ECHA
EUROPEAN CHEMICALS AGENCY

How to notify substances to the Classification and Labelling Inventory

Practical Guide 7

Version 1.1 – June 2012

LEGAL NOTICE
This document contains guidance on CLP explaining the CLP obligations and how to fulfil them. However, users are reminded that the text of the CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

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Practical guide 7:
How to notify substances to the Classification and Labelling Inventory

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NOTIFICATION

Highlights

- Importers and manufacturers must notify hazardous substances if they are placing them on the market, on their own or in mixtures and irrespective of the tonnage.
- Importers and manufacturers must notify substances subject to registration under the REACH Regulation if they are placing them on the market.
- Existing registrations of substances placed on the market may need to be updated with the CLP classification and labelling.
- Notification should be made within one month of placing a substance on the market.
- Notification is free of charge

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1. INTRODUCTION

1.1 What is this document about?

This document contains information which helps you to find out whether you have to notify your substances to the Classification and Labelling Inventory, which has been set up at the European Chemicals Agency (ECHA). It will also explain how to prepare for and submit a notification in accordance with Regulation (EC) No 1272/2008 (CLP Regulation). Nevertheless, it is assumed that you are already familiar with the key concepts and terms of classification and labelling because these are not explained in this document.

You may find this document especially useful if your company manufactures and places substances on the market in EU countries[1], or imports substances or mixtures from non-EU countries into the EU.

This document is important for you if your company carries out one or more of the following activities *and* places the involved substances or mixtures (preparation) on the market:

- Manufactures substances (including isolated intermediates) subject to registration in accordance with the REACH Regulation[2];
- Imports substances (e.g. dye stuffs) subject to registration in accordance with the REACH Regulation;
- Manufactures or imports substances which are classified as hazardous, irrespective of the quantity involved;
- Imports mixtures containing hazardous substances, irrespective of the quantity involved;
- Imports articles containing substances which are subject to registration under REACH Article 7.

This document is available and downloadable on the ECHA website in 22 official EU languages. The following chapters do not only provide you with basic information for notification, but also with links to the most important guidance documents and tools to complete your notification.

1.2 What is the CLP Regulation?

The CLP Regulation is the new EU legislation on Classification, Labelling and Packaging of substances and mixtures. It integrates the classification criteria of the United Nations Globally Harmonised System (GHS) into EU law. The CLP Regulation will gradually replace the Dangerous Substances Directive[3] (DSD) and the Dangerous Preparations Directive[4] (DPD).

The CLP Regulation stipulates that all substances must be classified and labelled according to

[1] The EU Member States are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Once the EFTA States that are signatories to the EEA Agreement (these are currently Iceland, Liechtenstein and Norway) have incorporated the CLP Regulation into their national legislation, references in this document to 'the EU' and 'the Member States' should be read to include the corresponding countries.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

[3] Council Directive 67/548/EEC the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous substances.

[4] Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

the CLP criteria from 1 December 2010 onwards[5] and that all mixtures must be classified and labelled according to the CLP criteria from 1 June 2015. Further guidance on the CLP Regulation is available in the Introductory Guidance on the CLP Regulation and more detailed information on classification and labelling in the Guidance on the Application of the CLP Criteria.

Both of these and the CLP Regulation, as well as other practical and explanatory documents, are available on the ECHA website under http://echa.europa.eu/web/guest/regulations/clp, see also the links at the end of this document.

With the entry into force of the CLP Regulation, Title XI of the REACH Regulation has been repealed. The harmonised classifications contained in Annex I to DSD have been transferred to Table 3.2 of Annex VI to the CLP Regulation and are legally binding.

1.3 What is notification under the CLP Regulation?

Articles 39 to 42 of the CLP Regulation deal with notification to the Classification and Labelling Inventory.

In general, notification under the CLP Regulation means that manufacturers and importers submit certain classification and labelling information of substances they are placing on the market to the Classification & Labelling Inventory held by ECHA (see Chapter 3 for practical details). The Inventory is a new database which did not exist under the previous legislation of classification and labelling (DSD and DPD).

Notification under the CLP Regulation applies to all hazardous substances of all tonnages and also to all non-hazardous substances subject to registration under REACH whenever they are placed on the market in the EU.

Notification under the CLP Regulation is due by certain time lines; see chapter 2.4 of this document.

1.4 What is the Classification & Labelling Inventory?

Information submitted in notifications is collected in a database called the Classification & Labelling Inventory. The database also contains information from REACH registration dossiers and on substances having a harmonised classification and labelling, i.e. the substances listed in Part 3 of Annex VI to the CLP Regulation.

Some information from the notifications is made available in the Public Classification and Labelling Inventory. The Public Classification and Labelling Inventory is a central source of information on the classification and labelling of substances for all users of chemicals.

The public version of the Classification and Labelling Inventory includes substance identifiers referred to in Article 119(1) of the REACH Regulation, the classification and labelling elements and any relevant specific concentration limit (SCL) or multiplying factor (M-factor) for each substance. The identity of the notifier will not be made publicly available. The same applies to the IUPAC name of certain substances where a corresponding confidentiality flag has been set, see also chapter 2.7 of this document.

[5] The classification of substances according to the DSD should still be included in the Safety Data Sheets until 1 June 2015.

2. IDENTIFICATION OF ROLES AND OBLIGATIONS

2.1 Do I have to submit a notification to the Inventory?

If you are one of the suppliers listed in the box in chapter 1.1. of this document, then you have to notify the classification and labelling of your substances to the Inventory.

Companies that manufacture substances or formulate mixtures outside the EU are not required to notify to the Classification & Labelling Inventory at the European Chemicals Agency (ECHA). Non-EU manufacturers and formulators who intend to import substances and mixtures into the EU should provide the relevant information (e.g. an IUCLID data set) to their EU importers who must submit the notification.

If non-EU manufacturers or formulators, for confidentiality reasons, do not want to disclose the composition of their substances or mixtures to their EU importers, they may appoint one of the importers to notify also on behalf of the other importers (see chapter 4.2. on notification as a group). Alternatively, a third party who is not itself a manufacturer or importer (e.g. an Only Representative (OR) who has already been appointed for the purposes of registration under REACH) may submit a group notification on behalf of the EU importers. Such a third party can submit the notification, but cannot take over the obligations of the importers that are part of the group. If such a solution is used, the submitting entity must be able to document that it has been mandated to act on behalf and in the name of the manufacturer(s)/importer(s) that are part of the group and that the manufacturer(s)/importer(s) acknowledge that they remain solely and fully responsible for fulfilling all their obligations associated with the notification.

The documentation related to the creation of this Group of manufacturers and importers together with the data and information on which C&L are based may need to be made available to the Competent Authorities and to the relevant Enforcement Authorities.

2.2 Which substances do I have to notify to the Inventory?

In general, the obligation to notify to the Classification & Labelling Inventory includes **all hazardous substances** within the scope of the CLP Regulation, either on their own or contained in a hazardous mixture above specified concentration limits, see attachment 1 to this document, and which are imported or manufactured and **placed on the market** within the EU. Also non-classified **substances subject to registration under the REACH Regulation**, i.e. a substance manufactured or imported in volumes at or above 1 tonne per year, must be notified (see also chapter 1.1). This includes substances on their own, substances contained in mixtures and those substances contained in imported articles where Article 7 of the REACH Regulation provides for registration. Note that you must notify a substance even if its classification and labelling is (completely) harmonised and it is listed in Part 3 of Annex VI to the CLP Regulation.

However, the obligation to notify does not apply to a number of **substances and mixtures in the finished state** and intended for the final user or for uses for which there is specific legislation in place, e.g. radioactive materials, medicinal products, cosmetic products and food and feeding stuffs. For more details, please see Article 1 "Purpose and scope" of the CLP Regulation.

Substances notified under Directive 67/548/EEC (NONS) are deemed to be registered under the REACH Regulation. For NONS manufactured or imported in a volume of more than or equal to 1 tonne per year, the respective dossiers will have to be updated with the CLP classifications without undue delay, and a separate notification is therefore not required.

For NONS notified below 1 tonne under Directive 67/548/EEC and for which no tonnage band update has been done, a separate notification to the Inventory will have to be made if the sub-

stance is classified as hazardous and placed on the market. This means that:

- If the annual volume of the NONS substance remains below 1 tonne, the company must do a C&L notification for this substance. As soon as the volume reaches this threshold, an update in the form of a registration dossier is required;
- If the annual volume has already reached or exceeds the 1 tonne threshold, an update in the form of a registration dossier is required.

Substances and mixtures for scientific research and development (R&D) are exempted from the CLP Regulation only if they are used under controlled conditions in accordance with Community workplace and environmental legislation and when they are not placed on the market. In situations where this is not the case, they would fall under the CLP Regulation irrespective of the tonnage, and they should be notified if they meet the criteria for classification as hazardous on the basis of the available information.

Substances for product and process orientated research and development (PPORD) should be notified to the C&L Inventory, irrespective of the tonnage, where they meet the criteria for classification as hazardous and when they are placed on the market. This applies also to PPORD substances in mixtures if the mixture is classified due to the substance.

The classification and labelling of **active substances contained in plant protection products[6] (PPPs) and biocidal products[7] (BPs)** is normally harmonised for all hazard classes and appears both in Tables 3.1 and 3.2 of Annex VI to the CLP Regulation. Notification to the Inventory must always be done for active substances when they are placed on the market.

Alloys are considered special preparations (CLP terminology: mixtures) under the REACH and CLP Regulations. The components of alloys need to be notified to the Inventory in case they are hazardous and contained in the alloy above specified concentration limits, see attachment 1 to this document.

Polymers must be notified to the Inventory if they are classified as hazardous and if they are imported or manufactured and placed on the market, on the basis of CLP Article 39(b) and 40. By contrast, **monomers** contained in such polymers are not considered as being placed on the market, and their notification is not necessary.

According to the CLP Regulation, importers of **articles** do not need to notify the classification and labelling of a substance contained in an article, unless the substance needs to be registered in accordance with Article 7 of the REACH Regulation.

2.3 Should I agree to the existing classification and labelling of a notified substance?

The classification and labelling of substances that have already been notified to the Inventory or that have a harmonised entry in Part III of Annex VI to the CLP Regulation will be displayed as background information where you make an online notification via REACH-IT.

If your substance has a harmonised classification and labelling in Annex VI, the CLP Regulation requires you to classify and label it accordingly. You must then tick the box "I agree" for the harmonised hazard classes and differentiations displayed during the online notification.

Where the classification and labelling of a substance is not harmonised, prospective notifiers and registrants of that substance shall make every effort to find a common classification and

[6] The substances concerned by Council Directive 91/414/EEC.
[7] The substances concerned by Directive 98/8/EC of the European Parliament and of the Council.

labelling to be included in the Inventory. Similar to the aforementioned case, this will be facilitated in the online notification via REACH-IT: where you consider a displayed classification and labelling appropriate, you can just tick the box "I agree" and the relevant fields of your notification dossier are automatically filled in.

Where the classification and labelling of a substance has already been agreed by different notifiers before the notification is carried out, e.g. in a SIEF, it may be appropriate for the manufacturers and/or importers involved to form a group and notify the classification and labelling to ECHA as a joint entry, see also chapter 4.2.

2.4 When should I notify a substance?

As a general rule, you must notify the classification and labelling of a substance within one month of placing it on the market. For importers, the one month delay is counted from the day when a substance, on its own or contained in a mixture, is physically introduced in the customs territory of the Community.

2.5 Should I submit a notification for substances that are subject to registration under the REACH Regulation?

You cannot submit a separate notification for a substance that you have placed on the market if you have already registered it under REACH ***and*** if the registration dossier contains the classification and labelling according to the CLP Regulation (section 2.1 of IUCLID 5). This is because the registration dossier then contains already the information that is required for substances to be notified to the Classification & Labelling Inventory.

The obligation to classify and label substances according to the new CLP criteria applied from 1 December 2010. This means that as from 1 December 2010, you must **always** include the CLP classification and labelling. Registration dossiers submitted before 1 December 2010 must be updated with this information without undue delay

If your substance is a phase-in substance to be registered in 2013 or 2018 only, but it is placed on the market earlier, you must submit a notification for this substance to the Classification & Labelling Inventory within one month of placing it on the market. Substances subject to registration under REACH and placed on the market must be notified even if they are not classified as hazardous.

The obligation to notify substances subject to registration under REACH also applies to those members of substance information exchange forums (SIEFs) who will register their substances in 2013 or 2018 only (the second and third REACH registration deadlines, respectively). Provided that the lead registrant has already submitted his registration, it is possible for the other SIEF members to agree to the classification & labelling provided by the lead registrant by ticking the box "I agree". The classification and labelling fields are then automatically filled in for the respective notification. However, this can only be done where the SIEF members have created their notification in REACH-IT. SIEF members may also decide to notify as a group of manufacturers and importers the agreed classification & labelling of a substance (see chapter 4.2.).

Note that PPORD substances notified in accordance with Article 9 to the REACH Regulation are not registered substances and therefore Article 39(a) of the CLP Regulation does not apply. In order to notify to the C&L Inventory a hazardous PPORD substance placed on the market (Article 39(b)), you cannot update your PPORD notification, but you have to submit a separate C&L notification.

2.6 When should I update my notification?

Whenever you become aware of new and reliable information which changes the classification and labelling of your substance, you must update the information provided in your notification. If you have provided the information required for notification in a registration dossier, you must update the respective registration dossier.

The requirement to update classification and labelling information of substances does not apply when **harmonised hazard classes and differentiations** are already listed in Table 3.1 in Annex VI to the CLP Regulation at the time of your notification.

In cases where a substance classification is harmonised after you have notified it to the Inventory, you should update your notification at the latest when that harmonised classification becomes legally applicable.

Also your contact details should be up-to-date.

2.7 Can I flag confidentiality of the information notified?

For certain substances, manufacturers and importers can flag confidentiality of the IUPAC name, in which case the notified IUPAC name will not be displayed on the public Inventory. The substances for which confidentiality of the IUPAC name is possible are those listed in Articles 119(2)(f) and (g) of REACH:

- Non-phase in substances,
- Substances only used as one or more of the following:
  - As intermediates;
  - In scientific research and development;
  - In product and process orientated research and development.

Confidentiality flags can only be set in **IUCLID**. They are free of charge. Further details are provided in Data Submission Manual (DSM) 12, see chapter 5 of this document.

Note that if you want to use an alternative name in your Safety Data Sheet or on the label, you need to make a request for an alternative name according to Article 24 of the CLP Regulation, and pay the related fee, or according to Article 15 to Directive 1999/45/EC (the Dangerous Preparations Directive), as appropriate.

3. NOTIFICATION IN PRACTICE

3.1 What information should I provide in the notification?

For each substance, the notification must include the information requested in Article 40 of the CLP Regulation:

- **Name** and **contact details** of the notifier;
- **Identity** of the substance, including name and other identifiers, information related to molecular and structural formula, composition and nature and amount of additives (see chapter 4.3. of this document and also specifications in sections 2.1. to 2.3.4. of Annex VI to the REACH Regulation);
- **Classification** of the substance according to the CLP criteria;
- In case the substance is classified in some but not all hazard classes or differentiations, an **indication of** whether this is due to lack of data, inconclusive data, or data which is conclusive for non-classification;
- **Specific concentration limits and M-factors**, including a justification for setting them; and
- **Label elements**, including hazard pictograms, signal words, hazard statements and any supplemental hazard statements.

3.2 How can I prepare for the notification?

Before submitting your notification to ECHA, you must classify and label your substance according to the CLP criteria. The following preparatory steps for classification and labelling should be completed:

1. **Make an inventory** of the substances and mixtures that you are manufacturing in the EU and that you are importing from non-EU countries;

2. **Clarify** whether any of these substances are exempted from the CLP Regulation (see Article 1 of the CLP Regulation);

3. **Check** whether any of your substances are subject to registration under the REACH Regulation;

4. **Collect** all available information on substances identity, including the IUPAC name, EINECS number, CAS number or other identity codes and clarify the qualitative and quantitative composition of your substances;

5. **Name the substances** in line with the guidance for identification and naming of substances under the REACH Regulation;

6. **Check** whether the substances are listed in Part 3 of Annex VI to the CLP Regulation, see http://echa.europa.eu/web/guest/regulations/clp/legislation, i.e. whether the classification and labelling of the substance is harmonised. If there is a harmonised classification and labelling for a substance this must be used, and you may not self-classify the substance for those hazard classes or differentiations. Based on adequate and reliable information you should self-classify those hazard classes and differentiations which are not covered by the harmonised classification and labelling;

7. **Gather** all available and reliable **information** on the hazardous properties of

any substance where the classification and labelling of your substance is not harmonised;

8. **Classify** your substance by comparing the available information with the classification criteria[8];

9. In cases where you want to specify a multiplying factor (M-factor) or set a specific concentration limit (SCL) according to Article 10 of the CLP Regulation, **provide a justification** using the relevant parts of sections 1, 2, and 3 of Annex I to the REACH Regulation;

10. **Determine** whether a mixture which contains a hazardous substance must be classified under the CLP Regulation due to the presence of that substance;

11. **Decide** if you want to establish **or join a group of manufacturers and/or importers** with other prospective notifiers and registrants of the same substance. A member of this group can then submit the notification on behalf of the group

12. **Create your REACH-IT account** (if not done already).

3.3 How can I create a notification?

You can use one of the following tools to prepare your classification and labelling notification:

A. IUCLID 5. You can specify all the requested information in IUCLID 5, and create a classification and labelling notification dossier in IUCLID.

- IUCLID 5 allows you 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.
- This option could be practical for you if you have used IUCLID 5 before.
- This option could also be practical for you, if you intend to submit a registration under the REACH Regulation (e.g. for the registration deadlines in 2013 or 2018)

B. BULK. You can create a bulk XML file containing more than one classification and labelling notification.

The bulk XML file can be created either using the excel tool provided by ECHA or by using the XML schema (this option may be preferred for users with an IT background).

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

[8] See Annex I to the CLP Regulation and the *Guidance on the application on the classification criteria* for further information.

- The bulk excel tool is available in 22 EU languages (select your language in the tool).

Note. *XML bulk submission can be used only when each substance is identified either by CAS or EC number and identified by one composition only. In addition, you can specify a Specific Concentration Limit (SCL) or an M-factor that is already mentioned in Annex VI to CLP. When you want to set an SCL or M-factor yourself, in line with Article 10 of CLP, you should attach a scientific justification to your notification (Article 40(1)(e)). Please note that attaching a document is not feasible in an xml bulk file; therefore the only way to include such an SCL or M-factor and to attach the requested scientific justification is to submit a C&L notification using IUCLID or the online tool.*

C. ONLINE. You can manually enter the required information in REACH-IT.

- If you need to notify only a few substances and you are not currently using IUCLID 5, an online notification via REACH-IT could be your preferred option.
- If your substance has a harmonised C&L according to Annex VI to CLP, the online tool will offer you the quickest solution to notify because the harmonised C&L appears automatically in the corresponding fields.
- In the online tool, you can agree with a C&L already notified or registered by another company.

Up-to-date information on the REACH-IT online notification functionality and the XML tool is available in the CLP section of the ECHA website at: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/notification-to-the-cl-inventory

3.4 How can I submit a notification?

Classification and labelling notifications must be submitted electronically via the REACH-IT portal on the ECHA website. **Please note that you need to create your company account in REACH-IT[9] before you start to notify your substances.**

You will find the notification application access point in the REACH-IT section of the website.

When you enter REACH-IT, go to the classification and labelling section of the main menu (on the left-hand side of the REACH-IT screen), you will be guided through dedicated pages where **you can choose from the three following possibilities** to submit your classification and labelling notification:

1. Submit a classification and labelling notification dossier created in **IUCLID 5**: prepare a notification dossier in your local IUCLID 5 installation and upload it directly in REACH-IT;

2. Submit a **bulk** notification: upload in REACH-IT an XML bulk file (format to be available on the ECHA website);

[9] See the link at the end of this document for further information.

3. Submit a classification and labelling notification **online** (available in the second quarter of 2010) by entering the required information substance by substance directly into the REACH-IT system.

After a successful submission, the following numbers are assigned to a C&L notification:

- A submission number for each submission;

- A reference number for each successfully notified substance;

- A list number in case the notified substance could not be identified by an EC number.

A notifier can submit only one notification per substance. However, each notification can contain more than one composition for the same substance (e.g. due to different impurity profiles) and each composition can be linked to a specific classification and labelling. This function is available in the IUCLID 5 submission only.

Practical tips for notification and choosing a submission tool

- **Do not wait** until the last minute to submit your classification and labelling notification to ECHA.
- If you need to notify a few substances only and you are currently not using IUCLID 5, the **online notification via REACH-IT** could be your preferred option.
- Use the online notification via REACH-IT, if you want to **agree** with a classification and labelling that has already been notified for the same substance.
- **Bulk notification** using the XML option may be more practical for companies who have to notify many chemical substances since it allows the submission of classification and labelling notifications for several substances in a single file.
- Use IUCLID 5 when you need to submit **several compositions for one substance** and specify classification and labelling for each composition.
- Use IUCLID 5 when you need to flag confidentiality of the IUPAC name for your substance.

3.5 How can I update a C&L notification?

You can update a C&L notification dossier by using any of the notification tools - **all notification tools are compatible with each other**.

Table1: compatibility between the different submission tools

Initial submission using:	Update with IUCLID 5 C&L notification	Update with Online tool	Update with Bulk xml	Update with Registration dossier
IUCLID 5 C&L notification	Yes	Yes	Yes	Initial registration
Online tool	Yes	Yes	Yes	Initial registration
Bulk xml	Yes	Yes	Yes	Initial registration
Registration dossier	NO !	NO !	NO !	Yes

For a successful update submission, your C&L notification must be clearly identified as an update of a previous successful notification and contain the following compulsory information:

- The exact reference number of the C&L notification you want to update: the reference number has the following format 02-XXXXXXXXXX-CC-XXXX;
- The EC or list number assigned to your substance;
- The previous submission number (in IUCLID only);
- A reason for update.

The update of a C&L notification requires:

- In **IUCLID:** to specify the assigned reference number (notification number) in section 1.3. You must also specify in the dossier header the previous submission number, tick the "update" box and specify the "update reason".
- In the **online tool:** to chose the option "Update a completed submission", and enter the previously assigned reference number.
- In the **xml bulk submission tool:** to specify for the substance(s) updated that the notification is an update and the previously assigned reference number.

Classification and Labelling submitted as part of a registration dossier cannot be updated via a C&L notification submission. To do so, you have to update your registration dossier, see REACH Article 22.

Only the company that submitted the notification will be able to update it. Where a notification has been submitted on behalf of a group of manufacturers and/or importers, only the company that submitted the notification is thus able to update it.

4. KEY INFORMATION

4.1 Placing on the market

Placing a substance or mixture on the market under the CLP Regulation means to make it physically available to third parties, whether in return for payment or free of charge. Also, importing from non-EU countries into the EU customs territory is considered as placing on the market. Placing on the market would include the situation where a substance or mixture is sent from a company or research institute to a laboratory with a different legal entity.

In relation to notification, placing on the market is a pre-condition: A substance which is referred to in Article 39 of the CLP Regulation should be notified only in cases where it is placed on the market. Nevertheless, notification is not needed if the information required under the CLP Regulation Article 40 has already been provided as part of a previous registration or notification by the same notifier.

A substance needs to be notified within a month from the date when it is actively placed on the market. All substances placed on the market on or after 1 December 2010 should have been notified by 3 January 2011..

Substances that are in stock are not considered to be placed on the market . They will only have to be notified, within 1 month, if they are placed on the market by their manufacturer or importer later on. A **distributor** who takes substances off the shelves where they have been stored for a while, in order to sell them to others, will **not have to notify,** as this obligation is **only** on **manufacturers** and **importers**.

4.2 Group of manufacturers or importers

The classification and labelling notification of a substance can be made by a group of manufacturers or importers. A group of manufacturers or importers can, for instance, be:

- a corporate company with different legal entities;
- several companies that have no specific links between each other;
- several companies from one specific industry sector; or
- a substance information exchange forum (SIEF)

In cases where a notification is done by a group, only one classification and labelling notification will be submitted on behalf of all group members. To this end, the group members should agree on the classification and labelling of the respective substance[10].

If the classification and labelling notification is submitted on behalf of a group, this shall be indicated in REACH-IT. For more details you should consult the Industry User Manual "IUM part 15: Manage your group of manufacturers or importers".

[10] In this context substances can be considered to be the same if the main constituents are the same and the substance has the same EC number or CAS number or IUPAC name. See further information in the *Guidance for identification and naming of substances under REACH*.

The members of a group are recommended to document fully their agreement, and the basis on which classification decisions have been made. On request, they have to make available to ECHA, to the competent authorities and to the relevant enforcement authorities of the Member States all the information used for the purposes of classification and labelling under the CLP Regulation.

When a group of manufacturers and/or importers cooperate in this way, each member shall remain fully responsible for the classification, labelling and packaging of substances and mixtures he places on the market, and for meeting any other requirements of the CLP Regulation.

4.3 Substance identification essentials

You have to identify your substance as specified in sections 2.1 to 2.3.4 of Annex VI to the REACH Regulation. The substance definitions in the CLP and REACH Regulations are identical although less information is required for the classification and labelling notification compared to the registration. The substance definition also corresponds to the definition of a substance in the 7th Amendment to the Dangerous Substances Directive[11]. The definition goes beyond a pure chemical compound defined by a single molecule. **It is recommended that all prospective notifiers consult the** Guidance for identification and naming of substances under REACH see the links to related material in chapter 5 of this document.

The approach to identify a substance depends on the substance type. Substances can be divided into two main groups:

A. 'Well defined substances': Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification information required by section 2 of Annex VI to the REACH Regulation. 'Well defined substances' are sub-divided as follows:

a) ***Mono-constituent substances,*** i.e., as a general rule, substances in which one constituent is present at a concentration of at least 80% (w/w); the remaining 20% are regarded as impurities / additives.

b) ***Multi-constituent substances,*** i.e., as a general rule, substances consisting of several main constituents present at concentrations ≥10% and <80 % (w/w). All constituents present <10% are regarded as impurities.

c) ***Substances defined by more than the chemical composition***, i.e. substances defined as mono- or multi-constituent substances but require additional parameters in order to identify the substance unequivocally. Such parameters may include, but are not limited to, crystalline structure, shape, hardness etc.

B. 'UVCB substances': Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified based on their composition alone. Further identifiers, depending on the type of UVCB substance, are required such as source or production process.

[11] Directive 92/32/EEC amending Directive 67/548/EEC.

All notified substances should contain sufficient information to enable each substance to be properly identified. Sections 2.1 to 2.3.4 of Annex VI to the REACH Regulation specify the information that must be provided to meet the criteria for proper identification of a substance for notification to the Classification & Labelling Inventory. In general, the identifiers should be unambiguous and consistent in all cases. For example, the IUPAC name should reflect the structural and molecular formula. All constituents should be identified by IUPAC name and CAS identifiers and include a structural formula. In terms of quantitative information, a concentration range (minimum and maximum) should be, as far as possible, provided for all constituents. The composition information should account for 100% of the substance.

5. FURTHER INFORMATION

The ECHA website is an easy way to access information.

The ECHA website provides a single point of access to information on the CLP and REACH Regulation containing:

- General information about the CLP Regulation and links to CLP guidance documents in the classification section;
- General information about the REACH Regulation in the 'About REACH' section;
- User manuals (IUCLID 5 and REACH-IT); and
- Submission manuals for notification (IUCLID-5, online, bulk, and management of groups of manufacturers/importers).

If you have questions on notification:

- The CLP / REACH helpdesk in your country provides advice on your roles, responsibilities and about available guidance and should be your first point of contact. The contact information of the national helpdesks can be found on the ECHA website;
- The ECHA Helpdesk will assist you with technical questions related to REACH-IT, IUCLID, registration under REACH and notification to the Classification and Labelling Inventory. You can submit your questions by filling in an information request form on the ECHA website; and
- Your industry association can be a good source of information for sector-specific questions.

Links to related material

CLP Section on the ECHA website

- http://echa.europa.eu/web/guest/regulations/clp

Public Classification & Labelling Inventory :

- http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

Guidance:

- **Introductory Guidance on the CLP Regulation**
  http://echa.europa.eu/documents/10162/13562/clp_introductory_en.pdf

- **Guidance on the Application of the CLP Criteria**
  http://echa.europa.eu/documents/10162/13562/clp_en.pdf

- **Technical Questions and Answers on C&L Notifications**
  http://echa.europa.eu/documents/10162/13656/cl_notif_technical_qa_en.pdf

- **CLP Frequently Asked Questions**
  http://echa.europa.eu/web/guest/support/faqs/clp-frequently-asked-questions

- **Guidance for substance identification and naming of substances under REACH and CLP**
  http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf

IT-tools and manuals:

- **IUCLID 5**

http://echa.europa.eu/iuclid

- **REACH-IT**
http://echa.europa.eu/reachit

- **REACH-IT supporting documents**
http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals

Manuals for notification

- **Data Submission Manual part 12 :** How to prepare and submit a C&L notification using IUCLID?

- **Industry User Manual part 16 :** How to do an online submission to the C&L Inventory

- **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

CLP Helpdesks:

- **National Helpdesks:**
First points of contact for companies from the European Economic Area (EEA).
http://echa.europa.eu/help/nationalhelp_contact_en.asp

- **ECHA Helpdesk:**
Provides support e.g. on IUCLID 5, REACH-IT and specific submissions of data via the REACH-IT portal. Non-EEA companies may turn to ECHA if they seek advice on the implementation of REACH or CLP Regulations in the EEA.
http://echa.europa.eu/web/guest/support/helpdesks/echa-helpdesk

EU legislation:

- **CLP Regulation (EC) No 1272/2008**
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF

- **1st Adaptation to Technical Progress (ATP) to the CLP Regulation**
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:235:0001:0439:en:PDF

- **2nd Adaptation to Technical Progress (ATP) to the CLP Regulation**
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:083:FULL:en:PDF

- **Unofficial consolidation of the CLP legal text (excluding Tables 3.1 and 3.2 to Annex VI)**
http://ec.europa.eu/enterprise/sectors/chemicals/files/ghs/2nd-atp-to-clp_fin_en.pdf

- **REACH Regulation (EC) No 1907/2006**
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF

- **Unofficial consolidation of the REACH Regulation, dated 10 December 2011**
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20111210:N:PDF

Attachment 1

Concentration limits for notification to the Inventory

As a general rule, any substance leading or contributing to the classification of a mixture should be notified.

CLP Article 39(b) requires the notification of hazardous substances within the scope of CLP that are placed on the market either on their own or in a mixture, where:

- The substance is contained in that mixture above the concentration limits specified in the Dangerous Preparations Directive 1999/45/EC (DPD), which results in the classification of the mixture according to the DPD criteria; or
- The substance is contained in that mixture above the concentration limits specified in CLP, which results in the classification of the mixture according to the CLP criteria.

The reference to concentration limits in the legal text refers to the following:

A. a concentration above which a substance shall be taken into account for classification as specified in the Table under DPD Article 3(3); **or**

B. a generic cut-off above which a substance shall be taken into account as specified in Table 1.1 of Annex I to CLP (where appropriate using the M-factor[12] as set out in of Part 4 of Annex I to CLP); **or**

C. a concentration limit as specified in: Part B of Annex II to DPD for human health hazards and in Part B of Annex III to DPD for environmental hazards; **or**

D. a generic concentration limit (GCL**)** as specified in the Tables of Part 3-5 of Annex I to CLP for the respective CLP hazard class and differentiation (where appropriate using the M-factor as set out in of Part 4 of Annex I to CLP); **or**

E. a specific concentration limit (SCL) as listed in the respective column of Table 3.1 or 3.2 of Annex VI to CLP or set by the classifier in accordance with CLP Article 10.

Thus, hazardous substances placed on the market in a mixture above the applicable concentration limits as referred to in bullet points C, D or E above, or above the applicable concentration as described in bullet point A or B would need to be notified to the C&L Inventory if their actual concentration in the mixture directly triggers or contributes to the classification of the mixture. A substance present in a mixture above the applicable concentration should also be notified in case other substances are already present at concentrations which are sufficient to result in the classification of the mixture.

For substances assigned an SCL, the lower of the SCL (see point E above) and the relevant concentration referred to under point A (DPD) or B (CLP) above should be used.

For substances not assigned an SCL, the lower of the relevant concentrations referred to under point A (DPD) or B (CLP) and the relevant concentration limit under point C (DPD) or D (CLP) above should be used.

[12] In CLP, the concept of SCL is not used for the hazard class hazardous to the aquatic environment. Instead, the M-factors concept is used. An M-factor is applied to the concentration of a substance classified as hazardous to the aquatic environment category acute 1 and category chronic 1. This M-factor shall be used for a substance when applying the summation method for classification of a mixture in which the substance is present. In practice this means that e.g. the cut-off value to be used for such a substance is always the generic cut-off value divided by the M-factor established for the ingredient substance of a mixture, hence (0.1/M)%.

For CLP hazard class acute toxicity where neither a GCL nor an SCL is applicable, the generic cut-off as specified in Table 1.1 of Annex I to CLP should be used.

More information on the classification based on concentration thresholds is given in the ECHA Guidance on the Application of the CLP criteria, in particular in chapter 1.6.3.4.2 (http://echa.europa.eu/clp/clp_help_en.asp).

Specific note on physical hazards

Notification to the Inventory must also be done for a substance classified for a physical hazard and contained in a mixture whenever the mixture is placed on the market and is classified for a physical hazard due to the presence of ***that*** substance. It should be noted that the physical hazard class to which the mixture belongs could be different from that of the substance(s) causing the physical hazard. For instance, a mixture containing a substance classified as oxidizing and a combustible substance (classified as flammable or not) may be classified as an explosive. An example is ANFO, a common civil explosive (classified as such), consisting of Ammonium Nitrate (classified as an oxidizing solid) and Fuel Oil (a combustible liquid). Expert judgment should be sought in case of doubt.

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