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GUIDANCE

Introductory Guidance on the CLP Regulation

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LEGAL NOTICE

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Introductory Guidance on the CLP Regulation

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Document History

Version	Comment	Date
n.a.	First edition	August 2009
Version 2.0 (not translated)	Fast-track update of the guidance limited to only: (i) Take into account the full entry into force of the CLP Regulation on the 1 June 2015 (i.e. remove the reference to the previous legislation); (ii) Take into account the end of the transition period for labelling mixtures according to the DPD and classifying their components according to the DSD; (iii) Remove obsolete and out of date information which is no longer relevant and would be now potentially misleading; (iv) Reformat the document in line with the current corporate identity. In particular the update includes the following: - Replacement of original Table of Content with new one according to ECHA guidance standard. - Deletion of original chapter 4 on transition to CLP (and consequently re-numbering of old chapter 5 onwards); relevant information on the applicable transitional provisions have been moved to a subchapter of chapter 3 ("Implementing CLP"). - Deletion of Figure 8.1 (in original chapter 8) because not in line with the current approach and potentially misleading. - Restructuring and update of chapter 9 (originally 10) on relevant sources of information. - Clarification in chapter 16 (originally chapter 17) on the requirements to update an SDS in force from 1 June 2015. Addition of the reference to the Article 31(3) of REACH as amended by CLP from 1 June 2015. - Addition in chapter 17 (originally 18), on the notification to the C&L Inventory, of the new available option consisting in the creation of a bulk XML file containing more C&L notifications. - Addition in chapter 18 (originally 19) of clarification that updated SDS must be provided to all recipients supplied with the substance or mixture within the preceding 12 months. - Deletion in chapter 19 (originally 20), on alternative chemical name, of text referring to obligations in place before 1 June 2015. - Reduction in chapter 21 (originally 22) of the information on how to submit a proposal for harmonised classification and labelling and provision of the reference to updated specific guidance. - Addition in chapter 25 (originally 26), on SIEFs, of the possibility	July 2015

	to contact ECHA Helpdesk to be provided with contact details of relevant SIEF members. - Split of Annex 2 (Glossary) into abbreviations and glossary and transfer of abbreviations to a new list at the beginning of the guidance. - Replacement throughout the document of the word "Community" with "Union" where not legal text quotation. - Update and addition of references to relevant guidance documents and other supporting material throughout the document.	
Version 2.1	Corrigendum limited to: - eliminate in Table 10 the indication of the obligation to fit with tactile warnings aerosols and containers fitted with a sealed spray attachment and containing substances or mixtures classified as presenting an aspiration hazard only. - update in Table 10 of the name of class "Flammable gases" to be in line with the 4th ATP.	August 2015

Preface

This document provides guidance on basic features and procedures laid down in Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation or simply "CLP") which entered into force on 20 January 2009 in the EU countries and has now relevance for European Economic Area (EEA) countries (i.e. it is implemented in the EU countries and in Norway, Iceland and Liechtenstein)[1].

The aim of the current update to this document is to provide an overview of the obligations under CLP, in particular after the end of the transition periods for classification, packaging and labelling[2] from the previous legislation[3]. For more detailed guidance on classification and labelling in accordance with the CLP criteria, and for information on general aspects concerning all hazard classes, we recommend that you consult the legal text of the CLP Regulation itself, including its annexes, together with the more specific guidance provided in the *Guidance on the Application of CLP Criteria* and the *Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 available at:* http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp.

We are aware that you may have to comply with the Regulation (EC) No1907/2006[4] (the REACH Regulation or simply "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.

[1] CLP was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 106/2012 of 15 June 2012 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement (OJ L 309, 8.11.2012, p. 6–6).

[2] Article 61 of CLP Regulation.

[3] Directive 67/548/EEC (Dangerous Substances Directive) and Directive 1999/45/EC (Dangerous Preparations Directive).

[4] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directive 91/155/EEC.93/67/EEC,93/105/EC and 2000/21/EC (OJ L 369,30.12.2006, corrected version in OJ l163, 29.05.2007,p.3).

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Abbreviations

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATP	Adaptation to Technical Progress (in this guidance "ATP" refers to an ATP to the CLP Regulation)
BPR	Biocidal Products Regulation; Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products repealing Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, as amended [OJ L 123, 24.4.98, p. 1], with effect from 1 September 2013
C&L Inventory	Classification and Labelling Inventory
CAS	Chemical Abstracts Service
CLH	Harmonised Classification and Labelling
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
CMR	Carcinogenicity, germ cell mutagenicity, reproductive toxicity
CSR	Chemical Safety Report
DPD	Dangerous Preparations Directive; Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations
DSD	Dangerous Substances Directive; Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
ECHA	European Chemicals Agency
EEA	European Economic Area
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EC	European Commission
EU	European Union

Fee Regulation	Commission Regulation (EU) No 440/2010 of 21 May 2010 on the fees payable to the European Chemicals Agency pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
ICAO	"International Civil Aviation Organisation" and refers to Annex 18 to the Convention on International Civil Aviation "The Safe Transport of Dangerous Goods by Air"
IUCLID	International Uniform ChemicaL Information Database
IUPAC	International Union of Pure and Applied Chemistry
M-factor	Multiplying factor
NIOSH	National Institute of Occupational Safety and Health
OECD	Organisation for Economic Cooperation and Development
PIC Regulation	Prior Informed Consent Regulation Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast) (OJ L 201 27.07.2012 p 60)
PPP	Plant Protection Product(s)
PPPR	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
(Q)SAR	(Quantitative) Structure-Activity Relationships
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety data sheet
SIEF	Substance Information Exchange Forum
UN	United Nations
UN RTGD	United Nations Recommendations on the Transport of Dangerous Goods
WHO	World Health Organisation

1. Introduction

1.1 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 (the CLP Regulation which entered into force on 20 January 2009[5], see http://echa.europa.eu/web/guest/regulations/clp/legislation). You will be introduced to 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 on the Application of the CLP Criteria* which provides also substance-specific guidance where this is relevant for a particular classification, e.g. for the aquatic classification of metals. For detailed guidance on the labelling and packaging requirements you are recommended to read the *Guidance on Labelling and Packaging in accordance with the CLP Regulation*[6].

Many provisions of CLP are closely linked to provisions under the REACH Regulation and other Union legislation. The most relevant links to REACH, to Regulation (EU) No 528/2012 on biocidal products (Biocidal Product Regulation or BPR) and to Regulation (EC) No 1107/2009 on plant protection products (Plant Protection Product Regulation or PPPR) are briefly explained in separate chapters of this guidance document. In addition, links with REACH are noted briefly in the individual chapters of this document, where appropriate.

1.2 Who is this guidance for?

This document has been written for suppliers of substances and mixtures and for those **producers or importers of certain specific articles**[7] who have to apply the rules for classification, labelling and packaging under CLP. Suppliers are **manufacturers of substances**, **importers of substances or mixtures**, **downstream users**, including **formulators** (producers of mixtures) **and re-importers**, and **distributors, including retailers, placing on the market substances on their own or in mixtures.** (see chapter 2 of this guidance document). This document is meant for those who already have a basic understanding of classification, labelling and packaging. This document will not explain everything from scratch, but will try to provide a good overview of the features of the CLP Regulation.

1.3 What is CLP, and why do we have it?

Trade in substances and mixtures is not only an issue relating to the internal (EU/EEA)[8] market, but also to the global market. Harmonised criteria for classification and labelling

[5] Since 1 June 2015, the CLP requirements fully apply also to mixtures.

[6] Both Guidance documents are available at http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp.

[7] 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 Articles 7 or 9 provide for registration or notification of a substance contained in an article.

[8] Please note that whenever there is a reference to the Union (EU) in this document, the term also covers the EEA countries Iceland, Liechtenstein and Norway. Please also note that with the entry into force of the Treaty of Lisbon in 2009, the term "Community" was replaced by "Union". The CLP Regulation had not yet been amended to implement this change at the time of drafting of this update and therefore the term "Community" is still used in some quotes from the legal text made within this document.

together with general principles of their application were carefully developed within the United Nations (UN) structure, with a view to facilitating worldwide trade while protecting human health and the environment. The result is called the Globally Harmonised System of Classification and Labelling of Chemicals the first edition of which was adopted in 2002 (GHS: http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html).

The CLP Regulation follows various declarations whereby the Union 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 Union 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.

The version of CLP to which this guidance currently refers is that based on the 4th revision of the GHS[9]. CLP additionally takes onboard some features and procedures from the previous EU system of classification and labelling, represented by the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD) that are not part of GHS. Therefore, CLP is similar to, but not identical to the way in which GHS is introduced into the legal framework of countries outside the EU (note that differences may exist between implementations in individual non-EU countries).

The CLP Regulation is legally binding across the Member States. It is directly applicable to all industrial sectors. CLP has superseded DSD and DPD. These directives, after a transitional period, were repealed, on 1 June 2015 (see chapter 3.3 of this guidance document).

1.4 What is hazard classification, labelling and packaging?

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 context, 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.

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 discussion 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**, must communicate the identified hazards of these substances or mixtures to other actors in the supply chain, including to consumers. 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 manage the associated risks.

CLP sets general packaging standards, in order to ensure the safe supply of hazardous

[9] Please note, the GHS is reviewed every two years.

substances and mixtures (CLP Recital 49 and CLP Title IV).

1.5 What about the assessment of risk?

The classification of a substance or a mixture reflects 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.

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

The European Chemicals Agency (ECHA or "the Agency") is an EU body which was originally established for the purpose of managing REACH. It plays a central role for the implementation of REACH and CLP (as well as of the Biocidal Products Regulation and PIC Regulation[10]), to ensure consistency across the EU.

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

[10] Prior Informed Consent Regulation (EU) No 649/2012.

2. Roles and obligations under CLP

2.1 Roles under CLP

The obligations placed on suppliers 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 1, which are based on the definitions contained in 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 (ECHA Guidance documents are available at http://echa.europa.eu/guidance-documents/guidance-on-reach).

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, independently 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.

Table 1 Identifying your role under CLP

Descriptions		Your role under CLP[1]
1	A natural or legal person established within the EU who produces or extracts a substance in the natural state within the EU.	**Manufacturer** [2]
2	A natural or legal person established within the EU who is responsible for the physical introduction into the customs territory of the EU.	**Importer**
3	A natural or legal person established within the EU, 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** [3] **(including formulator / re-**

		importer)
4	A natural or legal person established within the EU, 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 EU; 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 (4)**

Notes:

(1) It is important to note that CLP does not recognise the role of Only Representative.

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

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

(4) 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.

2.2 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 1. Tables 2 to 5 set out the obligations for each of the roles and indicate the key chapters of this guidance document in each case.

Table 2 Obligations of a manufacturer or importer

	Obligations under CLP	Key Chapters
1	You must classify, label and package substances and mixtures according to CLP before placing them on the market. You must 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 (CLP Article 4).	6
2	You must classify in line with CLP Title II (CLP Articles 5-14).	7 – 12
3	You must label in line with CLP Title III (CLP Articles 17-33).	13 – 15
4	You must package in line with CLP Title IV (CLP Article 35).	13 and 15
5	You must notify the classification and labelling elements to the classification and labelling inventory established at the Agency in case you place substances on the market (CLP Article 40).	17
6	You must 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 must, without undue delay, carry out a new evaluation of the relevant classification (CLP Article 15).	18
7	You must update the label following any change to the classification and labelling of that substance or mixture, in certain cases without undue delay (CLP Article 30).	15 and 18
8	If you have new information which may lead to a change of the harmonised classification and labelling elements of a substance (Part 3 of Annex VI to CLP), you must submit a proposal to the Competent Authority in one of the Member States in which the substance is placed on the market (CLP Article 37(6)).	21
9	You must 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 (CLP Article	20

	49).	

Note:

Importers and downstream users placing mixtures on the market must 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 3 Obligations of a downstream user (incl. formulator / re-importer)

Obligations under CLP		Key chapters
1	You must classify, label and package substances and mixtures according to CLP before placing them on the market. (CLP Article 4). 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.	6
2	In case you change the composition of the substance or mixture you place on the market: you must classify in line with CLP Title II (CLP Articles 5-14).	7 – 12
3	You must label in line with CLP Title III (CLP Articles 17-33).	13 – 15
4	You must package in line with CLP Title IV (CLP Article 35).	13 and 15
5	You must 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 must, without undue delay, carry out a new evaluation of the relevant classification (CLP Article 15).	18

Obligations under CLP		Key chapters
6	You must update the label following any change to the classification and labelling of that substance or mixture, in certain cases without undue delay (CLP Article 30).	13 and 18
7	If you have new information which may lead to a change of the harmonised classification and labelling elements of a substance you must submit a proposal to the Competent Authority in one of the Member States in which the substance is placed on the market (CLP Article 37(6)).	21
8	You must 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 (CLP Article 49).	20

Note:

Importers and downstream users placing mixtures on the market must 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 4 Obligations of a distributor (incl. retailer)

Obligations under CLP		Key chapters
1	You must label and package the substances and mixtures you place on the market (CLP Article 4).	13 – 15
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 (CLP Article 4).	6 and 13
3	You must label in line with CLP Title III (CLP Articles 17-33).	13 – 15
4	You must ensure the packaging is in line with CLP Title IV (CLP Article 35).	13 and 15
5	You must 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 (CLP Article 49). In case you take over the for a substance or mixture derived by another actor up in the supply chain, you must 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.	20

Table 5 Obligations of a producer of certain specific articles

Obligations under CLP		Key chapters
1	In case you produce and place on the market *an explosive article* as described in section 2.1 of Annex I to CLP, you must classify, label and package this article according to CLP before placing it on the market (CLP Article 4). The same obligations apply as for importers, see Table 2.2 above, apart from the obligation to notify the Agency.	6 – 15 18, 20, 21
2	As a producer or importer of articles, you must 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 (CLP Article 4). You must classify in line with CLP Title II (CLP Articles 5-14).	6 – 11

3. Implementing CLP

3.1 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, identify 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 the REACH Regulation, Regulation (EU) No 528/2012 on biocidal products, Regulation (EC) No 1107/2009 on plant protection products and CLP are closely interlinked, it is recommended to plan CLP processes together with processes related to REACH and these other regulations, if applicable.

3.2 What do you have to do?

As a manufacturer, importer or downstream user you have to classify your substances and mixtures, which may previously have been classified according to DSD or DPD, according to the CLP criteria. You must make sure their labels and packaging are in compliance with the CLP requirements, and that the safety data sheets (SDS) according to Article 31 and Annex II to REACH[11] reflect this information in accordance with CLP (CLP Article 4). CLP includes a transitional period for the implementation of its requirements, setting specific timelines for implementing the changes. Information about the transitional period, which is still applicable at the time of publication of this Guidance, is indicated in chapter 3.3.

In connection with the mixture classification, you may need to decide if and to what extent you can use the translation tables provided in Annex VII to CLP, translating the DSD and DPD classifications into closely corresponding or minimum CLP classifications (see chapter 8 and chapter 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 you, for example in SDSs that accompany substances and mixtures (CLP Article 4 (5)).

The deadlines for any changes to be made are set out in chapter 3.3 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 mixtures[12]. You may be able to use the Annex VII translation tables if you have no access to any data on your substances or mixtures. In such a situation you should take note of the guidance on the use of these tables which is available in chapter 1.7.2 of the *Guidance on the Application of the CLP Criteria*. It should be noted that some of the substances or mixtures that were not classified as dangerous under the DSD and DPD might have to be classified as hazardous under CLP; although conceptually similar, the coverage of CLP and the DSD or DPD is different;
- 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 have implemented CLP and how it affects 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 SDSs. 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:

[11] As of 1 June 2015, as amended by Regulation (EU) 2015/830.

[12] 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.

- 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 invest in a new system or update an existing one?
- how will I generate new labels? and
- packaging – are all of my packages in accordance with CLP?

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

- 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 III[13]);
  - how you dispose of hazardous wastes; and
  - safety at work and protective clothing for your employees.

3.3 Transition to CLP

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

From 1 June 2015, mixtures must be classified, labelled and packaged, before placing on the market, in accordance with CLP only. For substances the same obligation to classify, label and package according to CLP has already applied since 1 December 2010 – with the **additional** obligation to classify substances[14] also according to the DSD until 1 June 2015 (provided in the SDS). Thus for both substances and mixtures **only** classifications according to CLP are needed from this date.

However, mixtures already classified, labelled and packaged according to DPD and placed on the market before 1 June 2015 will only have to be re-labelled and re-packaged at the latest by 1 June 2017.

Substance and mixture classifications in accordance with CLP must be provided in the SDS for both substances and mixtures. There is no longer a requirement to provide in the SDS the DSD classifications either of substances themselves or of component substances in mixtures or the DPD classifications for mixtures; only CLP classifications are now mandatory. See the ECHA *Guidance on the compilation of safety data sheets* for more information.

[13] Directive 2012/18/EU amending and subsequently repealing (from 1 June 2015) Council Directive 96/82/EC.

[14] (and any mixtures classified, packaged and labelled according to CLP "early").

4. CLP similarities with and differences from DSD / DPD

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, just as the DSD and DPD were. It does not cover the transport of chemicals, however, Article 33 of CLP provides certain rules regarding the labelling of packaging also used for transport. 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 biocidal products, the labelling elements introduced through CLP may be complemented by further elements which are required by the relevant product-specific legislation.

4.1 Classification of substances

The EU has taken up in CLP all hazard classes from the GHS. However, within the hazard classes, some of the hazard categories were not taken up because they were not reflected in the DSD categories of danger, see also the explanation on the "building block approach" in Annex 4 to this document.

While the overall scope of classification under CLP is comparable with that under the DSD and DPD, 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 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 scope of the 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).

In addition, there are elements which were part of the DSD or DPD, but which are not included in the UN GHS. Under the DSD, certain hazards and properties led to additional labelling, 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 the 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.

Table 6 shows the hazard classes included in CLP. Each class includes one or more hazard categories.

Table 6 CLP hazard classes and categories

Physical hazards
Explosives (Unstable explosives, Divisions 1.1, 1.2, 1.3, 1.4, 1.5, and 1.6)
Flammable gases (including chemically unstable gases) (Categories 1 and 2; Categories A and B)
Aerosols (Categories 1, 2 and 3)
Oxidising gases (Category 1)
Gases under pressure (Compressed gas, liquefied gas, refrigerated liquefied gas, dissolved gas)
Flammable Liquids (Categories 1, 2 and 3)
Flammable solids (Categories 1 and 2)
Self-reactive substances and mixtures (Types A, B, C, D, E, F, & G)
Pyrophoric liquids (Category 1)
Pyrophoric solids (Category 1)
Self-heating substances and mixtures (Categories 1 and 2)
Substances and mixtures which in contact with water emit flammable gases (Categories 1, 2 and 3)

Oxidising liquids (Categories 1, 2 and 3)
Oxidising solids (Categories 1, 2 and 3)
Organic peroxides (Types A, B, C, D, E, F & G)
Corrosive to metals (Category 1)

Health hazards
Acute toxicity (Categories 1, 2, 3 and 4)
Skin corrosion/irritation (Categories 1[15], 1A, 1B, 1C and 2)
Serious eye damage/eye irritation (Categories 1 and 2)
Respiratory or skin sensitisation (Category 1, Sub-categories 1A and 1B)
Germ cell mutagenicity (Categories 1A, 1B and 2)
Carcinogenicity (Categories 1A, 1B and 2)
Reproductive toxicity (Categories 1A, 1B and 2) plus additional category for effects on or via lactation
Specific target organ toxicity (STOT) – single exposure ((Categories 1, 2) and Category 3 for narcotic effects and respiratory tract irritation, only)
Specific target organ toxicity (STOT) – repeated exposure (Category 1 and 2)
Aspiration hazard (Category 1)
Environmental hazards
Hazardous to the aquatic environment (Category Acute 1, Category Chronic 1, 2, 3, and 4)
Additional hazards

[15] Please note that with the implementation of the 8th ATP into CLP it will be clarified that classification in Category 1 will be possible where data is not sufficient for sub-categorisation for both substances and mixtures.

Hazardous to the ozone layer (Category 1)

4.2 Hazardous versus Dangerous

All substances and mixtures meeting the criteria of one or more of the hazard classes in CLP are considered hazardous. However, other pieces of EU legislation may still make reference to substance or mixture classifications as dangerous as defined in the DSD. Please find more information on this in chapter 22 of this guidance document.

4.3 Classification of mixtures

As in the previous DPD legislation, 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 the DPD – in contrast to the 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. Where calculations are required, the formulae often differ from those used under the 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 the DSD and DPD (CLP Article 9(3) and 9(4)).

4.4 Labelling

CLP replaced 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 introduced the two UN GHS signal words 'Danger' and 'Warning' to indicate the severity of a hazard as a new feature in EU legislation (see chapter 13 of this guidance document). However, CLP does not have labelling elements that correspond to the DSD indications of danger.

4.5 Harmonised classifications

In addition to self-classification where manufacturers, importers and downstream users have to identify hazards and classify substances and mixtures themselves, CLP also includes provisions for harmonised classification of substances to be applied directly (see chapter 6, chapter 7 and chapter 26 of this guidance document). Proposals for harmonised classification and labelling may be submitted either by Member State Competent Authorities or in some cases by manufacturers, importers and downstream users (see chapter 21 of this guidance document). Such proposals may in general only relate to substances which are carcinogenic, mutagenic or toxic to reproduction (CMR substances) and to respiratory sensitisers. Proposals for a harmonised classification which refers to other substance properties may also be submitted to the Agency if justification is provided demonstrating the need for harmonised classification and labelling at EU level (CLP Article 36(3))[16].

[16] Note also that substances that are active substances in the meaning of the Regulation (EU) No 528/2012 (BPR) on biocidal products or under Regulation (EC) No 1107/2009 (PPPR) on plant protection products are normally subject to harmonised classification and labelling (see chapters 23 and 21).

Harmonised classifications for substances listed in Annex I to the 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 to CLP.

5. CLP and DSD / DPD – key terms compared

5.1 Terms used for classification and labelling

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 7 presents the key terms from CLP and comparison with DSD/DPD (see also glossary in Annex 2 to this guidance).

Table 7 Key terms - DSD and DPD as compared to CLP

Terms Used	CLP	DSD / DPD
Mixture/s	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 (and REACH) definition of a mixture differs slightly from that of the UN GHS which may well be applied outside of the EU.	Term not used in DPD; identical to definition of 'preparation' in DPD (DPD Article 2).
Hazardous	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).	Term not used in DSD or DPD. Similar to term "dangerous" in DSD.
Hazard class / hazard category	The nature / severity of a physical, health or environmental hazard (CLP Article 2(1) and 2(2)).	Term not used in DSD / DPD. The terms "Category of Danger" was used with a similar meaning.

Pictogram	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 (CLP Article 2(3)). For example, this pictogram indicates an oxidising substance or mixture: 	Term not used in DSD. Similar but not identical to the danger symbols used under DSD and DPD.
Signal word	The words 'Danger' or 'Warning' are used to indicate the severity of the hazard (CLP Article 2(4)).	No equivalent in DSD or DPD.
Hazard statement	Hazard statements describe the nature of the hazards of a substance or mixture, including, where appropriate, the degree of hazard (CLP Article 2(5)). For example, H315: Causes skin irritation.	Term not used in DSD / DPD; instead, "risk phrase" was used. Similar, but not identical to the risk phrases used under DSD.

Precautionary statement	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 (CLP Article 2(6)). For example, P102: Keep out of reach of children.	Term not used in DSD or DPD; instead, "safety phrase" was used. Similar but not identical to the safety phrases under DSD (DSD Article 10).
Supplier	Any **manufacturer**, **importer**, **downstream user** or **distributor** placing on the market a substance, on its own or in a mixture, or a mixture (CLP Article 2(26)), see also chapter 2 of this guidance document.	Term not used in DSD or DPD.
Substance(s)	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 (CLP Article 2(7)).	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 (DSD Article 2).

6. General features of classification

6.1 Classification

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

- Classification triggered by **CLP** (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 must classify these substances or mixtures before placing them on the market, regardless of the 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 must 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 labelling and packaging of a substance or mixture is 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 is in accordance with CLP Titles III and IV (CLP Article 4(4)).

The classifications of all substances notified under CLP or registered under REACH are included in a classification and labelling inventory established at the Agency (CLP Article 42). The inventory indicates whether a classification is harmonised or whether it has been agreed between two or more notifiers or registrants.

REACH

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) (REACH Article 7(2)). The information to be provided also includes the use(s) of the substance(s) in the articles and the use(s) of the articles (REACH Article 7(4)).

6.2 Self-classification and harmonised classification

CLP includes provisions for two types of classification: self-classification and harmonised classification. If you are not familiar with these terms, 'self-classification' and 'harmonised 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 5 of chapter 2 of this document.

The requirement to self-classify is set out in CLP as it was under the DSD (and DPD). Under CLP all substances that do not have a harmonised hazard classification (see below) or where a harmonised classification covers only selected hazards classes or differentiations, have to be self-classified 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, and
- downstream users including formulators (producing mixtures).

Mixtures must always be self-classified by downstream users[17] or importers of mixtures.

One of the aims of a Substance Information Exchange Forum (SIEF) is to agree on the classification and labelling for the same substance where there is a difference in the classification and labelling of the substance between potential registrants (REACH Article 29).

Harmonised classification: the decision on classification for a particular hazard of a substance is taken at EU level (see also chapter 21 of this guidance document). Harmonised classifications of substances are included in the Tables of Part 3 of Annex VI to CLP. Harmonised classification applies to substances only.

The use of a harmonised classification and labelling of a substance (when one exists) 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 (producing mixtures) and distributors. For thousands of substances harmonised classification and labelling were listed in Annex I to the DSD. Upon entry into force of CLP Annex I to DSD was repealed (see chapter 7.1 for more information on the transfer of the existing information to the new system).

Harmonised classification and labelling under DSD normally considered all categories of danger. Under CLP, harmonisation of classification applies primarily to CMR properties and respiratory sensitisation. In addition, harmonisation of classification for other properties is done on a case-by-case basis. This means that for those end-points not covered by a harmonised classification, the manufacturer, importer or downstream user has to perform a self-classification. Substances regulated under Regulation (EU) No 528/2012 (BPR) on biocidal products or under Regulation (EC) No 1107/2009 (PPPR) on plant protection products are normally subject to harmonised classification and labelling for all hazardous properties (CLP Article 36(2)). For further information see chapter 21 and chapter 23 of this guidance document.

[17] As stated above, downstream users may also take over the classification derived by another actor in the supply chain provided that he does not change the composition of the substance or mixture.

7. Using harmonised classifications

7.1 Background

In order to take full account of the work and experience accumulated under the DSD, all harmonised classifications as well as most of the specific concentration limits of substances listed in Annex I to the DSD have been transferred to Part 3 of Annex VI to CLP. Furthermore, 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 the same Annex contains the original and non-translated Annex I to DSD.

When preparing Table 3.1 of Annex VI to CLP, the classification according to the DSD criteria sometimes did 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 classifications other than the minimum classifications must be applied are set out in point 1.2.1 of Annex VI to CLP.

Table 3.1 of Annex VI to CLP is continuously updated whenever the Commission has decided on further harmonised classifications and the updates are published as ATPs to CLP[18].

7.2 How to use the harmonised classifications

As said in chapter 6.2, the use of a harmonised classification and labelling of a substance (when one exists) is mandatory. For those end-points not covered by a harmonised classification, the manufacturer, importer or downstream user has to perform a self-classification.

A harmonised classification may include a Specific Concentration Limit (SCL) or a multiplication factor (M-factor). **SCLs** can be lower or higher than the generic concentration limits defined in Annex I to CLP and are included in the tables of Part 3 of Annex VI to CLP. Substances with a harmonised classification for the aquatic environment may have been assigned an **M-factor** which is the equivalent to an SCL set for other hazard classes (see also chapter 1.5 of the *Guidance on the Application of the CLP Criteria*). 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 be transferred from Annex I to DSD to Annex VI to CLP, e.g. in cases of a minimum classification under CLP. The minimum classification for a category is indicated by the asterisk (*) in the entry in Table 3.1 of Annex VI to CLP.

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 must set an M-factor. When a mixture including the substance is classified using the summation method, this M factor must be used.

[18] See for more information and for the list of published ATPs, the CLP page on the ECHA website at: http://echa.europa.eu/web/guest/regulations/clp/legislation.

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.

8. Using the translation tables

8.1 Translation of existing classifications

Annex VII to CLP provides a translation table for **manufacturers**, **importers** and **downstream users** to translate previously existing DSD or DPD classifications to CLP classifications. You may use these translation tables in case you or your supplier had already classified a mixture[19] according to DPD before 1 June 2015 and you have no further data available for the mixture and for the hazard class considered (see also the guidance given in chapter 1.7 of *the Guidance on the Application of the CLP Criteria*). In other words, the use of the translation table allows you to assign CLP classifications to your 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 for which there is a reasonable correlation between the DSD/DPD and CLP classifications. 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 arises, 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 only be taken as an indication of possible classification, because of the differences in concentration limits and calculation methods in CLP. In the particular case of "no classification" under the DPD, the table should **not** be used as there is no reasonable indication about a potential translation outcome.

Please note that whenever you have data on the mixture or the substances in the mixture, e.g. from safety data sheets supplied to you, evaluation and classification must be done in accordance with CLP Articles 9 to 13 (and the introduction to Annex VII to CLP).

[19] The use of the translation table assisted in the translation from DSD to CLP classification also of substances which were classified in accordance with the DSD before 1 December 2010. Since that date all substances must be classified in accordance with CLP.

9. Sources of information

9.1 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 chapter 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 chapter 2 of this guidance document, you may already have classified it under the DSD or DPD. You can then check what kind of information or data are already available in-house.

Supplier

A relevant source of information is an up-to date safety data sheet or other format of safety information received from your supplier(s) for the substance or mixture.

REACH (substances)

You can use the information you produce for compliance with REACH or that you obtain through information sharing in a SIEF (see also chapter 25 of this guidance document). In this situation, you may also refer to *the Guidance on information requirements and chemical safety assessment*, in particular to Chapter R.3, where collection of information is described in depth (see also chapter 26 of this guidance document).

You may also be able to obtain and use information for substances and mixtures evaluated under other EU 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://www.echa.europa.eu/web/guest/information-on-chemicals).

C&L Inventory

The Classification and Labelling Inventory on the ECHA website contains the classifications harmonised at EU-level (tables 3.1 and 3.2 of Annex VI to CLP) and classifications of substances as provided by the manufacturers and importers in their C&L notifications or REACH registration dossiers. There can be multiple classifications for the same substance due to, for example, the different composition, form or physical state of the substance placed on the market[20].

9.2 Other information sources

Information on the hazardous properties of substances can be sourced in databases which are accessible on the internet or from scientific journals. While Chapter R.3.4 of the

[20] Please, note that the C&L Inventory is subject to ECHA's legal notice http://echa.europa.eu/web/guest/legal-notice.

Guidance on information requirements and chemical safety assessment on the ECHA website (http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment) lists quite a number of major available databases 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.

EU information and data sources:

- ECHA databases: http://echa.europa.eu/information-on-chemicals
- EFSA (European Food Safety Authority, for active substances of plant protection products): http://www.efsa.europa.eu/

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 the related legal instruments (ADR, RID, ADN, IMDG Code and ICAO (see Annex 2 to this guidance document)) regulating the transport of dangerous goods. You may be able to use a 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 make use of 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 the data which are necessary for an unambiguous classification in accordance with 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 may even 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 now required by CLP to derive a CLP-compliant classification.

For selected 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://www.echemportal.org/echemportal/index?pageID=0&request_locale=en;
- 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/.

9.3 Testing

Having reviewed all available relevant sources of information, you may need to consider testing (see chapter 10 of this guidance document).

10. The role of testing in CLP

10.1 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 that 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 chapter 1.2 of the *Guidance on the Application of the CLP Criteria*).

10.2 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, which gives test methods and procedures normally used for classification of substances and mixtures for transport. This is available at http://www.unece.org/trans/danger/publi/manual/manual_e.html. 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[21], new testing must be carried out in compliance with a recognised quality system or by laboratories complying with a relevant recognised standard, such as EN ISO/IEC 17025[22]. Further guidance on this is provided in Part 2 of the *Guidance on the Application of the CLP Criteria*.

10.3 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)SARs, 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 directly applied to the criteria or to exploit available data on

[21] CLP Article 8(5).

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

mixtures that are similar to the one to be classified (CLP Article 9). Animal testing must only be undertaken when no other alternatives are available that provide adequate reliability and quality of data (CLP Article 7). New testing not involving animals may be performed where this warrants a more appropriate classification, e.g. 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 (CLP Article 7). Testing on non-human primates is prohibited (CLP Article 7).

In general, any new testing must be carried out in accordance with the test methods set out in Regulation (EC) No 440/2008; alternatively, the testing can be based on sound scientific principles that are internationally recognised or on internationally validated methods. Testing must 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 chapter 1.2 of the *Guidance on the Application of the CLP Criteria*). Moreover, new testing involving animals must be carried out in compliance with the principles of good laboratory practice and respect the rules of Directive 2010/63/EU. 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 must 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 must be based on the ingredient substance properties (CLP Article 6(4)). However, for alloys, there may be exceptions to this rule, see Annex IV of the *Guidance on the Application of the CLP Criteria*.

For further information in relation to individual hazards, please refer to chapters 2 to 4 of the *Guidance on the Application of the CLP Criteria*.

11. Classifying substances

11.1 Basic steps for classifying substances

There are four basic steps for classifying substances, as set out in Figure 1:

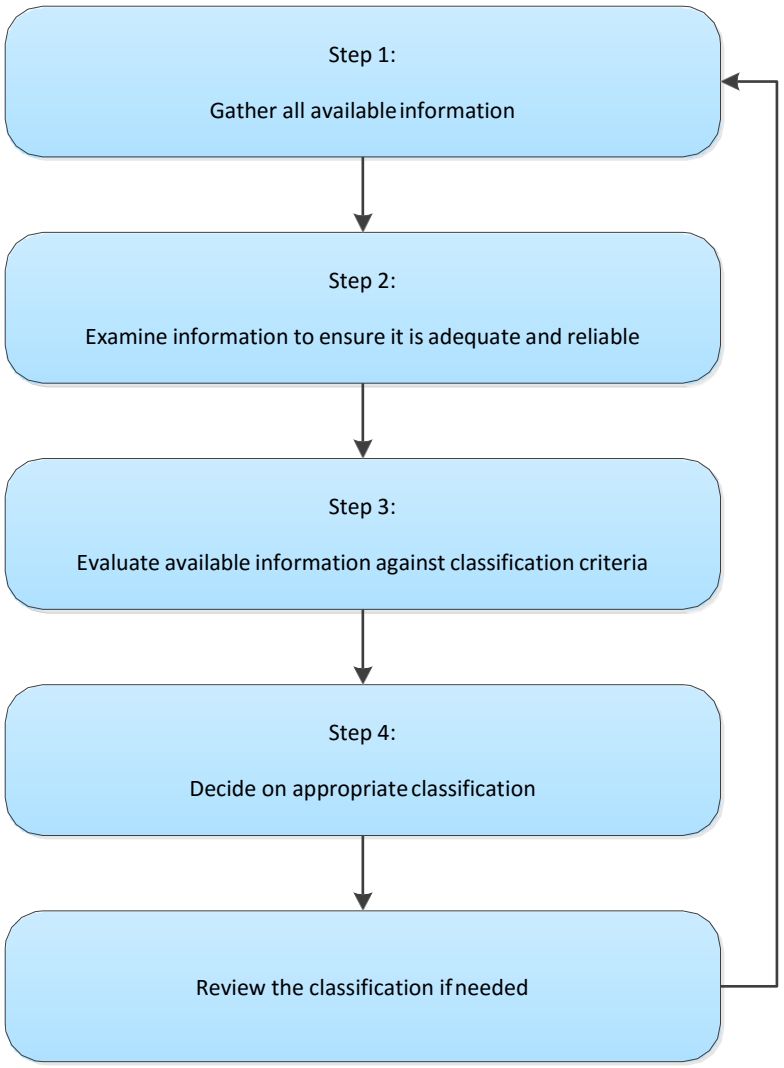

Figure 1 Four basic steps for classifying substances

11.2 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 in accordance with 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, and which are referred to in Part 2 of Annex I to CLP;

- 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 chapter 9 and 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 related to that specific hazard. In other words: You should check Annex VI first before starting to gather information.

REACH

One or several SIEF(s) need to be (or to have been) 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 (REACH Article 26 and 27).

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 (REACH Article 30). 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 (REACH Article 27).

11.3 Examine information to ensure it is adequate and reliable

You should consider whether you have the expertise to make a judgement about the adequacy and validity[23] 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 chapter 1.2 of the *Guidance on the Application of the CLP Criteria*.

11.4 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 class defined under CLP for which you have information.

If you cannot directly apply the classification criteria of a hazard class to the information you have, a weight of evidence determination requiring expert judgement will be needed. (see section 1.1.1 of Annex I to CLP and section 1.2 of Annex XI to REACH).

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, as a last resort, you may decide to perform new testing provided that you have exhausted all other means of generating information (see also chapter 10 of this guidance document).

Useful information on the hazard types is provided in the document "Notes and tips on hazard types" available on the mixture classification web page at

[23] More information on evaluation of the available information is provided in the *Guidance on Information requirements and Chemical Safety Assessment,* Chapter R.4.

http://echa.europa.eu/support/mixture-classification/evaluate-information-against-classification-criteria.

11.5 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 chapter 13 and chapter 16 of this guidance document). This exercise must be repeated for each hazard class defined under CLP for which you have information.

See also chapter 24 on the obligation under REACH triggered by the classification.

REACH

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)):

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

shall also include the steps of exposure assessment and risk characterisation (REACH Article 14(4)).

Together with assigning a classification, you must set so-called "specific concentration limits" (SCLs) where adequate and reliable scientific information shows that the hazard of the substance (e.g. as an impurity) 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).

For the aquatic toxicity classifications acute category 1 and chronic category 1, instead of SCLs you must set so-called "M-factors" (multiplication factors).

Specific concentration limits may not be set for harmonised classifications. Also M-factors for harmonised classifications can only be set by the manufacturer, importer or downstream user where no M-factor is given in Part 3 of Annex VI to CLP.

Further details on setting specific concentration limits and M-factors are provided in Part 1.5 of the *Guidance on the Application of the CLP Criteria*.

Please, note that the classification may need to be reviewed for many reasons (see the classification web page at http://echa.europa.eu/support/mixture-classification/).

12. Classifying mixtures

12.1 New features under CLP

Like the DPD, the classification of mixtures under CLP is for the same hazards as for substances. According to the tiered approach, available data on the mixture as a whole should primarily be used to determine the classification, except for the CMR properties and the biodegradation and bioaccumulation properties. If there is no data on the mixture, further approaches to mixture classification can be applied which may partly differ from those under DPD. For example, you may now apply the so-called bridging principles for certain health and environmental hazards, using data on similar tested mixtures and information on individual hazardous ingredient substances. When calculations are required, 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 of CLP 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.

12.2 Flexible approaches for different sets of information

The classification of mixtures involves the same basic steps as the classification of substances; see Figure 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 the webpage on mixture classification on the ECHA website (http://echa.europa.eu/web/guest/support/mixture-classification) and chapter 1.6 of the *Guidance on the Application of the CLP Criteria*.

As 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 1.6.4 of the *Guidance on the Application of the CLP Criteria*). Such compositional data may be available in the safety data sheet for the mixture, but further dialogue with the supplier may be necessary to obtain additional information.

If 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 in chapter 1.7 of the *Guidance on the Application of the CLP Criteria*: 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 chapter 8 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):

- 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 determination[24] (CLP Article 9(3) and section 1.1.1 of Annex I to CLP);

- 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

- for health and environmental hazards only: classification based on calculation or on concentration limits, including specific concentration limits and M-factors, in case substances which are classified for the particular hazard are present in the mixture. In this case you should also use any harmonised classifications for the substances present in the mixture, including any specific concentration limits and 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* under REACH on the Agency website: (http://echa.europa.eu/guidance-documents/guidance-on-reach);

- the bridging principles in chapter 1.6.3.2 of the *Guidance on the Application of the CLP Criteria*;

- the calculation methods in chapter 1.6.3.4 of the Guidance on the Application of the CLP Criteria; and

- the concentration limits, including specific concentration limits and M-factors, in chapter 1.6.3.4 of the *Guidance on the Application of the CLP Criteria*.

[24] 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 chapter 1.6 of the *Guidance on the application of the CLP criteria*.

13. Labelling

In this chapter an overview of the obligations related to labelling is provided. More detailed information is given in the *Guidance on labelling and packaging in accordance with the CLP Regulation,* available on the ECHA website.

13.1 What do you have to label?

A substance or mixture contained in packaging must be labelled in accordance with the CLP rules:

- if the substance or the mixture itself is classified as hazardous[25]; or
- if it is a mixture containing one or more substances classified as hazardous above the concentrations 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 applies (CLP Article 25(6)); and
- if it is an explosive article as described in Part 2.1 of Annex I to CLP.

Both substances and mixtures must be labelled according to the CLP requirements. A transitional period applies only to mixtures labelled in accordance with the DPD and already placed on the market before 1 June 2015. These mixtures must be relabelled latest on the 1 June 2017.

13.2 Who has to label?

In case you are a **manufacturer**, **importer**, **downstream user** (including formulator) or **distributor** (including retailer) you must 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 (see chapter 2 of this guidance document).

13.3 How do you have to 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 8 below:

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

Table 8 Label (and pictograms) sizes, as defined in section 1.2.1 of Annex I to CLP

Capacity of the package	Dimensions of label (in millimetres)	Dimension of each pictogram (in millimetres)
≤ 3 litres	If possible at least 52 x 74	Not smaller than 10 x 10 If possible, at least 16 x 16
> 3 litres but ≤ 50 litres	At least 74 x 105	At least 23 x 23
> 50 litres but ≤ 500 litres	At least 105 x 148	At least 32 x 32
> 500 litres	At least 148 x 210	At least 46 x 46

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 chapters 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, depending on the layers of packaging, when CLP labelling, transport labelling (or marking) or both are necessary (CLP Article 33).

13.4 In which language must the label be written?

Your labels must 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[26]. 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).

[26] Note that ECHA has published the table "Languages required for labels and safety data sheet" which is available on the labelling web page at http://echa.europa.eu/regulations/clp/labelling.

13.5 What information is required on the label?

If your substance or mixture requires labelling and is contained in packaging, it should include the labelling elements according to Article 17 of CLP:

- 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 must be clearly and indelibly marked on your labels. You must 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;
- 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;
- substances or mixtures classified as corrosive to metals but not corrosive to skin and/or eyes.

13.6 Product identifiers

You must use the same product identifiers on the labels as in 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 name[27], 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 need to 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 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) (see chapter 19 of this guidance document).

13.7 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

[27] 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.

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 must allow the hazard pictogram and its background to be clearly visible. Hazard pictograms are the shape of a square set at a point (diamond shape), and must 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 minimum surface area of the label as defined in Table 1.3 of section 1.2.1 of Annex I of CLP (and reported in Table 8 of subchapter 13.3 above), but the minimum area must not be less than 1 cm^2.

13.8 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.

13.9 Hazard statements

Your labels must 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 must 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 must be grouped together with the precautionary statements of the same language on the label (see below).

13.10 Precautionary statements

Your labels must 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 is provided in the *Guidance on labelling and packaging in accordance with the CLP Regulation* available on the ECHA website.

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

13.11 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 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 9.

Table 9 The code ranges of hazard and precautionary statements under CLP

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

13.12 Supplemental information

Your label must 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 to CLP. 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 must be labelled in accordance with Part 2 of Annex II, and the statements must also be placed in the section for supplemental information.

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 Union 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 Regulation (EU) No 528/2012, plant protection products authorised under Regulation (EC) No 1107/2009, 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 this section.

REACH

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.

13.13 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 normally required 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. This allows the reader to find all relevant hazard and safety information in one place.

In the following subchapter, an example for a label is given (figure 2). 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 the *Guidance on Labelling and Packaging in accordance with the CLP Regulation* available on the ECHA website.

13.14 When must you update your labels?

Your labels must 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 must ensure that the label is updated within 18 months. For substances or mixtures within the scope of Regulation (EU) No 528/2012 (BPR) or (EC) No 1107/2009 (PPPR), labels must be updated in accordance with these Regulations.

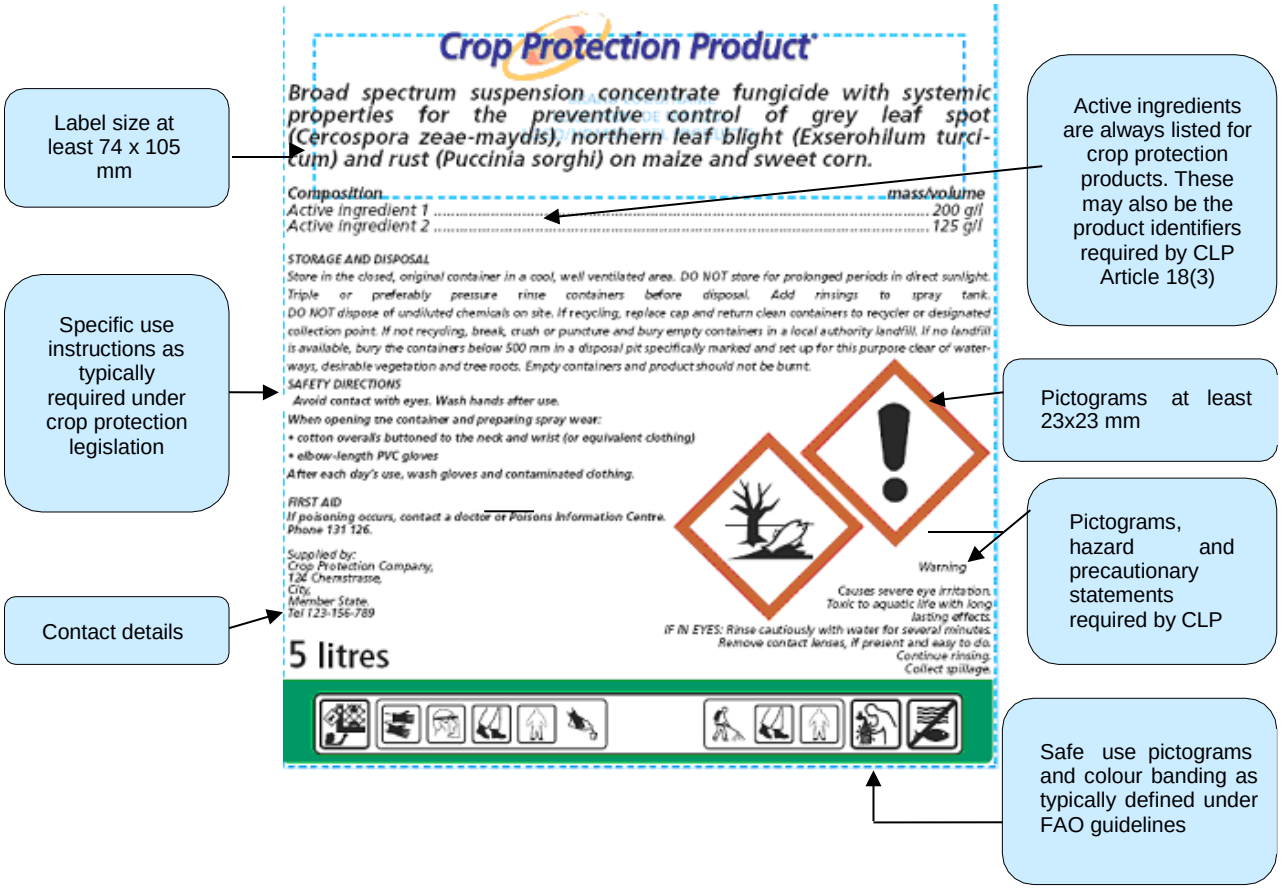

Figure 2 Example for a label incorporating information required by other legislation

13.15 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 to CLP (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).

14. Applying the precedence rules for labelling

14.1 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.

14.2 Signal words

Where you have to use the signal word "Danger", the signal word "Warning" must not appear on the label.

14.3 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 must 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) must not appear…


- **If GHS02 (flame) or GHS06 (skull and crossbones) applies,** then the use of GHS04 (gas cylinder) is optional….

or

Optional Optional

- **If GHS05 (corrosion) applies**, then GHS07 (exclamation mark) must 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) must 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.

14.4 Hazard statements

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

14.5 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 (some of) 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 the disposal of the substance or mixture, as well as the disposal of the packaging.

Further guidance and examples on the selection of precautionary statements is provided in the *Guidance on Labelling and Packaging in accordance with the CLP Regulation* available on the ECHA website.

15. Specific labelling and packaging situations

15.1 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 harm. How CLP deals with these situations, is set out in this chapter.

15.2 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 small[28] 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). Special rules are defined also for labelling of soluble packaging. These rules and exemptions are set out in section 1.5 of Annex I to CLP. For further guidance on how these rules and exemptions might apply to your packaged substances or mixtures, please see the *Guidance on Labelling and Packaging in accordance with the CLP Regulation*.

15.3 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 10 and Table 11 respectively. These provisions apply whatever the capacity of the packaging.

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

Table 10 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) *Wih the exception of aerosols or if in container with sealed spray attachment*	✓	✓
Germ cell mutagenicity (category 2)		✓
Carcinogenicity (category 2)		✓
Reproductive toxicity (category 2)		✓
Flammable gases (including chemically unstable gases) (category 1 and 2; categories A and B)		✓

Hazard Class (Category)	Child-resistant Fastenings	Tactile Warnings
Flammable liquids (category 1 and 2)		✓
Flammable solids (category 1 and 2)		✓

Table 11 Substances that trigger the CLP provisions for child-resistant fastenings (Annex II of CLP, point 3.1.1.3)

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

15.4 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.

16. Safety data sheets

Safety data sheets are an important communication tool in the supply chain. They help 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.

REACH

The requirement to provide a safety data sheet is set out in REACH Article 31 and Annex II to REACH[29] "Requirements for the compilation of safety data sheets".

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.

16.1 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:

- new knowledge on hazards becomes available;
- any of the other criteria listed in Article 31(9) of REACH for which an SDS update is required (see the *Guidance on compilation of safety data sheets* for more details)
- you wish to maintain on the market after 31 May 2017 a mixture which was already on the market before 1 June 2015 and was classified, labelled and packaged in accordance with the DPD and the SDS therefore referred to the DPD classification of the mixture and DSD classification of its components. Note that also the actual labels (and potentially packaging) will need to be updated to conform with CLP. For more information on the transitional period see also chapter 3 of this guidance document.

16.2 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) and Section 3 (Composition / Information on ingredients) of your safety data sheet. Changes should be indicated in Section 16 (Regulatory information). Also the full text of a new hazard statement must appear in Section 16 (Other information) of the safety data sheet.

[29] As of 1 June 2015, as amended by Regulation (EU) 2015/830.

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 (see chapter 22 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)) or vice versa.

You may also need to prepare new safety data sheets for mixtures which were not classified as hazardous under the 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 thresholds given in Article 31(3) of REACH. **In particular** from 1 June 2015, Article 31(3) (b) of REACH (amended by Article 59(2) of CLP) changed to (new text in **bold**):

"The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) No 1272/2008, but contains:

(a) …

(b) *in an individual concentration of ≥ 0,1 % by weight for non- gaseous mixtures at least one substance that is* ***carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitiser category 1, respiratory sensitiser category 1, or has effects on or via lactation or is*** *persistent, bioaccumulative and toxic* ***(PBT)*** *in accordance with the criteria set out in Annex XIII or very persistent and very bioaccumulative* ***(vPvB)*** *in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1)*; or

(c) …

17. The classification and labelling inventory – notifying substances

17.1 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 (CLP Article 42).

17.2 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));
- 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 present in a mixture above the concentration limits specified in Annex I of CLP, 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 do not need to notify separately a substance you have already registered under REACH when the information to be notified has already been provided as part of the REACH registration dossier. This also applies to certain substances contained in articles where REACH Article 7 provides for their registration.

Also 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 chapter 2 of this guidance document). This is because the notification for your substance will already have occurred at an earlier stage in the supply chain.

As to the notification deadline, you must notify within one month of placing the substance on the market. For importers, the one month delay is counted from the day when a substance, on its own or contained in a mixture, is physically introduced in the customs territory of the Union.

REACH

If you have already provided the information to be notified to the Agency in the form of a registration under REACH, you do not need to additionally submit a notification under CLP to the Agency (CLP Article 40(1)).

Registrants have REACH obligations in addition to the CLP obligations required from notifiers.

17.3 What information do you include in the notification?

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 is conclusive for non-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 in the inventory which differs from another entry for the same substance, you and the other notifier or registrant must make every effort to come to an agreed entry to be included in the inventory (CLP Article 41). A web-based discussion forum (C&L Platform) allows notifiers to discuss the classification and labelling of their substances and agree on appropriate classification[30]. 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 must classify it in accordance with the harmonised classification listed in Part 3 of Annex VI to CLP and include this classification in your notification (see chapter 7 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 must set an M-factor for the substance, based on available data. For further information see also chapter 1.5 of the *Guidance on the Application of the CLP Criteria*.

[30] For more information, please see the dedicated web page on the ECHA website at http://echa.europa.eu/regulations/clp/cl-inventory/cl-platform.

17.4 What format must you use for notification?

Your notification must 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)). You can also create a bulk XML file containing more than one C&L notification using the EXCEL tool provided by ECHA or by using the XML schema (this option may be preferred by users with an IT background).

All the necessary information and links to the tools are provided in the dedicated web page on the ECHA web site at http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/notification-to-the-cl-inventory. Figure 3 below shows a screen shot from IUCLID 5.

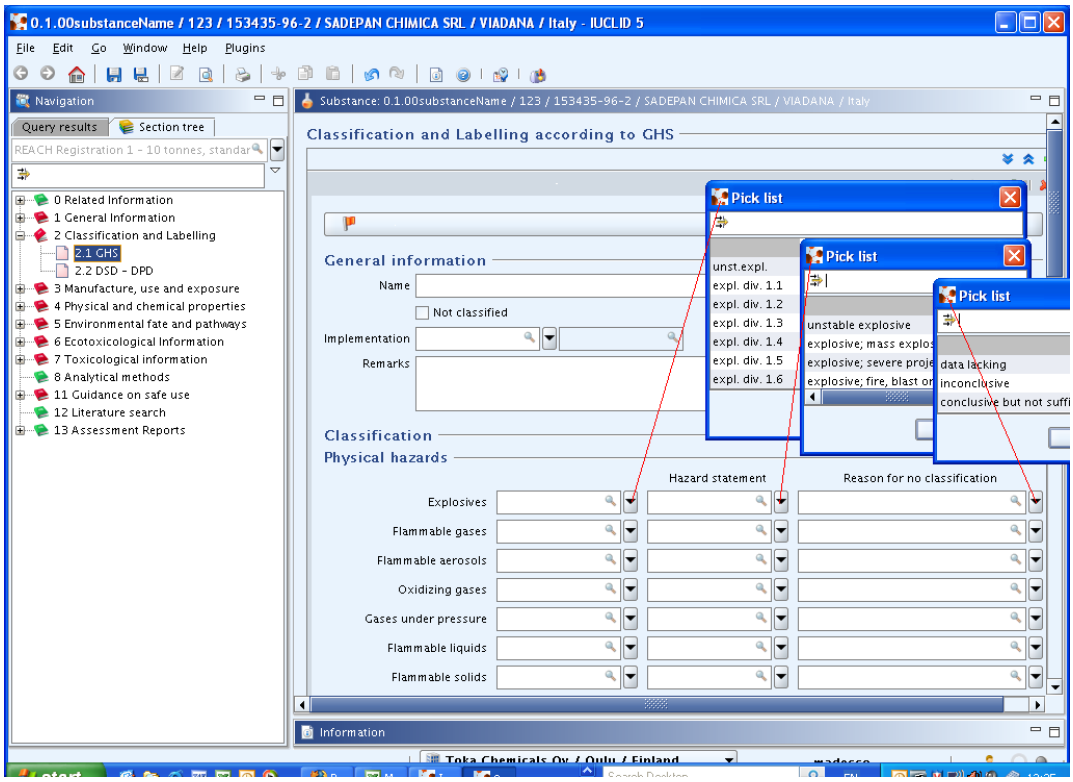

Figure 3 Screen shot from IUCLID 5

17.5 What happens next?

The Agency will add to the entry for the notified information:

- whether there is a harmonised classification and labelling at Union 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) will 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 for 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.

18. New hazard information

18.1 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."*

18.2 What do you have to do?

You need to 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 must 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 must update your labels and safety data sheets accordingly. An updated version of the SDS must be provided to all recipients to whom the substance or mixture has been supplied within the preceding 12 months. 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)).

REACH	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 (REACH Article 14 and 31).
	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 (REACH Article 31, 32 and 34).

The steps to take once you become aware of new hazard information for your substance or mixture are shown in Figure 4.

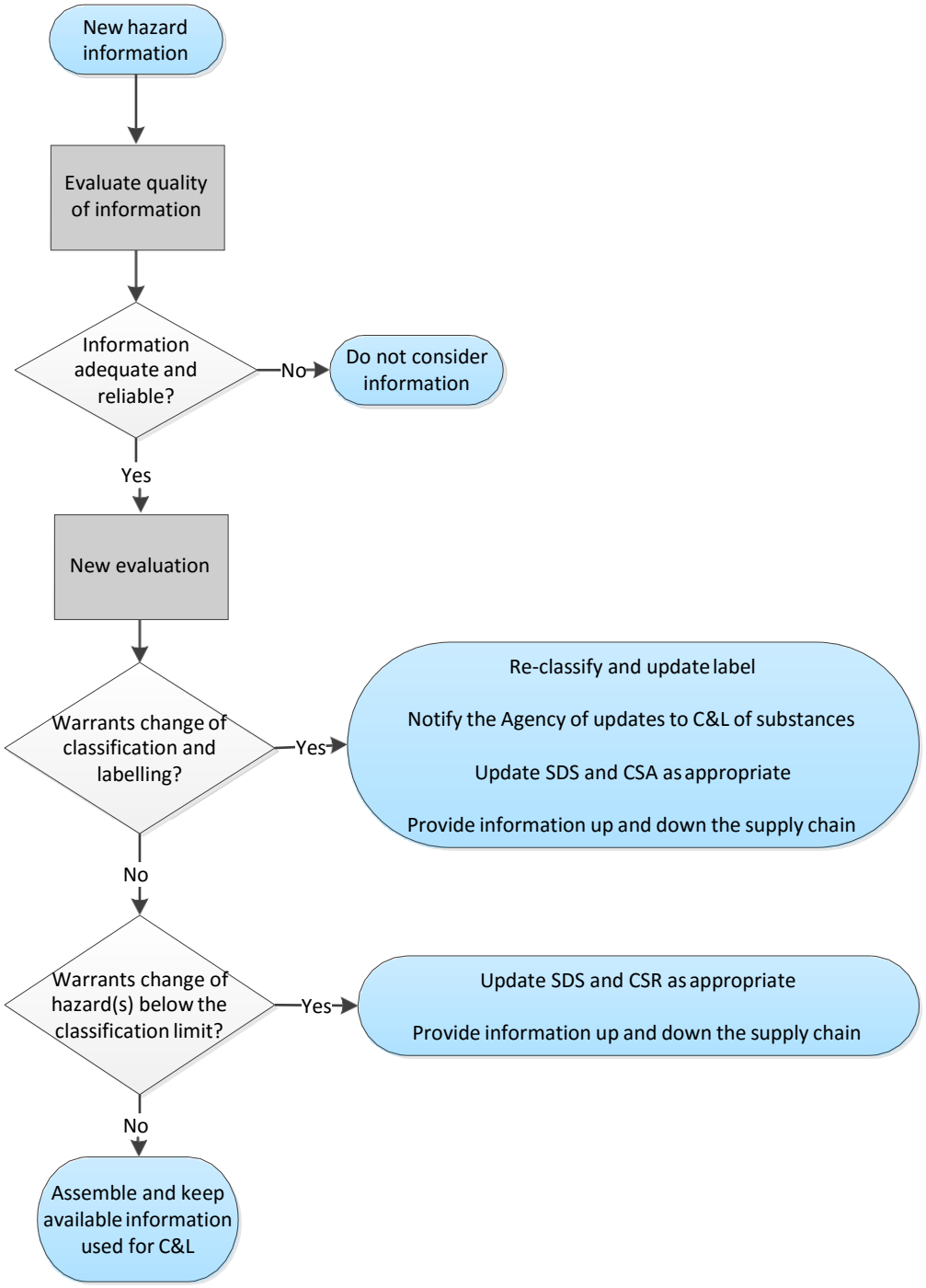

Figure 4 What to do about new hazard information

19. Request for use of an alternative chemical name

19.1 Introduction

Under CLP, substances and mixtures placed on the market must be well identified (see the paragraph on product identifiers in chapter 13 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/those 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'.

19.2 Who to submit the request to?

From 1 June 2015, you need to direct a request for an alternative chemical name to the Agency (ECHA), not to a Competent Authority, 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. Any requests for alternative chemical names approved by ECHA will be valid in all EU member states. This alternative chemical name can be used on the label and in the safety data sheet of the mixture instead of the substance name.

Under CLP the process and requirements for making the request differed in case the request was submitted before 1 June 2015. If a request for use of an alternative chemical name was submitted to a Member State Competent Authority under DPD and the request was approved before 1 June 2015, the use of the approved alternative chemical name can also continue after 1 June 2015.

19.3 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.

19.4 How to submit your request?

Your request should be submitted to ECHA in the format specified by ECHA and using any tools made available by ECHA (CLP Article 24(2), referring to REACH Article 111). The request must be accompanied by a fee as determined by the European Commission. ECHA may require further information from you if such information is necessary to make a decision. Practical information is available on the dedicated webpage on the ECHA website at: http://www.echa.europa.eu/support/dossier-submission-tools/reach-it/requesting-an-alternative-chemical-name-in-mixtures.

ECHA will notify you of its decision within six weeks of your request or the receipt of further required information. If ECHA 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.

20. Information records and requests

20.1 What record keeping do REACH and CLP require of you regarding classification and labelling?

As a supplier (**manufacturer** of substances, an **importer** of substances or mixtures or as **downstream user**), you need to assemble and keep available all the information that you used for the classification and labelling of your substance or mixture. This information must be kept for at least 10 years after you last supplied the substance or mixture (CLP Article 49). As a **distributor,** you must in the same way assemble and keep available all the information that you used for the labelling, see also Table 4 of chapter 2.

REACH

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 must 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 (REACH Article 36).

If your substance has been registered under REACH or is subject to other obligations under REACH, the information that must be kept under CLP must be kept together with that required for you to carry out your duties under REACH (CLP Article 49(1)).

20.2 Whom must you show this information to?

The Competent Authority/ies or the enforcement authorities of the Member State where you are established or ECHA may request all the information you used for the purpose of classification and labelling under CLP. Following such a request you need to 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 ECHA, and the Competent Authority needs to address its request to ECHA (CLP Article 49(3)).

All Member States are required to appoint a body or bodies (such as poison centres[31]) to be responsible for receiving information relevant for formulating preventative and curative measures, in particular for emergency health response. If you are an **importer** or **downstream user** placing mixture(s) on the market**,** these bodies must receive from you

[31] A list of appointed bodies has been prepared and made available by the Commission at http://ec.europa.eu/enterprise/sectors/chemicals/classification/poison-centres/index_en.htm#h2-1.

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).

21. Proposals for harmonised classification and labelling

21.1 What should a proposal be about?

Proposals for the harmonised classification and labelling of a substance should comprise proposals for inclusion of a new entry in or updating of an existing entry in 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.

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 Union-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)[32].

In contrast to other substances, active substances in the meaning of Regulation (EC) 1107/2009 (plant protection products) or (EU) 528/2012 (biocidal products) are normally to be subject to harmonised classification and labelling for all hazard classes (see chapter 23 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 (see chapter 7 of this guidance document). They must be submitted to the Agency.

21.2 Who can submit a proposal?

A Competent Authority of a Member State or 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 37[33]). 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 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 Union level is required.

[32] The fee to be paid to ECHA is laid down in the Fee Regulation (EU) No 440/2010.

[33] Please note that for active substances used in plant protection or biocidal products, only Member State competent authorities can submit proposals, i.e. not companies.

21.2 How do you submit a proposal as a company?

The procedure for submitting a proposal to the Agency for the harmonised classification of a substance is set out in CLP Article 37. Detailed and practical information is provided in the *Guidance on the preparation of dossiers for harmonised classification and labelling* available on the ECHA website.

The steps required for you to submit a proposal are summarised in Figure 5.

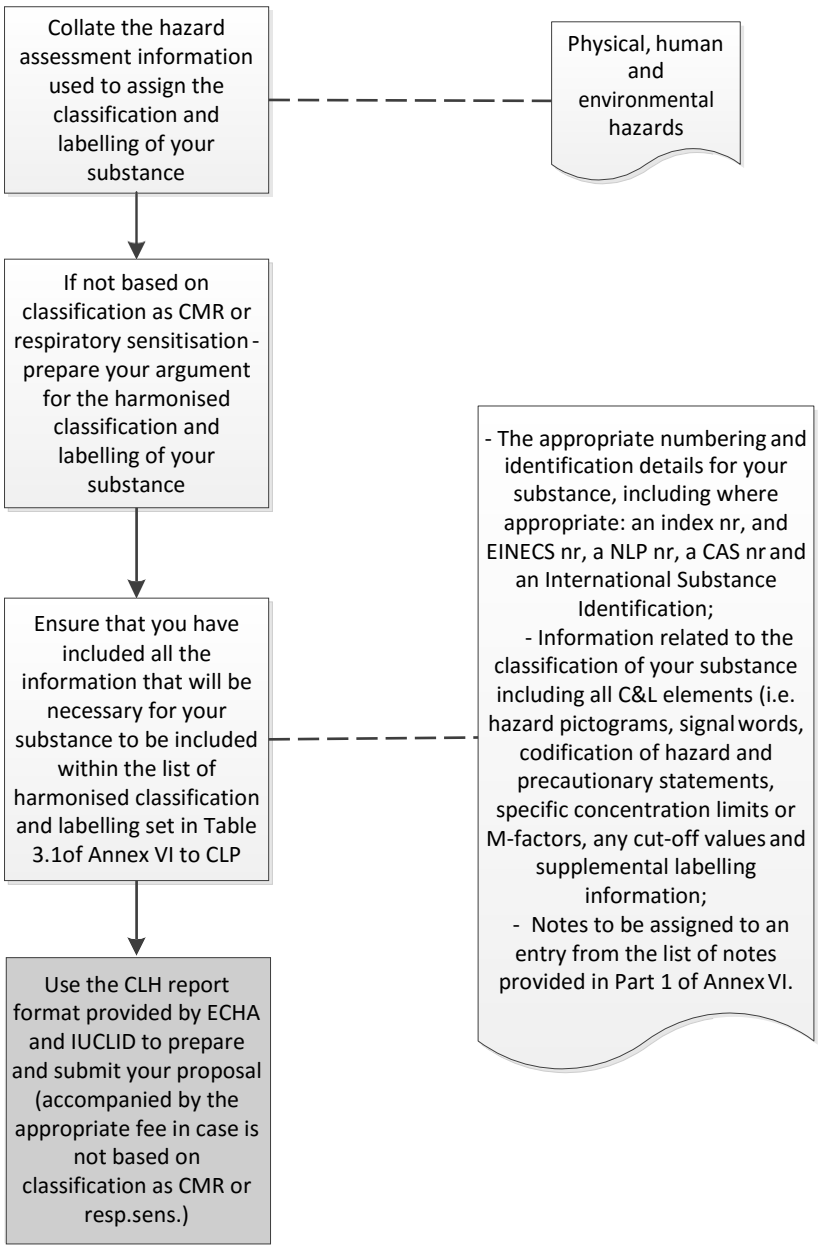

Figure 5 Steps required to prepare and submit a proposal

21.3 A proposal has been submitted: What happens next?

Once a proposal is submitted, all parties concerned will be given the opportunity to comment on it. The opportunity to comment will be provided via the ECHA website (http://www.echa.europa.eu/web/guest/harmonised-classification-and-labelling-consultation), in a specified commenting form, where comments can be introduced by a specified deadline.

The Committee for Risk Assessment of the Agency (RAC) 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 3.1 of Annex VI to CLP (which lists 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 a regulatory procedure with scrutiny by the European Commission.

The process followed by the Agency and the Commission following the submission of a proposal is summarised in Figure 6 (CLP Article 37).

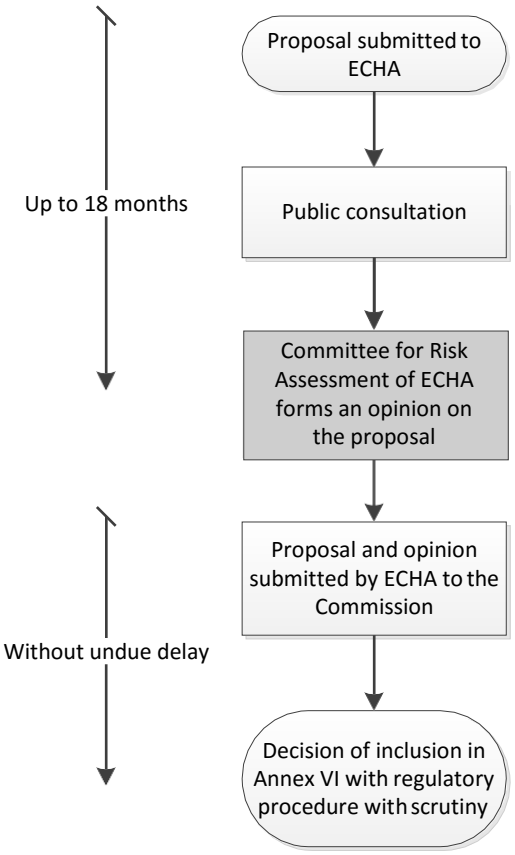

Figure 6 Process followed by the Agency and the Commission following the submission of a proposal for harmonised classification and labelling

22. Downstream legislation - an overview

22.1 Downstream legislation

Provisions under Union legislation other than CLP (downstream legislation) may be triggered by the classification of your substance or mixture. Such acts are for example:

- Registration, evaluation, authorisation and restriction of chemicals (REACH): Regulation (EC) No 1907/2006 of 18 December 2006 (See chapter 24 of this guidance document);
- Control of major-accident hazards involving dangerous substances (Seveso III): Directive 2012/18/EU of 4 July 2012;
- Plant protection products: Regulation (EC) No 1107/2009 (PPPR) of 31 October 2009 (See chapter 23 of this guidance document);
- Biocidal products: Regulation (EU) No 528/2012 (BPR) of 16 February 1998 (See Chapter 23 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: Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009;
- 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 (EU) No 649/2012 of 4 July 2012;

- Hazardous waste: Directive 2008/98/EC (Waste Framework Directive) and Commission Decision 2000/532/EC of 3 May 2000;

- Batteries and accumulators: Directive of the European Parliament and of the Council 2006/66/EC of 6 September 2006;

- End-of-life vehicles: Directive 2000/53/EC of 18 September 2000; and

- Waste electrical and electronic equipment (WEEE): Directive 2012/19/EU of the European Parliament and of the Council of 27 January 2002.

Some of these Union acts still refer to the previous directives on classification and labelling of substances and mixtures (preparations) i.e. DSD or DPD; they are in the process of being amended over time to take account of the CLP Regulation. For summaries of some of the interactions between CLP and REACH, BPR and PPPR, see chapters 23 and 24 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 were carried out: "Mixture" replaced "preparation" and references to CLP replaced 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; the Directive was recasted by the Regulation (EU) No 1223/2009.

- 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 Directive was recasted and on 13 August 2012 the new WEEE Directive 2012/19/EU entered into force[34].

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

22.2 "Dangerous" substances and preparations in EU downstream legislation

Some pieces of Union legislation may still refer to "dangerous" substances or preparations, to cover substances or preparations which meet DSD or DPD categories of danger.

As the CLP rules for the classification of substances have been effective since 2010 and those for mixtures since 2015, the relevant EU acts are in the process of being amended.

[34] The WEEE Directive is available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012L0019.

23. Biocidal products and plant protection products as customers of CLP

The provisions of CLP apply in full to any substance or mixture whose marketing and use is controlled by Regulation (EU) No 528/2012 on biocidal products (BPR) or by Regulation (EC) No 1107/2009 on plant protection products (PPPR). However, CLP in no way replaces the provisions of the BPR or those of the PPPR.

In practice, this means that your active substances and biocidal or plant protection products (mixtures) must be classified and labelled under CLP. You should consider any additional information required by the BPR or the PPPR to be supplemental labelling information for the purposes of the CLP Regulation (CLP Article 25) (see chapter 13 of this guidance document).

Substances that are active substances in the meaning of the PPPR or BPR are normally subject to harmonised classification and labelling (see chapters 7 and 21 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 CMRs 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 Union level (CLP Article 36(2)). In relation to proposals for harmonised classification, please note that only Member State Competent Authorities can submit such proposals for active substances used in plant protection or biocidal products.

Should you want to change the composition of a biocidal or plant protection product, you have to apply for a change to the authorisation of that product at the relevant Competent Authority of the Member State where you place it on the market or, in case of biocidal product for which a Union Authorisation was granted, at ECHA[35]. In your application you need to 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, you must do so in accordance with the provisions of CLP (CLP Article 30) (see chapter 18 of this guidance document). However, should your substance or product (mixture) fall within the scope of the PPPR or BPR and is subject to an authorization or registration decision according to one of those regulations, then the requirements of those regulations also apply (CLP Articles 15(5) and 30(3)).

[35] Please refer to Regulation (EU) No 354/2013 on changes in authorized biocidal products.

24. Obligations under REACH triggered by the classification of substances

In general your obligations under REACH are triggered by the quantity 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 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 must compile a safety data sheet in case your substance or mixture meets the criteria for classification (REACH Article 31);

- you must 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 1A or 1B according to CLP, or has dispersive use and is likely to be classified for human health or environmental effects.

In case you use a substance classified as CMR category 1A or 1B PBT or vPvB or identified as causing an equivalent level of concern, you should check whether the substance has been identified as a Substance of Very High Concern (SVHC), included in the candidate list, and possibly further prioritised and included in Annex XIV to REACH as a substance subject to authorisation. The authorisation process is independent of any tonnage produced (REACH Article 57 f). In this respect, it is important to regularly check Annex XIV and the Candidate List of SVHC as new substances are subjected to the Authorisation process[36].

Please also take note of the restrictions Annex XVII to REACH, especially those in relation to CMR substances which are set out in entries 28, 29 and 30.

[36] More information is available on the dedicated webpage on the ECHA website at http://echa.europa.eu/web/guest/regulations/reach/authorisation.

25. Substance Information Exchange Fora (SIEFs)

25.1 What is a SIEF?

According to REACH Article 29, a SIEF stands for 'Substance Information Exchange Forum'. REACH requires the formation of SIEFs 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 needs 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://www.echa.europa.eu/web/guest/regulations/reach/substance-registration/substance- information-exchange-fora.

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://echa.europa.eu/guidance-documents/guidance-on-reach.

25.2 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) must make every effort to come to an agreed entry, i.e. to an agreed classification and labelling, to be included in the classification and labelling inventory (CLP Article 41) where there are different entries for the same substance in the 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 in the inventory with different classification and labelling.

25.2 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). You can do so by contacting the ECHA Helpdesk which will communicate your contact details to the SIEF members.

25.3 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 his substance(s), stating his wish to become part of SIEF(s) for those substance(s) (REACH Article 28(1)):

"… … …

(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) his name and address 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;

(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, for which the available information is relevant for the application of Section 1.3 and 1.5 of Annex XI".

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.

26. 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 (some of them referred to in the chapters of this Guidance document) relating to REACH which are available to download from the Agency website *(*http://echa.europa.eu/guidance-documents/guidance-on-reach*)*. Of particular relevance to CLP are the guidance documents introduced here.

Guidance on the compilation of safety data sheets

This guidance document assists industry in determining tasks and requirements to be complied with in order to fulfil the obligations under Article 31 (requirements for safety data sheets) and Annex II of REACH.

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.e. 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 six main parts (A-F) and supporting reference guidance (R.2 to R.20). 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
- Part D - Builds the bridge to the use of exposure scenarios in the context of the chemical safety report and the extended safety data sheet.

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 chapter 25 of this guidance document).

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 the *Guidance on the Application of the CLP Criteria*.

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 12.

Table 12 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 mg/kg
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 3.1.3.6.1[37]:

$$\frac{100}{ATE_{mixture}} = \sum_{n} \frac{Ci}{ATEi}$$

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

Result: ATEmixture = 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 13.

[37] 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 13 Ingredient and mixture information

Ingredient	Weight (%)	Classification	Ingredient information
Ingredient 1	4	Skin Corr. 1	pH = 1.8
Ingredient 2	5	Skin Corr. 2	-
Ingredient 3	5	Category 3 (mild skin irritation)*	-
Ingredient 4	86	-	No data available

Mixture Information: The mixture has a pH = 4.0

* "Category 3 (mild skin irritant)" is not implemented in the EU and not included in CLP, therefore ingredient 3 is not classified under CLP.

Derivation of the mixture classification:

1. 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 pH $\leq$ 2 or pH $\geq$ 11.5, see paragraph 3.2.3.1.2 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 3.2.3.2.1 of Annex I to CLP;

3. 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

4. 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 ≥ 1% of a corrosive ingredient and as skin category 2 when it contains ≥ 3% of an irritant ingredient").

Result: For this mixture, the classification was classified as skin category 1 because ingredient 1 (Skin corr. 1) is in the mixture at a concentration above 1% and non-additivity is applied.

Annex 2. Glossary

Terms used in this guidance document

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

Aerosols: 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: 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 (Under REACH and CLP): 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: 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: a substance or a mixture of substances which induces cancer or increases its incidence

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

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

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

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

Downstream user: any natural or legal person established within the Union, 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) of REACH, is regarded as a **downstream user**;

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

Explosive substance: 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: 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: a gas having a flammable range with air at 20 °C and a standard pressure of 101.3 kPa;

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

Gas: 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: the "Globally Harmonised System of Classification and Labelling of Chemicals" developed within the United Nations (UN) structure;

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

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

Hazard pictogram (sometimes also referred to as "pictogram" in this document): 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; 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: fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in parts 2 to 5 of Annex I of CLP;

Import: the physical introduction into the customs territory of the Union;

Importer: any natural or legal person established within the Union who is responsible for import;

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

IMGD Code: the "International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea;

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;

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

Liquid: 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: 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: any natural or legal person established within the Union who manufactures a substance within the Union;

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

Mixture: a mixture or solution composed of two or more substances. However, UN GHS Chapter 1.2 includes the phrase, "in which they do not react" at the end of an otherwise identical definition;

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

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

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

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

Oxidising liquid: 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: 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: 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 Union, 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 Union, 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: 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: 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: 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;

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

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

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

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

Pyrotechnic substance: 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: Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals;

Registrant: 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: 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;

Self-heating substance: 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: 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;

Signal word: 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: 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: 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: a substance or mixture which does not meet the definitions of liquid or gas;

Substance: 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: 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";

Use: 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.

Annex 3. Additional sources of information

Please find here an overview of information sources and advice in relation to the CLP Regulation, in addition to the sources provided in chapter 9 of this guidance document.

1. ***Guidance on the Application of the CLP Criteria*****:** This *Introductory Guidance on the CLP Regulation* 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 *Guidance on the Application of the CLP Criteria.*

2. **Member State CLP/REACH helpdesks:** these are established in each Member State and are the points of contact for questions on CLP and REACH, 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 ECHA website: http://echa.europa.eu/web/guest/support/helpdesks*.*

3. **DG GROW**: overview and links to further information, including additional guidance at http://ec.europa.eu/growth/index_en.htm.

Annex 4. The UN GHS and CLP

A.4.1. 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.

A.4.2. 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.

A.4.3. 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 14.

Table 14 Hazard categories included in the UN GHS but not in CLP

Hazard classes	UN GHS hazard categories not in CLP	Comments
Flammable liquids	Cat. 4	Flammable liquids with a flash point ≤ 93ºC are used for the classification in the hazard class Aerosols
Acute toxicity	Cat. 5	
Skin corrosion/ irritation	Cat. 3	Mild skin 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	

A.4.4. 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 covered by both CLP and by transport legislation.

A.4.5. Plant protection products

CLP contains a special rule for the labelling of plant protection products which states that you must 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 chapter 23 of this guidance document.

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