ECHA
http://echa.europa.eu

Questions & Answers on

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

This document contains questions and answers on the CLP Regulation

LEGAL NOTICE

Reference: ECHA-09-QA-01-EN

Date: 27/05/2009

Language: EN

The European Chemicals Agency (ECHA) is producing this document to inform interested readers about the background to and basic provisions of Regulation (EC) No 1272/2008.
If you have questions or comments in relation to this document please submit them using the information request form (quote the reference and issue date). The information request form can be accessed via the Contact ECHA page at:

http://echa.europa.eu/about/contact-form_en.asp

European Chemicals Agency, PO Box 400, Annankatu 18, 00121 Helsinki, Finland

TABLE OF CONTENTS

[1] PBT means persistent, bio-accumulative and toxic, vPvB means very persistent and very bio-accumulative

1. Background

1.1. What is the EU legislation on classification, labelling and packaging about?

EU legislation on classification, labelling and packaging aims to ensure a high level of protection of human health and the environment and the functioning of the internal market. It does so by laying down EU-wide criteria that must be applied to determine whether a substance or mixture which is manufactured or imported into the European market has properties which could damage human health or the environment. In cases where the substance or mixture meets these so-called "classification criteria", i.e. if it has certain hazardous properties, the substance or mixture must be classified accordingly, e.g. for acute toxicity or for flammability. Suppliers must then communicate the identified hazards of these substances or mixtures to their customers, including to consumers. The most common tool for hazard communication is the labelling on the packaged substance or mixture, but also the Safety Data Sheet which is provided to other companies in the supply chain.

Hazard labelling allows alerting of the user of a substance or mixture to the presence of a hazard and the need to avoid exposure and the resulting risks. Further rules relating to packaging should help to ensure the safe supply of hazardous substances and mixtures.

The EU legislation on classification, labelling and packaging consists of three acts: The Dangerous Substances Directive (Directive 67/548/EEC, "DSD"), the Dangerous Preparations Directive (Directive 1999/45/EC, "DPD") and the new Regulation on classification, labelling and packaging of substances and mixtures, Regulation (EC) No 1272/2008 ("CLP Regulation" or "CLP") which entered into force on 20th January 2009.

1.2. Why did the UN develop the Globally Harmonised System (GHS) for classification and labelling of chemicals?

The United Nations Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) provides a basis for globally uniform physical, environmental, health and safety information on hazardous chemicals through the harmonisation of the criteria for their classification and labelling. It was developed at UN level with the aim of overcoming differing labelling information requirements on physical, health and environmental hazards for the same chemicals around the world. Moreover, it also aims to lower barriers to trade caused by the fact that every time a product was exported, it mostly had to be classified and labelled differently because of differing criteria.

For further information on the development of the UN GHS, please see http://www.unece.org/trans/danger/publi/ghs/histback_e.html.

1.3. Why did the EU develop a new legislation on classification, labelling and packaging?

At the World Summit for Sustainable Development in Johannesburg 2002, the Commission, the EU Member States and stakeholders from industry and non-governmental organisations

endorsed the UN recommendation to implement the GHS into domestic law by 2008. By means of a new Regulation, the EU aimed at lowering the non-tariff barriers to trade which were due to re-classification and re-labelling for the purpose of export to non-EU countries.

1.4. Which non-EU countries are implementing GHS?

Outside the EU many other countries have subscribed to implementing the GHS into domestic law, including the US, Canada, New Zealand, Brazil, China, the Philippines, Russia, Japan, Mexico, South Africa and various other African countries. The stage of implementation ranges from those countries which already have or are about to have in place their own GHS implementing scheme (e.g. EU, Japan, New Zealand, South Korea) to those countries where focussed activities on and development of a GHS implementing scheme are ongoing (e.g. the US) and to further countries which have just started their discussions with the view to implement the GHS. Each individual country employs its specific domestic legal instruments, e.g. sector-specific acts or national standards, to implement the GHS. In the EU, the UN GHS was integrated into the CLP Regulation which entered into force on 20th January 2009; it is directly applicable to industry.

Further information on the stage of implementation of the UN GHS in different countries is available on the UN ECE website, see:
http://www.unece.org/trans/danger/publi/ghs/implementation_e.html

1.5. Does the CLP Regulation facilitate trade between the EU and non-EU countries?

Yes, it does. An exporter will be able to use the same description of the hazards on the label in his home country and in the country he exports to. This means that, when exporting his product, he can save the costs of re-classification for reasons of compliance with different C&L requirements of the country he is exporting to. Conversely, a non-EU supplier who wants to import his substances and mixtures into the EU will experience the same benefits.

In general, a major motivation for the development of the UN GHS was to have a classification system that allows for globally uniform physical, environmental, health and safety information on hazardous chemicals. To achieve this aim the criteria for classification and labelling of substances and mixtures were harmonised at UN level. As many countries and main trading partners of the EU have subscribed to implementing the UN GHS, this opens the gate for substances and mixtures to have the same classification and labelling in EU as well as in non-EU countries.

2. Scope

2.1. What is a classification? And what is a harmonised classification?

The classification of a substance or mixture reflects the type and severity of the hazards of that substance or a mixture, i.e. its potential to cause harm to human beings or the environment. A specific classification is expressed through standardised descriptors, e.g. “acute toxicity category 1 (oral)” or “flammable liquids, category 2”. It is communicated through standardised phrases and symbols on labels and safety data sheets, e.g. the classification “acute toxicity category 1 (oral)” is communicated through the hazard phrase “Fatal if swallowed”, through the signal word “Danger” and through the skull and crossbones symbol.

The decision on a particular classification for a substance or mixture is mostly taken by the supplier of the substance or mixture (“self-classification”). In certain cases the decision on the classification of a substance is taken at Community level - see also question 2.3 and the chapter of this document on harmonised classification. The classification decided at Community level is called “harmonised classification”. A harmonised classification must be applied by default by the suppliers of the respective substance. The classifications of about 8,000 substances that have been harmonised at Community level in the past decades are listed in Annex VI to CLP.

2.2. What is the difference between hazard assessment and risk assessment?

Hazard assessment means the assessment of the intrinsic properties of substances. It should not be confused with risk assessment which relates a given hazard to the actual exposure of humans or the environment to the substance or mixture displaying this hazard.

2.3. What are the main changes compared to the previous legislation, i.e. the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD)?

While the main features of classification and labelling are similar under DSD/DPD and CLP, there are some differences which are due to the integration of the terminology, classification criteria and labelling elements of the UN GHS and to procedures taken over from Regulation (EC) No 1907/2006 (REACH). An overview of the most important differences is included in the table below and further explained in the text following the table:

DSD / DPD	CLP
DSD terminology, e.g. preparation, dangerous, category of danger, risk phrase, safety phrase	UN GHS terminology, i.e. mixture, hazardous, hazard class, hazard statement, precautionary statement
DSD categories of danger for physical, health and environmental hazards	UN GHS hazard classes including those differentiations which best reflect the DSD categories of danger; total number of hazard classes higher under CLP than the total number of categories of danger under DSD
DPD calculation rules ("conventional method") for the classification of preparations	UN GHS calculation methods (additivity, summation) deviating from the DPD calculation rules
Testing, human experience or calculation for mixture classification	Similar to DPD; in addition bridging principles that allow the classification of mixtures on the basis of data on similar tested mixtures and information on individual hazardous ingredient substances
DSD categories of danger plus additional labelling elements, e.g. R1 ("Explosive when dry")	UN GHS hazard classes plus supplemental labelling elements taken over from DSD e.g. EUH001 ("Explosive when dry")
If harmonised classification then normally for all categories of danger	If harmonised classification then for substances which are carcinogenic, mutagenic, toxic to reproduction or respiratory sensitisers; other effects on a case-by-case basis
Harmonised classification based on a Member State proposal	Harmonised classification based on a Member State proposal (provisions previously contained in REACH) or a proposal by a manufacturer, importer or downstream user
No notification procedure foreseen	Notification of the classification and labelling of substances to the Classification & Labelling Inventory established by ECHA (provisions previously contained in REACH)

- One of the formal changes to be aware of is a change in terminology which is directly taken over from the UN GHS: For example, "preparations" are called "mixtures" under CLP, the "risk phrases" and "safety phrases" are now called "hazard statements" and "precautionary statements", and "hazard classes" replace formally the well-known DSD "categories of danger".

- The EU has taken up in CLP those hazard classes from the UN GHS which best reflect the DSD categories of danger. These hazard classes are broken down further into hazard categories or differentiations which take account of the severity of the effect or the route of

exposure. While the overall scope of classification under CLP is comparable with DSD, the total number of hazard classes has increased, in particular for physical hazards (from 5 to 16), to align with the transport provisions.

- The criteria underlying the hazard classes and categories apply to both substances and mixtures. With regard to health and environmental mixture classification, the calculation rules have changed compared to DPD; also, so-called “bridging principles” are introduced as a new approach to classifying mixtures.

- There are elements which are part of DSD or DPD, but which are not included in the UN GHS, for example the EU hazard class “Hazardous to the ozone layer” or some hazards which have led to additional labelling under DSD, e.g. “R1 – Explosive when dry”. These elements are retained as supplemental labelling information and can be found in Part 5 of Annex I and in Annex II to CLP. In order to make clear that these supplemental labelling elements do not come from a UN classification, they are coded differently from the CLP hazard statements. For example: the DSD additional labelling R1 ("Explosive when dry") becomes EUH001 instead of H001.

- With regard to harmonisation of classification and labelling of substances at Community level, CLP lays down the harmonised classification of substances which are carcinogenic, mutagenic or toxic to reproduction (CMR substances) and of respiratory sensitisers category 1; proposals relating to other hazard classes may be submitted on a case-by-case basis where justification is provided demonstrating the need for harmonised classification and labelling at Community level. Proposals for such harmonised classification may be submitted either by Member State Competent Authorities or, and this is new under CLP, by manufacturers, importers and downstream users. Proposals from industry should relate to substances which are not yet listed in Annex VI. The provisions on harmonised classification include those that were transferred from Title XI of the REACH Regulation to CLP.

- CLP provides for the new obligation to notify the classification and labelling of substances placed on the market to a database established and maintained by the European Chemicals Agency (ECHA), the so-called Classification & Labelling Inventory. The provisions on notification to the Classification & Labelling Inventory at ECHA were transferred from Title XI of the REACH Regulation to CLP.

2.4. Will there be a change of protection level under CLP?

The general level of protection has not been changed since CLP takes over existing provisions of DSD and DPD while at the same time introducing those UN GHS criteria which most closely correspond to the DSD criteria. Nevertheless, as some criteria for classification under GHS differ from the corresponding EU criteria, there may be individual substances and mixtures which will be classified as hazardous in future although they are not classified as such currently, and vice versa.

2.5. Have all GHS hazard categories been introduced in the CLP?

No. The scope of the CLP Regulation has been kept as close as possible to the existing EU system. Therefore, although the CLP Regulation introduces all GHS hazard classes, it does not introduce those hazard categories that are not part of current EU legislation, thus none of the following GHS hazard categories is included in CLP:

- “flammable liquids category 4”,
- “acute toxicity category 5”,
- “skin corrosion/irritation category 3”,
- “aspiration hazard category 2” and
- “acute aquatic toxicity category 2 and 3”.

2.6. Why is there no additional labelling of PBT and vPvB[2] substances?

Under REACH, chemicals meeting the criteria for PBT / vPvB have to be controlled and their emissions reduced as much as possible, which means that widespread use of these substances will be unlikely. Chemicals that meet these criteria are mostly already classified and labelled for environmental hazards and in certain cases for toxicity; this will continue to be the case under CLP. However, during the legislative process a provision for future action in this regard was included in the CLP text, Article 53(2): it states that "the Member States and the Commission shall promote the harmonisation of the criteria for classification and labelling of substances as persistent, bio-accumulative and toxic (PBT) and as very persistent and very bio-accumulative (vPvB) at the level of the United Nations."

2.7. Will all substances and mixtures be within the scope of CLP?

Yes, most of them. In general, the scope of classification of substances and mixtures is based on two pieces of legislation, the CLP Regulation itself and the REACH Regulation (see CLP Article 4(2)), unless a substance is explicitly exempted from these acts:

Based on CLP, a manufacturer, importer or downstream user of chemical substances or mixtures to be placed on the market, must classify these substances or mixtures before placing them on the market, independently of the actual tonnage manufactured, imported or placed on the market.

Based on REACH, a manufacturer or importer must also classify substances which are **not** placed on the market if they are subject to registration or notification in line with Articles 6, 9, 17 or 18 of REACH. This includes the classification of monomers, on-site isolated intermediates, transported isolated intermediates as well as substances used for product and process-orientated research and development (PPORD).

Please note that a distributor (including a retailer) and a downstream user (including a formulator of mixtures or a re-importer of substances or mixtures) may use the classification of a substance or mixture derived in accordance with Title II of CLP by another actor in the

[2] PBT means persistent, bio-accumulative and toxic, vPvB means very persistent and very bio-accumulative

supply chain, for example from a Safety Data Sheet. Therefore, a downstream user may not change the composition of the substance or mixture.

2.8. Should articles be classified?

No, normally not. However, the obligation to classify applies to **producers or importers of certain explosive articles** which meet the definition set out in section 2.1 of Annex I to CLP before placing them on the market. Other articles are not subject to any classification, labelling and packaging obligations of the CLP Regulation. In addition, if you are a **producer or importer of an article,** you would still have to classify the substances contained in it where Articles 7 and 9 of REACH provide for their registration or notification and such substances have not already been registered for that use. This includes the classification of those substances in articles which are used for product and process-orientated research and development (PPORD).

3. Obligations

3.1. What are the main obligations under CLP for companies supplying substances or mixtures?

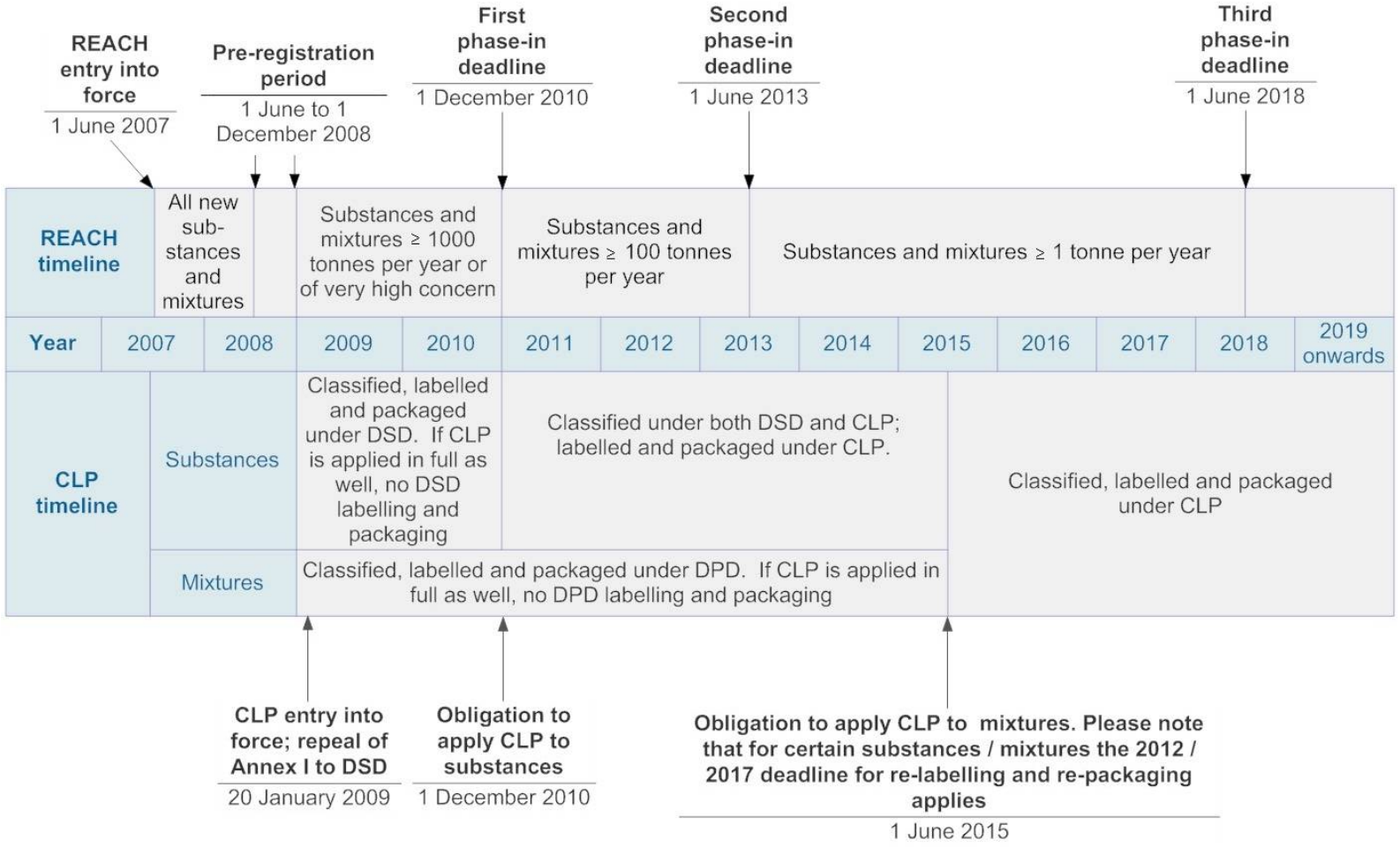
The main obligation imposed on manufacturers and importers of substances, downstream users, including formulators of mixtures and re-importers of substances or mixtures benefiting from an exemption from Article 2(7)(c) REACH, is to **classify, label and package** substances and mixtures in accordance with the CLP Regulation. Distributors (including retailers) of substances and mixtures need to label and package in accordance with CLP.

Manufacturers and importers (or groups of manufacturers or importers) who place a hazardous substance on the market, will also have to **notify** certain information, in particular the substance identity and the classification and labelling of that substance to ECHA, unless this information has already been submitted as part of a registration under REACH. ECHA will then include the notified information in the Classification & Labelling Inventory. See also the section on notification below.

3.2. What is the transitional period and what is it for?

Under CLP, the transitional period is the period of time granted to suppliers of chemicals to change from the DSD / DPD classification system to the CLP rules. Transitional provisions are set out in CLP Article 61, defining essentially two target dates that affect the classification, hazard communication and packaging of hazardous substances and mixtures, namely 1st December 2010 and 1st June 2015.

The applicability of the CLP rules by the aforementioned dates and their relationship to the REACH registration deadlines for phase-in substances are illustrated in the figure below:


REACH entry into force
1 June 2007
Pre-registration period
1 June to 1 December 2008
First phase-in deadline
1 December 2010
Second phase-in deadline
1 June 2013
Third phase-in deadline
1 June 2018
REACH timeline
All new sub-stances and mixtures
Substances and mixtures ≥ 1000 tonnes per year or of very high concern
Substances and mixtures ≥ 100 tonnes per year
Substances and mixtures ≥ 1 tonne per year
Year
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019 onwards
CLP timeline
Substances
Mixtures
Classified, labelled and packaged under DSD. If CLP is applied in full as well, no DSD labelling and packaging
Classified under both DSD and CLP; labelled and packaged under CLP.
Classified, labelled and packaged under CLP
Classified, labelled and packaged under DPD. If CLP is applied in full as well, no DPD labelling and packaging
CLP entry into force; repeal of Annex I to DSD
20 January 2009
Obligation to apply CLP to substances
1 December 2010
Obligation to apply CLP to mixtures. Please note that for certain substances / mixtures the 2012 / 2017 deadline for re-labelling and re-packaging applies
1 June 2015

3.3. Why is there no tonnage threshold for classification and labelling in CLP?

Neither CLP nor REACH nor the old legislation contain a tonnage threshold for the classification and labelling provisions since workers and consumers who use chemical substances and mixtures have to be warned and protected, regardless of the tonnage of substance or mixture manufactured or imported.

4. Inventory

4.1. What is the Classification & Labelling Inventory and what can it be used for?

The Classification & Labelling (C&L) Inventory is a database which will contain basic classification and labelling information on notified and registered substances. It will also contain the list of harmonised classifications (Annex VI). It will be established and maintained by ECHA.

The C&L Inventory serves multiple purposes:

- It is a tool for hazard communication and a source of basic information on classified substances and on non-classified substances subject to registration which are placed on the market, for the general public, Member State Competent Authorities and suppliers under CLP and REACH;
- It reveals disagreement on the classification and labelling of the same substance, thus pointing to the possibility of considering further discussion, evaluation needs or the need for harmonisation of a particular classification and labelling of a substance;
- It is an important tool for hazard communication and risk management, e.g. when Member State Competent Authorities assess the need for potential authorisations and restrictions of hazardous substances under REACH.

4.2. What will the Classification & Labelling Inventory contain?

Firstly, the C&L Inventory will contain the identity of the notified or registered substance, the classification of the substance, the reason why a classification has not been assigned in cases where a substance has been classified in some but not all hazard classes or differentiations, specific concentration limits or M-factors (multiplying factors)[3] and the labelling elements for the substance.

[3] See question 8.6. on M-factors

Secondly, ECHA will also include the following information:

- whether there is a harmonised classification for a particular entry;
- whether an entry is a joint entry between registrants of the same substance;
- whether it is an agreed entry;
- whether the entry differs from another entry on the Inventory for the same substance.

4.3. Why must a notifier indicate the reason for non-classification?

The old legislation has created some confusion because a lack of classification cannot be interpreted as the absence of a hazard: a non-classification may also be due to inconclusive data or lack of data. For registered substances, REACH requires that the reasons for lack of classification are stated in the Chemical Safety Report. With respect to substances to be notified and classified in some but not all hazard classes or differentiations, the CLP Regulation requires that this information be provided with the notification.

4.4. Do those who have to classify also have to notify to the Classification & Labelling Inventory?

Only manufacturers and importers who place a hazardous substance on the market, either on its own or contained in a hazardous mixture, or who place on the market a substance that is subject to registration under REACH will have to notify the classification and labelling of the substance to ECHA. No notification is required when the same information (i.e. the classification in accordance with the CLP criteria) has already been submitted as part of a registration under REACH by the same manufacturer or importer. Downstream users including formulators of mixtures, distributors and producers or importers of articles do not need to notify.

4.5. Which substances have to be notified to the C&L Inventory?

The following substances will have to be notified to the C&L Inventory:

- Substances subject to registration under REACH (≥ 1 tonne/year) and placed on the market, unless a supplier has already registered the substance with a classification and labelling according to CLP (together with the classification according to DSD);
- Substances classified as hazardous under CLP and placed on the market irrespective of the tonnage; and
- Substances classified as hazardous under CLP and present in a mixture above the concentration limits specified in Annex I of CLP or as specified in Directive 1999/45/EC, where relevant, which results in classification of the mixture as hazardous, and where the mixture is placed on the market.

4.6. Why is there no quantitative limit for notification of classification to the C&L Inventory?

The obligation to notify the classification and labelling of hazardous substances was introduced through REACH and then taken over by CLP. The intention is to also obtain basic information on the hazardous properties of those substances which are manufactured or imported in volumes of less than 1 tonne/year or which are not subject to registration, but which are placed on the market. The information will be kept and published at one central location, i.e. within the Classification & Labelling Inventory established by ECHA. Currently the C&L notification is the only way in which information on substances below the 1 tonne per year threshold placed on the market will be available to downstream users and the authorities: the information can be taken into account by them for hazard communication and risk management purposes, including proposals for authorisation, restriction and harmonised classification.

5. Labelling

5.1. Why is labelling based on hazard and not on risk?

While hazard-based labelling allows conveying of the same information to the user of a chemical, independent of any use situation, risk-based labelling would be dependent on a specific use and exposure situation. As the latter cannot always be foreseen and may also change when handling a substance or mixture, labelling based on risk may not reflect the actual exposure situation. Further to this, risk-based labelling does not allow judgement of or conclusions on the appropriateness of risk management measures.

The old EU system for labelling of chemicals is based on conveying information on hazards, not on risk, and the CLP Regulation continues this well-established EU approach. Hazard-based labelling as required in the EU legislation allows for independent decisions on appropriate risk management measures which may vary in view of different use settings and target groups.

5.2. Why are there different deadlines for re-labelling and re-packaging?

According to CLP, re-labelling and re-packaging of substances and mixtures which are already in the supply chain (“on the shelves”) before 1st December 2010 (substances) and 1st June 2015 (mixtures) may be postponed until 1st December 2012 and 1st June 2017, respectively. The additional two years are granted in order to avoid unnecessary burdens of re-labelling and re-packaging on enterprises reclassifying their substances and mixtures according to CLP.

5.3. Manufacturer A produces substance A, which was placed on the market for the first time before 1st December 2010. The production is continuous and new batches of the same substance are produced every month. Must a batch produced between 1st December 2010 and 1st December 2012 be labelled according to DSD or CLP?

A batch of a substance produced between 1st December 2010 and 1st December 2012 must be classified, labelled and packaged according to the CLP Regulation. However, the same batch must also be classified according to DSD and this information shall be made available to downstream users (in particular formulators of mixtures) by means of a Safety Data Sheet.

6. Collection and evaluation of data

6.1. Can classifications derived under transport legislation be used for the purposes of CLP?

Yes, sometimes. Many of the UN GHS criteria (by hazard class), in particular those relating to physical hazards, are already implemented through the UN Model Regulations and related legal instruments regulating the transport of dangerous goods, e.g. in the European Agreement concerning the International Carriage of Dangerous Goods by Road, see http://www.unece.org/trans/danger/publi/adr/adr_e.html. A transport classification can be used as one source of information for the classification and labelling of a given substance, provided the following is taken into account:

- Transport classifications do not include all of the GHS categories for physical, health and environmental hazards, so the absence of a transport classification for a given substance does not mean that it should not be classified under CLP;
- In relation to physical hazards, testing may be necessary in order to provide data for an unambiguous classification according to CLP;
- Under transport legislation, special provisions may be linked to the entries in the Dangerous Goods List (ADR, part 3) which have to be met for the substance in order to be classified in the respective class for transport. In these cases the classification for the purposes of supply and use, i.e. CLP, might be different. Further to this, one substance may even have two different entries with two different classifications where one of the classifications is linked to one or more special provisions.

6.2. Is animal testing required for health and environmental classifications under CLP?

There is no requirement to perform animal testing for the purpose of classification. Furthermore, it is clearly specified that new animal testing may be performed only in case a supplier has exhausted all other means of generating reliable and adequate information for the purpose of classification. This includes application of the rules provided for in section 1 of Annex XI to REACH. These rules refer to the use of existing data, use of data from tests not carried out according to the principles of Good Laboratory Practice (GLP), use of

historical human data, application of weight of evidence and use of (Q)SARs[4], *in-vitro* methods and read-across. Expert judgement should be used in order to apply the criteria, for example to evaluate available test data that cannot be applied directly to the criteria or to exploit available data on mixtures which are similar to the one to be classified. Testing on non-human primates is prohibited.

6.3. Is testing required for determining physical hazards?

CLP requires testing for physical hazards, unless adequate and reliable information is already available. The physical hazards of substances and mixtures should be determined through testing based on the methods or standards referred to in part 2 of Annex I to CLP. These can be found for example in the UN Manual of Tests and Criteria, see the website http://www.unece.org/trans/danger/publi/manual/manual_e.html, which is normally used to classify substances and mixtures for transport.

6.4. How can alternative methods to animal testing be used?

By reference to Annex XI of the REACH Regulation, CLP encourages the use of alternative testing and non-testing methods. As the results of alternative testing and non-testing methods may not directly correspond to the classification criteria, they should be evaluated in the context of a weight of evidence approach involving expert judgement.

4 (Q)SAR stands for qualitative or quantitative structure-activity relationship.

7. Safety Data Sheets

7.1. Do Safety Data Sheets need to reflect the new classification and labelling elements according to the CLP rules?

While requirements for Safety Data Sheets are laid down in REACH, cf. Article 31 and Annex II to the REACH Regulation, they were amended through Articles 57-59 of the CLP Regulation. The amendments provide for the following:

- until 1st June 2015, the classification of a substance according to DSD *shall* be provided in the Safety Data Sheet; after 1st December 2010 also the CLP classification *shall* be provided. This will apply to both Safety Data Sheets for substances on their own and to Safety Data Sheets for mixtures containing these substances.
- until 1st December 2010, if a substance is classified, labelled and packaged according to CLP, the CLP classification *shall* appear on the Safety Data Sheet, alongside the classification based on the DSD. However, a supplier *may* choose to identify the CLP classification of a substance in advance of applying CLP to it in full (i.e. no labelling and packaging according to the CLP rules). Where this happens, the supplier *may* include this information on the accompanying Safety Data Sheet, under the 'other information' heading;
- until 1st June 2015, the classification of a mixture according to DPD *shall* be provided in the Safety Data Sheet;
- until 1st June 2015, if a mixture is classified, labelled and packaged according to CLP, the CLP classification *shall* appear on the safety data sheet, alongside the classification based on the DPD. However, a supplier *may* choose to identify the CLP classification of a mixture in advance of applying CLP to it in full (i.e. no labelling and packaging according to the CLP rules). Where this happens, the supplier *may* include this information on the accompanying Safety Data Sheet, under the 'other information' heading;
- from 1st June 2015, substance and mixture classifications according to CLP *shall* be provided in the Safety Data Sheet. From this date the old legislation (DSD and DPD) will be repealed, and classifications according to DSD or DPD will no longer be allowed.

These rules are also displayed in the table below:

Deadline	The Safety Data Sheet …
until 1st June 2015	… shall contain the classification of a substance according to DSD; after 1st December 2010 the CLP classification shall also be provided. This will apply to both Safety Data Sheets for substances on their own and to Safety Data Sheets for mixtures containing these substances.
until 1st December 2010	… shall contain the classification of a substance according to DSD. However, if a substance is already classified, labelled and packaged according to CLP, the Safety Data Sheet for the substance shall also contain the CLP classification.
until 1st June 2015	… shall contain the classification of a mixture according to DPD. However, if a mixture is already classified, labelled and packaged according to CLP, it shall also contain the CLP classification.
from 1st June 2015	… shall contain substance and mixture classifications according to CLP.

8. Harmonised classification

8.1. Within the EU, classifications have been harmonised for decades. What happens to Annex I to the Dangerous Substance Directive (DSD) which contains harmonised classifications of about 8,000 substances?

Annex I to DSD has been transferred to Table 3.2 of Annex VI to CLP. The transfer is important for two reasons: First, Annex I to DSD was repealed on entry into force of CLP. Secondly, the harmonisation effort of the past decades is retained such that the harmonised classifications can and must still be used by suppliers: They can and must be applied when classifying substances and mixtures according to DSD and DPD during the transitional period (Table 3.2 of Annex VI) and when classifying according to the CLP Regulation (Table 3.1). The latter is possible because the DSD classifications have been translated (i.e. converted) into corresponding CLP classifications according to Table 3.1.

In the case of physical hazards, the translations have been based on a re-evaluation of available data. With regard to health and environmental hazards, the translations were done by use of a translation table (Annex VII to CLP); in all cases where the DSD and CLP criteria did not match sufficiently, a minimum classification has been assigned.

At entry into force of the CLP Regulation, Annex VI contains all the harmonised classifications up to and including the 29th Adaptation to Technical Progress (ATP) of DSD.

8.2. On entry into force of the CLP Regulation on 20th January 2009, Annex I to Directive 67/548/EEC was deleted and transferred to the CLP Regulation. What should a supplier do with the substances from the 30th and 31st Adaptation to Technical Progress (ATP) of DSD which are not yet included in Annex VI to CLP?

The 30th and 31st Adaptations to Technical Progress (ATP) amended Annex I to Directive 67/548/EEC by introducing new and updated harmonised classifications. These harmonised classifications could not be incorporated into Annex VI to the CLP Regulation.

Therefore, the European Commission has prepared a proposal for a 1st ATP to the CLP Regulation with a view to transferring the harmonised classifications contained in the 30th and 31st ATPs into Annex VI to the CLP Regulation. This ATP has meanwhile received a favourable comitology vote; it will take the form of a Regulation and, therefore, be directly applicable throughout the EU.

On the issue of deletion of Annex I to Directive 67/548/EEC (and by extension deletion of the two implementing directives):

Annex I was deleted by Article 55(11) of the CLP Regulation as of its entry into force (20th January 2009). However, the gap created by this deletion should be short-lived. It should be filled once the first ATP of the CLP Regulation enters into force, which is expected to be by the middle of 2009. In the meantime, companies are strongly encouraged to apply the harmonised classifications contained in the 30th and 31st ATPs for the substances not yet listed in Annex VI to the CLP Regulation. Directive 67/548/EEC and the CLP Regulation set forth the basic principle of self-classification based on available information. In this case, the fact that the classifications have been harmonised and will soon be included in Annex VI will be a very strong reason to self-classify the substance by using the newly harmonised classifications listed in the 30th and 31st ATPs for the substances not covered by an existing entry in Annex VI of the CLP Regulation.

8.3. Who can make proposals for harmonised classification and labelling under CLP?

Member State Competent Authorities as well as manufacturers, importers and downstream users can submit proposals for harmonised classification and labelling of a substance. However, proposals for updates of already harmonised classifications can only be submitted by Member State Competent Authorities. In case a manufacturer, importer or downstream user proposes a harmonised classification referring to hazard categories other than CMR or respiratory sensitisation, the corresponding proposal is accompanied by a fee which is still to be specified in a Commission Regulation.

8.4. Is it possible to harmonise classifications for all substances?

This would require huge additional resources for ECHA, the Commission and Member States and seems to be practically impossible. The CLP Regulation does however foresee a partial implementation of this idea by requiring a harmonised classification for the most problematic hazard classes (CMRs and respiratory sensitisers), so that public resources are used efficiently. However, since it is recognised that harmonised classifications may also be

necessary for other hazards, Member States, manufacturers, importers and downstream users may submit respective proposals on a case-by-case basis.

8.5. Why were the generic concentration limits (GCLs) contained in Annex I to DSD not transferred to Table 3.2 of Annex VI to CLP?

The primary idea behind inclusion of the GCLs in Annex I to DSD was to provide classifiers with an “all in one” table. As Table 3.1 which contains the classifications in accordance with the CLP criteria no longer contains any generic concentration limits, it was decided to delete them from Table 3.2 (classifications in accordance with 67/548/EEC) as well, in order to avoid confusion and improve readability between the tables. Further to this, deletion improves consistency with the second ATP of Directive 1999/45/EC (Dangerous Preparations Directive, DPD).

8.6. What is an M-factor?

An M-factor is a multiplying factor. The concept of M-factors has been established to give an increased weight to substances that are very toxic for the aquatic environment when classifying mixtures containing these substances. Where there is no harmonised M-factor listed in Annex VI to CLP for a specific substance, manufacturers, importers and downstream users should set an M-factor themselves when classifying substances for acute aquatic toxicity category 1 or chronic aquatic toxicity category 1.

8.7. Should there be a UN list of harmonised classifications?

At this stage it is the general view of the UN Subcommittee of Experts on the GHS (UN SCE GHS) that it would be premature to implement a UN list of harmonised substance classifications – currently it is considered to have already been a major step that so many countries have agreed to implement the same harmonised criteria for classification and labelling.

Questions & Answers on
Regulation (EC) No 1272/2008 on
classification, labelling and packaging of substances and mixtures

European Chemicals Agency Annankatu 18, P.O. Box 400, FI-00121 Helsinki Finland
Tel. +358 9 6861 80 | Fax +358 9 6861 8210 | http://echa.europa.eu | info@echa.europa.eu