

Introductory Guidance on the CLP Regulation

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



LEGAL NOTICE

This document contains guidance to Regulation (EC) No 1272/2008 (CLP Regulation). 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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PREFACE

This document provides guidance on basic features and procedures laid down in the new Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation or simply “CLP”) which entered into force on 20 January 2009 in the EU countries and is expected to enter into force in Norway, Iceland and Liechtenstein as well in the near future. It represents Module 1 of the overall guidance related to the CLP Regulation.

This Module 1 guidance is mainly addressed to suppliers, i.e. to **manufacturers of substances, importers of substances and mixtures, downstream users, distributors of substances and mixtures and producers and importers of certain specific articles**. While it is not expected that readers of this guidance document have active experience with classifying substances and mixtures, it is assumed they have a basic knowledge of the current system of classification and labelling, as represented by the Dangerous Substances Directive 67/548/EEC and the Dangerous Preparations Directive 1999/45/EC.

When creating this document, the aim was to provide its legal and technical content in easily digestible format, in order to allow a quick and effective orientation on the obligations under CLP. For the purpose of classification and labelling according to the criteria, and for information on general aspects concerning all hazard classes, we recommend that you consult the legal text itself, including its annexes, together with the more specific guidance provided in Module 2 of the overall guidance on the CLP Regulation.

We are aware that you may have to comply with REACH as well. Therefore, we have highlighted throughout this guidance the relevant REACH obligations which play a role in the context of CLP. Furthermore, we point to those guidance documents related to REACH which can assist in applying the CLP Regulation.

This document benefited a lot from the experience and know-how of Member State and stakeholder experts who have shown strong commitment to the Module 1 project. The Commission and the European Chemicals Agency are grateful for the many valuable contributions received. We hope that this document will help you to comply with the obligations of the new Regulation.

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1. Introduction

About this guidance

This guidance document has been written to help you to find your way around the requirements of Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation or simply CLP) which entered into force on 20 January 2009, see <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2008:353:SOM:EN:HTML>. You will be made familiar with the basic features and procedures of CLP but are advised to consult the legislative text for additional details and to confirm understanding. In relation to the classification criteria as such you are recommended to consult the guidance document on the application of the CLP rules for classification, labelling and packaging of substances and mixtures (Module 2). The document also provides substance-specific guidance where this is relevant for a particular classification, e.g. for the aquatic classification of metals.

Many provisions of CLP are closely linked to provisions under Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and other Community legislation. The most relevant links to REACH, to Directive 98/8/EC on biocidal products and to Directive 91/414/EEC on plant protection products are briefly explained in separate sections of this guidance document. In addition, REACH links are noted briefly in the individual sections of this document, where appropriate.

Who is this guidance for?

This document has been written for suppliers of substances and mixtures (preparations) and for those **producers or importers of certain specific articles**¹ who have to apply the new rules for classification, labelling and packaging under CLP. Suppliers are **manufacturers of substances, importers of substances or mixtures, downstream users**, including **formulators** (manufacturers of mixtures) **and re-importers**, and **distributors, including retailers, placing on the market substances or mixtures**. (☞ [see section 2 of this guidance document](#)). It is meant for those who already have a basic understanding of classification and labelling, either because of the application of the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD) or because of knowledge of the United Nations Globally Harmonised System of Classification and

¹ As a producer or importer of an article you are only affected by CLP if you produce or import an explosive article as described in section 2.1 of Annex I to CLP or where REACH Article 7 or 9 provide for registration or notification of a substance contained in an article.

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Labelling of Chemicals (UN GHS) itself (*see below*). This document will not explain everything from scratch, but will try to provide a good overview of the features of the new CLP-Regulation.

What is CLP, and why do we have it?

Trade in substances and mixtures is not only an issue relating to the internal market, but also to the global market. With a view to facilitating worldwide trade while protecting human health and the environment, harmonised criteria for classification and labelling together with general principles of their application have been carefully developed over a period of 12 years within the United Nations (UN) structure. The result was called the Globally Harmonised System of Classification and Labelling of Chemicals (*UN GHS*):
http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html).

The CLP Regulation follows various declarations whereby the Community confirmed its intention to contribute to the global harmonisation of criteria for classification and labelling through the incorporation of the internationally agreed GHS criteria into Community law. Enterprises should benefit from the global harmonisation of rules for classification and labelling and from consistency between, on the one hand, the rules for classification and labelling for supply and use and, on the other hand, those for transport.

CLP is currently based on the 2nd revision of the UN GHS. It takes onboard basic features and procedures from DSD and DPD. Therefore, CLP will be similar but may not be identical to the way GHS is introduced into the legal framework of countries outside the EU.

The CLP Regulation is legally binding across the Member States. It is directly applicable to industry. CLP will supersede DSD and DPD over time. These directives will finally be repealed after a transitional period, i.e. on 1 June 2015 (^{CP} *see section 4 of this guidance document*).

What is hazard classification, labelling and packaging?

Similar to DSD, one of the main aims of CLP is to determine whether a substance or mixture displays properties that lead to a classification as hazardous. Please note that whenever there is talk about ‘substances and mixtures’ in this guidance document, this also covers those “certain specific articles” which are subject to classification according to Part 2 of Annex I to CLP.

Once such properties are identified and the substance or mixture is classified accordingly, **manufacturers, importers, downstream users and distributors** of substances and mixtures, as well as **producers and importers of certain specific articles**, should communicate the identified hazards of these substances or mixtures to other actors in the supply chain, including to consumers.

The hazard of a substance or mixture is the potential for that substance or mixture to cause harm. It depends on the intrinsic properties of the substance or mixture. In this connection hazard evaluation is the process by which information about the intrinsic properties of a substance or mixture is assessed to determine their potential to cause harm. In cases where the nature and severity of an identified hazard meets the classification criteria, hazard classification is the assignment of a standardised description of this hazard of a substance or a mixture causing harm to human health or the environment.

Hazard labelling allows for the communication of hazard classification to the user of a substance or mixture, to alert the user to the presence of a hazard and the need to avoid exposures and the resulting risks.

CLP sets general packaging standards, in order to ensure the safe supply of hazardous substances and mixtures (*CLP Recital 49 and CLP Title IV*).

What about the assessment of risk?

The classification of chemicals is to reflect the type and severity of the intrinsic hazards of a substance or mixture. 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. Nevertheless, the common denominator for both classification and risk assessment is hazard identification and hazard assessment.

What is the role of the European Chemicals Agency (ECHA or the Agency)?

The European Chemicals Agency (the Agency) is a Community body which was established for the purpose of managing REACH. It is central to the implementation of both REACH and CLP, to ensure consistency across the EU.

The Agency through its Secretariat and specialised Committees provides Member States and the institutions of the Community with scientific and technical advice on questions relating to chemicals which fall within its remit. In general, the specific tasks of the Agency include:

- providing industry with technical and scientific guidance and tools on how to comply with the obligations of CLP (*CLP Article 50*);
- providing Member State Competent Authorities with technical and scientific guidance on the operation of CLP (*CLP Article 50*);
- providing support to the helpdesks set up under CLP (*CLP Articles 44 and 50*);
- establishing and maintaining a classification and labelling inventory in the form of a database and receiving notifications to the classification and labelling inventory (*CLP Article 42*);
- receiving proposals for the harmonised classification of a substance from Member State Competent Authorities and suppliers, and submitting an opinion on such proposals for classification to the Commission (*CLP Article 37*);
- receiving, evaluating and deciding upon the acceptability of requests to use an alternative chemical name (*CLP Article 24*); and
- preparing and submitting to the Commission draft exemptions from the labelling and packaging requirements (*CLP Article 29(5)*).

2. Roles and obligations under CLP

Roles under CLP

The obligations placed on a supplier of substances or mixtures under CLP will mostly depend upon their role towards a substance or mixture in the supply chain. It is therefore most important that you identify your role under CLP.

To identify your role, read the five different descriptions set out in Table 2.1, which are based on CLP Article 2. For further clarifications in relation to the roles of “**downstream user**” or “**distributor**”, you may consult the “Guidance for downstream users” on the ECHA website (http://guidance.echa.europa.eu/guidance_en.htm).

Where a description matches your activities, your role under CLP is set out to the right of that description. Please read each of the descriptions carefully as you may have more than one role under CLP.

Please note that CLP obligations to classify, label and package are generally linked to the supply of substances or mixtures. However, independent of any supply, classification is also relevant for the correct preparation of a registration or notification for the purposes of REACH. This guidance should therefore also serve those preparing such submissions under REACH. Labelling and packaging obligations are generally not relevant when a registration or notification is prepared for the purposes of REACH but no supply is taking place.

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Table 2.1: Identifying your role under CLP

Descriptions		Your role under CLP
1	A natural or legal person established within the Community who produces or extracts a substance in the natural state within the Community	Manufacturer (1)
2	A natural or legal person established within the Community who is responsible for the physical introduction into the customs territory of the Community	Importer

Table 2.1: Identifying your role under CLP (cont.)

Descriptions		Your role under CLP
3	A natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities	Downstream User ⁽²⁾ (including formulator / re-importer)
4	A natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties	Distributor (including retailer)
5	A natural or legal person who makes or assembles an article within the Community; where an article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition	Producer of articles ⁽³⁾

Notes:

(1) In everyday language the term “manufacturer” can cover both the (natural/legal) person making substances and the (natural/legal) person making mixtures (formulator). In contrast to this everyday language, the term “manufacturer” in REACH and CLP only covers the person making substances. The formulator is a “downstream user” under REACH and CLP.

(2) A distributor or consumer is not a downstream user.

(3) As a producer or importer of an article you are only affected by CLP if you produce or import an explosive article as described in section 2.1 of Annex I to CLP or where REACH Article 7 or 9 provide for registration or notification of a substance contained in an article.

Obligations under CLP

CLP places a general obligation for all suppliers in the supply chain to co-operate, so as to meet the requirements for classification, labelling and packaging set out in this Regulation (*CLP Article 4(9)*). Otherwise, your specific obligations under CLP depend upon your role in the supply chain, as determined in Table 2.1. Tables 2.2 to 2.5 set out the obligations for each of the roles and indicate the key sections of this guidance document in each case.

Table 2.2: Obligations of a manufacturer or importer		
Obligations under CLP		Key Sections
1	You should classify, label and package substances and mixtures according to CLP before placing them on the market You should also classify substances not placed on the market that are subject to registration or notification in line with Articles 6, 9, 17 or 18 of REACH (<i>CLP Article 4</i>)	7
2	You should classify in line with CLP Title II (<i>CLP Articles 5-14</i>)	8 – 13
3	You should label in line with CLP Title III (<i>CLP Articles 17-33</i>)	14 – 16
4	You should package in line with CLP Title IV (<i>CLP Article 35</i>)	14 and 16
5	You should notify the classification and labelling elements to the classification and labelling inventory established at the Agency in case you place substances on the market (<i>CLP Article 40</i>)	18
6	You should take all reasonable steps available to you to make yourself aware of new scientific or technical information that may affect the classification of the substances or mixtures you place on the market. When you become aware of such information which you consider to be adequate and reliable you should, without undue delay, carry out a new evaluation of the relevant classification (<i>CLP Article 15</i>)	19
7	You should update the label following any change to the classification and labelling of that substance or mixture, in certain cases without undue delay (<i>CLP Article 30</i>)	14 and 19

Table 2.2: Obligations of a manufacturer or importer (cont.)		
Obligations under CLP		Key Sections
8	If you have new information which may lead to a change of the harmonised classification and labelling elements of a substance (<i>Part 3 of Annex VI to CLP</i>) you should submit a proposal to the Competent Authority in one of the Member States in which the substance is placed on the market (<i>CLP Article 37(6)</i>)	22
9	You should assemble and keep available all the information required for the purposes of classification and labelling under CLP for a period of at least 10 years after you have last supplied a substance or mixture. This information should be kept together with the information required in Article 36 of REACH (<i>CLP Article 49</i>)	21
<p>Note: Importers and downstream users placing mixtures on the market should be prepared to provide certain information relating to mixtures to those Member State bodies which are responsible for receiving such information in order to formulate preventative and curative measures, in particular in the event of emergency health response (<i>CLP Article 45</i>).</p>		

Table 2.3: Obligations of a downstream user (incl. formulator / re-importer)		
Obligations under CLP		Key Sections
1	You should classify, label and package substances and mixtures according to CLP before placing them on the market. (<i>CLP Article 4</i>). However, you may also take over the classification for a substance or mixture derived in accordance with Title II of CLP already by another actor in the supply chain, provided that you do not change the composition of this substance or mixture	7

Table 2.3: Obligations of a downstream user (incl. formulator / re-importer) (cont.)		
Obligations under CLP		Key Sections
2	In case you change the composition of the substance or mixture you place on the market: You should classify in line with CLP Title II (<i>CLP Articles 5-14</i>)	8 – 13
3	You should label in line with CLP Title III (<i>CLP Articles 17-33</i>)	14 – 16
4	You should package in line with CLP Title IV (<i>CLP Article 35</i>)	14 and 16
5	You should take all reasonable steps available to you to make yourself aware of new scientific or technical information that may affect the classification of the substances or mixtures you place on the market. When you become aware of such information which you consider to be adequate and reliable you should, without undue delay, carry out a new evaluation of the relevant classification (<i>CLP Article 15</i>)	19
6	You should update the label following any change to the classification and labelling of that substance or mixture, in certain cases without undue delay (<i>CLP Article 30</i>)	14 and 19
7	If you have new information which may lead to a change of the harmonised classification and labelling elements of a substance you should submit a proposal to the Competent Authority in one of the Member States in which the substance is placed on the market (<i>CLP Article 37(6)</i>)	22

Table 2.3: Obligations of a downstream user (incl. formulator / re-importer) (cont.)

Obligations under CLP		Key Sections
8	You should assemble and keep available all the information required for the purposes of classification and labelling under CLP for a period of at least 10 years after you have last supplied a substance or mixture. This information should be kept together with the information required in Article 36 of REACH (<i>CLP Article 49</i>)	21

Note: Importers and downstream users placing mixtures on the market should be prepared to provide certain information relating to mixtures to those Member State bodies which are responsible for receiving such information in order to formulate preventative and curative measures, in particular in the event of emergency health response (*CLP Article 45*).

Table 2.4: Obligations of a distributor (incl. retailer)

Obligations under CLP		Key Sections
1	You should label and package the substances and mixtures you place on the market (<i>CLP Article 4</i>)	14 – 16
2	You may take over the classification for a substance or mixture derived in accordance with Title II of CLP already by another actor in the supply chain, for example from a Safety Data Sheet supplied to you (<i>CLP Article 4</i>)	7 and 14
3	You should label in line with CLP Title III (<i>CLP Articles 17-33</i>)	14 – 16
4	You should package in line with CLP IV (<i>CLP Article 35</i>)	14 and 16

Obligations under CLP		Key Sections
5	<p>You should assemble and keep available all the information required for the purposes of classification and labelling under CLP for a period of at least 10 years after you last supply a substance or mixture. This information should be kept together with the information required in Article 36 of REACH (<i>CLP Article 49</i>).</p> <p>In case you take over the classification for a substance or mixture derived by another actor up in the supply chain, you should ensure that all the information required for the purpose of classification and labelling (e.g. Safety Data Sheet) is kept available for a period of at least 10 years after you last supply the substance or mixture.</p>	21

Obligations under CLP		Key Sections
1	<p>In case you produce and place on the market <i>an explosive article</i> as described in section 2.1 of Annex I to CLP, you should classify, label and package this article according to CLP before placing it on the market (<i>CLP Article 4</i>).</p> <p>The same obligations apply as for importers, see Table 2.2 above, apart from the obligation to notify the Agency</p>	7 – 16 19, 21, 22
2	<p>As a producer or importer of articles, you should also classify substances not placed on the market that are subject to registration or notification in line with Articles 7(1), 7(2), 7(5) or 9 of REACH (<i>CLP Article 4</i>). You should classify in line with CLP Title II (<i>CLP Articles 5-14</i>)</p>	7 – 12

3. Preparing for CLP

Where to start?

Your first step is gaining an understanding of CLP and its implications for your business.

You should therefore:

- develop an inventory of your substances and mixtures (including those substances contained in mixtures) and substances contained in articles, who your suppliers are, who your customers are and how they use them. It is likely that you will already have gathered much of this information in relation to REACH;
- assess the need for training of the appropriate technical and regulatory staff in your organisation;
- monitor the website of your Competent Authority and of the Agency to keep up-to-date with the developments of the regulations and related guidance; and
- seek advice from your trade associations on what assistance they can offer you.

As REACH, Directive 98/8/EC on biocidal products, Council Directive 91/414/EEC on plant protection products and CLP are closely interlinked, it is recommended to plan CLP processes together with processes related to REACH and the legislation on biocidal products and plant protection products, if applicable.

What do you have to do?

As a **manufacturer, importer or downstream user** you will have to classify your substances and mixtures, which may already have been classified according to DSD or DPD, according to the CLP criteria and change their labels, Safety Data Sheets and in some cases their packaging as well (*CLP Article 4*). The timelines for these changes are listed in section 4 of this guidance document.

In connection with classification, you will also need to decide to what extent you want to use the translation tables as provided in Annex VII to CLP, translating current DSD and DPD classifications into closely corresponding or minimum CLP classifications (*see [section 8](#) and [section 9](#) of this guidance document*).

As a **distributor** you are obliged to ensure that your substances and mixtures are labelled and packaged in accordance with CLP Titles III and IV, before placing them on the market. To comply with this obligation you may use information supplied to

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you, for example in Safety Data Sheets that accompany substances and mixtures (*CLP Article 4 (5)*).

The deadlines for any changes to be made are set out in section 4 of this guidance document.

To gain an understanding of the scale of the work involved, you must be prepared to:

- apply the CLP criteria to your substances and mixtures², or use their existing classifications and the Annex VII translation tables if you have no data on your substances or mixtures. In this situation you should take note of the guidance on the use of these tables which is available in Part 1.8 of Module 2. You should not forget to consider any substances or mixtures that are currently not dangerous under DSD and DPD as under CLP some previously non-dangerous substances or mixtures may be classified as hazardous;
- consider the REACH registration deadlines for your substances and the likely amount of information that may be available to you on these substances. You may need to contact your suppliers for more information; and
- contact your suppliers to see how they anticipate CLP and how it will affect the substances or mixtures you use. If you formulate new mixtures using other mixtures as an ingredient (mixtures within mixtures), you will need to contact your suppliers to discuss what information on the mixture and its components will be available to you, including through Safety Data Sheets. Likewise, if you supply mixtures to customers who formulate them into other mixtures, you will need to consider how you will share information on the mixture and its components with them.

You should think about the resources that you might need, asking yourself:

- do I have sufficient appropriate technical and regulatory staff, or will I need additional resources or external expertise?
- Safety Data Sheet authoring software – do I need to update my system?
- how will I generate new labels? and
- packaging – will any of my packaging that I applied in accordance with DSD, DPD or transport legislation need to be changed due to transition to CLP?

² As a producer or importer of an article you are only affected by CLP if you produce or import an explosive article as described in section 2.1 of Annex I to CLP or where REACH Article 7 or 9 provide for registration or notification of a substance contained in an article.

Having carried out this exercise, you will have to make an assessment of the implications of the new classification of your substances or mixtures. You can then draw up a priority list of actions, taking account of the:

- transition periods for substances and mixtures;
- costs and resources likely to be involved with classifying and labelling your substances and mixtures; and
- implications for downstream legislative issues, for example:
 - the amount of hazardous material you can store on your site (Seveso II);
 - how you dispose of hazardous wastes; and
 - safety at work and protective clothing for your employees.

4. Transition to CLP

Introduction

The CLP Regulation entered into force on 20 January 2009. However, not all the provisions of the CLP Regulation will be obligatory immediately: There are the transitional provisions set out in CLP Article 61 which define two target dates that affect the classification, hazard communication and packaging of hazardous substances and mixtures, namely 1 December 2010 and 1 June 2015.

The applicability of the new rules by the three dates mentioned above is described below; the relationship of these three dates to the REACH deadlines is illustrated in Figure 4.1.

1) CLP came into force on 20 January 2009

From 20 January 2009 the following rules apply:

- until 1 December 2010, substances *must* continue to be classified, labelled and packaged in accordance with DSD. However, a substance *may* also be classified, labelled and packaged according to CLP before this date. When this is done, the labelling and packaging provisions of DSD shall no longer apply to the substance. This means that labelling and packaging *must* respect the provisions of CLP;
- until 1 June 2015, mixtures *must* continue to be classified, labelled and packaged in accordance with DPD. However, a mixture *may* also be classified, labelled and packaged according to CLP before this date. When this is done, the labelling and packaging provisions of DPD shall no longer apply to the mixture. This means that labelling and packaging *must* respect the provisions of CLP;
- until 1 June 2015, the classification of a substance according to DSD *must* be provided in the Safety Data Sheet. This will both apply to Safety Data Sheets for substances on their own and to Safety Data Sheets for mixtures containing these substances;
- until 1 December 2010, if a substance is classified, labelled and packaged according to CLP, the CLP classification *must* 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. Where this happens, the supplier may include this information on the accompanying Safety Data Sheet, under the 'other information' heading;
- until 1 June 2015, the classification of a mixture according to DPD *must* be provided in the Safety Data Sheet;

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- until 1 June 2015, if a mixture is classified, labelled and packaged according to CLP, the CLP classification *must* 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. Where this happens, the supplier may include this information on the accompanying Safety Data Sheet, under the 'other information' heading;
- from 20 January 2009 Title V starts to apply, so **manufacturers, importers and downstream users** can submit proposals for harmonised classification to the Agency (*CLP Article 37(2)*) and shall submit a proposal to a Member State Competent Authority in case they have new information which may lead to change in harmonised classification and labelling (*CLP Article 37(6)*, see also [section 22 of the guidance document](#)).

2) 1 December 2010: CLP replaces DSD for the classification, labelling and packaging of substances

From 1 December 2010 the following rules shall apply:

- substances *must* be classified in accordance with both DSD and CLP;
- substances *must* be labelled and packaged in accordance with CLP only, but substances already classified, labelled and packaged according to DSD and placed on the market (i.e. "on the shelves") before 1 December 2010 will only have to be re-labelled and re-packaged by 1 December 2012;
- until 1 June 2015, mixtures *must* continue to be classified, labelled and packaged in accordance with DPD. However, a mixture *may* also be classified, labelled and packaged according to CLP before this date. When this is done, the labelling and packaging provisions of DPD shall no longer apply to the mixture. This means that labelling and packaging *must* respect the provisions of CLP;
- until 1 June 2015, the classification of a substance according to DSD *must* be provided in the Safety Data Sheet, in addition to the CLP classification. This will both apply to Safety Data Sheets for substances on their own and to Safety Data Sheets for mixtures containing these substances;
- until 1 June 2015, the classification of a mixture according to DPD *must* be provided in the Safety Data Sheet;
- until 1 June 2015, if a mixture is classified, labelled and packaged according to CLP, the CLP classification *must* 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. Where this happens, the supplier may include this information on the accompanying Safety Data Sheet, under the 'other information' heading.

3) 1 June 2015: CLP replaces DPD for the classification, labelling and packaging of mixtures

From 1 June 2015 the following rules shall apply:

- substances *must* be classified in accordance with CLP only;
- *mixtures must* be classified, labelled and packaged in accordance with CLP only, but mixtures already classified, labelled and packaged according to DPD and placed on the market (i.e. “on the shelves”) before 1 June 2015 will only have to be re-labelled and re-packaged by 1 June 2017; and
- substance and mixture classifications according to CLP *must* be provided in the Safety Data Sheet.


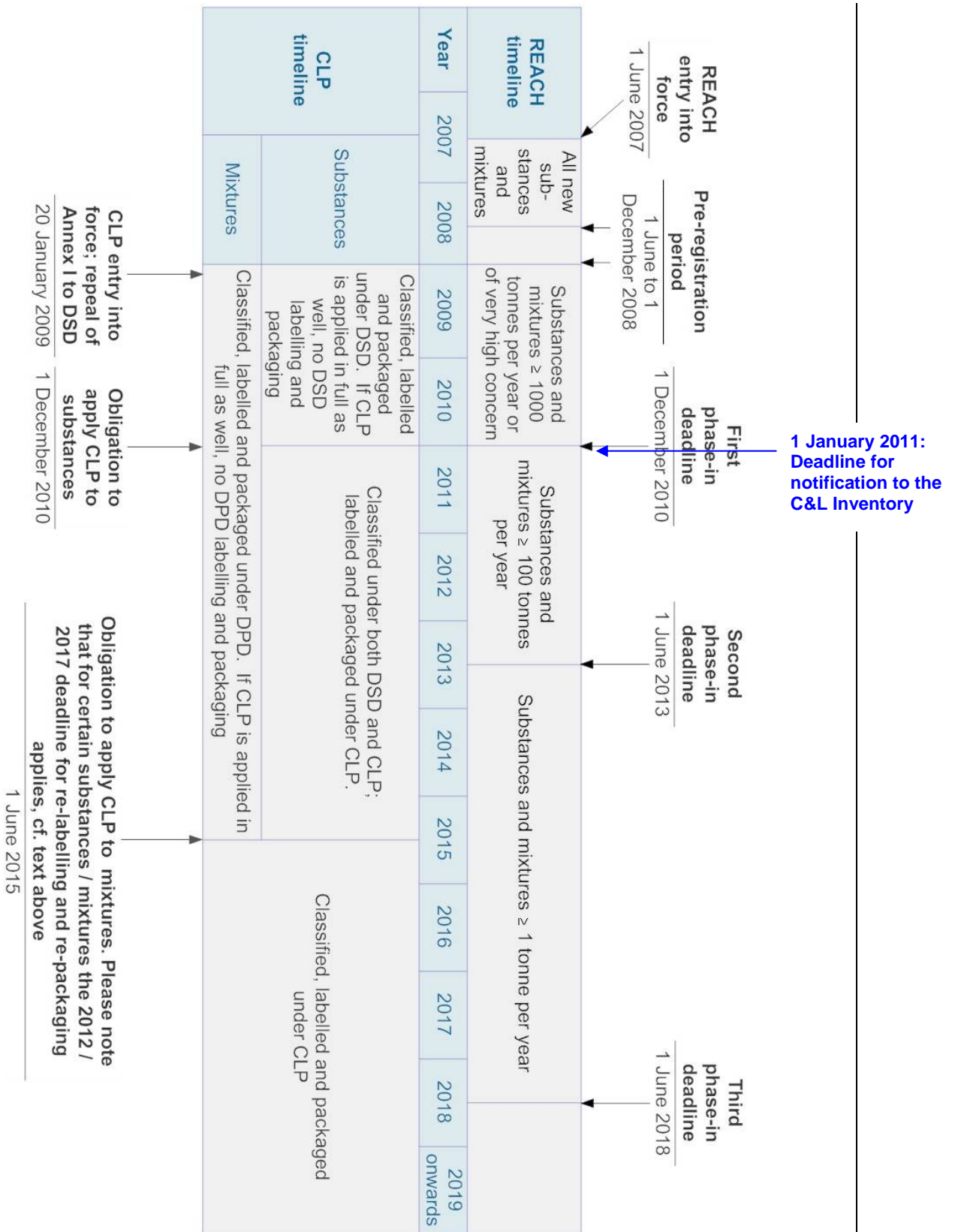
	<p>Registrations submitted before 1 December 2010 shall contain the classification and labelling according to DSD.</p> <p>It is advisable to also include the classification and labelling in accordance with CLP in the registration dossier. In that case, you do not need to submit a notification</p>
	<p>Registrations submitted between 1 December 2010 and 1 June 2015 shall contain the classification according to CLP. The registration dossier may also contain the classification according to DSD</p>
	<p>Registrations submitted after 1 June 2015 shall contain only the classification according to CLP alone</p>

Figure 4.1: Timelines for CLP and REACH



5. Similarities and differences to DSD / DPD

Similarities and differences

The Dangerous Substances Directive 67/548/EEC (DSD), the Dangerous Preparations Directive 1999/45/EC (DPD) and CLP are conceptually similar in that they all deal with:

- classification;
- hazard communication through labelling; and
- packaging.

CLP is aimed at workers and consumers, and covers the supply and use of chemicals. It does not cover the transport of chemicals, although testing for physical hazards is largely inspired from the UN Recommendations on the Transport of Dangerous Goods. Classification for transport is covered by the Framework Directive (2008/68/EC) implementing the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) and the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN).

Please note that the CLP Regulation is a horizontal piece of legislation to cover substances and mixtures in general. For certain chemicals, e.g. plant protection products or flavourings, the labelling elements introduced through CLP may be complemented by further elements which are required by the relevant product-specific legislation.

Classification of substances

The EU has taken up in CLP those hazard classes from the UN GHS which most closely match the DSD categories of danger, see also the explanation on the “building block approach” in Annex 4 to this document. Hazard classes are broken down further into hazard categories or differentiations which take account of particular modifications of a specific hazard.

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), leading to a more explicit differentiation of physical properties. On the whole, the

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classification criteria for substances have sometimes changed compared to the DSD criteria, see e.g. the criteria for explosivity and acute toxicity.

Although CLP adopts the great majority of the UN GHS hazard categories, it does not include a few categories that go beyond the current scope of DSD (*see Annex 4 to this document*). However, if you export to other regions outside the EU you may need to consider these. More information can be found on the UNECE GHS website (http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html).

Also, there are elements which are part of DSD or DPD, but which are not (yet) included in the UN GHS, for example the additional EU hazard class “Hazardous to the ozone layer” (DSD: R 59) and some hazards which have lead 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, EUH001 is used, but not H001, to reflect R1 of DSD.

Those supplemental labelling elements (statements) which pertain to the physical and health properties referred to in sections 1.1 and 1.2 of Annex II to CLP are only applied if the substance or mixture has already a classification according to one or several CLP criteria.

Packaging containing substances or mixtures that meet the criteria for classification under the EU hazard class “Hazardous for the ozone layer” (Part 5 of Annex I to CLP) should always have the supplemental labelling elements which reflect this classification put on their label.

Table 5.1 shows the hazard classes included in CLP. Each class includes one or more hazard categories. For detailed information on how these hazard classes match the current DSD categories of danger, you may consult Part 1.8 of Module 2.

Table 5.1: CLP hazard classes and categories
Physical hazards
Explosives (Unstable explosives, Divisions 1.1, 1.2, 1.3, 1.4, 1.5, and 1,6) ^U
Flammable gases (Category 1 and 2) ^U
Flammable aerosols (Category 1 and 2) ^U

Oxidising gases (Category 1) ^D
Gases under pressure (Compressed gas, liquefied gas, refrigerated liquefied gas, dissolved gas)
Flammable Liquids (Category 1, 2 and 3) ^D
Flammable solids (Category 1 and 2) ^D
Self-reactive substances and mixtures (Type A, B, C, D, E, F, & G) (Types A and B) ^D
Pyrophoric liquids (Category 1) ^D
Pyrophoric solids (Category 1) ^D
Self-heating substances and mixtures (Category 1 and 2)
Substances and mixtures which in contact with water emit flammable gases (Category 1, 2 and 3) ^D
Oxidising liquids (Category 1, 2 and 3) (Cat 1 and 2) ^D
Oxidising solids (Category 1, 2 and 3) (Cat 1 and 2) ^D
Organic peroxides, (Type A, B, C, D, E, F & G) (Types A to F) ^D
Corrosive to metals (Category 1)

Health hazards
Acute toxicity, (Category 1, 2, 3 and 4) ^U
Skin corrosion/irritation, (Category 1A, 1B, 1C and 2) ^U
Serious eye damage/eye irritation, (Category 1 and 2) ^U
Respiratory or skin sensitisation (Category 1) ^U
Germ cell mutagenicity, (Category 1A, 1B and 2) ^U
Carcinogenicity, (Category 1A, 1B and 2) ^U
Reproductive toxicity (Category 1A, 1B and 2) ^U plus additional category for effects on or via lactation
Specific target organ toxicity (STOT) – single exposure ((Category 1, 2) ^U and Category 3 for narcotic effects and respiratory tract irritation, only)
Specific target organ toxicity (STOT) – repeated exposure (Category 1 and 2) ^U
Aspiration hazard (Category 1) ^U
Environmental hazards
Hazardous to the aquatic environment (Acute Category 1, Chronic Category 1, 2, 3, and 4) ^U
Hazardous to the ozone layer ^U
^U CLP hazard classifications (whole hazard class or the highlighted categories) which reflect “classified as dangerous” under DSD/DPD.

Hazardous versus Dangerous

ALL substances and mixtures meeting the criteria of one or more of the hazard classes in CLP are considered *hazardous*. However, many other pieces of Community legislation which make reference to substance or mixture classifications, for example the Chemical Agents Directive 98/24/EC, refer to substances or mixtures classified as *dangerous*, as defined in DSD. Please find more information on this in section 23 of this guidance document.



From 1 December 2010, the term ‘dangerous’ under REACH will be translated explicitly into the corresponding CLP classifications, except for obligations related to Safety Data Sheets which apply to substances meeting the criteria for classification as hazardous. From 1 June 2015, SDS will finally also relate to mixtures classified as hazardous.

Classification of mixtures

Like the DPD, the classification of mixtures under CLP is for the same hazards as for substances. As with substances, available data on the mixture as a whole should primarily be used to determine the classification. If this cannot be done, further approaches to mixture classification may be applied which may partly differ from those under DPD – in contrast to DPD, you may now apply the so-called “bridging principles” for some health and environmental hazards, using data on similar tested mixtures and information on individual hazardous ingredient substances. In case of calculations, the formulae often differ from those used under DPD. As to the application of expert judgement and weight of evidence determination, these principles are now more explicit in the legal text when compared to DSD and DPD ([CLP Article 9\(3\) and 9\(4\)](#)).

Labelling

CLP replaces the DSD risk phrases, safety phrases and symbols with the mostly equivalent UN GHS hazard statements, precautionary statements and pictograms. In general, the phrases are very similar, although they may use slightly different wording. Also, CLP introduces the two UN GHS signal words ‘Danger’ and ‘Warning’ to indicate the severity of a hazard as a new feature in EU legislation (^{6b} [see section 14 of this guidance document](#)). However, CLP does not have labelling elements that correspond to the DSD indications of danger.

Harmonised classifications

In addition to self-classification where **manufacturers, importers and downstream users** will have to identify hazards and classify substances and mixtures themselves, CLP also includes provisions for *harmonised classification of substances* to be applied directly (*see [section 7](#), [section 8](#) and [section 27](#) of this guidance document*). Proposals for such harmonised classification may be submitted either by Member State Competent Authorities or, and this is new under CLP, by **manufacturers, importers, or downstream users** themselves (*see [section 22](#) of this guidance document*). Such proposals shall relate to substances which are carcinogenic, mutagenic or toxic to reproduction (CMR substances) and to respiratory sensitisers category 1. In addition, **Member States, manufacturers, importers and downstream users** might also submit proposals for a harmonised classification to the Agency which refer to other substance properties if justification is provided demonstrating the need for harmonised classification and labelling at Community level (*CLP Article 37(2)*).

Harmonised classifications for those substances currently listed on Annex I to DSD have been translated into the new CLP classifications; they can be found in Table 3.1 of Annex VI to CLP. The classifications based on the DSD criteria can be found in Table 3.2 of Annex VI.

6. DSD / DPD and CLP – key terms compared

Terms used for classification and labelling

You will find that the terms used in CLP are very similar to those used in the DSD and DPD but not identical. To help you to better understand CLP, Table 6.1 presents the key terms from the DSD and DPD beside their CLP equivalent (see [glossary in Annex 2 to this guidance](#)).

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Table 6.1: Key terms - DSD and DPD as compared to CLP

Terms Used	DSD / DPD	CLP
Mixture/s	Term not used in DPD; identical to definition of 'preparation' in DPD (DPD Article 2)	This term means the same as "preparation" under DPD; Definition: "A mixture or solution composed of two or more substances" (CLP Article 2(8)). The CLP definition of a mixture differs slightly from that of the UN GHS which may well be applied outside of the EU
Preparation/s	Definition: "Mixtures or solutions composed of two or more substances" (DPD Article 2)	Term not used in CLP; identical to definition of 'mixtures' in CLP
Hazardous	Term not used in DSD or DPD	A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in CLP Annex I, is hazardous (CLP Article 3)

Table 6.1: Key terms - DSD and DPD as compared to CLP (cont.)

Terms Used	DSD / DPD	CLP
Dangerous	Substances or mixtures fulfilling the criteria for the categories of danger set out in DSD, Article 2 (2)	Term not used in CLP; REACH and other Community acts will refer to explicit CLP classifications which reflect the previous scope of “dangerous”
Category of Danger	The nature of a hazard (danger) of a substance or preparation	Term not used in CLP; REACH and other Community acts will refer to explicit CLP classifications which reflect the previous scope of “dangerous”
Hazard class / hazard category (CLP)	Term not used in DSD / DPD	The nature / severity of a physical, health or environmental hazard (<i>CLP Article 2(1) and 2(2)</i>)
Indication/s of danger	A short description of the hazard (danger) posed by a substance For example, ‘Explosive’ or ‘Corrosive’	No equivalent under CLP

Table 6.1: Key terms - DSD and DPD as compared to CLP (cont.)



Terms Used	DSD / DPD	CLP
Danger Symbol	<p>Pictorial presentation of the danger posed by dangerous substances and mixtures (Annex II to DSD)</p> <p>For example, this symbol indicates an oxidising substance or preparation</p> 	<p>Term not used with the same meaning in CLP; instead, “pictogram” is used. Equivalent but not always identical to the pictograms used under CLP</p> <p>For example, this pictogram indicates an oxidising substance or mixture</p> 
	<p>Many CLP pictograms are similar but not identical to the symbols relating to certain categories of danger under DSD and DPD</p>	
Pictogram (See “Danger Symbol”)	<p>Term not used in DSD; instead, “danger symbol” is used. Equivalent but not always identical to the danger symbols used under DSD and DPD</p>	<p>A graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information on the hazard concerned (<i>CLP Article 2(3)</i>)</p>
Signal word	<p>No equivalent in DSD or DPD</p>	<p>The words ‘Danger’ or ‘Warning’ are used to indicate the severity of the hazard (<i>CLP Article 2(4)</i>)</p>

Table 6.1: DSD / DPD – key terms compared (cont.)

Terms Used	DSD / DPD	CLP
<p>Risk phrase (R phrase)</p>	<p>Indication of intrinsic hazards <i>(DSD Article 23, as set out in Annex III to DSD)</i></p> <p>For example, R38: Irritating to the skin</p>	<p>Term not used in CLP; instead, “hazard statement” is used. Equivalent but not always identical to the hazard statements under CLP</p> <p>For example, H315: Causes skin irritation</p>
<p>Hazard statement</p>	<p>Term not used in DSD / DPD; instead, “risk phrase” is used. Equivalent but not always identical to the risk phrases used under DSD <i>(DSD Article 23, as set out in Annex III to DSD)</i></p> <p>For example, R38: Irritating to the skin</p>	<p>Hazard statements describe the nature of the hazards of a substance or mixture, including, where appropriate, the degree of hazard <i>(CLP Article 2(5))</i></p> <p>For example, H315: Causes skin irritation</p>
<p>Safety phrase (S phrase)</p>	<p>Phrases related to the safe use of the substance <i>(DSD Article 23, as set out in Annex IV to DSD)</i></p> <p>For example, S2: Keep out of the reach of children</p>	<p>Term not used in CLP; instead, “precautionary statement” is used. Equivalent but not always identical to the precautionary statements used under CLP</p> <p>For example, P102: Keep out of reach of children</p>

Table 6.1: DSD / DPD – key terms compared (cont.)

Terms Used	DSD / DPD	CLP
Precautionary statement	<p>Term not used in DSD or DPD; instead, “safety phrase” is used. Equivalent but not always identical to the safety phrases under DSD (<i>DSD Article 10</i>)</p> <p>For example, S2: Keep out of the reach of children</p>	<p>A description of the measure or measures recommended to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use (<i>CLP Article 2(6)</i>)</p> <p>For example, P102: Keep out of reach of children</p>
Supplier	<p>Term not used in DSD or DPD</p>	<p>Any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture (<i>CLP Article 2(26)</i>), see also section 2 of this guidance document</p>
Substance/s	<p>Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the mixtures and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (<i>DSD Article 2</i>)</p>	<p>A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any identified impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (<i>CLP Article 2(7)</i>)</p>

7. General features of classification

Classification

The obligation to classify is based on two pieces of legislation, the CLP Regulation itself and the REACH Regulation:

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- Classification triggered by the CLP Regulation (*CLP Article 4(1)*).**

If you are a **manufacturer, importer** or **downstream user** of chemical substances or mixtures to be placed on the market, you should **classify** these substances or mixtures before placing them on the market, independent from any tonnage manufactured, imported or placed on the market. Note that this obligation also covers certain explosive articles (*see section 2.1 of Annex I to CLP*); and
- Classification triggered by REACH (*CLP Article 4(2)*).**

If you are a **manufacturer** or **importer**, you should also classify substances which you do not place 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 intermediates as well as substances used for product and process-orientated research and development (PPORD).


Finally, if you are a **producer or importer of an article**, you would still have to classify the substances contained in it where REACH Articles 7 and 9 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.

The hazard classes for classification are set out in parts 2 to 5 of Annex I to CLP.

Please note that:

- a **producer of an article** that complies with the definition of an explosive article as set out in section 2.1 of Annex I to CLP has the obligation to classify, label and package these articles according to CLP before placing them on the market (*CLP Article 4(8)*);
- a **distributor** (including a retailer) may take over the classification for a substance or mixture derived in accordance with Title II of CLP by another actor in the supply chain, for example from a Safety Data Sheet (*CLP Article 4(5)*). However, a **distributor** must ensure that any (re-)labelling and (re-)packaging of a substance or mixture should be in accordance with CLP Titles III and IV (*CLP Article 4(4)*); and

- a **downstream user** (including a formulator of mixtures or a re-importer of substances or mixtures) may take over the classification for a substance or mixture derived in accordance with Title II of CLP by an actor in the supply chain, for example from a Safety Data Sheet; provided that he does not change the composition of the substance or mixture (*CLP Article 4(6)*). Also, a **downstream user** must ensure that any (re-)labelling and (re-)packaging of a substance or mixture should be in accordance with CLP Titles III and IV (*CLP Article 4(4)*).


	<p>The classifications of all substances notified or registered under REACH or CLP will be included in a classification and labelling inventory established at the Agency (<i>CLP Article 42</i>). The inventory will indicate whether a classification is harmonised or whether it has been agreed between two or more notifiers or registrants</p>
	<p>Producers of articles must provide information on substances contained in articles to the Agency as far as these are substances of very high concern (SVHC), they are present in those articles above 1 tonne per producer or importer per year and contained in the articles in concentrations above 0.1% (w/w) (<i>REACH Article 7(2)</i>). The information to be provided also includes the use(s) of the substance(s) in the articles and the use(s) of the articles (<i>REACH Article 7(4)</i>)</p>

Self-classification and harmonised classification

CLP includes provisions for two sorts of classification: self-classification and harmonised classification. If you are not familiar with these terms, 'harmonised classification' and 'self-classification' are described briefly below:

- **Self-classification:** the decision on a particular hazard classification and labelling of a substance or mixture is taken by the **manufacturer, importer** or **downstream user** of that substance or mixture, or, where applicable, by those producers of articles who have the obligation to classify, see Table 2.5 of section 2 of this document.

The requirement to self-classify is set out both under DSD (and DPD) and CLP. Under CLP, **manufacturers of substances, importers of substances or mixtures, producers or importers of explosive articles or of articles where REACH provides for registration or notification, downstream users including formulators (making mixtures) and distributors** have to self-classify those substances that do not have a harmonised hazard classification, see below, or where a harmonised classification is available for selected hazards only. Mixtures must always be self-classified by **downstream users or importers of mixtures**.

	One of the aims of a Substance Information Exchange Forum (SIEF) is to agree the classification and labelling for the same substance where there is a difference in the classification and labelling of the substance between potential registrants (<i>REACH Article 29</i>)
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- **Harmonised classification:** the decision on classification for a particular hazard of a substance is taken at Community level (^o[see also section 22 of this guidance document](#)). Harmonised classifications of substances are included in the Tables of Part 3 of Annex VI to CLP.

The use of a harmonised classification and labelling of a substance is mandatory. It has to be applied by all suppliers of the same substance, i.e. by **manufacturers of substances, importers of substances or mixtures, producers or importers of explosive articles or of articles where REACH provides for registration or notification, downstream users including formulators (making mixtures) and distributors**. For around 8,000 substances harmonised classification and labelling were listed in Annex I to DSD. Upon entry into force of CLP Annex I to DSD was repealed. In order to take full account of the work and experience accumulated under DSD, all harmonised classifications as well as most of the specific concentration limits of substances listed in Annex I to DSD have been transferred to Part 3 of Annex VI to CLP: in Table 3.1 the substances are classified according to CLP while Table 3.2 contains the original classifications based on the DSD criteria.

Harmonised classification and labelling under DSD normally comprised all categories of danger. In future, harmonisation of classification will apply for CMR properties and respiratory sensitisation. In addition, harmonisation of classification for other properties will be done on a case-by-case basis. Substances regulated under Directive 98/8/EC (BPD) on biocidal products or under Council Directive 91/414/EEC (PPPD) on plant protection products shall

normally be subject to harmonised classification and labelling for all hazardous properties ([CLP Article 36\(2\)](#)). For further information see [☞](#) section 22 and [☞](#) section 24 of this guidance document.

8. Using harmonised classifications

Background

In order to take full account of the work and experience accumulated under DSD, all previously harmonised DSD substance classifications have been translated into harmonised CLP classifications. The result of these translations is displayed in Table 3.1 of Annex VI to CLP, while Table 3.2 of Annex VI to CLP contains the original and non-translated Annex I to DSD up to and including the 29th ATP (adaptation to technical progress). It is the intention of the Commission to include both the 30th and 31st ATP into Annex VI of the CLP Regulation through an ATP to the CLP Regulation.

When preparing Table 3.1 of Annex VI to CLP, the classification according to the DSD criteria did sometimes not fully correspond to a classification according to the CLP criteria, in particular for physical hazards, acute toxicity and STOT repeated exposure. For the physical hazards, the “translations” shown in the table have been based on a re-evaluation of available data. For the relevant health hazards, substances have been given a CLP minimum classification. **Manufacturers** or **importers** should apply this classification, but must classify in a more severe hazard category in case they have further information which shows that this is more appropriate. The situations where other than the minimum classifications must be applied are set out in point 1.2.1 of Annex VI to CLP.

In future, Table 3.1 will be updated when the Commission has decided on further harmonised classifications. Until 31 May 2015, a corresponding entry will also be added to Table 3.2.

How to use the harmonised classifications

You will find guidance on how to use the CLP harmonised classifications in Figure 8.1 below. Note that the minimum classification for a category is indicated by the reference * in Table 3.1 of Annex VI to CLP.

Specific Concentration Limits (SCLs) that are lower or higher than the generic concentration limits defined in Annex I to CLP are included in the tables of Part 3 of Annex VI to CLP. This applies also to most of the SCLs that have previously been assigned under DSD. Substances with a harmonised classification for the aquatic environment may have been assigned an **M-factor (multiplication factor)** which is the equivalent to an SCL set for other hazard classes, see also Part 1.5 of Module 2. M-factors and SCLs are indicated in Table 3.1 of Annex VI in the same column.

Where an asterisk (*) appears in this column, a respective concentration limit cannot

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be transferred from Annex I to DSD to Annex VI to CLP, e.g. in cases of a minimum classification under CLP. Again the classifications for acute toxicity and STOT, repeated exposure, may be particularly affected.

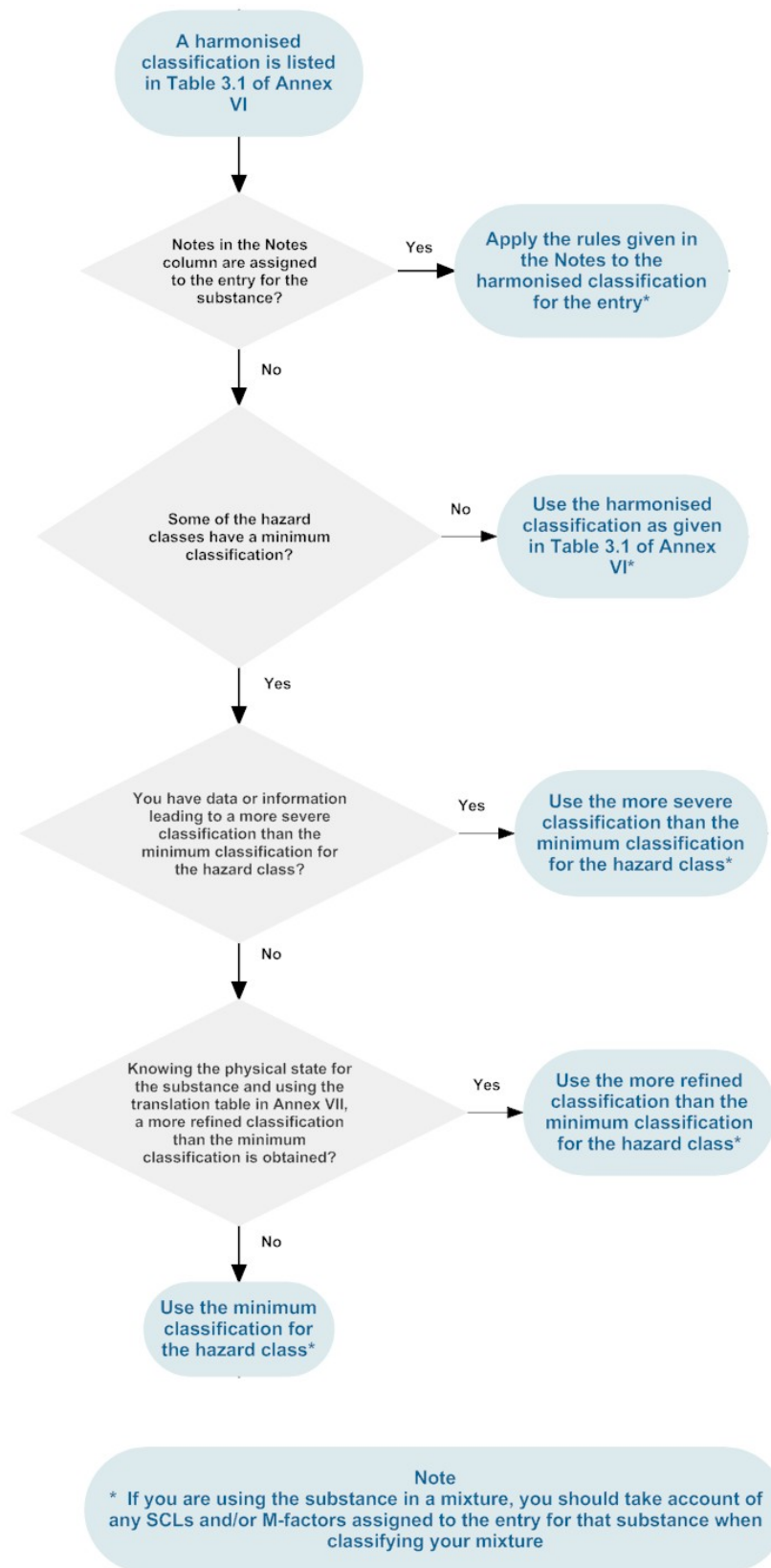
If you are using the substance in a mixture, you should take account of any SCLs and/or M-factors assigned to the entry for that substance when classifying your mixture. Where an M-factor is not given in Part 3 of Annex VI for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, you shall set an M-factor. When a mixture including the substance is classified using the summation method, this M factor shall be used.

Unlike Annex I to DSD, Table 3.2 of Annex VI to CLP no longer includes the generic concentration limits. These have been removed to improve readability and improve consistency with the 2nd ATP of Directive 1999/45/EC (DPD). Table 3.2 is applicable with the entry into force of CLP.

You should also make sure you fully consider the impact of any special instructions which appear in the Notes column of Table 3.1 of Annex VI to CLP. These Notes may adjust the final classification because:

- the substance (acids, bases, etc.) is placed on the market as an aqueous solution at various concentrations;
- the route of exposure or the nature of the effects leads to a differentiation of the classification of the hazard class;
- the substance is marketed in a form which does not have the physical hazards indicated by the classification;
- the substance has a stabiliser or inhibitor which may affect the classification;
- for certain complex oil- and coal-derived substances, the substance contains less than the indicated level of a particular marker substance; or
- the substance has only been classified for some hazard properties.

Figure 8.1: Aspects to consider when using harmonised classifications



9. Using the translation tables

Translation of existing classifications

Annex VII to CLP provides a translation table for **manufacturers, importers and downstream users** to translate existing DSD or DPD classifications to CLP classifications. You may use these translation tables in case you or your supplier have already classified a substance according to DSD before 1 December 2010 or mixture according to DPD before 1 June 2015 and you have no further data available for the substance or mixture and for the hazard class considered, see also the guidance given in Part 1.8 of Module 2. In other words, the use of the translation table allows you to assign CLP classifications to your substances or mixtures instead of classifying them from scratch in accordance with CLP Title II and the criteria set out in Annex I to CLP (*CLP Article 61(5)*).

The translation table covers those hazards where there is a reasonable correlation between the DSD/DPD and CLP. Where there is no corresponding classification under CLP, you will need to assess these properties yourself using the criteria in Annex I to CLP. Insufficient correlation is given for example in the following situations:

- in the case of **flammable solids**, it is not possible to interpret across the DSD and CLP criteria. Therefore, translation is not possible;
- in the case of **acute toxicity**, the classification bands of the two systems overlap, and until data are available a minimum classification using the translation table may be used. **However, you should review this carefully** in case you have data which allows the substance or mixture to be classified more accurately.

Particular care needs to be taken when using the translation table for mixtures, as there are a number of limitations to its use. For mixtures originally classified on the basis of test results, the table may be used as for substances. However, for those mixtures originally classified on the basis of the DPD concentration limits or the DPD conventional calculation method, the proposed translation outcome under CLP should carefully be considered, because of the differences in concentration limits and calculation methods in CLP. In the particular case of “no classification” under DPD, the table should not be used as there is no reasonable indication about a potential translation outcome.

You can also use the translation table for substances with harmonised classifications included in Table 3.1 of Annex VI to CLP where the entry for that substance does not cover the hazard class or differentiation to be translated. You may check the Notes column of Table 3.1 to see if this is the case (Note H).

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Please note that whenever you have data for the substance or mixture, e.g. from Safety Data Sheets supplied to you, evaluation and classification shall be done in accordance with CLP Articles 9 to 13 ([introduction to Annex VII to CLP](#)).

More specific guidance on the use of the translation table is provided in Part 1.8 of Module 2.

10. Sources of information

Where to find information?

You will need to gather information about the properties of your substance or mixture in order to classify and label it. This section provides you with guidance on where to find such information ([☞] *for additional sources of useful information, see Annex 3 to this guidance document*).

Search in-house

In case you have to classify a substance or mixture in compliance with one of the roles set out in section 2 of this guidance document, you may already have classified it under DSD or DPD. You can then check what kind of information or data are already available in-house.

REACH (substances)

You can use the information you produce for compliance with REACH or you obtain through information sharing in a SIEF ([☞] *see also section 26 of this guidance document*). In this situation, you may also refer to the "Guidance on information requirements and chemical safety assessment", in particular to section R.3, where collection of information is described in depth ([☞] *see also section 27 of this guidance document*).

You may also be able to obtain and use information for substances and mixtures evaluated under other Community legislation, such as that regulating biocidal products and plant protection products. As REACH also places a duty to communicate information on substances and mixtures up and down the supply chain, you should use the information given on Safety Data Sheets or consult the supplier/s of your substances. You will also be able to find relevant, non-confidential information on substances manufactured or imported into the EU on the Agency website (<http://echa.europa.eu/reach/>).

Transport Directives (substances)

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 (ADR, RID, ADN, IMDG Code and ICAO ([☞] *see Annex 2 to this guidance document*)) regulating the transport of dangerous goods. You can use a

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transport classification as one of your sources of information for the classification and labelling of your substance as far as it is not included in Annex VI to CLP. Before you use a transport classification, you should be aware of the following:

- transport classifications do not include all of the GHS categories for physical, health and environmental hazards, so the absence of a transport classification for your substance does not mean that you should not classify it under CLP. In relation to physical hazards, this means that you may have to test in order to provide for the data which are necessary for an unambiguous classification according to CLP;
- under transport legislation, sometimes special provisions are linked to the entries in the Dangerous Goods List (ADR, part 3) which have to be met in order to be classified in the respective class for transport. In these cases the classification for the purposes of supply and use might be different. Further to this, one substance even may have two different entries with two different classifications where one of the classifications is linked to one or more special provisions; and
- transport classification may be based on another set of information than is required now by CLP to derive a CLP-compliant classification.

Other information sources

Information on the hazardous properties of substances can be sourced in databases which are accessible on the internet and in scientific journals. While section R.3.4 of the "Guidance document on information requirements and chemical safety assessment" on the ECHA website lists quite a number of major available data bases and databanks (some are free of charge, but others require payment of a fee), you can find below a small selection of such sources. Please note that they may not present all sources available; any mention of a data source does not imply endorsement of its content.

As to EU information and data sources, we would like to mention:

- ESIS (European Chemical Substances Information System) on the website of the JRC Consumer Products Safety and Quality Unit website: <http://ecb.jrc.it/esis/>; and
- EFSA (European Food Safety Authority, for active substances of plant protection products): http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_ScientificOpinionPublicationReport.htm

As to non-EU sources, please find a second list below. Please note that this list is given for information purposes only; mention of a data source does not imply endorsement of its content:

- EChem Portal from OECD: <http://webnet3.oecd.org/echempportal/>;
- RTECS (Registry of Toxic Effects of Chemical Substances) available from the NIOSH (US National Institute of Occupational Safety and Health) website: <http://www.cdc.gov/niosh/rtecs/>;
- USEPA (United States Environmental Protection Agency) website: <http://www.epa.gov/>;
- IRIS (Integrated Risk Information System) available from the USEPA website: <http://cfpub.epa.gov/ncea/iris/index.cfm>;
- OSHA (US Occupational Safety & Health Administration) website: <http://www.osha.gov/>;
- NICNAS (National Industrial Chemicals Notification and Assessment Scheme - Australia) website: <http://www.nicnas.gov.au/>;
- TOXNET website which include databases such as Toxline and HSDB: <http://toxnet.nlm.nih.gov/>;
- IPCS (International Programme on Chemical Safety) INCHEM website: <http://www.inchem.org/>; and
- scientific literature: the PubMed portal from the US National Library of Medicine searches 100's of relevant journals, many of which are available free of charge. <http://www.ncbi.nlm.nih.gov/entrez/>.

Testing

Having reviewed other sources of information, you may need to consider testing. (C⁸⁰ see section 11 of this guidance document).

11. The role of testing in CLP

The role of testing

CLP requires a **manufacturer, importer or downstream user** to gather relevant and available information on all hazardous properties of a substance or mixture. This information should be rigorously assessed, in order to decide whether the substance or mixture should be classified.

For physical hazards, you are obliged to generate new information for the purposes of classification and labelling, unless adequate and reliable information is already available. However, the obligation to test does not apply for health and environmental hazards, see also below.

In general, if new data are generated, then certain quality conditions should be met to ensure the classification based on them is sound. Tests should be carried out on the substance or mixture in the form(s) or physical state(s) in which it is placed on the market and can reasonably be expected to be used, see also Part 1.2 of Module 2.

Testing for physical hazards

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. In case there are test results available which are based on other methods or standards, then these data may still be used, provided they are adequate for the purpose of hazard determination. To conclude on the adequacy you or the expert involved should check that there is sufficient documentation to assess the suitability of the test used, and whether the test was carried out using an acceptable level of quality assurance.

In case you need to carry out new tests, please note that from 1 January 2014 at the latest, new testing should be carried out in compliance with a recognised quality system or by laboratories complying with a relevant recognised standard, such as EN ISO/IEC 17025³. Further guidance on this is provided in Part 2 of Module 2.

³ EN ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories.

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Testing for health and environmental hazards

CLP does not oblige you to perform new testing. However, you may perform new testing provided that you have exhausted all other means of generating information, including by applying the rules provided for in section 1 of Annex XI to REACH (*CLP Article 8*). 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, use of historical human data, application of weight of evidence and use of (Q)SAR's⁴, *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 (*CLP Article 9*). Animal testing should only be undertaken when no other alternatives are available that provide adequate reliability and quality of data. New testing not involving animals may be performed where this warrants a more appropriate classification, e.g. in case of transformation/dissolution testing for the aquatic hazard classification of metals and sparingly soluble metal compounds. Testing on humans is not allowed for the purposes of the CLP Regulation. However, data obtained from clinical or epidemiological studies or scientifically valid case studies may be used. Testing on non-human primates is prohibited (*CLP Article 7*).

In general, any new testing shall be carried out in accordance with the test methods set out in Regulation (EC) No 440/2008; alternatively, it can be based on sound scientific principles that are internationally recognised or on internationally validated methods.

Testing shall be carried out on the substance or mixture in the form(s) or physical state(s) in which it is placed on the market and in which it can reasonably be expected to be used (*for further guidance see Part 1.2 of Module 2*). Moreover, new testing involving animals must be carried out in compliance with the principles of good laboratory practice and respect the rules of Directive 86/609/EEC. Normally, it will be necessary for you to outsource such testing.

For mixtures, the same rules apply as for substances – where data are already available on the mixture as a whole, this should primarily be considered. However, in relation to the carcinogenic, mutagenic or toxic to reproduction (CMR) properties of a mixture, the classification shall normally be based on the classification of the ingredient substances, applying the relevant concentration thresholds. Only in exceptional cases you may use available test data on the mixture itself, i.e. where these indicate CMR properties that have not been identified from the individual ingredient substances (*CLP Article 6(3)*). Mixture classification for the aquatic hazard taking account of biodegradation and bioaccumulation should be based on the

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

ingredient substance properties (*CLP Article 6(4)*). However, for alloys, there may be exceptions from this rule, see Part 4.1 of Module 2.

For further information in relation to individual hazards, please refer to Parts 2-4 of Module 2.

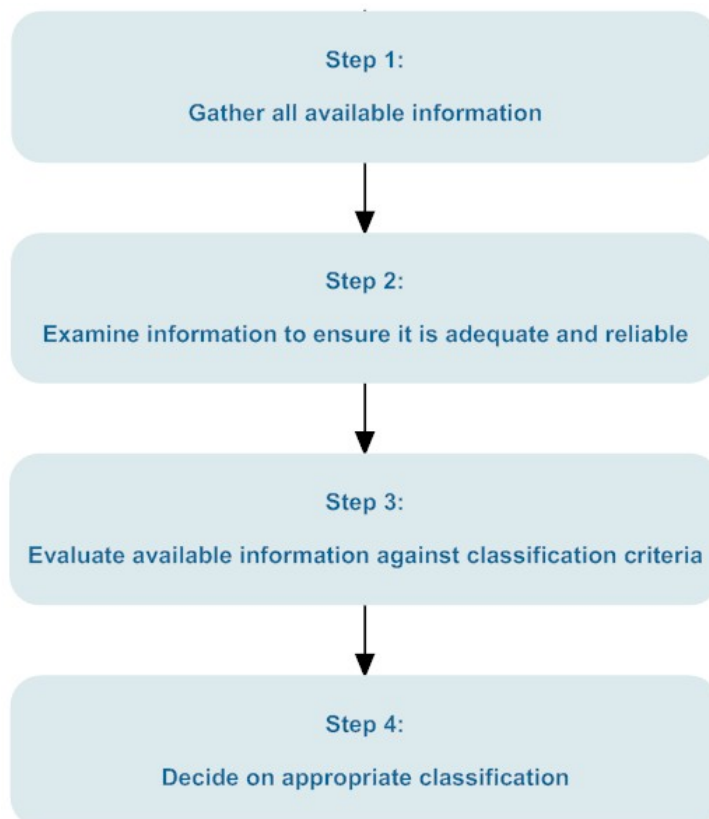
12. Classifying substances

Basic steps for classifying substances

There are four basic steps for classifying your substances, as set out in Figure 12.1:

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Figure 12.1: Four basic steps for classifying your substances




Gathering available information

You should gather relevant and reliable information to help determine the classification for each of your substances. This information may include:

- results of tests carried out according to the Test Method Regulation (EC) No 440/2008 (*CLP Article 5(1)(a)*);
- results of testing carried out according to sound scientific principles that are internationally recognized or methods validated according to international procedures (*CLP Article 5(1)(a) and Article 8(3)*). This includes results of testing based on methods or standards as laid down in the UN Manual of Tests and Criteria and which are referred to in Part 2 of Annex I;
- results of the application of non-test methods such as (Q)SAR, read-across, category approach (*CLP Article 5(1)(c) and section 1 of Annex XI to REACH*) and

- human experience for all types of hazards, including epidemiological data, data from accident databases and occupational data (*CLP Article 5(1)(b)*);
- any new scientific information (*CLP Article 5(1)(d)*); and
- any other information generated under internationally recognised chemical programmes (*CLP Article 5(1)(e)*).

For a list of information sources see ^o section 10 and ^o Annex 3 to this guidance document. Please note that where the substance has a harmonised classification and a related entry in the tables of Annex VI to CLP, you are not required to gather available information for that specified hazard. In other words: You should check Annex VI first before starting to gather information.

	One or several SIEF(s) will need to be formed for each pre-registered substance (phase-in) with the same chemical identity. One of the principal aims of a SIEF is to agree on the classification and labelling of a substance where there is a difference between the potential registrants
	In case you want to register a non-phase-in substance, you may get access to test data through the inquiry process (<i>REACH Article 26 and 27</i>)
	If another member of a SIEF, or a previous registrant, has test data from using vertebrate animals, he is obliged to share this information with you, following the payment of a suitable cost share (<i>REACH Article 30</i>). You can also request test data from studies not involving vertebrate animals, if available. However, there is no obligation for the sharing of non-animal test data (<i>REACH Article 27</i>)

Examine information to ensure it is adequate and reliable

You should consider whether you have the expertise to make judgements about the adequacy and validity of the hazard information obtained. If not, you may need to consult an expert. You, or the expert involved, should examine the information you have gathered to ascertain whether it is adequate and reliable for the purpose of classification.

The information should relate to the forms or physical states in which the substance is used or placed on the market and in which it can reasonably be expected to be used (*CLP Articles 5(1) and 9(5)*). For further guidance see Part 1.2 of Module 2.

Evaluate information against the classification criteria

First you, or the expert involved, must check if the information gathered reveals a hazardous property.

Please note that in practice the physical hazards of a substance may differ from those shown by tests, e.g. in case of certain ammonium-nitrate-based compounds (oxidising / explosive properties) and certain halogenated hydrocarbons (flammable properties). Such experience must be taken into account for the purpose of classification ([CLP Article 12\(a\)](#)).

Then you must check if the information is directly comparable to the respective hazard criteria. This exercise must be repeated for each hazard classification defined under CLP for which you have information.

If the classification criteria of any considered hazard class cannot be applied directly to the information you have, e.g. in case this information reflects other entities and units than laid down in the CLP criteria, or for the purpose of classifying a substance for CMR properties, a weight of evidence determination requiring expert judgement will need to be undertaken, see section 1.1.1 of Annex I to CLP and section 1.2 of Annex XI to REACH. This is to determine if the substance has a certain hazardous property ([CLP Article 9\(3\)](#)).


A weight of evidence determination is based on *all* the available information, such as the results of suitable in-vitro tests, adequate animal tests, similarities with other substances (grouping, read-across), quantitative structure-activity relationships ((Q) SARs) and human experience, such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations. Particular account should be taken of the consistency of the information from each source, see also section 1.1.1 of Part 1 of Annex I to CLP. This will require consultation of an expert.

If the information available to you is not sufficient to conclude on the physical hazards of your substance, then you must perform new tests to determine the *physical* hazards if required in Part 2 of Annex I to CLP. For the determination of the *health and environmental* hazards of your substance, you may decide to perform new testing provided you have exhausted all other means of generating information (⁶⁶ [see also section 11 of this guidance document](#)).

Decide on an appropriate classification

If the evaluation of the hazard information shows that the substance meets the criteria for classification for a particular hazard, then you must assign the respective classification (hazard class and category) and the appropriate labelling elements for the label and/or the Safety Data Sheet, i.e. the signal words, hazard statements, hazard pictograms and precautionary statements (☞ [see also section 14 and ☞ section 17 of this guidance document](#)). This exercise must be repeated for each hazard class defined under CLP for which you have information.

Where a substance has been classified in accordance with DSD before 1 December 2010 **manufacturers, importers** and **downstream users** may, as far as they have no further data available, translate the classifications of the substance to the new system using the translation (conversion) tables in Annex VII to CLP (☞ [see also section 9 of this document and Part 1.8 of Module 2](#)).

	<p>Where a substance is subject to registration under REACH in quantities of 10 tonnes or more per year, you will have to perform a chemical safety assessment which, if the substance is classified in one of the following hazard classes defined in Annex I (CLP Article 58(1)):</p> <ul style="list-style-type: none">• physical hazards: 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;• health hazards: 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;• environmental hazards: 4.1;• additional hazard classes: 5.1 <p>shall also include the steps of exposure assessment and risk characterisation (REACH Article 14(4))</p>
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Together with assigning a classification, you must set so-called “specific concentration limits” (SCL’s) where adequate and reliable scientific information shows that the hazard of the substance contained in another substance or mixture is already evident when it is present at a level below the concentrations set for any hazard class in Part 2 of Annex I or the generic concentration limits defined in parts 3 to 5 of Annex I for any hazard class. In exceptional circumstances where the hazard of a substance is not evident above these thresholds, you may also set higher specific concentration limits (*CLP Article 10*).

Instead of SCL’s you must set so-called “M-factors” (multiplication factors) for the aquatic classifications acute category 1 and chronic category 1.

Specific concentration limits shall not be set for harmonised classifications. M-factors for harmonised classifications shall be set only in case no M-factor is given in Part 3 of Annex VI to CLP.

Further details on setting specific concentration limits and M-factors will be provided in Part 1.5 of Module 2.

13. Classifying mixtures

New features under CLP

Like the DPD, the classification of mixtures under CLP is for the same hazards as for substances. As a general rule and as with substances, available data on the mixture as a whole should primarily be used to determine the classification. If this cannot be done, further approaches to mixture classification may be applied which may partly differ from those under DPD – in contrast to DPD, you may now apply the so-called bridging principles for some health and environmental hazards, using data on similar tested mixtures and information on individual hazardous ingredient substances. In case of calculations, the formulae often differ from those used under DPD. As to the application of expert judgement and weight of evidence determination, these principles are now more explicit in the legal text when compared to DSD and DPD (*CLP Article 9(3) and (4)*).

In case you cannot exploit available test data on the mixture as a whole, the key to its classification will be sufficient information on the ingredients of the mixture.

Flexible approaches for different sets of information

The classification of mixtures involves the same basic steps as the classification of substances, see Figure 12.1.

In general, CLP provides for a number of different approaches that may be used to classify a mixture. It is important to make sure that you choose the most appropriate method for your mixture for each hazard class or category. This will depend upon whether you are assessing your mixture for physical, health or environmental hazards and upon the sort of information that is available to you. For more details please consult Part 1.7 of Module 2.

As a general advice, you should try to get a clear picture on which substances and mixtures are supplied to you, in particular when you formulate mixtures yourself. Basic information on substances would include the substance identity, its classification and concentration in the mixture and, where relevant, details of any impurities and additives (including their identity, classification and concentration). A useful source for such information would be the Safety Data Sheet from the supplier of the substance.

Where you are using an ingredient which is supplied as a mixture, you need to know what component substances are in that mixture together with their concentrations and classifications, as far as possible, see also Part 1.7 of Module 2. Such compositional

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data may be available on the Safety Data Sheet for the mixture, but further dialogue with the supplier may be necessary to obtain additional information.

As far as you or your supplier have already classified a mixture according to DPD before 1 June 2015 and you have no further data available, you may use the translation table instead of classifying your mixture according to Title II of CLP (*introduction to Annex VII to CLP*). However, this translation table should only be used after consulting the relevant guidance provided Part 1.8 of Module 2: the guidance given will inform you where you must pay special attention when using the translation table and where its use may not be appropriate (☞ *see also section 9 of this guidance document*).

In the particular case of “no classification” under DPD, the table cannot be used as there is no reasonable indication about a potential translation outcome.

When your mixture has not been classified previously or when you decide to classify in line with Title II of CLP: Depending on the information you have and on the hazard under consideration, you should classify using the approaches below in the following sequence (*CLP Article 9*):

1. classification derived using data on the mixture itself, by applying the substance criteria of Annex I to CLP. Please note that there are deviations from this rule in relation to CMR hazards and the bioaccumulation and biodegradation properties as far as contributing to a classification as “hazardous to the aquatic environment” (*CLP Article 6(3) and 6(4)*). Where the criteria cannot be directly applied to the available data, you should use expert judgement for the evaluation of the available information in a weight of evidence determination⁵ (*CLP Article 9(3) and section 1.1.1 of Annex I to CLP*);
2. for health and environmental hazards only: classification based on the application of the so-called bridging principles, which make use of data on similar tested mixtures and information on individual hazardous ingredient substances. Expert judgement should be applied to ensure that existing data on similar mixtures can be exploited for as many mixtures as possible; and
3. for health and environmental hazards only: classification based on calculation or on concentration thresholds, including specific concentration limits and M-factors, in case substances are present in the mixture which are classified for the hazard at issue. In this case you should also use any harmonised classifications for the substances present in the mixture, including any specific concentration limits and

⁵ Please note that the stated hazards of the ingredient substances may not always be indicative for the hazard of the mixture (e.g. alloys). Careful assessment of the mixture is then recommended, based on specific guidance given in Module 2.

M-factors that are provided in Annex VI to CLP or in the classification & labelling inventory.

Please find further guidance on the application of

- weight of evidence determination in the “Guidance on information requirements and chemical safety assessment” on the Agency website (<http://guidance.echa.europa.eu/>);
- the bridging principles in Part 1.7 of Module 2;
- the calculation methods in Part 1.7 of Module 2; and
- the concentration limits, including specific concentration limits and M-factors, in Parts 1.5, 1.6 and 1.7 of Module 2.

14. Labelling

What should you label?

A substance or mixture contained in packaging should be labelled according to the CLP rules:

- if the substance or the mixture itself is classified as hazardous⁶; or
- if it is a mixture containing one or more substances classified as hazardous above the concentrations as referred to in Part 2 of Annex II to CLP, even if the mixture itself is not classified overall as hazardous. In this case the supplemental labelling as set out in Part 2 of Annex II to CLP shall apply (*CLP Article 25(6)*); and
- if it is an explosive article as described in Part 2.1 of Annex I to CLP.

The timing for the applicability of labelling obligations according to the CLP rules is set out in detail in section 4 of this guidance document.

Who should label?

In case you are a **manufacturer**, **importer**, **downstream user** (including formulator) or **distributor** (including retailer) you should label any substance or mixture requiring labelling and contained in packaging, see above, before you place it on the market (*CLP Article 4(4)*). This applies also to **producers and importers of articles** which are explosive according to the criteria in Part 2 of Annex I to CLP.

In case you are a **distributor**, you do not need to classify from scratch for the purposes of labelling, but may take over the classification of a substance or mixture from your supplier, provided it is derived in accordance with CLP Title II (*CLP Article 4(5), CLP Articles 5-16*). The same rule applies if you are a **downstream user**, provided you do not change the composition of the substance or mixture supplied to you (⁶ *see section 2 of this guidance document*).

⁶ Some forms are exempted from labelling, see section 1.3 of Annex I to CLP.

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How should you label?

Your labels should be firmly affixed to one or more surfaces of the packaging immediately containing your substance or mixture (*CLP Article 31*). They should be readable horizontally when the package is set down normally.

Your labels should be of a minimum size in relation to the volume of the packaging, see Table 14.1 below:

Capacity of the package	Dimensions of label / millimetres
≤ 3 litres	If possible at least 52 x 74
> 3 litres but ≤ 50 litres	At least 74 x 105
> 50 litres but ≤ 500 litres	At least 105 x 148
> 500 litres	At least 148 x 210

You can display the labelling information on the packaging itself rather than have a label. This means that you can print the labelling information directly on the package itself instead of sticking on the packaging a label which contains the labelling information. However, all of the labelling requirements described in the sections below should be followed.

If your label is intended to meet the requirements of both CLP and the rules for the transport of dangerous goods (ADR, RID, ICAO, IMDG) - so called combined labelling - then you need to check, dependent on the layers of packaging, when CLP labelling, transport labelling (or marking) or both are necessary (*CLP Article 33*).

What languages should be included on your label?

Your labels should be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. In this connection you may wish to check the relevant national legislation where such provisions are laid down.

In general, you can use more languages than those required by the Member States provided that the same information appears in all languages used (*CLP Article 17(2)*) and that the label still fulfils the requirement of being easy to read (*CLP Article 31*).

What information is required?

If your substance or mixture requires labelling and is contained in packaging, it should be labelled with the following information (called labelling elements) (*CLP Article 17*):

- the name, address and telephone number of the supplier/s of the substance or mixture;
- the nominal quantity of the substance or mixture in the packages made available to the general public, unless this quantity is specified elsewhere on the package; product identifiers; and, where applicable;
 - hazard pictograms;
 - signal word;
 - hazard statements;
 - appropriate precautionary statements; and
 - supplemental information.

The labelling elements described above should be clearly and indelibly marked on your labels. You should also ensure that they stand out clearly from your labels' background and be of such size and spacing as to be easily read.

You may also need to incorporate information required by other legislation into your labels, for example information required by legislation concerning biocidal products, plant protection products, detergents and aerosol dispensers, see also below.

Note that specific labelling requirements are laid down in section 1.3 of Annex I to CLP. They apply to (*CLP Article 23*):

- transportable gas cylinders;
- gas containers intended for propane, butane or liquefied petroleum gas;
- aerosols and containers fitted with a sealed spray attachment and containing substances classified as presenting an aspiration hazard;
- metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers; and
- explosives, as referred to in section 2.1 of Annex I to CLP, placed on the market with a view to obtaining an explosive or pyrotechnic effect.

Product identifiers

You must use the same product identifiers on the labels as on the Safety Data Sheets for your products.

Taking into account the rules on the use of languages as set out above, product identifiers for substances must be either (*CLP Article 18*):

1. a name and an identification number as given in Part 3 of Annex VI to CLP; or
2. a name and an identification number as they appear in the classification & labelling inventory, as far as the substance is not included in Part 3 of Annex VI to CLP; or
3. the CAS number and the IUPAC name, or the CAS number and another internationally recognised name⁷, if the substance is neither included in Part 3 of Annex VI CLP nor in the classification and labelling inventory managed by the Agency; or
4. if no CAS number is available and none of the above apply, the IUPAC name or another internationally recognised name.

Taking into account the rules on the use of languages as set out above, product identifiers for mixtures must be both:

1. the trade name or the designation of the mixture; and
2. the identity of all substances in the mixture that contribute to the classification of the mixture as to acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT), or aspiration hazard.

To reduce the number of chemical names on the label, you do not need to use more than four chemical names unless necessary due to the nature and severity of the hazards. The chemical names you select should identify the substances primarily responsible for the major health hazards which have caused your classification and choice of hazard statements.

If you believe that identifying a substance contained in your mixture in one of the ways described above puts the confidential nature of your business or intellectual property

⁷ Where the IUPAC name exceeds 100 characters, you can use one of the other names (usual name, trade name or abbreviation) referred to in section 2.1.2 of Annex VI REACH provided that your notification to the Agency, in accordance with CLP Article 40, includes both the IUPAC name and the other name you are planning to use.

rights at risk, you can submit a request to the Agency to use a more descriptive general name identifying the most important functional groups or an alternative designation (*CLP Article 24*) (⁶⁰ see [section 20 of this guidance document](#)).

Hazard pictograms

A hazard pictogram is a pictorial presentation of a particular hazard. Accordingly, the classification of your substance or mixture determines the hazard pictograms that should be displayed on your label, as set out in parts 2 (physical hazards), 3 (health hazards) and 4 (environmental hazards) of Annex I to CLP (*CLP Article 19*). The applicability of hazard pictograms according to the specific hazard class and hazard category can also be found in Annex V to CLP.

The colour and presentation of your labels should allow the hazard pictogram and its background to be clearly visible. Hazard pictograms should be in the shape of a square set at a point (diamond shape), and should have a black symbol on a white background with a red border ([section 1.2.1 of Annex I to CLP](#)). Each hazard pictogram should cover at least one fifteenth of the surface area of the harmonised label, but the minimum area shall not be less than 1 cm².

Signal words

A signal word indicates to the reader if a hazard is generally more severe or less severe. The label should include the relevant signal word in accordance with the classification of the hazardous substance or mixture. In case your substance or mixture displays a more severe hazard, the label should bear the signal word 'danger', and in case of less severe hazards, it should bear the signal word 'warning' (*CLP Article 20*).

The signal word relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class as set out in parts 2 to 5 of Annex I to CLP. Some hazard categories (for example explosives, division 1.6) do not have a signal word.

Hazard statements

Your labels should also bear the relevant hazard statements describing the nature and severity of the hazards of your substance or mixture (*CLP Article 21*).

The hazard statements relevant for each specific hazard classification are set out in the tables contained in parts 2 to 5 of Annex I to CLP. If a substance classification is harmonised and included in Part 3 of Annex VI to CLP, the corresponding hazard statement relevant for this classification should be used on the label, together with any other hazard statement for a non-harmonised classification.

Annex III to CLP lists the correct wording of the hazard statements as they should appear on the labels. The hazard statements of one language should be grouped together with the precautionary statements of the same language on the label, see below.

Precautionary statements

Your labels should bear the relevant precautionary statements (*CLP Article 22*), giving advice on measures to prevent or minimise adverse effects to human health or the environment arising from the hazards of your substance or mixture. The complete set of precautionary statements relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in parts 2 to 5 of Annex I to CLP.

Precautionary statements should be selected in line with Article 28 and with Part 1 of Annex IV to CLP. Any selection should also take into account the hazard statements used and the intended or identified use or uses of the substance or mixture. Normally, not more than six precautionary statements should appear on the label, unless necessary to reflect the nature and the severity of the hazards. In order to provide assistance with the selection of the most appropriate precautionary statements, further guidance will be provided in due course.

Part 2 of Annex IV to CLP lists the correct wording of the precautionary statements as they should appear on your labels. The precautionary statements of one language should be grouped together with the hazard statements of the same language on the label, see below.

Codes for hazard and precautionary statements

Hazard and Precautionary statements are codified using a unique alphanumerical code which consists of one letter and three numbers, as follows:

- the letter “H” (for “hazard statement”) or “P” (for “precautionary statement”). Please note that hazard statements carried through from DSD and DPD, but which are not yet included in the GHS are codified as “EUH”;
- a digit designating the type of hazard, e.g. “2” for physical hazards; and
- two numbers corresponding to the sequential numbering of hazards such as explosivity (codes from 200 to 210), flammability (codes from 220 to 230), etc.

The code ranges for the hazard and precautionary statements under CLP are set out in Table 14.2.

Hazard Statements: H	Precautionary Statements: P
200 – 299 Physical hazard	1 00 General
300 – 399 Health hazard	2 00 Prevention
400 – 499 Environmental hazard	3 00 Response
	4 00 Storage
	5 00 Disposal

Supplemental information

Your label should include the relevant supplemental information when your substance or mixture that has been classified as hazardous has the physical or health properties described in sections 1.1 and 1.2 of Annex II. Any statement must be worded as described in those sections and Part 2 of Annex III (*CLP Article 25*).


Similarly, where a mixture contains any substance classified as hazardous, it shall be labelled in accordance with Part 2 of Annex II, and the statements shall also be placed in the section for supplemental information. The labelling elements, but no hazard pictogram, which reflect a classification as “hazardous for the ozone layer” must be included in the section for supplemental labelling information as well.

You can add information of your own in the section for supplemental labelling.

However, this information should:

- provide further useful details;
- not make it more difficult to identify the required label elements;
- be consistent with the classification of a substance or mixture. This implies also to avoid inconsistent statements such as “non-toxic”, “non-harmful” or “ecological”; and
- not contradict or cast in doubt the validity of the information given by the labelling elements which reflect a classification according to parts 2-5 of Annex I to CLP.

Any labelling elements resulting from other Community acts should be placed in this section as well (*CLP Article 32(6)*). For example, the additional labelling elements required for biocidal products authorised under Directive 98/8/EC, plant protection products authorised under Council Directive 91/414/EEC, the content of VOC (volatile organic compounds) of paints according to Directive 2004/42/EC or any labelling required by Annex XVII to the REACH Regulation should be included in the section for supplemental information.

	Article 65 of REACH provides that the holders of authorization as well as downstream users including the substances in a mixture shall include the authorisation number on the label before they place the substance or the mixture on the market for an authorised use
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How should you organise your labels?

You can organise your labels as you see fit. However, the hazard pictograms, signal word, hazard statements and precautionary statements should be kept together on your labels.

You can choose the order of the hazard and precautionary statements. However, you are requested to group them together on the label by language (*CLP Article 32*). In case more than one language is used on the label, the hazard and precautionary statements of the same language should be treated as one package and grouped together on the label, see also Part 5.1 of Module 2. This allows the reader to find all relevant hazard and safety information in one place!

On the following page, an example for a label is given. This example illustrates how supplemental information required by other legislation can be incorporated in the CLP label. The supplemental information in this example is the kind of information that is typically included in the label of crop protection products.

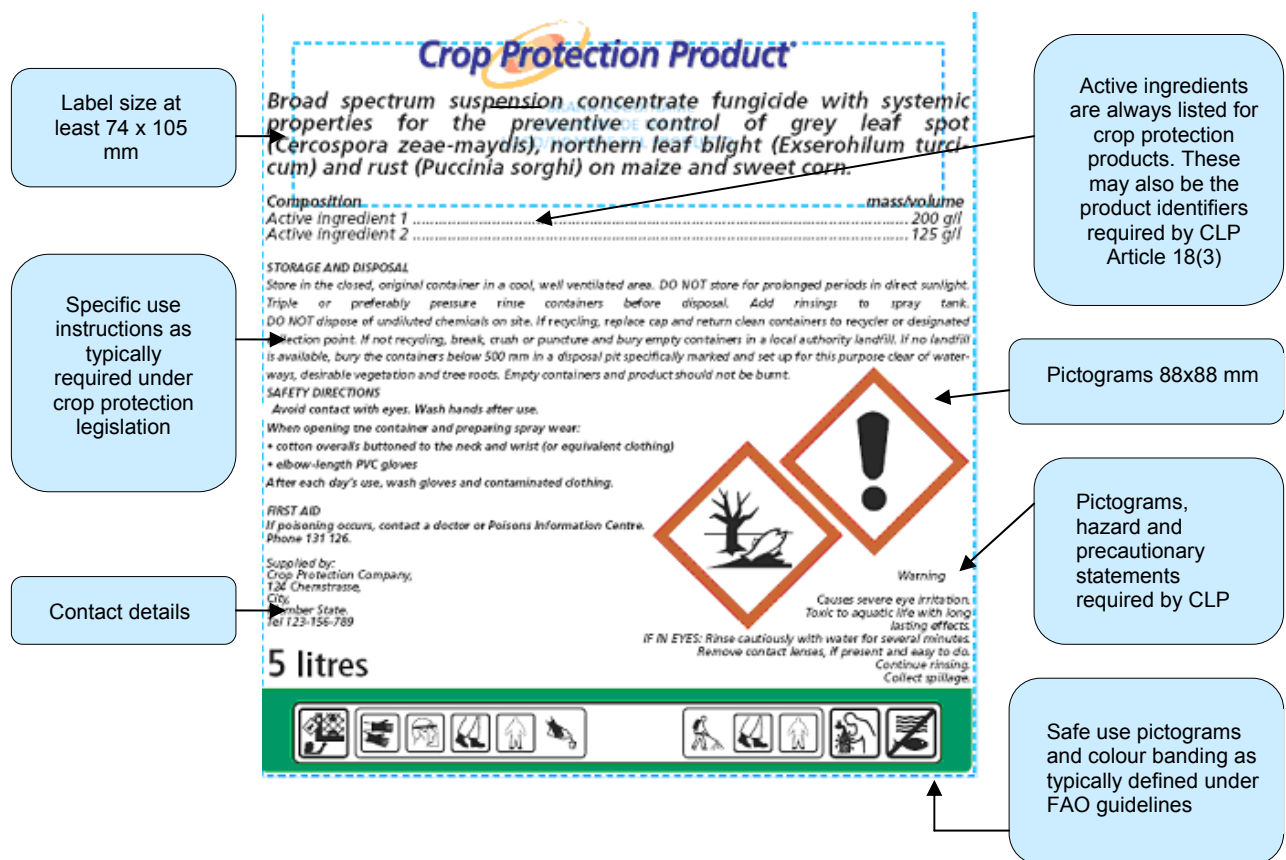
Further labelling examples are provided in Part 5.1 of Module 2.

When should you update your labels?

Your labels should be updated without undue delay following any changes to the classification and labelling of your substance or mixture where the new hazard is more severe or where new supplemental labelling elements are required under Article 25 (*CLP Article 30*). This would also include non-classified mixtures containing at least one substance classified as hazardous.

Where other labelling elements are required, e.g. where the revised classification will be less severe or the telephone number changed, the supplier of a substance or mixture shall ensure that the label is updated within 18 months. For substances or mixtures within the scope of Directive 98/8/EC (biocidal products Directive) or 91/414/EEC (plant protection products Directive), labels must be updated in accordance with these directives.

Figure 14.1: Example for a label incorporating information required by other legislation



Unpackaged substances and mixtures

In general substances and mixtures, especially those supplied to the general public, should be supplied in packaging together with the necessary labelling information. Where unpacked materials are supplied to professional users, labelling information and other relevant hazard information is provided through other means than a label, usually the Safety Data Sheet. In exceptional circumstances, substances and mixtures may also be supplied to the general public unpackaged. In case the substance or mixture is listed in Part 5 of Annex II (currently only cement and concrete in the wet state), a copy of the labelling elements is always required, for example on an invoice or bill (CLP Article 29(3), Part 5 of Annex II to CLP).

15. Applying the precedence rules for labelling

Application of the precedence rules

If a substance or mixture possesses several hazardous properties, a system based on principles of precedence is used to determine the most appropriate label elements, so as to limit the information on the label to the most essential information and not overburden or confuse the user.

Signal words

Where you have to use the signal word “Danger”, the signal word “Warning” shall not appear on the label.

Hazard pictograms

Where the classification of a substance or mixture would result in more than one pictogram on the label, the rules of precedence summarised below apply to reduce the number of pictograms required (*CLP Article 26*). As a general rule, you should include those pictograms which indicate the most severe hazard category of each hazard class. This would also apply in case a substance has both harmonised and non-harmonised classifications (*CLP Article 26(2)*).

The precedence rules relating to hazard pictograms are:

- **For physical hazards**, if your substance or mixture is classified with GHS01 (exploding bomb), then GHS02 (flame) and GHS03 (flame over circle) are optional, except in cases where more than one pictogram is compulsory (Annex I to CLP, section 2.8 self-reactive substances and mixtures Type B and section 2.15, organic peroxides Type B)...



Optional

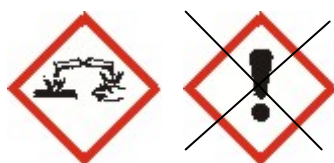
Optional

- **For health hazards**, if GHS06 (skull and crossbones) applies, then GHS07 (exclamation mark) shall not appear...

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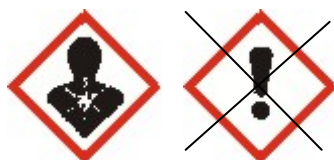


- If **GHS05 (corrosion)** applies, then GHS07 (exclamation mark) shall not be used for skin or eye irritation ...



... but may still be used for other hazards

- If **GHS08 (health hazard)** appears for **respiratory sensitisation**, then GHS07 (exclamation mark) shall not be used for skin sensitisation or for skin or eye irritation ...



... but may still be used for other hazards

Please note that the transport rules on labelling may apply to your substance or mixture as well. In certain cases, a particular CLP hazard pictogram on the packaging may be omitted, as set out in CLP Article 33.

Hazard statements

All hazard statements should appear on the label, unless there is obvious duplication or redundancy.

Precautionary statements

You should review the whole set of precautionary statements that can be assigned due to the hazard classification of your substance or mixture and discard any which are clearly unnecessary or redundant. You should aim to have no more than six precautionary statements on the label, unless more are necessary to reflect the severity of the hazards. To reduce the number of precautionary statements you may combine them to form one statement only (*Annex IV to CLP*). If your substance or

mixture requires labelling and is to be sold to the general public, you must include one precautionary statement on its disposal and on the disposal of its packaging.

Further guidance and examples on the selection of precautionary statements will be provided in due course by the Agency. A thought starter for further guidance is provided in Annex V of Module 2.

16. Specific labelling and packaging situations

Same substance – variety of labelling and packaging situations

The labelling and packaging requirements of CLP aim at protecting users from the hazards posed by substances or mixtures. However, certain types of packaging may not be suited for labelling. Also, hazardous substances and mixtures may be contained in various layers of packaging; in addition they may be covered by both the CLP and the transport labelling requirements. And finally, particular requirements may be necessary to protect the general public from severe damage. How CLP deals with these situations, is set out in this section.

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Labelling exemptions for small or difficult to label packaging

If you are a **manufacturer**, **importer**, **downstream user** or **distributor** who supplies substances or mixtures in packaging that is too small⁸ or of such form or shape that it is impossible to meet the requirements of CLP Article 31, CLP provides for exemptions to labelling and packaging requirements (*CLP Article 29*). These exemptions are set out in section 1.5 of Annex I to CLP. For further guidance on how these exemptions might apply to your packaged substances or mixtures, please see Part 5.1 of Module 2.

Chemicals supplied to the general public: Packaging rules for the provision of child-resistant fastenings and tactile warnings

If you supply substances and mixtures to the **general public**, you may have to fit child-resistant fastenings and/or tactile warnings to your packaging (*Part 3 of Annex II to CLP*). These provisions are triggered by either a specific hazard class/category or by the concentration of specific substances as set out in Table 16.1 and Table 16.2 respectively. These provisions apply whatever the capacity of the packaging.

⁸ It should be noted that a packaging volume of 125 ml or more cannot be considered as too small.

Table 16.1: The hazard classifications that trigger the CLP provisions for child-resistant fastenings and/or tactile warnings

Hazard Class (Category)	Child-resistant Fastenings	Tactile Warnings
Acute toxicity (category 1 to 3)	✓	✓
Acute toxicity (category 4)		✓
STOT single exposure (category 1)	✓	✓
STOT single exposure (category 2)		✓
STOT repeated exposure (category 1)	✓	✓
STOT repeated exposure (category 2)		✓
Skin corrosion (category 1A, 1B and 1C)	✓	✓
Respiratory sensitisation (category 1)		✓
Aspiration hazard (category 1)* <i>Not aerosols or if in container with sealed spray attachment</i>	✓	
Aspiration hazard (category 1)	✓	✓
Germ cell mutagenicity (category 2)		✓
Carcinogenicity (category 2)		✓
Reproductive toxicity (category 2)		✓
Flammable gases (category 1 and 2)		✓
Flammable liquids (category 1 and 2)		✓
Flammable solids (category 1 and 2)		✓

Table 16.2: Substances that trigger the CLP provisions for child-resistant fastenings and/or tactile warnings

Identification of the substance	Concentration limit	Child-resistant Fastenings	Tactile Warnings
Methanol	≥ 3%	✓	
Dichloromethane	≥ 1%	✓	

Specific rules for labelling of various layers of packaging


CLP Article 33 sets out new rules for situations where packaging of hazardous substances or mixtures consists of outer, inner and possibly also intermediate packaging. As a general rule, where the labelling of an outer packaging is in principle subject to both the transport and the CLP rules, the labelling or marking in accordance with transport legislation is sufficient, and the CLP labelling need not appear.

Similarly, where a hazard pictogram required by CLP relates to the same hazard as in the rules for the transport of dangerous goods, the hazard pictogram required by this Regulation need not appear on the outer packaging. For further differentiations with regard to various layers of packaging please refer to CLP Article 33.

17. Safety Data Sheets

Safety Data Sheets are an important communication tool in the supply chain, helping all the actors in the chain to meet their responsibilities in relation to the management of risks arising from the use of substances and mixtures.

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	<p>The requirement to provide a Safety Data Sheet is set out in REACH Article 31. Further specifications of their content is included in REACH Annex II, “Guide To The Compilation Of Safety Data Sheets”</p> <p>The information given in the Safety Data Sheet should be consistent with that given in the chemical safety report (CSR) where a CSR is required under REACH Article 14 or 37. The exposure scenarios documented in the CSR must be annexed to the Safety Data Sheet for substances manufactured or imported at 10 tons or more per year</p>
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When do you need to update?

In relation to classification and labelling and in the context of CLP, an existing Safety Data Sheet will require an update when:

- you have classified, labelled and packaged your substance or mixture according to CLP which has already been classified according to DSD / DPD. In case you want to issue a Safety Data Sheet before 1 June 2015 for such a substance or mixture, you would have to include both the DSD / DPD classifications and the new CLP classifications, including any specific concentration limits or M-factors for substances, in the Safety Data Sheet. For detailed information see also section 4 of this guidance document; and
- new knowledge on hazards becomes available.

What do you need to update?

Any new or revised classification, including any changes of specific concentration limits or M-factors for substances, should be included in Section 2 (Hazard Identification), Section 3 (Composition / Information on Ingredients) and your new labelling in Section 15 (Regulatory Information) of your Safety Data Sheet. The full text of a new hazard statement shall appear in Section 16 (Other Information) of the Safety Data Sheet.

You will also need to review the other sections of your Safety Data Sheets to ensure they are consistent with the information on which the new or revised classification is based. For example, you may have generated or identified new information about the physical, health or environmental hazards of your substance or mixture as part of the classification process. Therefore you should review the information provided in Section 9 (Physical and Chemical Properties), Section 11 (Toxicological Information) and Section 12 (Ecological Information) of your Safety Data Sheets and include any appropriate new or updated information.

If your substance or mixture classifications have changed (increased or decreased in severity of hazard), you should consider any impacts of these changes on how your substance or mixture should be safely managed, taking into account any effects from downstream legislation (⁶⁰ [see section 23 of this guidance document](#)). In connection with REACH, you should check if the information in the chemical safety report (CSR) should be updated in line with any update of the Safety Data Sheet (Section 7 (Handling and Storage), Section 8 (Exposure Controls/Personal Protection) or 13 (Disposal Considerations)).

You may also need to prepare new Safety Data Sheets for substances or mixtures which were not classified as hazardous under the DSD and DPD but are now classified as hazardous or contain one or more component substances classified as hazardous for health or environmental effects above the specified threshold of $\geq 1\%$ by weight for non-gaseous preparations and $\geq 0.2\%$ by volume for gaseous preparations ([REACH Article 31\(3\)](#)).

18. The classification and labelling inventory – notifying substances

The classification and labelling inventory

Information on substance identity and classification and labelling of a substance should be notified to the Agency. The Agency will include this information in a particular database, called the classification and labelling inventory.

Who needs to notify?

Are you a **manufacturer** or **importer** (or a member of a group of manufacturers or importers) who places a substance on the market? If you are, you will have to notify certain information to the Agency (*CLP Article 40*) if your substance is:

- subject to registration under REACH (≥ 1 tonne/year) and placed on the market (*CLP Article 39(a)*). Please note that a substance that you have already registered under REACH shall not be notified further by you in case the information to be notified has already been provided as part of the registration dossier. This will also apply to certain substances contained in articles where REACH Article 7 provides for their registration;
- classified as hazardous under CLP and is placed on the market, irrespective of the tonnage (*CLP Article 39(b)*); or
- classified as hazardous under CLP and is present in a mixture above the concentration limits specified in Annex I of CLP or as specified in Directive 1999/45/EC, which results in the classification of the mixture as hazardous, and the mixture is placed on the market (*CLP Article 39(b)*).

Please note that you have to update the information you sent for notification in case you have new information that leads to a revision of the classification and labelling elements of a substance (*CLP Article 40(2)*). In case you have registered, but not notified, a substance and you have new hazard information, you need to update the relevant registration dossier.

If you are a **downstream user** who formulates a mixture, a **distributor** or a **producer of articles in the meaning of REACH Article 7**, you do not need to notify to the Agency (see [section 2 of this guidance document](#)). This is because the notification for your substance will have occurred already at an earlier stage in the supply chain.

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As to the notification deadline:

For substances which are placed on the market **before and still, or again, on 1 December 2010**, the deadline for notification to the inventory is one month after this date, i.e. 1 January 2011. However, as 1 January is a Saturday and 2 January falls on a Sunday, the notification deadline is in practice the 3 January 2011. The same applies for substances that are placed on the market on 1 December 2010 for the first time.

For example, you as manufacturer or importer supply a substance on 30 November 2010 and on 1 December 2010. The obligatory one month notification deadline is to be calculated from 1 December 2010. Taking into account that 1 January 2011 will be a Saturday, your notification is in practice due on **3 January 2011** at the latest. You can, of course, voluntarily notify before 1 December 2010 already.

Prospective notifiers should bear in mind that the period from 24 December 2010 to 2 January 2011 will be an official holiday for ECHA. Accordingly, it is recommended that, where possible, a notification is submitted before 24 December 2010, as this would allow for any technical problems with the submission tool to be resolved in a timely manner, thus reducing the risks of difficulties in making a successful notification.

For substances placed on the market after 1 December 2010, the one month period has to be calculated from the first time they are placed on the market after 1 December 2010. This will also apply to substances which have been placed on the market before 1 December 2010, but which are not placed on the market on 1 December 2010 itself, but only again afterwards.

For example, you as manufacturer or importer supply a substance on 8 November 2010, then you stop supplying for a while, and then you again supply it on 1 February 2011. The obligatory one month notification deadline is to be calculated from 1 February 2011 and therefore your notification is due on 1 March at the latest. You can, of course, voluntarily notify before 1 December 2010 already.



If you have already provided the information to be notified to the Agency in form of a registration under REACH, you shall not submit an additional notification to the Agency afterwards (*CLP Article 40(1)*)

	<p>If you manufacture or import substances in quantities less than 1000 tonnes per year and it is not a phase-in substance that is classified as CMR category 1 or 2 according to DSD in quantities at or above one tonne per year, or as N; R50/53 at or above 100 tonnes per year, you may not have registered your substance under REACH by 1 December 2010 and will therefore have to notify it by 1 January 2011, provided you place them on the market on 1 December 2010</p>
	<p>Registrants have REACH obligations in addition to the CLP obligations required from notifiers</p>

What do you notify?

If you have to notify your substance, your notification to the Agency should include (*CLP Article 40(1)*):

- your identity, as specified in section 1 of Annex VI to the REACH Regulation;
- the identity of the substance, as specified in section 2.1 to 2.3.4 of Annex VI to REACH;
- the CLP classifications of the substance;
- 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).

The CLP Regulation requires that in case your notification results in an entry on the inventory which differs from another entry for the same substance, you and the other notifier or registrant shall make every effort to come to an agreed entry to be included in the inventory (*CLP Article 41*). However, you may classify your substance differently to another entry, provided you include the reasons in your notification.

In contrast, where your substance has a harmonised classification, you shall classify in accordance with the harmonised classification listed in Part 3 of Annex VI to CLP and include this classification in your notification (⁶⁶ *see section 8 of this guidance document*). 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), you shall set an M-factor for the substance, based on available data. For further reading see also Parts 1.6 and 1.7 of Module 2.

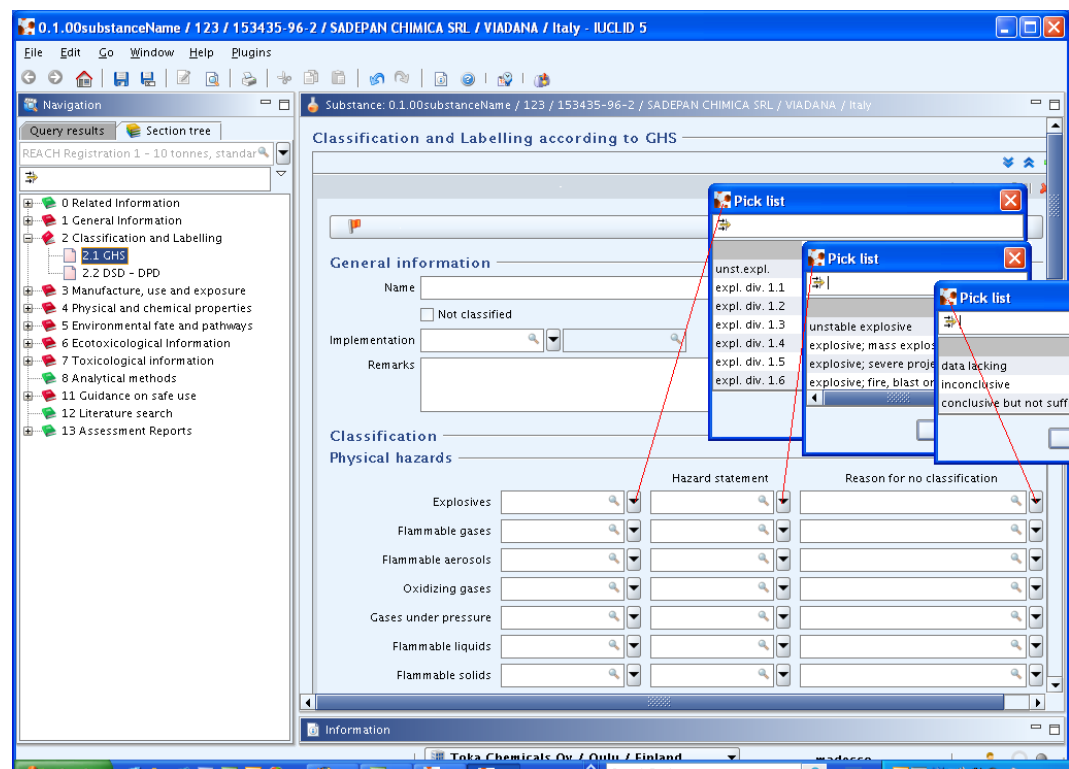
What format should you use for notification?

Your notification shall be in the format specified by the Agency. The notification dossier can either be created online by use of the REACH-IT tool or it can be created in IUCLID 5 (International Uniform Chemical Information Database) and submitted via REACH-IT (*CLP Article 40(1)*).

The IUCLID 5 software tool and user manuals are available to download from <http://ecwbui5.jrc.it/>, free of charge. The REACH-IT tool can be accessed from <https://reach-it.echa.europa.eu/reach/public/welcome.faces>.

Figure 18.1 shows a screen shot from IUCLID 5.

Figure 18.1: Screen shot from IUCLID 5



What happens next?

The Agency will add to the notified information:

- whether there is a harmonised classification and labelling at Community level by inclusion in Annex VI for the substance;
- whether the entry is a joint entry between registrants of the same substance;
- whether the entry is agreed by two or more notifiers or registrants; or
- whether the entry differs from another entry for the same substance.

Please note that those parts of the notified information which correspond to the information referred to in REACH Article 119(1) shall be publicly accessible, i.e.

- the name in the IUPAC nomenclature for hazardous substances;
- if applicable, the name of the substance given in EINECS; and
- the classification and labelling of the substance.

With regard to the name in IUPAC-nomenclature for certain substances and for non-phase-in substances which are hazardous, see REACH Article 119(2)(f) and (g), you may send a justification to the Agency why publication of that name is potentially harmful for your commercial interests (submission in accordance with REACH Article 10(a)(xi)). In case this justification is accepted as valid by the Agency, that name will not be publicly accessible.

19. New hazard information

You need to keep up to date with hazard information!


Under CLP, it is up to you as a **manufacturer, importer** or **downstream user** to keep up to date with new scientific or technical information that could alter the classification and labelling of any substances or mixtures that you supply, as it is expressed in CLP Article 15: *“manufacturers, importers and downstream users shall take all reasonable steps available to them to make themselves aware of new scientific or technical information that may affect the classification of the substances or mixtures they place on the market.”*

What do you have to do?

You should assess new hazard information to ascertain whether or not it is adequate and sufficiently reliable to carry out a new evaluation of the classification of your substance or mixture. If it is, you should then carry out a new evaluation without undue delay (*CLP Article 15(1)*). In case a change in the classification of your substance or mixture is warranted, you should update your labels accordingly. This update is to be done without undue delay where the new hazard is more severe or where new supplemental labelling elements are required (*CLP Article 30(1)*). For other changes to the labelling you should update the corresponding label within 18 months (*CLP Article 30(2)*).

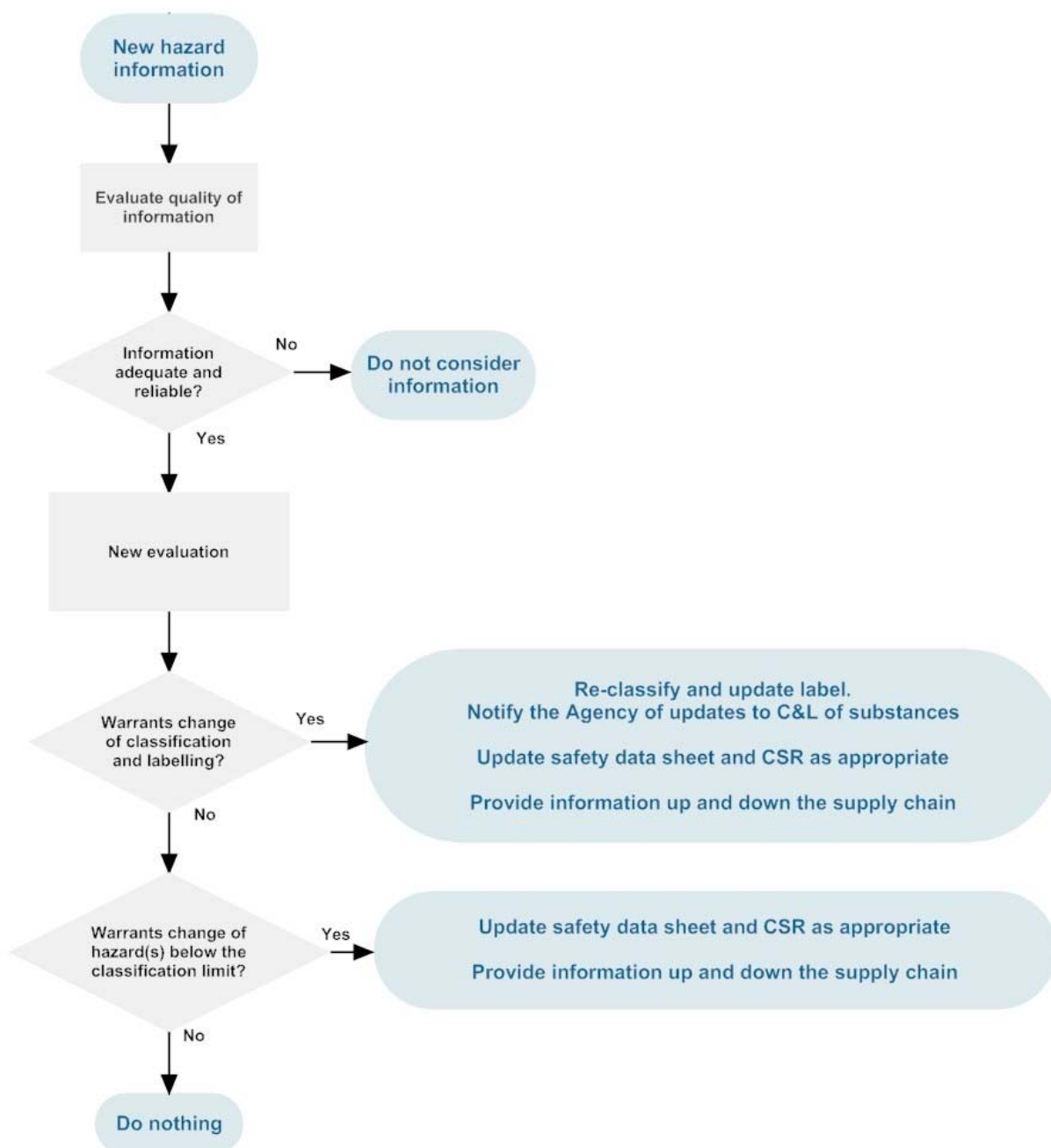
Please note that in case of a change of the classification and labelling of a substance, you must notify the Agency of any such change (*CLP Article 40(2)*).

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	<p>Chemical safety assessments and reports and Safety Data Sheets will have to be updated when new information on hazards becomes available or when the classification and labelling changes (<i>REACH Article 14 and 31</i>)</p>
	<p>You should pass on new hazard information and any changes to the classification and labelling that you have made to the next actor or distributor up and down the supply chain (<i>REACH Article 31, 32 and 34</i>)</p>

The steps to take once you become aware of new hazard information for your substance or mixture are shown in Figure 19.1.

Figure 19.1: What to do about new hazard information



20. Request for use of an alternative chemical name

Introduction

Under CLP, substances and mixtures placed on the market should be well identified (*see the paragraph on product identifiers in ^o section 14 of this guidance document*). However, as a **manufacturer, importer** or **downstream user** you may be concerned that the disclosure on the label or Safety Data Sheet of the chemical identity of one or several substances contained in your mixture(s) puts the confidential nature of your business, in particular your intellectual property rights, at risk (*CLP Article 24*). In such cases, CLP allows for you to submit a request to the Agency to use an alternative chemical name which refers to that substance/s in a mixture either by means of a name that identifies the most important functional chemical groups or by means of an alternative designation. Such requests are referred to here as ‘requests for use of an alternative chemical name’.

Under CLP, the process and requirements for making a request for an alternative chemical name differ, depending upon whether your request is submitted before or after

1 June 2015.

Before 1 June 2015

If you have already classified, labelled and packaged your mixture according to CLP before 1 June 2015, you should direct a request to use an alternative chemical name to the Agency, in line with the provisions set out in CLP.

Where you have not yet classified, labelled and packaged your mixture according to CLP you should continue to direct a request for use of an alternative chemical name to a Member State Competent Authority under the provisions of the previous system of classification and labelling, as set out in the Dangerous Preparations Directive 1999/45/EC (DPD) Article 15. Your request should demonstrate that the disclosure on the label or Safety Data Sheet of the chemical identity of the concerned substance in a mixture will put at risk the confidential nature of your intellectual property.

Which substances are included?

You can only make requests for use of an alternative chemical name for those substances in a mixture that have been classified under DSD, for example as irritant (excluding chemicals that cause severe eye damage) or as acutely toxic or harmful, and which have not been assigned a Community occupational exposure limit.

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How do you submit a request?

Your request should be made to your Member State Competent Authority in accordance with the provisions of Annex VI to DPD and should provide the information required in the form in Part A of that Annex. Your Competent Authority may nevertheless request further information from you if such information appears necessary in order to evaluate the validity of the request.

Your Competent Authority will notify you of its decision and you should forward a copy of this decision to each of the Member States where you wish to market your substance or mixture.

What happens after 1 June 2015?

Should your request be approved before 1 June 2015 under DPD, you can continue to use the approved alternative chemical name under CLP (*CLP Article 24*).

After 1 June 2015

After 1 June 2015, you should direct a request for an alternative chemical name to the Agency, as set out in CLP Article 24. Your request should demonstrate that the disclosure on the label of the chemical identity of your substance or mixture puts the confidential nature of your business, in particular your intellectual property rights, at risk.

Which substances are included?

You can make a request for an alternative chemical name for any substance in the mixture that has not been assigned a Community exposure limit, and where that substance is classified exclusively as one or more of the hazard categories set out in point 1.4.1 of Part 1 of Annex I to CLP, namely:

- any of the hazard categories relating to physical hazards (Part 2 of Annex I to CLP);
- acute toxicity, category 4;
- skin corrosion / irritation, category 2;
- serious eye damage / eye irritation, category 2;
- specific target organ toxicity – single exposure, category 2 or 3;
- specific target organ toxicity – repeated exposure, category 2; and
- hazardous to the aquatic environment, chronic category 3 or 4.

Further to this, the use of the alternative chemical name should meet the need to provide enough information for necessary health and safety precautions to

ensure that risks from handling the mixture can be controlled. It is up to the applicant to demonstrate that this is the case.

How do you submit a request?

Your request should be submitted to the Agency in the format specified by the Agency and using any tools made available by the Agency (*CLP Article 24(2), referring to REACH Article 111*). The request shall be accompanied by a fee as determined by the Commission. The Agency may require further information from you if such information is necessary to take a decision.


The Agency will notify you of its decision within six weeks of your request or the receipt of further required information. If the Agency raises no objections within six weeks of the request or the receipt of further required information, the use of the requested name is deemed to be allowed.

21. Information records and requests

What record keeping does CLP require of you?

As a **manufacturer** of substances, an **importer** of substances or mixtures or as **downstream user**, you should assemble and keep available all the information that you used for the classification and labelling of your substance or mixture. This information should be kept for at least 10 years after you last supplied this substance or mixture (*CLP Article 49*). As a **distributor** you should assemble and keep available all the information that you used for the labelling in the same way, see also Table 2.4 of section 2.

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	REACH requires you to assemble and keep available all the information necessary to carry out your duties under REACH for a period of at least 10 years after you last manufactured, imported, supplied or used a substance or mixture. You should submit this information or make it available without delay upon request to the Member State Competent Authority/ies where you are established or to the Agency (<i>REACH Article 36</i>)
	If your substance has been registered under REACH or is subject to other obligations under REACH, the information that should be kept under CLP should be kept together with that required for you to carry out your duties under REACH (<i>CLP Article 49(1)</i>)

Who should you show this information to?

The Competent Authority/ies or the enforcement authority of the Member State where you are established or the Agency may request all the information you used for the purpose of classification and labelling under CLP. Following such a request you should provide this information. However, if the information requested by a Competent Authority is included in your notification under CLP, or your registration under REACH, this information will be available to the Agency, and the Competent Authority should address its request to the Agency (*CLP Article 49(3)*).

All Member States are required to appoint a body/ies responsible, such as poison centres, for receiving information relevant for formulating preventative and curative measures, in particular for emergency health response. If you are an **importer** or **downstream user** these bodies must receive from you the necessary information, inter alia on the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health and physical effects. The information you

provide must include the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency (*CLP Article 45*).

22. Proposals for harmonised classification and labelling

When can a proposal be made?

Proposals for the harmonised classification and labelling of a substance should comprise proposals for inclusion in as well as for updating of Annex VI to CLP and should normally be made if that substance fulfils the classification criteria for *(CLP Article 36)*:

- respiratory sensitisation, category 1;
- germ cell mutagenicity, categories 1A, 1B or 2;
- carcinogenicity, categories 1A, 1B or 2; or
- reproductive toxicity, categories 1A, 1B or 2.

Further to this, proposals relating to other hazard classes or their differentiations may be made, provided that the need for Community-wide action is justified, see below.

In contrast to other substances, active substances in the meaning of Directive 91/414/EEC (plant protection products) or Directive 98/8/EC (biocidal products) shall normally be subject to harmonised classification and labelling for all hazard classes and labelling elements (⁹ *see section 24 of this guidance document*).

Proposals can refer to the inclusion of the classification of a substance into Part 3 of Annex VI to CLP or for the updating of an existing Annex VI entry (⁹ *see section 8 of this guidance document*). They must be submitted to the Agency.

Who can make a proposal?

A Competent Authority of a Member State as well as a **manufacturer, importer and downstream user** of a substance may submit a proposal to the Agency for the harmonised classification and labelling of a substance *(CLP Article 37⁹)*. A Competent Authority may make such a proposal even for a hazard for which harmonised classification and labelling already exists for that substance. In contrast, a **manufacturer, importer or downstream user** cannot make such a proposal for a hazard for which harmonised classification and labelling already exists for that substance; on the other hand, if he has new information which may lead to a change in the harmonised classification and labelling of a substance; he must contact the Competent Authority in one of the Member States in which the substance is placed on the market and submit a proposal to it *(CLP Article 37(6))*. If the proposal of the

⁹ Please note that for active substances used in plant protection or biocidal products, only Member State competent authorities can submit proposals, but not companies.

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Competent Authority or the **manufacturer, importer or downstream user** pertains to other hazard classes than CMR or respiratory sensitizers, a justification demonstrating the need for action at Community level is required. In case the Agency finds that new information does not support an existing harmonised classification and labelling the Agency may inform the relevant authority.

How does a company submit a proposal?

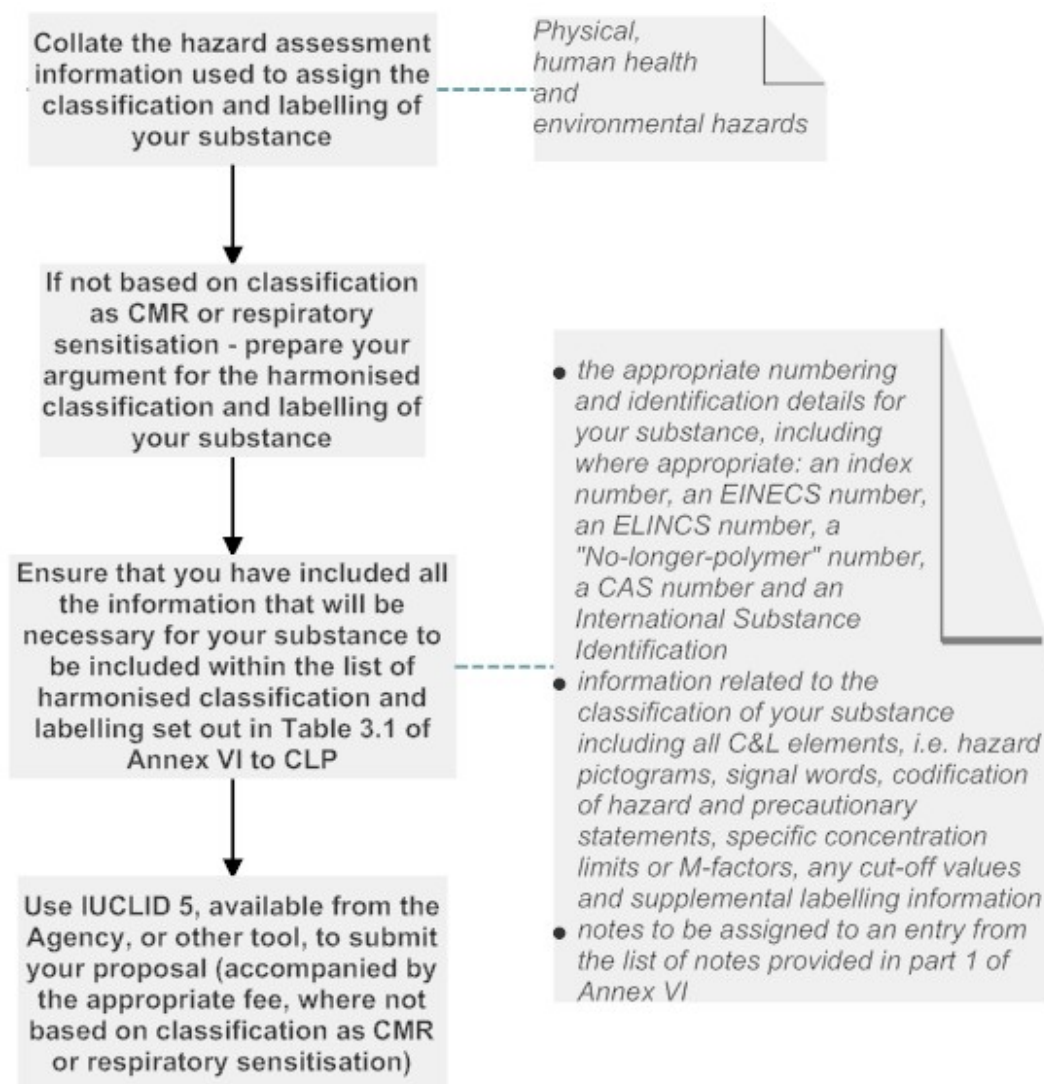
The procedure for submitting a proposal to the Agency for the harmonised classification of a substance is set out in CLP Article 37. Your proposal should be drawn up in accordance with the relevant parts of sections 1, 2 and 3 of Annex I to the REACH Regulation and should contain robust study summaries in relation to the hazard(s) for which harmonised classification and labelling is proposed. In addition, it should contain the relevant information necessary for inclusion in the classification and labelling inventory as set out in Part 1 of Annex VI to CLP. The proposal shall follow the format set out in Part B of the Chemical Safety Report of section 7 of Annex I to the REACH Regulation. You should also use the electronic formats and packages such as IUCLID 5, prepared by the Agency for submissions under REACH as set out in REACH Article 111, see http://echa.europa.eu/reachit/portal_en.asp and <http://iuclid.echa.europa.eu/>

For any proposal which does not refer to a classification for carcinogenicity, germ cell mutagenicity, reproductive toxicity (CMR) or respiratory sensitisation you should provide arguments justifying the need for Community-wide harmonisation of the classification and labelling in relation to the hazard(s) covered by your proposal. Such a proposal should also be accompanied by the appropriate fee as determined by the Commission in a Commission Regulation to be adopted in accordance with CLP Article 37(3).

The steps required for you to submit a proposal are summarised in Figure 22.1. Please note that specific guidance on submitting a proposal for inclusion of a substance (classification) in Annex VI to CLP is under preparation at the Agency.

The Agency is developing guidance on the preparation and submission of proposals for harmonised classification and labelling.

Figure 22.1: The steps required for submitting a proposal



A proposal has been submitted: What happens next?

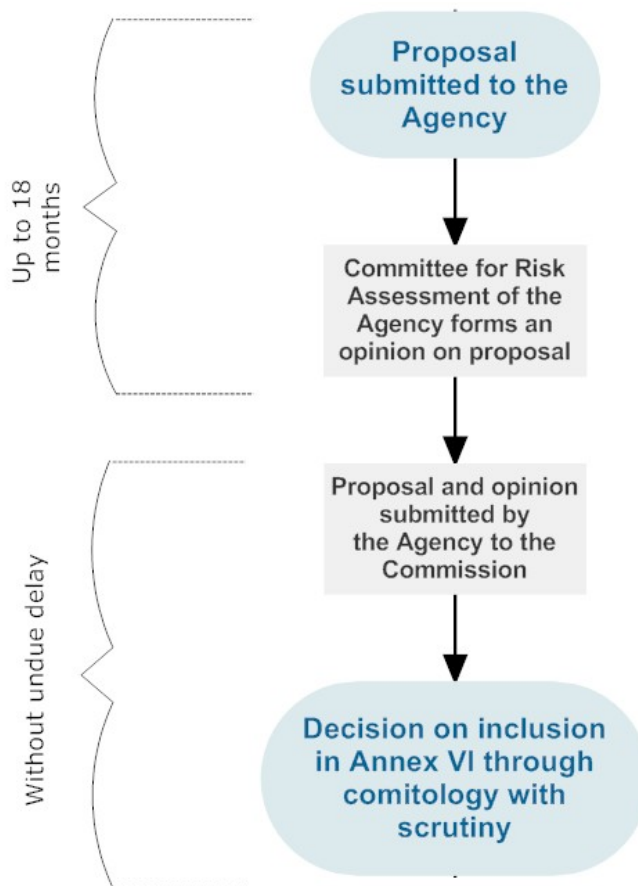
Once submitted, all parties concerned will be given the opportunity to comment on the proposal. The opportunity to comment will be provided on the ECHA website (http://echa.europa.eu/consultations/harmonised_cl_en.asp), in the specified submission form, where comments can be introduced by a specified deadline.

The Committee for Risk Assessment of the Agency will form an opinion on a proposal for the harmonised classification and labelling of a substance within eighteen months (*CLP Article 37(4)*), and the Agency will then forward this opinion to the Commission. Should the Commission find that your proposal and justification are appropriate, it will

propose to include your substance in Table 3.1¹⁰ of Annex VI to CLP, listing substances with harmonised classification and labelling, together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits and M-factors. The procedure to include a substance in Annex VI is called “comitology with scrutiny”, leading to a Commission decision.

The process followed by the Agency and the Commission following the submission of a proposal is summarised in Figure 22.2 (*CLP Article 37*).

Figure 22.2: The process followed by the Agency and the Commission following the submission of a proposal



¹⁰ Until 31 May 2015, a corresponding entry shall also be included in Table 3.2 of Annex VI to CLP.

23. Downstream legislation - an overview

Downstream legislation

Provisions under Community legislation other than CLP (downstream legislation) may be triggered by the classification of your substance or mixture. The corresponding acts are:

- Registration, evaluation, authorisation and restriction of chemicals (REACH): Regulation (EC) No 1907/2006 of 18 December 2006 (☞ [See Section 25 of this guidance document](#));
- Control of major-accident hazards involving dangerous substances (Seveso II): Council Directive 96/82/EC of 9 December 1996;
- Plant protection products: Council Directive 91/414/EEC (PPPD) of 15 July 1991 (☞ [See Section 24 of this guidance document](#));
- Biocidal products: Directive 98/8/EC (BPD) of 16 February 1998 (☞ [See Section 24 of this guidance document](#));
- Chemical agents at work: Council Directive 98/24/EC of 7 April 1998;
- Carcinogens and mutagens at work: Directive 2004/37/EC 29 April 2004;
- Young people at work: Council Directive 94/33/EC of 22 June 1994;
- Pregnant and breastfeeding women at work: Council Directive 92/85/EEC of 19 October 1992;
- Health and safety signs at work: Council Directive 92/58/EEC of 24 June 1992;
- Cosmetic products: Council Directive 76/768/EEC of 27 July 1976;
- Toy safety: Council Directive 88/378/EEC of 3 May 1988 as amended by Directive 93/68/EEC;
- Detergents: Regulation (EC) No 648/2004 of 31 March 2004;
- Eco-label award scheme: Regulation (EC) No 1980/2000 of 17 July 2000;
- Aerosol dispensers: Council Directive 75/324/EEC of 20 May 1975. CLP Article 14 (2c) takes account of the Aerosols Directive Article 8 (1a);
- Limitation of emissions of volatile organic compounds: Council Directive 1999/13/EC (VOCD) of 11 March 1999 and Directive 2004/42/EC of 21 April 2004;
- Ambient air quality assessment and management: Council Directive 1996/62/EC of 27 September 1996;
- Export and import of dangerous chemicals: Regulation (EC) No 689/2008 of 17 June 2008;
- Hazardous waste: Council Directive 91/689/EC of 12 December 1991, including Commission Decision 2000/532/EC of 3 May 2000;
- Batteries and accumulators: Council Directive 91/157/EEC of 18 March 1991;
- End-of-life vehicles: Directive 2000/53/EC of 18 September 2000; and

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- Waste electrical and electronic equipment (WEEE): Directive 2002/96/EC of 27 January 2002.

A number of these Community acts still refer to the current directives on classification and labelling; they will be amended over time to take account of the new CLP Regulation. For summaries of some of the interactions between CLP and REACH, BPD and PPPD, see Sections 19 to 22 of this guidance document.

CLP was adopted as part of a package of legislation, comprising also:

- Regulation (EC) No 1336/2008 to amend Regulation (EC) No 648/2004 of 31 March 2004 on detergents. The following changes are carried out: “Mixture” replaces “preparation” and references to CLP replace those to DSD and DPD; and
- Directive 2008/112/EC to amend six Community Directives:
 - Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products: “Mixture” replaces “preparation” and references to CLP replace those to DSD. Insertion of general reference to Test Method Regulation (EC) No 440/2008, reference to CMR criteria under CLP and concept of “dangerous” translated into CLP hazard classifications;
 - Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys: “Mixture” replaces “preparation”, concept of “dangerous” translated into CLP hazard classifications;
 - Council Directive 1999/13/EC (VOCD) of 11 March 1999 and Directive 2004/42/EC of 21 April 2004 on the limitation of emissions of volatile organic compounds: “Mixture” replaces “preparation” (both directives), insertion of reference to CLP in VOCD Article 5(6) for substances (from 1 Dec 2010) and for mixtures (from 1 June 2015). Also, insertion of reference to CLP CMR criteria and hazard statements in VOCD Article 5(6), (8), (9) and (13) for substances (from 1 Dec 2010) and for mixtures (from 1 June 2015);
 - Directive 2000/53/EC of 18 September 2000 on end-of-life vehicles: Concept of “dangerous” translated into CLP hazard classifications; and
 - Directive 2002/96/EC of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment: “Mixture” replaces “preparation”, references to CLP replace those to DSD; concept of “dangerous” translated into CLP hazard classifications.

The changes resulting from Regulation (EC) No 1336/2008 and Directive 2008/112/EC are to come into force in line with the CLP implementation dates i.e. upon entry-into-force of CLP, on 1 December 2010 and on 1 June 2015, respectively.

Dangerous substances and preparations in EU downstream legislation

Many pieces of Community legislation refer to “dangerous” substances or preparations, to cover substances or preparations which meet DSD or DPD categories of danger. A typical example is the Chemical Agents Directive 98/24/EC. CLP does not build on this concept, but defines substances or mixtures which meet the CLP classification criteria as “hazardous”.

As the CLP rules for the classification of substances will be effective by 2010 and for mixtures by 2015, the relevant EU acts will have to be amended. To preserve their scope, they would have to refer explicitly to those CLP hazard classes and categories reflecting the previous scope of “classified as dangerous” where there was previously a reference to “classified as dangerous” under DSD/DPD. REACH has been amended in this way through CLP Article 58, with the exception of the rules for Safety Data Sheets where the concept of “hazardous” is introduced.

24. Biocidal products and plant protection products

Directives on biocidal and plant protection products as customers of CLP

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The provisions of CLP apply in full to any substance or mixture whose marketing and use is controlled by Directive 98/8/EC (BPD) on biocidal products (*BPD Articles 9 and 20*) or by Council Directive 91/414/EEC on plant protection products (PPPD) (*PPPD Article 1*). However, CLP in no way replaces the provisions of the BPD or those of the PPPD.

In practice, this means that your active substances and biocidal or plant protection products (mixtures) should be classified and labelled under CLP. You should consider any additional information required by BPD or the PPPD to be supplemental labelling information for the purposes of the CLP Regulation (*CLP Article 25*) (☞ *see section 14 of this guidance document*).

Substances that are active substances in the meaning of the PPPD or BPD shall *normally* be subject to harmonised classification and labelling (☞ *see sections 8 and 22 of this document*), i.e. all hazard classifications and labelling elements will be harmonised. This is a difference to other substances where only the classification and labelling elements for CMR's and respiratory sensitisers will normally be harmonised while other classifications and the related labelling elements will only be harmonised on a case-by-case basis if justification is provided demonstrating the need for such action at Community level (*CLP Article 36(2)*). In relation to proposals for harmonised classification, please note that for active substances used in plant protection or biocidal products, only Member State Competent Authorities can submit proposals, but not companies.

Should you want to change the composition of a biocidal or plant protection product, you have to apply for a change to the registration or authorisation of that product at the relevant Competent Authority of the Member State where you place it on the market. In your application you should mention that you had to review the classification of your product due to a change of its composition, where this was appropriate.

Should information become available which results in the updating of the classification and labelling of your substance or mixture covered by CLP, you must do so in accordance with the provisions of CLP (*CLP Article 30*) (☞ *see section 19 of this guidance document*). However, should your substance or product (mixture) fall within the scope of the PPPD or BPD and is subject to an authorization or registration

decision according to one of those directives, then the requirements of those directives also apply (*CLP Articles 15(5) and 30(3)*).

25. Classification-based obligations under REACH

Obligations under REACH triggered by the classification of substances

In general your obligations under REACH are triggered by the amount of a substance that you manufacture or import. Specific obligations may also depend upon the classification of all (or any) substances and mixtures, in particular:

- should you manufacture or import a phase-in substance that is classified as CMR category 1 or 2 according to DSD in quantities at or above 1 tonne per year or as R50/53 according to DSD in quantities at or above 100 tonnes per year, you should register this substance by 30 November 2010 at the latest ([REACH Article 23](#));
- should you manufacture or import a substance at or above 10 t/year, you are obliged to assess exposure and characterise the related risk for the preparation of the chemical safety report in case this substance meets the criteria for classification ([REACH Article 14](#));
- you should prepare a Safety Data Sheet in case your substance or mixture meets the criteria for classification ([REACH Article 31](#));
- you should provide all of the information required under REACH Annex VII (and CLP Title V, if appropriate) if you manufacture or import a phase-in substance in quantities between 1 and 10 tonnes per year that is likely to be classified as CMR category 1 or 2 according to DSD or category 1A or 1B according to CLP (from 1 December 2010), or has dispersive use and is likely to be classified for human health or environmental effects under DSD or CLP (from 1 December 2010).

In case you use a CMR substance of category 1 or 2 according to DSD or of category 1A or 1B according to CLP (from 1st December 2010), respectively, this use will be subject to authorisation as far as this substance has been identified as a Substance of Very High Concern (SVHC), included in the candidate list, further prioritised and included in Annex XIV to REACH, independent of any tonnage produced ([REACH Article 57 ff.](#));

Any restrictions in relation to CMR substances which are set out in points 28, 29 and 30 of Annex XVII to REACH continue to apply. Please note that certain references to DSD and DPD in points 28, 29 and 30 of Annex XVII to REACH have been converted to references to CLP through CLP Articles 57 and 59.

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26. Substance Information Exchange Fora (SIEFs)

What is a SIEF?

According to REACH Article 29, a SIEF stands for ‘Substance Information Exchange Forum’. REACH requires the formation of SIEF’s by industry, to share data among **manufacturers** and **importers** of pre-registered phase-in substances or phase-in substances without pre-registration, **holders of information** on substances that are used in plant protection products or biocidal products as well as **downstream users** and **data holders**, i.e. other stakeholders who have to share, and are willing to share, relevant information with potential registrants. Thus a SIEF is first of all a forum to share data and other information on a given substance.

A SIEF will need to be formed for each pre-registered substance with the same chemical identity. One of its principal aims is to **agree on the classification and labelling of a substance** where there is a difference between the potential registrants.

Further information on the purpose and functioning of SIEFs can be obtained on the Agency’s website under http://echa.europa.eu/pre-registration/SIEF_en.asp.

For more detailed information and guidance on SIEFs and other data sharing issues please also refer to “Guidance on data sharing” produced by the Agency and freely available for download from: http://guidance.echa.europa.eu/guidance_en.htm.

Why are SIEFs being considered within guidance on CLP?

It may happen that a supplier classifies the same substance differently from another supplier, for example in case he has used different test data. CLP requires that the notifiers (CLP) and registrants (REACH) shall make every effort to come to an agreed entry, i.e. to an agreed classification and labelling, to be included in the inventory (*CLP Article 41*) where there are different entries for the same substance on the classification and labelling inventory. As many registrants and notifiers will already be in contact through the SIEFs, this will facilitate the agreement on entries.

Nevertheless, varying impurity profiles of the same substance may render agreement on the classification and labelling impossible so that the same substance may have several entries on the inventory with different classification and labelling.

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Do you have to join a SIEF?

No, if you are a **downstream user** of a substance or if you have not pre-registered your substance(s) under REACH, either because you **manufacture** or **import** a substance below 1 tonne/year or you have a non-phase-in substance, then you do not have to become a member of a SIEF (*REACH Articles 28 and 29*). However, you are still required to make every effort to come to an agreed classification and labelling entry for your substance. It may be advisable, therefore, to communicate with the SIEF specific to your substance(s). Further information on how to contact the SIEF specific to your substance(s) will be provided at the ECHA website in due time.

Can you join a SIEF?

If you have pre-registered or registered your substance(s) under REACH, then you are legally required to be part of the SIEF(s) specific to your substance(s).

If you have not pre-registered or registered your substances(s), then you can still join a SIEF(s), if you are a “data holder”. A data holder is any person (including **downstream users** and third parties) holding information/data relevant to a phase-in substance and willing to share it. This data holder can identify himself via REACH-IT and lodge a request to ECHA with a view to being a participant in the SIEF for that substance, to the extent that he will provide information to other SIEF members. He can do so by submitting to the Agency, via REACH-IT, some or all of the information listed below or any other information relevant to your substance(s), stating his wish to become part of SIEF(s) for those substance(s) (*REACH Article 28*):

- “(a) the name of your substance as specified in section 2 of Annex VI, including its EINECS and CAS number or, if not available, any other identity codes;*
- (b) the name and address of your organisation and the name of the contact person and, where appropriate, the name and address of the person representing your organisation in accordance with Article 4 as specified in section 1 of Annex VI;*
- (c) the envisaged deadline for the registration and the tonnage band; and*
- (d) the name(s) of your substance(s) as specified in section 2 of Annex VI, including their EINECS and CAS number or, if not available, any other identity codes”.*

It should be noted that REACH does not provide for the data holder to have an active role in deciding on classification and labelling proposals. The data holder can thus only provide data to other active members (potential registrants) of the SIEF and request cost sharing for the data supplied.

27. REACH guidance documents relevant to CLP

REACH guidance documents relevant to CLP

Physical, health and environmental hazard assessments are an important part of the REACH registration process, and you may find additional helpful information in various guidance documents that will help you to understand and assess the hazards of your substance or mixture. The Agency has published a range of guidance documents relating to REACH which are available to download from the Agency website (http://guidance.echa.europa.eu/guidance_en.htm). Of particular relevance to CLP are the guidance documents introduced here.

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Guidance on registration

This guidance document gives clarification on the roles “**manufacturer**” and “**importer**”.

Guidance for downstream users

This guidance document gives clarification on the roles “**downstream user**” and “**distributor**”.

Guidance on requirements for substances in articles

This guidance document gives clarification on the role “**producer (importer) of articles**”.

Guidance on information requirements and chemical safety assessment

This guidance document gives advice on how to carry out certain steps which are common to hazard assessment under REACH and classification, i.a. where to find available information, how to assess collected data or how to use non-testing information. Expert knowledge may be required to understand and use this advice. The document is made up of seven parts (A-G). Part B contains concise guidance on hazard assessment. This covers information requirements on intrinsic properties of a substance under REACH, including the collection of information, non-testing approaches and the so-called integrated testing strategies for generating relevant information for each hazard.

The chapters relevant for classification and labelling are as follows:

- Chapter R.3 - Guidance on collection of available information;
- Chapter R.4 - Evaluation of information;
- Chapter R.6 - In-depth guidance on non-testing approaches;
- Chapter R.7 - Information on how to derive appropriate information for classification and labelling (hazard-specific guidance); and
- Chapter D.9 - Builds the bridge to the use of exposure scenarios in the context of the chemical safety report and the extended Safety Data Sheet.

Please note that these documents have not been updated after the adoption of CLP. Guidance given in these documents, including on suitability for classification and labelling, may therefore not be fully consistent with the CLP criteria.

Guidance on data sharing

This document provides detailed information and guidance on SIEFs and other data sharing issues, e.g. the obligations of **downstream users** as far as they are data holders ([↗ see also section 26 of this guidance document](#)).

Under development: **Guidance on the preparation and submission of proposals for harmonised classification**

Annex 1. Examples from the UN GHS pilot trials

Introduction

The examples provided have been designed in a way that they show the typical sequence of evaluation as laid down in CLP Article 9. They are based on the examples provided in the UN GHS Pilot Trials (*see UN document ST/SG/AC.10/C.4/2008/23*). The first example has been simplified for demonstration purposes.

Further examples providing detailed illustration of the many aspects of CLP can be found in Parts 3 and 4 of Module 2.

A1. Examples from the UN GHS pilot trials

A2. Glossary

A3. Additional sources of information

A4. The UN GHS and CLP

A1.1. Example of the Application of the Mixtures Classification Criteria: Hazard: Acute oral toxicity

The following example demonstrates the classification of a mixture for acute oral toxicity, taking account of the evaluation steps set out in CLP Article 9 and in Part 3.1 of Annex I to CLP. In this example, test data are given for all ingredients; for ingredient 2, there are only range data available which lie within one of the acute toxicity range estimates in Table 3.1.2 of Annex I to CLP. The ingredient information is set out in Table A1.1.

Table A1.1: Ingredient information

Ingredient	Weight (%)	Test data
Ingredient 1	16	LD50: 1,600 mg/kg
Ingredient 2	4	Acute toxicity range estimate: 300 < LD50 < 1,200
Ingredient 3	80	LD50: 1,050 mg/kg

Derivation of the mixture classification:

1. Classification via application of substance criteria is not possible since acute toxicity data was not provided for the mixture as a whole (*see CLP Article 9(1), 9(2) and 9(3) and paragraph 3.1.3.4 of Annex I to CLP*);
2. Classification via the application of bridging principles is not possible since data on a similar mixture was not provided (*see CLP Article 9(4) and paragraph 3.1.3.5.1 of Annex I to CLP*); and

3. Classification of the mixture based on ingredient data can be considered, in accordance with Article 9(4) and paragraph 3.1.3.6 of Annex I to CLP;
- applying the “relevant ingredients” concept from paragraph 3.1.3.3(a) means that all ingredients will be considered when applying criteria in paragraph 3.1.3.6;
 - data is available for all ingredients so criteria in paragraph 3.1.3.6.1 apply; and
 - ingredients 1, 2 & 3 are all included in the ATE(mixture) calculation because they have data that fall within a CLP acute toxicity category.

Apply the equation in paragraph 3.1.3.6.1¹¹:

$$\frac{100}{ATE_{mixture}} = \sum_n \frac{Ci}{ATE_i}$$

$$\frac{100}{ATE_{mixture}} = \frac{16}{1,600} + \frac{4}{500} + \frac{80}{1,050}$$

Result: ATE_{mixture} = 1,006 mg/kg. This means that based on the ingredient data, the mixture would have to be classified as category 4 of hazard class acute oral toxicity.

A1.2. Example of the Application of the Mixtures' Classification Criteria: Hazard: Skin corrosion / irritation

The following examples demonstrate the classification of a mixture for skin corrosion / irritation. In this example, expert judgement is applied, concluding that additivity of the hazards of the individual ingredients may not apply (*paragraphs 3.2.3.3.4 and 3.3.3.3.4 of Annex I to CLP*). The ingredient information is set out in Table A1.2.

¹¹ The figure “500” in the formula above is taken from Table 3.2 of Annex I to CLP (so-called converted acute toxicity point estimate).

Table A1.2: Ingredient and mixture information			
Ingredient	Weight (%)	Classification	Ingredient information
Ingredient 1	4	Skin Category 1	pH = 1.8
Ingredient 2	5	Skin Category 2	-
Ingredient 3	5	Skin Category 3	-
Ingredient 4	86	-	No data available
Mixture Information: The mixture has a pH = 4.0			

Derivation of the mixture classification:

- Classification via application of substance criteria is not possible since test data (other than a pH) was not provided for the mixture, see CLP Article 9(1) and 9(2) and paragraph 3.2.3.1.1 of Annex I to CLP:
 - the overall mixture pH of 4.0 does not result in classification in Category 1 since this does not fall within the criteria of $\text{pH} \leq 2$ or $\text{pH} \geq 11.5$, see paragraph 3.2.3.1.2 of Annex I to CLP;
- Classification via the application of bridging principles is not possible since data on a similar mixture was not provided, see CLP Article 9(4) and paragraph 3.2.3.2.1 of Annex I to CLP;
- Classification of the mixture based on ingredient data can be considered, see CLP Article 9(4) and paragraph 3.2.3.3 of Annex I to CLP; and
- Ingredient 1 with a pH = 1.8 is an ingredient for which additivity might not apply as described in paragraph 3.2.3.3.4.1 and summarized in Table 3.2.4. Expert judgment would be needed to determine whether or not additivity applies, which is to be based on the knowledge of the ingredients.

Given the limited information in this example, the classifier of this mixture chose to apply non-additivity as a conservative approach - without information on the mode of action of ingredient 1, the mixture could be corrosive regardless of the overall pH. Therefore, the criteria described in paragraph 3.2.3.3.4.3 were applied (i.e. "A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table 3.2.3, due to chemical characteristics that make this approach unworkable, should be classified as skin category 1A, 1B or 1C if it contains $\geq 1\%$ of a corrosive ingredient and as skin category 2 when it contains $\geq 3\%$ of an irritant ingredient").

Result: For this mixture, the classification was classified as skin category 1 because ingredient 1 (skin category 1) is in the mixture at a concentration above 1%

Annex 2. Glossary

Terms used in this guidance document

ADN means the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways annexed to resolution No. 223 of the Inland Transport Committee of the Economic Commission for Europe, as amended,

ADR means the European Agreement concerning the International Carriage of Dangerous Goods by Road under framework Directive 94/55/EC, as amended;

Aerosols means aerosol dispensers, any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state;

Alloy means a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means; alloys are considered to be mixtures for the purposes of CLP;

Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

Aspiration means the entry of a liquid or solid chemical substances or mixture into the trachea and lower respiratory system directly through the oral or nasal cavity, or indirectly from vomiting;

Carcinogen means a substance or a mixture of substances which induces cancer or increases its incidence

CLP or CLP Regulation means Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures;

CMR means a substance or mixture which is carcinogenic, mutagenic or toxic to reproduction

Corrosive to metals means materially damaging, or even destroying, metals by chemical action of a substance or a mixture;

Distributor means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties;

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Downstream user means any natural or legal person established within the Community, other than the **manufacturer** or the **importer**, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A **distributor** or a **consumer** is not a **downstream user**. A **re-importer**, exempted pursuant to Article 2(7)(c) REACH Regulation, shall be regarded as a **downstream user**;

DPD means the “Dangerous Preparations Directive (1999/45/EC)”;

DSD means the “Dangerous Substances Directive (67/548/EEC)”;

EINECS means “European Inventory of Existing Commercial Chemical Substances”;

Explosive article means an article containing one or more explosive substances;

Explosive substance means a solid or liquid substance (or mixture of substances) which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic substances are included even when they do not evolve gases;

Eye irritation means the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application;

Flammable gas means a gas having a flammable range with air at 20 °C and a standard pressure of 101.3 kPa;

Flammable liquid means a liquid having a flash point of not more than 60°C. **Flash point** means the lowest temperature (corrected to a standard pressure of 101.3 kPa) at which the application of an ignition source causes the vapours of a liquid to ignite under specified test conditions;

Flammable solid means a solid which is readily combustible, or may cause or contribute to fire through friction;

Gas means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa; or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa;

GHS means the “Globally Harmonised System of Classification and Labelling of Chemicals” developed within the United Nations (UN) structure;

Hazard category means the division of criteria within each hazard class, specifying hazard severity;

Hazard class means the nature of the physical, health or environmental hazard;

Hazard pictogram (sometimes also referred to as “pictogram” in this document) means a graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information;

Hazard statement means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard;

Hazardous means fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in parts 2 to 5 of Annex I of CLP;

IMDG Code means the “International Maritime Dangerous Goods Code” for the transport of dangerous goods by sea;

Import means the physical introduction into the customs territory of the Community;

Importer means any natural or legal person established within the Community who is responsible for import;

Intermediate means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance;

INCHEM refers to an Internet based tool providing a range of chemical safety related information produced by International Programme on Chemical Safety and the Canadian Centre for Occupational Health;

IUCLID means the International Uniform Chemical Information Database;

Label means an appropriate group of written, printed or graphic information elements concerning a hazardous substances or mixture, selected as relevant to the target sector (s), that is affixed to, printed on, or attached to the immediate container of a hazardous substance or mixture, or to the outside packaging of a hazardous substances or mixture (definition follows chapter 1.2 of the UN GHS);

Label element means one type of information that has been harmonised for use in a label, e.g. hazard pictogram, signal word;

Liquid means a substance or mixture which at 50 °C has a vapour pressure of not more than 300 kPa (3 bar), which is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa. A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to the ASTM D 4359- 90 test; or to the test for determining fluidity (penetrometer test)

prescribed in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);

M-factor means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present;

Manufacturer means any natural or legal person established within the Community who manufactures a substance within the Community;

Manufacturing means production or extraction of substances in the natural state;

Mixture means a mixture or solution composed of two or more substances (Note: “Mixture” (CLP) and “preparation” (REACH) are synonymous). However, UN GHS Chapter 1.2 includes the phrase, “in which they do not react” at the end of an otherwise identical definition;

Monomer means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

Mutagen means an agent giving rise to an increased occurrence of mutations in populations of cells and /or organisms;

Mutation means a permanent change in the amount or structure of the genetic material in a cell;

Notifier means the manufacturer or the **importer**, or **group of manufacturers or importers** notifying to the Agency;

Organic peroxide means a liquid or solid organic substance which contains the bivalent -O-O-structure and may be considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term also includes organic peroxide formulations (mixtures);

Oxidising gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does;

Oxidising liquid means a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material;

Oxidising solid means a solid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material;

Phase-in substance means a substance which meets at least one of the following criteria:

(a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);

(b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004 or on 1 January 2007, but not placed on the market by the **manufacturer** or **importer**, at least once in the 15 years before the entry into force of the REACH Regulation, provided the **manufacturer** or **importer** has documentary evidence of this; and

(c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004 or on January 2007, by the **manufacturer** or **importer** at any time between, 18 September 1981 and 31 October 1993 inclusive, and before entry into force of the REACH Regulation it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in the REACH Regulation, provided the **manufacturer** or **importer** has documentary evidence of this;

Placing on the market means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.

Polymer means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules should be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; and

(b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;

Precautionary statement means a phrase that describes recommended measure(s) to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use or disposal;

(Q)SAR means "(quantitative) structure-activity relationships";

Product identifier means details permitting the identification of the substance or mixture;

Pyrophoric liquid means a liquid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air;

Pyrophoric solid means a solid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air;

Pyrotechnic article means an article containing one or more pyrotechnic substances;

Pyrotechnic substance means a substance or mixture of substances designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions;

REACH and REACH Regulation means Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals;

Registrant means the **manufacturer** or the **importer** of a substance or the **producer or importer of an article** submitting a registration for a substance under the REACH Regulation;

Respiratory sensitiser means a substance that induces hypersensitivity of the airways following inhalation of the substance;

RID means The Regulations concerning the International Carriage of Dangerous Goods by Rail under framework Directive 96/49/EC [Annex 1 to Appendix B (Uniform Rules concerning the Contract for International Carriage of Goods by Rail) (CIM) of COTIF (Convention concerning international carriage by rail)], as amended;

SDS means “Safety Data Sheet”;

Self-heating substance means a solid or liquid substance, other than a pyrophoric substance, which, by reaction with air and without energy supply, is liable to self-heat; this substance differs from a pyrophoric substance in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days);

Self-reactive substance means a thermally unstable liquid or solid substance liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes substances or mixtures classified under CLP as explosive, organic peroxides or as oxidising;

Serious eye damage means the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application;

SIEF means a Substance Information Exchange Forum;

Signal word means a word that indicates the relative level of severity of hazards to alert the potential reader of the hazard; the following two levels are distinguished:

(a) Danger means a signal word indicating the more severe hazard categories; and

(b) Warning means a signal word indicating the less severe hazard categories;

Skin corrosion means the production of irreversible damage to the skin, namely visible necrosis through the epidermis and into the dermis, following the application of a test substance up to 4 hours;

Skin irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours;

Skin sensitiser means a substance that will induce an allergic response following skin contact. The definition for “skin sensitiser” is equivalent to “contact sensitiser”;

Solid means a substance or mixture which does not meet the definitions of liquid or gas;

Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any identified impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

Symbol means a graphical element intended to succinctly convey information;

UN GHS means the international criteria agreed by the United Nation Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures, called the “Globally Harmonised System of Classification and Labelling of Chemicals”;

UN RTDG means the United Nations Recommendations on the Transport of Dangerous Goods; and

Use means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

Organisations

Agency means the “European Chemicals Agency,” also known as the ECHA, established under the REACH Regulation;

CAS means “Chemical Abstract Service”;

Competent Authority (CA) means the authority or authorities or bodies established by the Member States to carry out the obligations arising from the CLP Regulation;

ECHA means the “European Chemicals Agency,” also known as “the Agency,” established under the REACH Regulation;

EU means the “European Union”;

ICAO means the “International Civil Aviation Organisation” and refers to Annex 18 to the Convention on International Civil Aviation “The Safe Transport of Dangerous Goods by Air”;

IUPAC means the “International Union of Pure and Applied Chemistry”;

NIOSH means the US “National Institute of Occupational Safety and Health”;

OECD means the “Organisation for Economic Cooperation and Development”; and

UN means the “United Nations”.

Annex 3. Additional sources of information

Further information

Please find here an overview of information sources and advice in relation to the CLP Regulation, in addition to the sources provided in section 10 of this guidance document.

A1. Examples

A2. Glossary

A3. Additional sources of information

A4. The UN GHS and CLP

1. **Module 1 on basic guidance to the CLP Regulation:** This document has been written to help you to find your way around the requirements of CLP. Should you require more specific guidance on the application of CLP to the classification of your substances and mixtures, please consult Module 2 of the guidance package related to the CLP Regulation.
2. **Member State CLP/REACH helpdesks:** Points of contact for questions on CLP and REACH are the helpdesks established in each Member State, cf. CLP Article 44. It is possible that your Member State Competent Authority will choose to combine their CLP and REACH helpdesks, but they are not obliged to do so. To find the contact details for your REACH helpdesk please consult the Agency website: http://echa.europa.eu/reach/helpdesk/nationalhelp_contact_en.html.
3. **REACH Guidance:** DG Enterprise - http://ec.europa.eu/enterprise/reach/index_en.htm - overview and links to further information, including additional guidance - http://ec.europa.eu/enterprise/reach/ghs_guidance_helpdesks_en.htm

Annex 4. The UN GHS and CLP

Background

The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) was agreed by the United Nations (UN) in Geneva in December 2002. The GHS is introduced in the EU legislative framework through the CLP Regulation which is legally binding and directly applicable in the Member States of the EU.

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Additional hazard classes

The introduction of the UN GHS hazard classes in the EU is based on the so-called “building block approach”, allowing the different countries and jurisdictions to introduce those hazard classes and categories in domestic law which they consider relevant.

CLP includes all of the hazard classes of the UN GHS. As CLP also builds on the previous system of classification and labelling, consisting of DSD and DPD, also the EU category of danger ‘*hazardous to the ozone layer*’ is taken up in CLP. It is expected that a corresponding hazard class will be adopted at UN level soon.

UN GHS categories not included in CLP

Based on the building block approach, CLP does not always include all hazard categories included in the UN GHS as they were not part of DSD, as shown in Table A 4.1.

Table A4.1: Hazard categories included in the UN GHS but not in CLP

Hazard classifications	UN GHS hazard categories not in CLP	Comments
Flammable liquids	Cat. 4	Flammable liquids with a flash point $\leq 93^{\circ}\text{C}$ are used for the classification of flammable aerosols
Acute toxicity	Cat. 5	
Skin corrosion/ irritation	Cat. 3	Mild irritant

Serious eye damage/ eye irritation	Cat. 2B	CLP Cat. 2 is equivalent to Cat. 2A of UN GHS
Aspiration hazard	Cat. 2	
Hazardous to the aquatic environment	Acute Cat. 2 and Cat. 3	

Additional labelling and packaging rules

CLP includes special rules not included in the UN GHS for substances and mixtures in small packaging (*CLP Article 29*), on supplemental hazard information (*Part I of Annex II to CLP*), on supplemental label elements for certain mixtures (*Part 2 of Annex II to CLP*) and for the provision of child-resistant fastenings and/or tactile warnings (*Part 3 of Annex II to CLP*). Also, it includes rules for the situation when a substance is both covered by CLP and by transport legislation.

Plant protection products

CLP contains a special rule for the labelling of plant protection products which states that you should include the following wording in addition to the requirements of Directive 91/414/EEC (*Part 4 of Annex II to CLP*):

EUH401 - “To avoid risks to human health and the environment, comply with the instructions for use.”

For more information about the classification and labelling of plant protection products please consult ^o section 24 of this guidance document.

