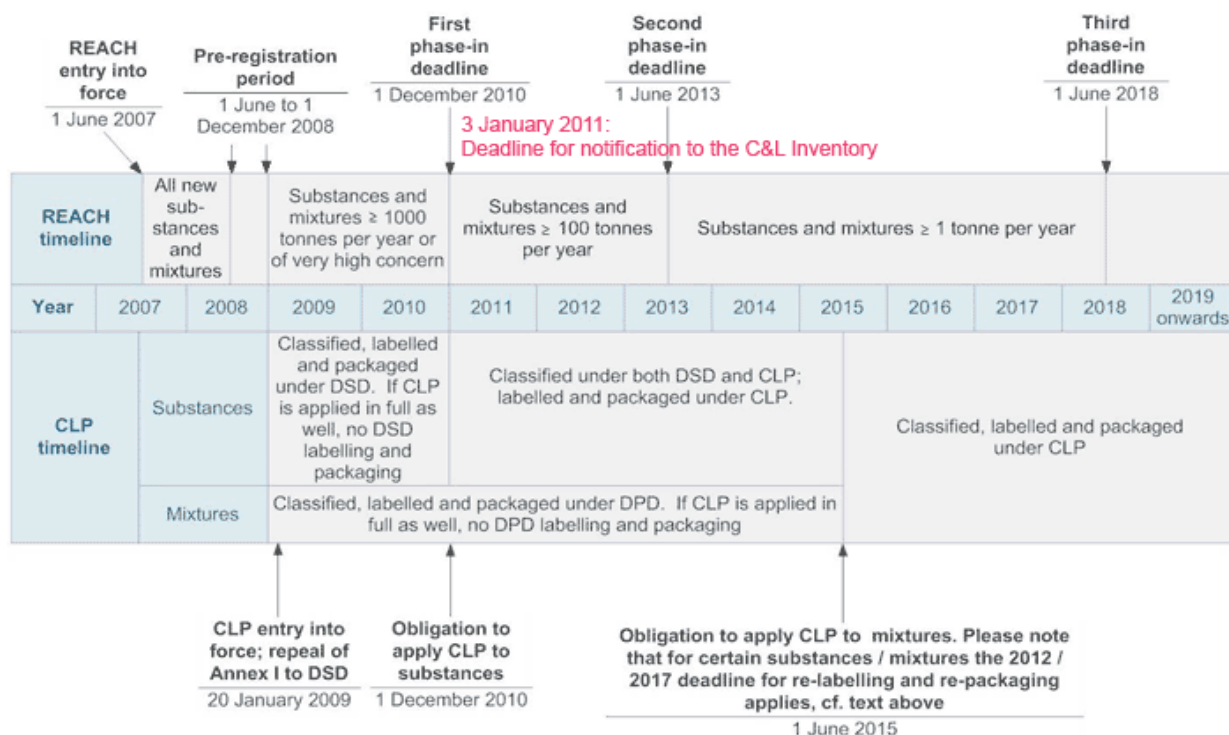
II. WHAT? (Source:http://echa.europa.eu/reachit/inventory_notification/notification_what_en.asp)

Each notification should include:

- Name and contact details of the notifier;

- Identity of the substance, including name¹ and other identifiers, information related to molecular and structural formula, composition, nature and amount of additives;
- Classification of the substance according to the CLP criteria;
- Reason for "no classification" in case the substance is classified in some but not all hazard classes or differentiations indicating whether this is due to
 - lack of data,
 - inconclusive data, or
 - data which is conclusive for non-classification;
- Specific concentration limits or M-factors, where relevant, including a justification for setting them; and
- Label elements, including hazard pictograms, signal words, hazard statements and any supplemental hazard statements.

III. **WHEN?** (Source: http://echa.europa.eu/clp/clp_regulation/transition_en.asp)



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¹ Regarding the claim of confidentiality for the disclosure of IUPAC name (potential CBI issues), discussions are ongoing with authorities and the Guidance is planned to be updated as soon as possible. This claim of confidentiality would only be possible via the IUCLID tool (see below).

C&L NOTIFICATION (THE “PROCEDURE”)

Source: http://echa.europa.eu/reachit/inventory_notification/notification_how_en.asp

The notification file can only be submitted electronically via the REACH-IT portal on the ECHA website. A Legal Entity must first sign up in REACH-IT and create an account to be able to submit a notification.

IMPORTANT point, with further description below: a Legal Entity has to prepare a notification file (in .xml or .i5z format, comparable to .doc format for Microsoft Word document), using one of the three tools available (IUCLID 5 / BULK / ONLINE, see below). When this notification file is ready, the Legal Entity submitting the notification file can submit it EITHER only for its own Legal Entity, OR on behalf of a Group of Manufacturers / Importers (see below).

Step 1: Creation of an account in REACH-IT (<https://reach-it.echa.europa.eu/reach/public/welcome.faces>).

In order to create an account, the procedure to be followed is available at: http://echa.europa.eu/reachit/createaccount-it_en.asp

Where the Legal Entity already has an account, it is not necessary to create a new account for the purpose of notification.

OPTIONAL, Step 2: Group functionality - Creation of a notification group (so called “group of Manufacturers / Importers or Group of MI”)

The notifiers may also form a **group of manufacturers and/or importers** and notify as a group their agreed classification and labelling to the Inventory. This step is not compulsory.

The group of MI can be created either directly in REACH-IT or using an off-line tool. (Group creator, available after agreement of terms and conditions at [tools download](#))

Step 3: Preparation of the C&L notification file

A Legal Entity can use one of the following tools to prepare its C&L notification file:

A. IUCLID 5.

A Legal Entity can specify all the requested information in IUCLID 5 ([IUCLID 5 website](#) is the access point to download the software), and create a C&L notification dossier in IUCLID. The notification file will, with this tool, be in the **.i5z** format.

- IUCLID 5 allows the Legal Entity to include more than one composition for the same substance (e.g. due to different impurity profiles) and link each composition to a specific classification and labelling. *Note that each notifier can submit only one notification per substance and this is the only tool where you can submit several compositions for one substance.*
- Previous users of IUCLID 5 may find this practical.
- Also practical for those intending to submit a registration under REACH (e.g. for the registration deadlines in 2013 or 2018)

B. BULK.

A Legal Entity can create a bulk XML file containing more than one C&L notification.

The bulk XML file can be created either using the Excel tool or by using the XML schema (available after agreement of terms and conditions at [tools download](#)). The notification file will, with this tool, be in the **.xml** format.

- The bulk XML file allows the Legal Entity to submit notification information for several or a large number of substances defined by their EC or CAS number in a single file.

- XML bulk submission can only be used when each substance is identified either by CAS or EC number and identified by one composition only. In addition, no M-factor or SCL can be set, if it is not already specified in Annex VI to the CLP Regulation for the substance to be notified.

C. ONLINE.

A Legal Entity can manually enter the required data in REACH-IT (*available since May 31st 2010*).

- If the Legal Entity only needs to notify a few substances and is not currently using IUCLID 5, an online notification via REACH-IT could be your preferred option.
- This option could be practical for SMEs.

Overview of the limitations / specific features per tool available:

Limitations / Specific feature	IUCLID 5 tool	Bulk tool	On-line tool
More than one composition for the same substance in the notification file	X		
More than one substance in the notification file		X	
Substance NOT identified by an EC or CAS number	X		X
Set of M-factor or SCL , if not already specified in Annex VI of the CLP Regulation	X		X
"I agree to an already submitted C&L" box ticking concept			X

Step 4: Submission of the C&L notification file in REACH-IT

- Having prepared the C&L notification dossier file, the Legal Entity can submit it to ECHA via REACH-IT (<https://reach-it.echa.europa.eu/reach/public/welcome.faces>).
- In REACH-IT, the notifier will be guided through dedicated pages to submit his/her C&L notification file. During the submission of the notification file, the Legal Entity will be asked whether it submits the notification:
 - on its own, or
 - on behalf of a Group of Manufacturers or Importers (MI) . Later in the document, the Legal Entity notifying on behalf of a Group of MI is named as the "Group Notifier"

The following Manuals, available on the ECHA website, give further information:

- [Data Submission Manual part 12 \(DSM\)](#): How to prepare and submit a C&L notification using IUCLID?
- [Industry User Manual part 15](#): Manage your group of Manufacturers or Importers
- [Industry User Manual part 6](#): section 3.1.2.5 is related to submission of I5 C&L notification

Those manuals are available in the 22 EU languages.

C&L Notification Submission reports

The CLP Regulation doesn't describe the IT process and the documents the notifiers would receive after having submitted their notification to ECHA. However, the CLP Regulation, *Article 46, on Enforcement and Reporting*, states that “*Member States shall take all necessary measures, including maintaining a system of official controls, to ensure that substances and mixtures are not placed on the market, unless they have been classified, labelled, notified and packaged in accordance with this Regulation*”.

In order to manage the processing of C&L notification in REACH-IT, ECHA created the concept of submission reports with Submission Number and Reference Number (see below): it is expected that these reports would allow notifiers to show compliance towards Member States Competent Authorities.

Two situations are possible:

A/ The submission is NOT done on behalf of a “Group of MI”

For all notifications done, as soon as the submission in REACH-IT will be performed, a **Submission Report will be available in PDF format, downloadable in the REACH-IT message box**, to the L.E. notifying, with a Submission Number and Date.

When the processing is finalised in ECHA, a reference number will be assigned in the Submission Report. If the “Bulk” tool was used, a reference number would be assigned to each of the Substance listed successfully notified.

B/ The submission is done on behalf of a “Group of MI”

The same as above applies, especially, just *ONE Submission number is released* and it is the responsibility of the Legal Entity having submitted the notification on behalf of the group (Group Notifier) to distribute the information to the members of the Group.

There will be no different “reference number” assigned by substance successfully notified, for each Legal Entity part of the Group.

For example, if Legal Entities A / B / C / D / E are part of a Group, and a bulk notification file is created for Substances X / Y / Z, all the L.E.s will have the same unique submission number, and the same Reference Numbers for each substance successfully notified.

- So same Reference Number (e.g. 111) for substance X for the 5 L.E.s
- So same Reference Number (e.g. 222) for substance Y for the 5 L.E.s
- So same Reference Number (e.g. 333) for substance Z for the 5 L.E.s

Again, it is the responsibility of the Group Notifier to distribute the Submission Report, with all the Reference numbers, to the members of the Group

The user will also have the possibility to download the information related to the C&L notifications he has submitted in .csv and .pdf formats (group composition + all the substances notified by a group).

For information, “fake reports” kindly provided by ECHA, are displayed below.

- UC52: bulk notification + group of MI



UC52-bulkSR_EF122
313-66.pdf

- UC13: bulk notification without group of MI



UC13-bulkSR_VK122
132-43.pdf

- UC56: notification via IUCLID 5 + group of MI



UC56-15SR_KV12220
0-37.pdf

Important note:

As the submission reports will contain companies' information that may be Confidential Business Information (CBI) (e.g. reveal supply chain information), the Group functionality is to be handled carefully.

How to prepare? Some suggestions ...

For substances to be registered under the REACH regime before 30th November 2010, the C&L notification is done via the submission of the registration dossier. **The registration dossier should contain the C&L according to CLP.** If not and still based on DSD, an update of the registration is required without undue delay. This update does not entail the payment of a fee to ECHA.

For the other cases and in particular registrations after 1 December 2010, the (pre-)SIEFs may be a way to contact other Legal Entities interested in the same substance and agree on the C&L.

The submission of the notification on behalf of a Group could be used, the Legal Entities part of the Group being the (pre-)SIEF Members, keeping in mind the responsibility and actions to be done by the "Group Notifier".

- Use of the Group Functionality
 - This functionality may be of interest for companies with many Legal Entities, in order to make just one notification on behalf of several Legal Entities of the same company for one or several substances
 - The submission of a notification on behalf of a group could also be used in other cases than the above case (e.g. members of a same SIEF, group of universities, laboratories)
 - ➔ The submission on behalf of a group means that all the Legal Entities of the Group listed agree on the C&L information prepared in the notification file. The special role of the "Group Notifier", as it has to distribute / share the Submission Report to the members of the Group and also the Reference Number(s) when these are available, suggests considering contractual arrangements. In that respect, it should be noted that REACH IT Industry User Manual Part 15 – Manage your Group of Manufacturers or Importers indicates in 2.2 (page 7 of version 1.0) that "(...) the members of a Group of MI shall fully document the basis on which they created their group of MI, and shall make available to the Competent Authorities and, on request, to the relevant Enforcement Authorities the documentation related to the creation of this group of MI together with the data and information on which C&L are based".
- Use of the "BULK tool"
 - This tool is useful to make just one submission for many substances. There are however some limitations... (*XML bulk submission can only be used when each substance is identified either by CAS or EC number and identified by one composition only.* In addition, no M-factor or SCL can be set, if it is not already specified in Annex VI to the CLP Regulation for the substance to be notified).
- I am an SME...
 - The simplest way to submit your notification would be the "online" tool.

- **Updating** the C&L data:
 - For the substances with a Registration Dossier submitted before Dec. 2010 **and** that do not contain already the C&L according to the CLP criteria: the concerned Legal Entity will have to submit an update of its Registration dossier “without undue delay” after 1 December 2010 (CLP Art. 61 – transitional provisions) adding in the Registration Dossier the CLP Classification and Labelling (section 2.1 of IUCLID). Please note that this updated registration dossier has to be complete and has to pass the TCC (REACH article 22-3).

The only exception to this rule is explained in the DSM 5 (annex 4) and is related to NONS update. In the case of NONS update not related to a tonnage band update (and only in that case), then a “light TCC” will be performed.

- For the substances without a registration dossier: submit a C&L notification update via the online tool or via the bulk tool or via the CLP IUCLID5 dossier template. You can do so before or after 3 January 2011.
- Update of NONS C&L for compliance with the CLP Regulation:

Legal Entities have to retrieve the IUCLID version of the SNIF files from their national authorities, with the associated REACH Registration Number. If no change occurred in the Tonnage Band, ONLY the section 2.1 of IUCLID 5.2 should be filled with the information on C&L according to the CLP Regulation. Finally the Legal Entity should submit this updated Registration Dossier, ECHA going to apply a “light TCC”. (cf DSM 5 (annex 4) for more details on the exact IUCLID fields to complete)

Sources and further information:

- Cefic intranet (Click-in), accessible to Cefic Membership only:

Cefic Issue sheets on

 - [Classification, Labelling and Packaging \(CLP\) Regulation](#)
 - [Globally Harmonised System of classification & labelling \(GHS\)](#)
 - [REACH-IT and IUCLID - The ECHA software tools supporting REACH](#)
- ECHA web pages:
 - [CLP Section on ECHA Website](#)
 - [Notification to the Classification & Labelling Inventory](#)
 - [What is CLP?](#)
 - [Introductory Guidance on the CLP Regulation](#)
 - [Guidance on the Application of the CLP Criteria](#)
 - [FAQ on Classification and Labelling](#)
 - [Q&A on Classification and Labelling](#)
 - http://echa.europa.eu/help/help_docs_en.asp and then click on “C&L notifications”
- Commission web pages:
 - DG ENVI: http://ec.europa.eu/environment/chemicals/ghs/index_en.htm
 - DG ENTR: <http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/>