

# Classification & Labelling Inventory: role of ECHA and notification requirements

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**Summary.** The CLP Regulation introduces the criteria of the UN Globally Harmonised System of Classification and Labelling (UN GHS) in the EU. The European Chemicals Agency (ECHA) manages the CLP related tasks – such as harmonised classification and labelling, handling requests for alternative names and maintaining the Classification & Labelling Inventory (C&L) – to ensure consistent implementation in the EU. The obligations for industry depend on their role in the supply chain. Manufacturers and importers have to notify to ECHA the identity and classification and labelling of substances within one month of placing them on the market either on their own or in a mixture, and regardless of the quantity. As of 3 January 2011 ECHA has received some 3.1 million notifications of over 107 000 substances. This information is stored in the C&L Inventory and accessible to Member State Competent Authorities. The non-confidential information will be made publicly available on ECHA's website in 2011.

*Key words:* Regulation (EC) no. 1272/2008, CLP, C&L notification, C&L Inventory, ECHA, harmonised C&L.

**Riassunto** (*Inventario delle classificazioni e delle etichettature: ruolo dell'ECHA e requisiti della notifica*). Il Regolamento CLP introduce nell'Unione Europea i criteri del sistema armonizzato globale delle Nazioni Unite per la classificazione ed etichettatura. L'European Chemicals Agency (ECHA) gestisce le attività relative a tale regolamento – quali la classificazione ed etichettatura armonizzate, le richieste di nomi alternativi e l'inventario delle classificazioni e delle etichettature – per garantire una implementazione coerente nell'Unione Europea. Gli obblighi per le industrie dipendono dal loro ruolo nella catena d'approvvigionamento. Fabbricanti e importatori devono notificare all'ECHA l'identità e la classificazione ed etichettatura delle sostanze, sia in quanto tali sia contenute in una miscela, entro un mese dalla loro immissione sul mercato, e indipendentemente dalla quantità. Al 3 gennaio 2011 l'ECHA ha ricevuto circa 3,1 milioni di notifiche per oltre 107 000 sostanze. Questa informazione è contenuta nell'inventario delle classificazioni e delle etichettature ed è accessibile alle autorità competenti degli stati membri. Le informazioni non-confidenziali saranno rese pubbliche sul sito di ECHA nel 2011.

*Parole chiave:* Regolamento (CE) no. 1272/2008, CLP, notifica, Inventario C&L, ECHA, classificazione ed etichettatura armonizzata.

## INTRODUCTION

Trade in chemical substances and mixtures is global and the hazard communication between regulatory areas has been complex due to different classification and labelling systems. The United Nations has developed over 12 years harmonised criteria for classification and labelling of chemicals together with general principles of their application, the so called Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The new system will facilitate worldwide trade in chemicals while protecting human health and the environment [1].

The Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) introduces the GHS criteria in the EU. CLP has entered into force on 20 January 2009 and until 1 June 2015 it will stepwise replace the previous legislation for chemical substances and preparations [2].

## THE EUROPEAN CHEMICALS AGENCY (ECHA)

ECHA was founded in 2007 and placed in Helsinki, Finland, as one of the agencies of the European Union. It manages the EU chemicals Regulation (REACH) [3] and the new Regulation on classification, labelling and packaging of chemicals (CLP) across Europe. In particular the REACH Regulation has been designed to completely overhaul the way that the safety of chemicals is assessed, implemented and communicated within Europe. REACH lays down the duties of the Agency.

### *Structure of the Agency*

The day to day management of the Agency is the responsibility of the executive director.

The Governing body of the Agency is the Management Board which is made up of representa-

tives from each of the EU and EEA Member States and representatives of the European Commission, the European Parliament and independent persons nominated by the Commission. In addition to the Management Board there are three different scientific committees – the Committee for Risk Assessment (RAC), the Committee for Socio-Economic Analysis (SEAC), and the Member State Committee (MSC) – the Forum for Exchange of Information on Enforcement, and the Board of Appeal. The Committee for Risk Assessment provides the best possible scientific advice on the risks of chemicals. One of its tasks is to provide opinions on proposals for harmonisation of classification and labelling.

### OVERVIEW ON OBLIGATIONS UNDER CLP *ECHA's role*

ECHA manages the process for harmonisation of classification and labelling (C&L), it maintains the C&L Inventory, and assesses requests for the use of an alternative name for a substance in a mixture, if this mixture is classified, labelled and packaged according to the CLP criteria. ECHA also provides guidance and IT-tools for industry to comply with the requirements of the CLP Regulation.

#### *Industry's obligation*

Companies' obligations and responsibilities under CLP depend on their role in the supply chain. CLP affects everybody who is:

- a registrant under REACH;
- a manufacturer or importer of substances or mix-

- tures (preparations) that he places on the market;
- a downstream user, who uses substances or mixtures supplied to him for the formulation of other products that he places on the market, e.g. adhesives, cleaning products, paints, motor oils;
- a distributor (retailer), who stores and places on the market a substance or a mixture for others;
- a producer or importer of articles that are explosive or that contain substances that are intentionally released or are on the candidate list of substances of very high concern;
- involved in research and development of chemicals.

Each of these roles implies specific obligations under CLP and it is worth to note that a company may have several roles.

Manufacturers, importers and downstream users, incl. formulators of mixtures and re-importers, are responsible for classifying, labelling and packaging their substances and mixtures before placing them on the market. CLP also requires manufacturers and importers to classify substances subject to registration or notification under REACH, even if they are not placed on the market. If a substance has a harmonised classification in the EU, it has to be used. Substances with harmonised classification are listed in Annex VI to CLP. Additionally, the “non-harmonised” hazard classes have to be self-classified if the classification criteria are met, based on adequate and reliable information.

Distributors (including retailers) have to label and package substances and mixtures in accordance with the classification.

**Table 1** | *Scope of the notification: specific substances and roles in the supply chain [4, 13]*

**Re-fillers** need to notify only if they receive substances and mixtures from an actor outside the EU.

**Re-importers** do not need to notify if they fulfil all the criteria to be considered as downstream users.

**Distributors** (incl. retailers) need to notify only if they import substances and mixtures from a non-EU source, as they count as importers in these cases.

**Recovered substances** have to be notified. During notification (via REACH-IT), it is possible to agree by means of a mouse-click to the C&L information of the original substance as provided by the registrant in the Inventory.

“**NONS**” under the Dangerous Substance Directive are deemed to be registered under the REACH. Dossiers have to be updated with the CLP classifications without undue delay after 1 December 2010 according to REACH. Other manufacturers and importers need to notify in the Inventory. 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 substance is classified as hazardous and placed on the market.

**Waste** under the Waste Framework Directive is exempted from CLP. Instead, residues recovered as substances or mixtures do fall under the scope of CLP.

**Ingredients of substances or mixtures that in the finished state are exempted from CLP** (e.g. cosmetic and medicinal products) have to be notified if placed on the market.

**Food and feeding stuffs** are normally exempted from CLP.

**A polymer** is a substance and must be notified if it fulfils the criteria for classification as hazardous and it is placed on the market. By contrast, **monomers** contained in such polymers are not considered as being placed on the market, and their notification is not necessary.

**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

**Substances for scientific research and development (R&D)** and **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.

The classification and labelling of **active substances contained in plant protection products (PPPs) and biocidal products (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.

Manufacturers and importers further have the obligation to notify to ECHA certain information on the substances that they are placing on the market. This information is stored in the Classification & Labelling Inventory. Re-fillers and distributors only need to notify if they import their chemicals from a non-EU country (*see also Table 1*).

## NOTIFICATION TO THE C&L INVENTORY

### *Obligation to notify*

Manufacturers and importers of hazardous substances have to notify the C&L of their substances to ECHA within one month after placing them on the EU market, unless the substance is exempted from CLP. This applies to hazardous substances on their own or in mixtures above concentration limits leading to the classification of the mixture. For hazardous substances there is no tonnage threshold for notification. Another group of substances that need to be notified are those that are subject to registration under REACH. This means that also non-classified substances that are manufactured in quantities of more than 1 tpa need to be notified where they are placed on the EU market.

However, the duty to notify does not apply if the manufacturers or importer has already submitted the corresponding information as part of a registration under REACH. In that case, the information needed for the C&L Inventory will be extracted from the registration dossier.

A C&L notification can also be made by a group of manufacturers or importers.

*Table 1* gives some examples for substances categories and ECHA's interpretation whether they fall under the scope of CLP. They are based on the frequently asked questions (FAQ) and the question and answers (Q&A) sections published on the ECHA website, which should be consulted for more detailed explanation [4, 5].

The first deadline for notification was 3 January 2011 and applied to all substances that were on the market on 1 December 2010. For substances placed on the market later EU<sup>1</sup> based manufacturers and importers have to notify the respective classification and labelling within one month of placing them on the market.

Placing a chemical substance or mixture on the market means making it physically available to third parties, regardless of whether this is in return for payment or free of charge. Substances which are either imported or sent as samples are also considered as being placed on the market. A substance is regarded as imported as soon as it is physically brought into the Communities customs territory.

A non-EU company can appoint one of its importers to notify on behalf of all the others. Where an only

representative has already registered a substance before it has to be notified, the importers covered by the registration do not need to notify to the Inventory.

### *Content of the notification and choice of tools*

Before submitting the C&L notification the manufacturer or importer placing a substance on the market needs to make sure that the C&L of the substance is correct. This means that he has to gather all available and relevant information and examine the information to ensure its adequacy and reliability. The next step is the evaluation of the available information against the classification criteria and the decision on the C&L. Detailed guidance on how to apply the criteria is available on the ECHA website [6, 7].

The notification to ECHA must include the following information:

- the identity of the notifier, as specified in Annex VI of REACH;
- the identity of the substance, as specified in Annex VI of REACH;
- the classification of the substance according to the CLP criteria;
- where the substance has been classified in some but not all CLP hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification;
- where applicable, specific concentration limits, or M-factors related to the classification as hazardous for the aquatic environment, *i.e.* acute category 1 and chronic category 1, together with a justification for their use; and
- the labelling elements for the substance, including the supplemental hazard statements referred to in CLP Article 25(1).

Submission of a notification is done via the REACH-IT portal on the ECHA website. First, the company has to sign up in REACH-IT and create an account. Companies can submit only one notification per substance.

Companies can notify their substances either individually or as a group of manufacturers or importers. When notifying as a group, only one notification is submitted on behalf of all the members of the group.

To carry out the notification, three tools are available on ECHA's website: IUCLID 5, a bulk notification tool, and an online tool.

In IUCLID 5, a dossier is created using a *CLP notification* template. IUCLID 5 is the only tool that allows the specification of more than one composition and more than one classification and labelling for the same substance. The tool is useful for companies which need to submit their REACH registration dossiers after the January 2011 notification deadline because in this way, the information used for making a notification will already exist in IUCLID for the upcoming registration.

The bulk notification tool is based on XML format and allows to submit notification information for several substances in a single file. An additional excel tool is made available to make the creation of the XML file easier. The bulk notification tool can also be used

<sup>1</sup>The reference to the EU in this text also includes Iceland, Norway and Liechtenstein.

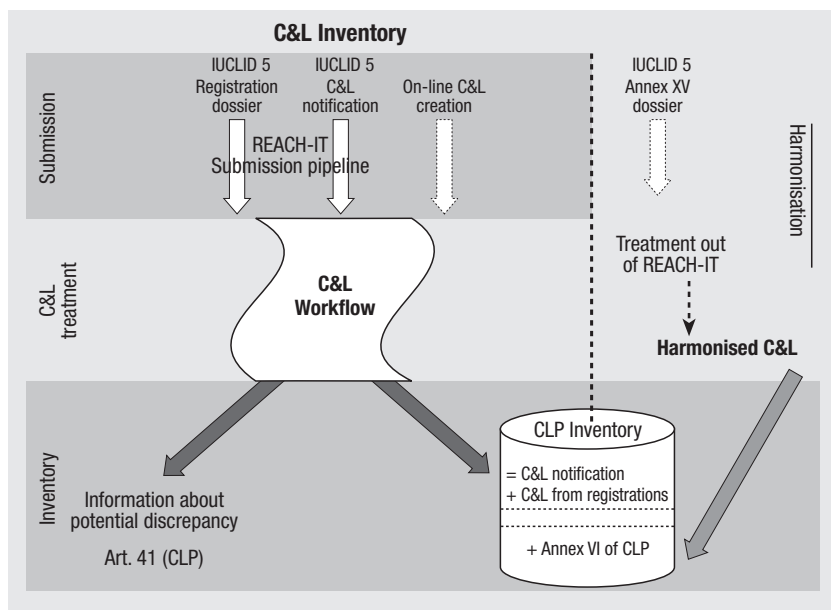


Fig. 1 | Information flow in the C&L Inventory (Source: ECHA).

for non-classified substances. However, the prerequisite is that the substances have either an EC or CAS number and they have only one composition or one classification and labelling.

With the online tool the required information is manually entered directly into REACH-IT. This might be the preferred option if a company is only notifying a few substances. The tool has an Agree button which allows the notifier to agree with an existing entry in the Inventory for the same substance while creating his own notification.

All of the tools are compatible with each other and notifications made with one can be updated with the others. On top of this, all the tools can be combined with a submission on behalf of a group [8]. User manuals are available on ECHA's website in 22 languages [9-13].

The CLP Regulation requires that in case the notification results in an entry on the Inventory which differs from another entry for the same substance, the other notifiers and/or registrants shall make every effort to come to an agreed entry to be included in the Inventory (CLP Article 41). However, a substance may be classified differently to another entry, provided the reasons are included in the notification.

In contrast, where the substance has a harmonised classification, the notifier shall classify in accordance with the harmonised classification listed in Part 3 of Annex VI to CLP and include this classification in the notification.

Please note that where an M-factor is not given in Part 3 of Annex VI for substances classified as hazardous for the aquatic environment (category acute 1 or chronic 1) the notifier shall set an M-factor for the substance, based on available data [6].

### The C&L Inventory

The C&L Inventory is a central database of basic C&L information of substances on the EU market irrespective of their production volume. It collects the C&L information of substances submitted to ECHA in the REACH registration dossiers and C&L notifications under CLP. It also includes the list of substances having a harmonised C&L, *i.e.* listed in Annex VI of CLP. The full database is accessible to the Member State Competent Authorities. Key information of the database will be extracted to the public Inventory which will be available at the ECHA web site in 2011. Companies' identity or confidential information will not be dis-

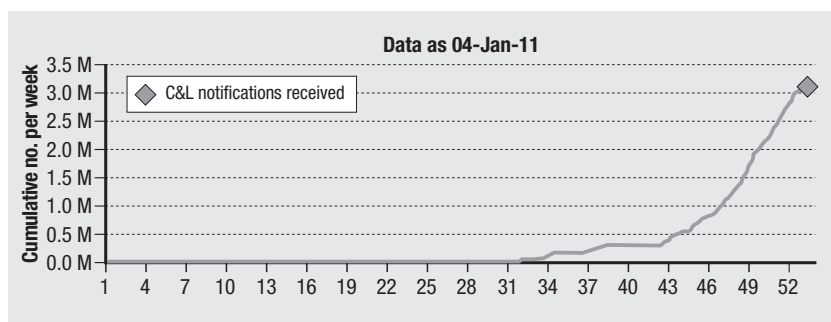


Fig. 2 | Trends in C&L notifications received in 2010-2011 by week. (Source: ECHA).



**Table 2** | C&L notifications per country – TOP 10 [14]

Country	Percentage of notifications received (total no. 3.1 million)
Germany	26%
United Kingdom	16%
France	9%
Belgium	6%
Italy	6%
Spain	4%
Poland	4%
The Netherlands	4%
Hungary	3%
Czech Republic	3%

closed. *Figure 1* gives an overview of the information flow in the C&L Inventory.

#### FIRST EXPERIENCE FROM C&L NOTIFICATIONS BY THE 3 JANUARY 2011 DEADLINE

Some companies have notified their substances already at the beginning of 2010 but the peak of C&L notifications was received in December 2010 (*Figure 2*). Submissions from Germany, the United Kingdom and France together account for about half of the notifications. *Table 2* lists the notifications received per country for the “Top 10”. By the deadline of 3 January 2011 more than 3.1 million notifications covering a total of over 107 000 substances were received by ECHA. The submitted notifications enable ECHA to establish the C&L Inventory.

ECHA will analyse the Inventory and improve the guidance provided to notifiers as necessary. Based on the first checks it seems that some notifiers might have had problems in correctly applying the harmonised classification and labelling that are based on the so-called group entries. Group entries in Annex VI of CLP cover more than one substance, for example “arsenic compounds, with the exception of those specified elsewhere in Annex VI”. In some cases substances may even be covered by more than one group entry. Lead oxalate (EINECS no. 212-413-5) is for instance covered by the entry for lead compounds (Index no. 082-001-00-6) as well as for salts of oxalic acid (607-007-00-3) (Foreword to Annex I of Dir. 67/548/EEC; General explanatory Notes; Groups of substances) [15]. In these cases, the labelling of the substance reflects the labelling for each of the two group entries. In cases where different classifications for the same hazard are given, the most severe classification shall be applied [2]. The following explanations are provided in the legislation:

*CLP Annex VI Part I: Introduction to the list of harmonised classification and labelling*

*1.1.1.5 Entries for groups of substances.*

*“A number of group entries are included in Part 3. In these cases, the classification and labelling requirements will apply to all substances covered by the description.*

*In some cases, there are classification and labelling requirements for specific substances that would be covered by the group entry. In such cases a specific entry is included in Part 3 for the substance and the group entry will be annotated with the phrase ‘except those specified elsewhere in this Annex’.*

*In some cases, individual substances may be covered by more than one group entry. In these cases, the labelling of the substance reflects the labelling for each of the two group entries. In cases where different classifications for the same hazard are given, the most severe classification shall be applied.*

*Entries in Part 3 for salts (under any denomination) cover both anhydrous and hydrous forms unless specifically specified otherwise.*

*EC or CAS numbers are not usually included for entries which comprise more than four individual substances”.*

The fact that group entries often do not have an allocated EC or CAS number might be one of the reasons that some notifiers fail to notice that the harmonised classification and labelling need to be applied to their substance.

The receipt of classification and labelling notifications under the CLP Regulation is an ongoing process. Manufacturers and importers placing on the market a hazardous substance on its own or in a mixture, or a substance subject to REACH registration, shall notify its classification and labelling within one month to ECHA. Therefore, the number of notified substances and notifications received will continue to increase and the C&L Inventory will be updated regularly.

#### CONCLUSION

With the C&L Inventory the EU implementation of GHS contains a strong element of hazard documentation and communication for all substances placed on the market irrespective of their production volume. The first submission deadline posing a challenge for ECHA and industry alike has been successfully passed. The number of notifications received indicates that manufacturers and importers make an effort to fulfil their obligations. A first spot check of the Inventory however shows that in some cases the quality needs to be improved, especially when applying harmonised classification for group entries. Any such observations made in the notifications received will be used to provide better guidance to industry and thereby ultimately improving the quality of C&L notifications and the Inventory as a whole.

This text reflects the personal view of the author and does not necessarily constitute the official position of ECHA.

### Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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