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EUROPEAN CHEMICALS AGENCY

GUIDANCE

Introductory Guidance on the CLP Regulation

Version 3.0
January 2019

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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mixtures according to the DPD and classifying their components according to the DSD; (iii) Remove obsolete and out of date information which is no longer relevant and would be now potentially misleading; (iv) Reformat the document in line with the current corporate identity.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 section 4 on transition to CLP (and consequently re-numbering of old section 5 onwards); relevant information on the applicable transitional provisions have been moved to a subsection of section 3 ("Implementing CLP"); - Deletion of Figure 8.1 (in original section 8) because not in line with the current approach and potentially misleading; - Restructuring and update of section 9 (originally 10) on relevant sources of information; - Clarification in section 16 (originally 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 section 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 section 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 section 19 (originally 20), on alternative chemical name, of text referring to obligations in place before 1 June 2015; - Reduction in section 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 section 25 (originally 26), on SIEFs, of the possibility 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"	July 2015

	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
Version 3.0	Fast-track update of the guidance document to: (i) take into account the end of the transition period for labelling mixtures according to the DPD; (ii) take into account the 9th – 12th Adaptations to Technical and Scientific Progress (ATPs) to the CLP Regulation; (iii) Remove obsolete and out-of-date information. In particular, the update includes the following: - Deletion of the text relating to the transitional period for application of the CLP requirements, in particular in sections 3, 4, 12 and 13, including deletion of former section 3.3 "Transition to CLP" and renaming of section 4, previously titled "CLP similarities with and differences from DSD / DPD", into "Outline of the CLP Regulation"; - Deletion of the references to the Substance Information Exchange Fora (SIEFs) in section 24 (former section 25); - Deletion of Annex 1 on examples from the UN GHS pilot trials of 2008 for the application of the mixtures classification criteria; - Merging of former section 4.1 "Classification of substances" and 4.3 "Classification of mixtures" into new section 4.1 "Classification of substances and mixtures"; - Merging of former section 11 "Classifying substances" and 13 "Classifying mixtures" into new section 11 "Classifying substances and mixtures"; - Addition of new section 11.6 "Step 5: Review the classification if needed"; - Replacement of references to IUCLID 5 by references to IUCLID 6 in section 16.4 (former section 17.4); - Update of outdated or broken links; - Update of the list of abbreviations and glossary terms; - Use of the term "section" instead of "chapter"; - Renumbering of sections; - Reformatting of the document.	January 2019

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. 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*.

As you may also have to comply with the Regulation (EC) No1907/2006[2] (the REACH Regulation or simply "REACH"), we have highlighted throughout this guidance the relevant REACH obligations which play a role in the context of the CLP Regulation. Furthermore, we point to those guidance documents related to the REACH Regulation which can assist in applying the CLP Regulation.

[1] The CLP Regulation 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] 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 annexed to resolution No. 223 of the Inland Transport Committee of the Economic Commission for Europe, as amended
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road under framework Directive 94/55/EC, as amended
ATE	Acute Toxicity Estimate: acute toxicity values are expressed as (approximate) LD_{50} (oral, dermal) or LC_{50} (inhalation) values or as ATEs.
ATP	Adaptation to Technical and Scientific 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	Carcinogenic, mutagenic, toxic for reproduction
CRF	Child-resistant fastening
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
EC	European Commission
EU	European Union
GCL	Generic Concentration Limit
GHS	(United Nations) Globally Harmonised System of Classification and Labelling of Chemicals: it defines the criteria internationally agreed by the United Nation Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures
HSDB	Hazardous Substances Data Bank
ICAO	"International Civil Aviation Organisation", refers to Annex 18 to the Convention on International Civil Aviation "The Safe Transport of Dangerous Goods by Air"
IMDG	"International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
IPCS	International Programme on Chemical Safety
IRIS	Integrated Risk Information System
IUCLID	International Uniform ChemicaL Information Database
IUPAC	International Union of Pure and Applied Chemistry
M-factor	Multiplying factor
NICNAS	(Australia) National Industrial Chemicals Notification and Assessment Scheme
NIOSH	(United States) National Institute of Occupational Safety and Health
OECD	Organisation for Economic Cooperation and Development
OSHA	(United States) Occupational Safety and Health Administration
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]
PPPR	Plant Protection Products Regulation: 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	Regulation 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
RTGD	(United Nations) Recommendations on the Transport of Dangerous Goods
RTECS	Registry of Toxic Effects of Chemical Substances
SCL	Specific Concentration Limit
SDS	Safety data sheet
SVHC	Substance of Very High Concern
TWD	Tactile warnings of danger
Toxline	Toxicology Literature Online database
TOXNET	Toxicology Data Network
UFI	Unique Formula Identifier
UN	United Nations
US EPA	United States Environmental Protection Agency

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, see https://echa.europa.eu/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*[3].

Many provisions of the CLP Regulation are closely linked to provisions under the REACH Regulation and other Union legislation. The most relevant links to the REACH Regulation, to Regulation (EU) No 528/2012 on biocidal products (Biocidal Products Regulation or BPR) and to Regulation (EC) No 1107/2009 on plant protection products (Plant Protection Products Regulation or PPPR) are briefly explained in separate sections of this guidance document. In addition, links with REACH are noted briefly in the individual sections 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[4] who have to apply the rules for classification, labelling and packaging under the CLP Regulation. 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 section 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)[5] market, but also to the global market. Harmonised criteria for classification and labelling together with general principles of their application were carefully developed within the

[3] Both Guidance documents are available at https://echa.europa.eu/guidance-documents/guidance-on-clp.

[4] As a producer or importer of an article you are only affected by the CLP Regulation 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.

[5] Please note that, whenever there is a reference to the Union (EU) in this document, the term also covers the European Economic Area (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.

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 (GHS), the first edition of which was adopted in 2002 (see also: 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 the CLP Regulation to which this guidance document currently refers is that based on the 7th revision of the UN GHS[6]. The CLP Regulation additionally takes on board some features and procedures from the previous EU system of classification and labelling, represented by Directive 67/548/EEC ("Dangerous Substances Directive" (DSD)) and Directive 1999/45/EC ("Dangerous Preparations Directive" (DPD)), that are not part of the UN GHS. Therefore, the CLP Regulation is similar to, but not identical to the way in which the UN GHS is introduced into the legal framework of countries outside the EU (note that differences may exist between implementation in individual non-EU countries).

The CLP Regulation is legally binding across the EU/EEA Member States. It is directly applicable to all industrial sectors. The old directives, DSD and DPD, were repealed after a transitional period, on 1 June 2015.

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 due to its physical properties or its effects on human health or the environment.

One of the main aims of the CLP Regulation 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" that 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 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.

[6] Please note that the UN GHS is reviewed every two years. The 6th (2015) and 7th (2017) revisions to the UN GHS will be implemented in the CLP Regulation through the CLP 12th ATP.

The CLP Regulation sets general packaging rules, in order to ensure the safe supply of hazardous 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 that 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 processes. It plays a central role for the implementation of the REACH and CLP Regulations (as well as of the Biocidal Products Regulation and PIC Regulation[7]), 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 (substances and mixtures) which fall within its remit. Some of the specific tasks of the Agency under the CLP regulation include:

- providing industry with technical and scientific guidance and tools on how to comply with the obligations of the CLP Regulation (CLP Article 50);
- providing Member State Competent Authorities with technical and scientific guidance on the operation of the CLP Regulation (CLP Article 50);
- providing support to the national helpdesks set up under the CLP Regulation (CLP Articles 44 and 50);
- establishing and maintaining a classification and labelling (C&L) inventory in the form of a database and receiving notifications to the C&L 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)).

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

2. Roles and obligations under the CLP Regulation

2.1 Roles under the CLP Regulation

The obligations placed on suppliers of substances or mixtures under the CLP Regulation 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 the CLP Regulation.

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 can consult the *Guidance for downstream users* on the ECHA website.

Where a description matches your activities, your role under the CLP Regulation 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 the CLP Regulation.

Please note that the 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 the REACH Regulation. Labelling and packaging obligations are generally not relevant when a registration or notification is prepared for the purposes of the REACH Regulation but no supply is taking place.

Table 1 Identifying your role under the CLP Regulation

Descriptions		Your role under the CLP Regulation[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 the CLP Regulation 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 the REACH and CLP Regulations only covers the person producing substances. The formulator is a "downstream user" under the REACH and CLP Regulations.

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

(4) As a producer or importer of an article, you are only affected by the CLP Regulation 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 provides for registration or notification of a substance contained in an article.

2.2 Obligations under the CLP Regulation

The CLP Regulation 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 the CLP Regulation depend upon your role in the supply chain, as determined in Table 1. Tables 2 to 5 below set out the obligations for each of the roles and indicate the key sections of this guidance document in each case.

Table 2 Obligations of a manufacturer or importer

	Obligations under the CLP Regulation	Key sections
1	You must classify, label and package substances and mixtures according to the CLP Regulation 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 REACH Articles 6, 9, 17 or 18 (CLP Article 4).	6
2	You must classify in line with CLP Title II (CLP Articles 5-14).	7 – 11
3	You must label in line with CLP Title III (CLP Articles 17-33).	12 – 14
4	You must package in line with CLP Title IV (CLP Article 35).	12 and 14
5	You must notify the classification and labelling elements to the C&L inventory established at the Agency in case you place substances on the market (CLP Article 40).	16
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).	17
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).	14 and 17
8	If you have new information that 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)).	20

Obligations under the CLP Regulation		Key sections
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 REACH Article 36 (CLP Article 49).	19
10	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 and Annex VIII).	19 [8]

Table 3 Obligations of a downstream user (including formulator / re-importer)

Obligations under the CLP Regulation		Key sections
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 the CLP Regulation 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 – 11
3	You must label in line with CLP Title III (CLP Articles 17-33).	12 – 14
4	You must package in line with CLP Title IV (CLP Article 35).	12 and 14

[8] See also the *Guidance on harmonised information relating to emergency health response*.

Obligations under the CLP Regulation		Key sections
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).	17
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).	12 and 17
7	If you have new information that 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)).	20
8	You must assemble and keep available all the information required for the purposes of classification and labelling under the CLP Regulation 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 REACH Article 36 (CLP Article 49).	19
9	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 and Annex VIII).	19[9]

[9] See also the *Guidance on harmonised information relating to emergency health response*.

Table 4 Obligations of a distributor (including retailer)

	Obligations under the CLP Regulation	Key sections
1	You must label and package the substances and mixtures you place on the market (CLP Article 4).	12 – 15
2	You may take over the classification for a substance or mixture derived in accordance with Title II of the CLP Regulation already by another actor in the supply chain, for example from a safety data sheet supplied to you (CLP Article 4).	6 and 12
3	You must label in line with CLP Title III (CLP Articles 17-33).	12 – 15
4	You must ensure the packaging is in line with CLP Title IV (CLP Article 35).	12 and 14
5	You must assemble and keep available all the information required for the purposes of classification and labelling under the CLP Regulation 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 REACH Article 36 (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 purposes 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.	19

Table 5 Obligations of a producer of certain specific articles

Obligations under the CLP Regulation		Key sections
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 the CLP Regulation before placing it on the market (CLP Article 4). The same obligations apply as for importers (see Table 2 above), apart from the obligation to notify the Agency.	6 – 14 17, 19, 20
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 the CLP Regulation

3.1 Where to start?

Your first step is gaining an understanding of the CLP Regulation 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 the REACH Regulation;
- 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 the CLP Regulation are closely interlinked, it is recommended to plan CLP processes together with processes related to the REACH Regulation 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, 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 (SDSs) according to Article 31 and Annex II to REACH[10] reflect this information in accordance with the CLP Regulation (CLP Article 4).

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 the information supplied to you, for example, in the SDSs that accompany substances and mixtures (CLP Article 4 (5)).

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[11]. It should be noted that some of the substances or mixtures that were not classified as dangerous under the DSD and DPD might be classified as hazardous under the CLP Regulation;

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

[11] As a producer or importer of an article you are only affected by the CLP Regulation 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 Article 9 provides for registration or notification of a substance contained in an article.

- consider the information that may be available to you for substances subject to REACH registration. You may need to contact your suppliers for more information; and
- contact your suppliers to see how they have implemented the CLP Regulation 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:

- do I have sufficient appropriate technical and regulatory staff, or will I need additional resources or external expertise?
- SDS - 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 the CLP Regulation?

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[12]);
  - how you dispose of hazardous wastes; and
  - safety at work and protective clothing for your employees.

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

4. Outline of the CLP Regulation

The CLP Regulation deals with:

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

It is aimed at workers and consumers, and covers the supply and use of chemicals, being similar in scope to the old EU chemicals legislation (DSD and DPD). It does not cover the transport of chemicals, however, CLP Article 33 provides certain rules regarding the labelling of packaging also used for transport. Testing for physical hazards comes mostly 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 Regulation 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 the CLP Regulation may be complemented by further elements which are required by the relevant product-specific legislation.

4.1 Classification of substances and mixtures

The EU has taken up in the CLP Regulation all the hazard classes from the UN 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 3 to this guidance document). If you export to other regions outside the EU you may still need to consider these categories. More information can be found on the UNECE GHS website (http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html).

While the overall scope of classification under the CLP Regulation 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 17), leading to a more explicit differentiation of physical properties. On the whole, some of the classification criteria for substances and mixtures have changed in comparison to the DSD/DPD criteria, as for example the criteria for explosivity and acute toxicity.

In addition, there are elements that were part of the DSD or DPD, but that are not included in the UN GHS. Under the DSD, certain hazards and properties led to additional labelling, e.g. "R14 - Reacts violently with water". 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, EUH014 is used, but not H014, to reflect R14 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 is already classified as hazardous in accordance with the CLP criteria.

Table 6 shows the hazard classes included in the CLP Regulation. 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 (Categories 1A (including unstable gases(Categories A and B) and pyrophoric gases*) 1B and 2
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)
Desensitised explosives*

Health hazards
Acute toxicity (Categories 1, 2, 3 and 4)
Skin corrosion/irritation (Categories 1, 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 (Categories 1 and 2)
Aspiration hazard (Category 1)
Environmental hazards
Hazardous to the aquatic environment (Category Acute 1, Categories Chronic 1, 2, 3, and 4)
Additional hazards
Hazardous to the ozone layer (Category 1)

* The hazard category for pyrophoric gases and hazard class for desensitised explosives have been introduced by the 6th revision to the UN GHS (2015) and will be implemented in the CLP Regulation through the CLP 12th ATP.

The classification of mixtures under the CLP Regulation 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. The so-called "bridging principles" can be applied 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. The principles of the application of expert judgement and weight-of-evidence determination are also given in the legal text (CLP Articles 9(3) and 9(4)).

4.2 Hazardous versus Dangerous

All substances and mixtures meeting the criteria of one or more of the hazard classes in the CLP Regulation are considered hazardous. However, other pieces of EU legislation might still make reference to substance or mixture classifications as dangerous as defined in the DSD. Please find more information on this in section 21 of this guidance document.

4.3 Labelling

The CLP Regulation implements the use of the UN GHS hazard statements, precautionary statements and pictograms. The CLP Regulation also includes the use of the two UN GHS signal words 'Danger' and 'Warning' to indicate the severity of a hazard (see section 12 of this guidance document).

4.4 Harmonised classification

In addition to self-classification where manufacturers, importers and downstream users themselves have to identify hazards and classify substances and mixtures, the CLP Regulation also includes provisions for harmonised classification of substances to be applied directly (see sections 6, and 25 of this guidance document). Proposals for harmonised classification and labelling (CLH) may be submitted either by the Member State Competent Authorities or in some cases by manufacturers, importers and downstream users (see section 20 of this guidance document). Such proposals are in general only foreseen to relate to substances that are carcinogenic, mutagenic or toxic to reproduction (i.e. CMR substances) and to respiratory sensitisers. Proposals for a harmonised classification that refer to other substance properties may also be submitted to the Agency if a justification is provided demonstrating the need for harmonised classification and labelling at EU level (CLP Article 36(3))[13].

The harmonised classifications for substances that were listed in Annex I to the DSD were translated into CLP classifications. All harmonised classifications, the old ones that originated from DSD and the new ones agreed under the CLP Regulation, are now listed in Table 3 of Part 3 of Annex VI to CLP.

[13] Note also that substances that are active substances in the meaning of the BPR or under the PPPR are normally subject to harmonised classification and labelling (see sections 21 and 23 of this guidance document).

5. Terms used for classification and labelling

Table 7 presents the key terms from the CLP Regulation (see also glossary in Annex 1 to this guidance document).

Table 7 Key terms used in the CLP Regulation

CLP terms	
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).
Hazard class / hazard category	The nature / severity of a physical, health or environmental hazard (CLP Articles 2(1) and 2(2)).
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.
Mixture(s)	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.
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: 

Precautionary statement	A description of the measure(s) 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.
Signal word	The words 'Danger' or 'Warning' are used to indicate the severity of the hazard (CLP Article 2(4)).
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)).
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 section 2 of this guidance document.

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 the **CLP Regulation** (CLP Article 4(1)):

  If you are a manufacturer, importer or downstream user of chemical substances or mixtures to be placed on the market, you 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).

- Classification triggered by the **REACH Regulation** (CLP Article 4(2)):

  If you are a manufacturer or importer, you must also classify substances that you do not place on the market if they are subject to registration or notification in line with REACH Articles 6, 9, 17 or 18. 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 that are used for PPORD.

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 the CLP Regulation 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 CLP Title II by another actor in the supply chain, for example from an SDS (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 CLP Title II by an actor in the supply chain, for example from an SDS, provided that they do 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 the CLP Regulation or registered under the REACH Regulation are included in a C&L 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 (SVHCs), they are present in those articles above one 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

The CLP Regulation includes provisions for two types of classification: self-classification and harmonised classification, briefly described 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 in section 2 of this guidance document).

The requirement to self-classify is set out in the CLP Regulation. Under the CLP Regulation, all substances that do not have a harmonised hazard classification (see below) or for which 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 the REACH Regulation provides for registration or notification, and
- downstream users, including formulators (producing mixtures).

Mixtures must always be self-classified by the downstream users[14] or the importers of those mixtures.

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

Harmonised classification: the decision on classification for a particular hazard of a substance is taken at EU level (see also section 20 of this guidance document). Harmonised classifications of substances are included in Table 3 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 on their own or in mixtures, producers or importers of explosive articles or of articles where the REACH Regulation provides for registration or notification, downstream users including formulators (producing mixtures) and distributors.

Harmonised classification and labelling under the DSD normally considered all categories of danger. Under the CLP Regulation, 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 endpoints not covered by a harmonised classification, the manufacturer, importer or downstream user has to perform a self-classification. Substances regulated under the BPR or under the PPPR are normally subject to harmonised classification and labelling for all hazardous properties (CLP Article 36(2)). For further information see sections 20 and 22 of this guidance document.

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, were translated into harmonised CLP classifications and transferred into Part 3 of Annex VI to CLP.

When preparing Table 3 of Part 3 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 and importers should apply this classification, but must classify in a more severe hazard category in case they have further information that 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 Part 1 of Annex VI to CLP.

Table 3 of Part 3 of Annex VI to CLP is continuously updated whenever the European Commission (EC) has agreed on further harmonised classifications. The updates are published as Adaptations to Technical and Scientific Progress (ATPs) to the CLP Regulation[15].

7.2 How to use the harmonised classifications

As indicated in section 6.2 of this guidance document, the use of a harmonised classification and labelling of a substance (when one exists) is mandatory. For those endpoints 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), a multiplication factor (M-factor) or an Acute Toxicity Estimate (ATE). **SCLs** can be lower or higher than the generic concentration limits defined in Annex I to CLP and are included in Table 3 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 section 1.5 of the *Guidance on the Application of the CLP Criteria*). Substances with a harmonised classification for acute toxicity may have been assigned an **ATE**, which is used to determine the classification of mixtures containing them. SCLs, M-factors and ATEs are indicated in Table 3 of Part 3 of Annex VI to CLP, in the same column. Where an asterisk (*) appears in this column, it means that it was not possible to transfer the concentration limit from Annex I to the DSD to Annex VI to CLP, for instance in cases of a minimum classification under the CLP Regulation. The minimum classification for a category is indicated by an asterisk (*) in the entry in Table 3 of Part 3 of Annex VI to CLP.

If you are using the substance in a mixture, you should take account of any SCLs, M-factors and/or ATEs assigned to the entry for that substance when classifying your

[15] For more information and for the list of published ATPs, see the CLP page on the ECHA website at: https://echa.europa.eu/regulations/clp/legislation.

mixture. Where an M-factor is not given in Part 3 of Annex VI to CLP 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. When applying a harmonised ATE for the classification of a mixture for acute toxicity, the additivity formula described in section 3.1.3.6 of Annex I to CLP must be used. If harmonised ATE values are missing for acute toxicity the correct value has to be established by using the available data.

You should also make sure you fully consider the impact of any special instructions that appear in the Notes column of Table 3 of Part 3 of Annex VI to CLP.

8. Using Annex VII for translation from DSD/DPD to CLP classification

Annex VII to CLP was included to provide a translation table for **manufacturers**, **importers** and **downstream users** to translate previously derived DSD or DPD classifications to CLP classifications. The use of the translation table was appropriate when no further data besides the DSD or DPD classification was available for a substance or a mixture and for the hazard class considered (see also section 1.7 of the *Guidance on the Application of the CLP Criteria*).

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 that allow the substance or mixture to be classified more accurately.

There are a number of limitations to the use of the table. For mixtures originally classified on the basis of test results, the table might 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 the CLP Regulation should only be taken as an indication of possible classification, because of the differences in concentration limits and calculation methods. 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.

For the reasons mentioned above, the use of the table is not considered relevant anymore. However, if you consider still using it, note that whenever you have data on the mixture or the substances in the mixture, e.g. from SDSs 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).

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 section provides you with guidance on where to find such information (for additional sources of useful information, see Annex 2 to this guidance document).

Search in-house

In case you have to classify a substance or mixture in compliance with one of the roles set out in section 2 of this guidance document, you should check what kind of information or data are already available in-house.

Supplier

A relevant source of information is an up-to-date SDS 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 the REACH Regulation or that you obtain through information sharing (see also section 24 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 section 25 of this guidance document).

You may also be able to obtain and use information for substances and mixtures evaluated under other pieces of EU legislation, such as those regulating biocidal products and plant protection products. As the REACH Regulation also places a duty to communicate information on substances and mixtures up and down the supply chain, you should use the information given in SDSs 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 (https://www.echa.europa.eu/web/guest/information-on-chemicals).

Classification & Labelling Inventory

The C&L Inventory on the ECHA website contains the classifications harmonised at EU level (Table 3 of Part 3 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[16].

9.2 Other information sources

Information on the hazardous properties of substances can be sourced in databases that are accessible on the internet or from scientific journals. While section R.3.4 of the *Guidance on information requirements and chemical safety assessment* on the ECHA

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

website 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: https://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 1 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 UN 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 the CLP Regulation. In relation to physical hazards, this means that you may have to test in order to provide the data that are necessary for an unambiguous classification in accordance with the CLP Regulation;
  - 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 the CLP Regulation 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;
- Registry of Toxic Effects of Chemical Substances (RTECS) available from the United States National Institute of Occupational Safety and Health (NIOSH) website: https://www.cdc.gov/niosh/rtecs/;
- United States Environmental Protection Agency (US EPA) website: https://www.epa.gov/;
- Integrated Risk Information System (IRIS) available from the US EPA website: https://www.epa.gov/iris;
- United States Occupational Safety & Health Administration (OSHA) website: https://www.osha.gov/;

- Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) website: https://www.nicnas.gov.au/;
- Toxicology Data Network (TOXNET) website, which includes databases such as the Toxicology Literature Online (Toxline) database and Hazardous Substances Data Bank (HSDB): https://toxnet.nlm.nih.gov/;
- International Programme on Chemical Safety (IPCS) INCHEM website: http://www.inchem.org/; and
- scientific literature: the PubMed portal from the US National Library of Medicine searches hundreds of relevant journals, many of which are available free of charge https://www.ncbi.nlm.nih.gov/.

9.3 Testing

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

10. The role of testing in the CLP Regulation

10.1 The role of testing

The CLP Regulation 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 section 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 manual is available at http://www.unece.org/trans/danger/publi/manual/manual_e.html. Available test results obtained with other methods or standards may still be used, provided that they are adequate for the purpose of hazard determination. To conclude on the adequacy of the data, 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[17], 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[18]. 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

For health and environmental hazards, the CLP Regulation will only allow you to perform new testing when 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 (quantitative) structure-activity relationships ((Q)SARs), *in vitro* methods and read-across. Expert judgement should be used in order to apply the CLP criteria, for example to evaluate available test data that cannot be directly compared with

[17] CLP Article 8(5).

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

the criteria or to exploit available data on 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, for example 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 the Test Methods Regulation (EC) No 440/2008, which sets out the test methods to be applied for the purposes of the REACH Regulation; 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 section 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 on the protection of animals used for scientific purposes. 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 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 sections 2 to 4 of the *Guidance on the Application of the CLP Criteria*.

11. Classifying substances and mixtures

11.1 Basic steps

There are five basic steps for classifying substances and mixtures, as set out in Figure 1:

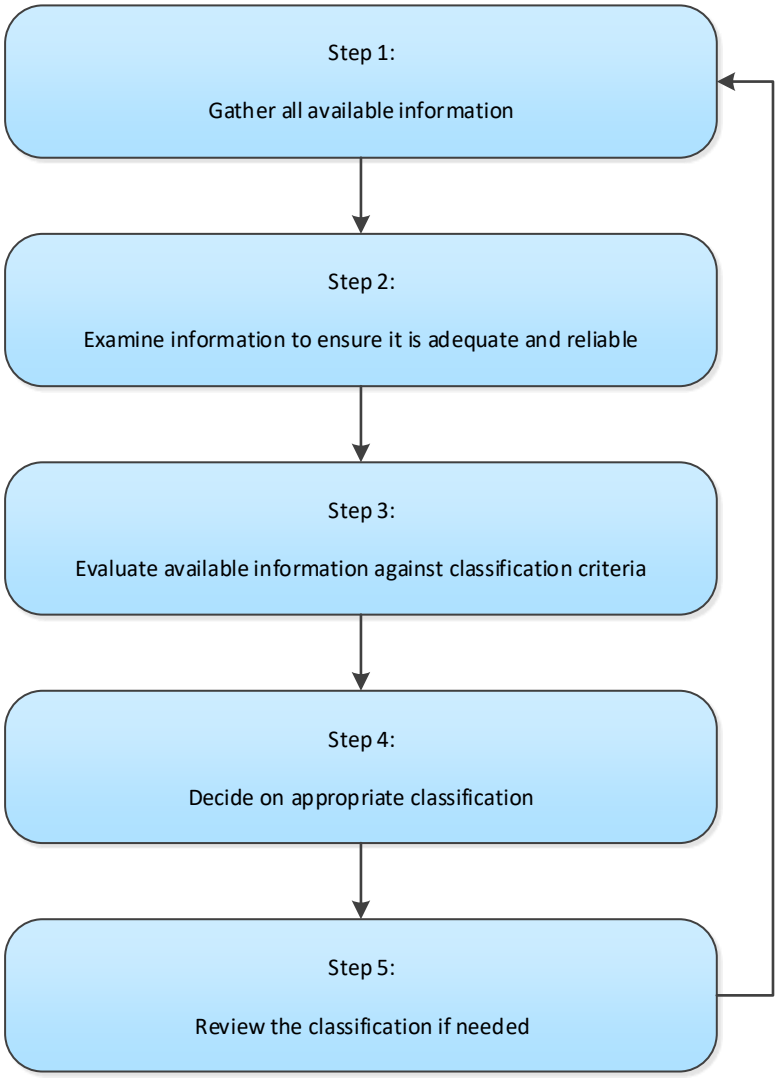

Figure 1 Five basic steps for classifying substances and mixtures

11.2 Step 1: Gather available information

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

- results of tests carried out in accordance with the Test Methods 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 Articles 5(1)(a) and 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 on substances 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 section 9 and Annex 2 to this guidance document. Please note that where the substance has a harmonised classification and a related entry in the Table 3 of Part 3 of Annex VI to CLP, you are not required to gather available information related to that specific hazard (without prejudice to CLP article 37(6)). In other words, you should check Annex VI first before starting to gather information.

REACH

Registrants for the same substance have the obligation under REACH to jointly submit data, including data for the purpose of classification and labelling with limited exceptions (REACH Article 11(1) and (3)). The REACH inquiry process needs to be used to ask for access to test data (REACH Articles 26 and 27).

For the classification of a mixture, available data on the mixture as a whole should primarily be used according to the tiered approach, 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. For example, you may 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 (see also section 11.7 of this Guidance document). Where you cannot exploit available test data on the mixture as a whole, the key to its classification is sufficient information on the ingredients of the mixture.

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 SDS from the supplier of the substance.

Where you are using an ingredient that is supplied as a mixture, you need to know what component substances are in that mixture together with their concentrations and classifications, to the extent possible (see also section 1.6.4 of the *Guidance on the Application of the CLP Criteria*). Such composition data may be available in the SDS for the mixture, but further dialogue with the supplier may be necessary to obtain additional information.

11.3 Step 2: 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[19] 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 or mixture 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 section 1.2 of the *Guidance on the Application of the CLP Criteria*.

11.4 Step 3: 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 or a mixture may differ from those shown by testing, for instance in the 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)).

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

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

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 the CLP Regulation 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) or mixtures (bridging principles), (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 or mixture, 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 section 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 https://echa.europa.eu/support/mixture-classification/evaluate-information-against-classification-criteria.

11.5 Step 4: Decide on an appropriate classification

If the evaluation of the hazard information shows that the substance or mixture 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 SDS, i.e. the signal words, hazard statements, hazard pictograms and precautionary statements (see also sections 12 and 15 of this guidance document). This exercise must be repeated for each hazard class defined under the CLP Regulation for which you have information.

See also section 23 on the obligation under the REACH Regulation triggered by the classification.

Where a substance is subject to registration under the REACH Regulation in quantities of 10 tonnes or more per year, you will have to perform a chemical safety assessment. If the substance is classified in one of the following hazard classes defined in Annex I to CLP (REACH Article 14(4)):

- 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,

then the chemical safety assessment must also include the steps of exposure assessment and risk characterisation (REACH Article 14(4)).

When assigning a classification to a substance, you may also have to set so-called "specific concentration limits" (SCLs). SCLs are required where adequate and reliable scientific information shows that any hazard arising from the substance is already evident when it is present in a mixture or another substance (e.g., as an impurity) at a concentration below the concentration limits set in Annex I to CLP . In exceptional circumstances, where the hazard of a substance is not evident above these thresholds, you may also set higher SCLs (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).

If harmonised ATE values are missing for acute toxicity, the correct value has to be established by using the available data.

SCLs, M-factors or ATEs for harmonised classifications can only be set by the manufacturer, importer or downstream user where no SCL, M-factor or ATE is given in Part 3 of Annex VI to CLP.

Further details on setting SCLs and M-factors are provided in section 1.5 of the *Guidance on the Application of the CLP Criteria*.

11.6 Step 5: Review the classification if needed

Note that a classification may need to be reviewed for many reasons (see also the classification web page at https://echa.europa.eu/support/mixture-classification/), for instance:

- if there are changes in the harmonised classification of the substances in Table 3 of Part 3 of Annex VI to CLP;
- if there are changes in classification in the SDS from your supplier;
- if there are changes in the mixture as a result of changes in the concentrations of one or more hazardous constituents, changes in composition or significant variations from batch to batch;

- if new information is available on your substance, e.g. when REACH registration dossiers are updated;
- if there are changes in the classification criteria.

You need to keep up-to-date with both emerging new information and legislative changes in order to adapt the classification of your substance or mixture in accordance with the outcome of the new evaluation and also update the related label, notification and SDS as soon as possible.

Changes to harmonised classifications or CLP criteria through an ATP to CLP must be adopted following a transitional period of normally eighteen months following their publication in the official journal of the European Union.

11.7 Flexible approaches for classifying mixtures based on different sets of information

In general, the CLP Regulation 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 (https://echa.europa.eu/support/mixture-classification) and section 1.6 of the *Guidance on the Application of the CLP Criteria*.

Depending on the information you have available 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 Articles 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[20] (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 SCLs, M-factors and ATEs, in case substances that are classified for the particular hazard are present in the mixture. In this case, you

[20] 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 Section 1.6 of the *Guidance on the application of the CLP criteria*.

should also use any harmonised classifications for the substances present in the mixture, including any SCLs, M-factors and ATEs that are provided in Annex VI to CLP or in the C&L inventory.

Please find further guidance on the application of:

- Weight-of-evidence determination in the *Guidance on information requirements and chemical safety assessment* under the REACH Regulation;
- the bridging principles in section 1.6.3.2 of the *Guidance on the Application of the CLP Criteria*;
- the calculation methods in section 1.6.3.4 of the *Guidance on the Application of the CLP Criteria*; and
- the concentration limits, including SCLs and M-factors, in section 1.6.3.4 of the *Guidance on the Application of the CLP Criteria*.

12. Labelling

In this section, 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.

12.1 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[21]; 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.

12.2 Who has to label?

If 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** that are explosive according to the criteria in Part 2 of Annex I to CLP.

If 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 that 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 that you do not change the composition of the substance or mixture supplied to you (see section 2 of this guidance document).

12.3 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):

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

Table 8 Label (and pictogram) 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 that contains the labelling information. However, all of the labelling requirements described in the sections below should be fulfilled.

If your label is intended to meet the requirements of both the CLP Regulation 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). For further details, please see section 5.4 of the *Guidance on labelling and packaging in accordance with the CLP Regulation*.

12.4 In which language(s) 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[22]. 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 State(s), 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).

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

12.5 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 CLP Article 17:

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

The labelling elements described above 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.

12.6 Product identifiers

You must use the same product identifiers on the labels as in the SDSs 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 C&L inventory, as far as the substance is not included in Part 3 of Annex VI to CLP; or
3. the Chemical Abstracts Service (CAS) number and the International Union of Pure and Applied Chemistry (IUPAC) name, or the CAS number and another internationally recognised name[23], if the substance is neither included in Part 3 of Annex VI to CLP nor in the C&L inventory managed by the Agency; or
4. the IUPAC name or another internationally recognised name, if no CAS number is available and none of the above apply.

Taking into account the rules on the use of languages as set out above, product identifiers for mixtures must include 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 for 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 that 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 section 18 of this guidance document).

12.7 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 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 to CLP (and reported in Table 8 of section 12.3 above), but the pictogram area must not be less than 1 cm^2.

[23] 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 to 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.

12.8 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.

12.9 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 must 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).

12.10 Precautionary statements

Your labels must bear the relevant precautionary statements (CLP Article 22), which give 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 must be selected in line with CLP Article 28 and Part 1 of Annex IV to CLP. Any selection must 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. For the selection of the most appropriate precautionary statements, further guidance is provided in section 7 of 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 must 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).

12.11 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 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 the CLP Regulation are set out in Table 9.

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

Hazard Statements: H	Precautionary Statements: P
200 – 299 Physical hazard	100 General
300 – 399 Health hazard	200 Prevention
400 – 499 Environmental hazard	300 Response
	400 Storage
	500 Disposal

The inclusion of these codes on the label is however not required and only the hazard and precautionary statements themselves must appear on the label.

12.12 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 to CLP (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 to CLP, and the statements must also be placed in the section for supplemental information.

For mixtures subject to submission requirements under CLP Article 45 and Annex VIII to CLP, a unique formula identifier (UFI) must be printed on or affixed to the label, or printed on the packaging in proximity of the other label elements, if applicable. This will enable

any poison centre called upon for advice on how to deal with a poisoning incident with a product to rapidly and unambiguously identify the mixture(s) contained in it and retrieve the corresponding submitted information (for more details, see the *Guidance on harmonised information relating to emergency health response – Annex VIII to CLP* and section 4.8.1.1 of the *Guidance on labelling and packaging in accordance with the CLP Regulation*).

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 also means that inconsistent statements such as "non-toxic", "non-harmful" or "ecological" must be avoided; and
- not contradict or cast in doubt the validity of the information given by the labelling elements reflecting 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 REACH, should be included in this section.

REACH

REACH Article 65 provides that the holders of an authorisation as well as **downstream users** including the substances in a mixture must include the authorisation number on the label before they place the substance or the mixture on the market for an authorised use.

12.13 How should you organise your labels?

You can organise your labels in any way that leads to best clarity. However, the hazard pictograms, signal word, hazard statements and precautionary statements should be kept together on the 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 section, 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 section 6 of the *Guidance on labelling and packaging in accordance with the CLP Regulation*.

12.14 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 CLP 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 the BPR or the PPPR, labels must be updated in accordance with these Regulations.

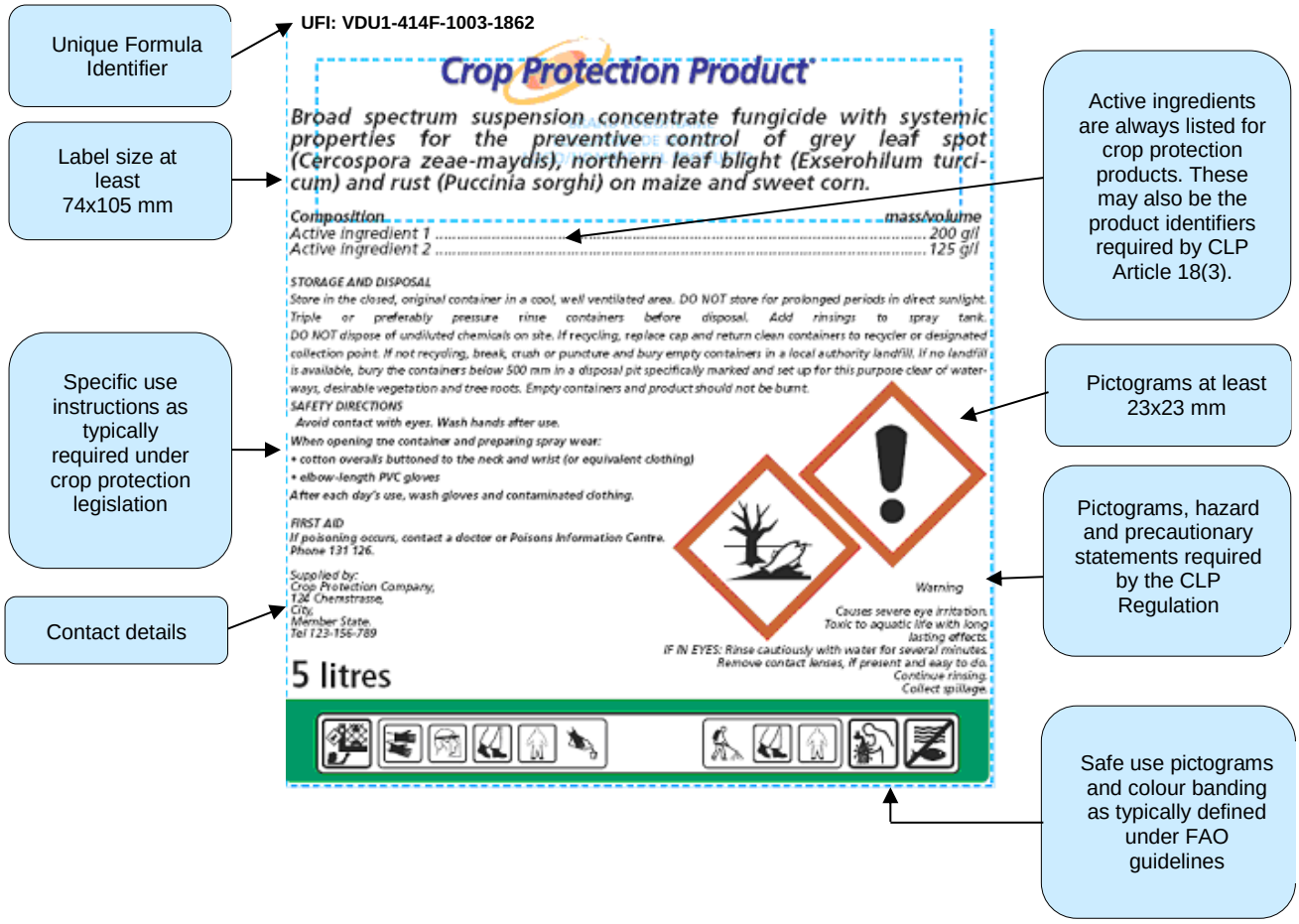

Figure 2 Example for a label incorporating information required by other legislation

12.15 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 unpackaged materials are supplied to professional users, labelling information and other relevant hazard information are provided through other means than a label, usually in the SDS. 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).

13. Applying the precedence rules for labelling

13.1 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.

13.2 Signal words

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

13.3 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….

Optional

or

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.

13.4 Hazard statements

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

13.5 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 that 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 provide flexibility in the application of precautionary phrases, combinations or consolidations of precautionary statements are encouraged to save label space and improve readability. 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*.

14. Specific labelling and packaging provisions

14.1 Variety of labelling and packaging situations

The labelling and packaging requirements of the CLP Regulation 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 the CLP Regulation deals with these situations, is described in this section.

14.2 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 a packaging that is too small[24] or of such form or shape that it is impossible to meet the requirements of CLP Article 31, the CLP Regulation 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 section 5.3 of the *Guidance on labelling and packaging in accordance with the CLP Regulation*.

14.3 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 (CRFs) and/or tactile warnings of danger (TWDs) 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 Tables 10 and 11, respectively. These provisions apply whatever the capacity of the packaging.

Additional safety measures for liquid consumer laundry detergents contained in soluble packaging for single use are in place to make the packaging less attractive and more difficult to open for children. In particular, CLP Article 35(2) and section 3.3 of Annex II to CLP provide requirements for the outer and inner (soluble) packaging. For further details, please see section 3.4 of the *Guidance on labelling and packaging in accordance with the CLP Regulation*.

[24] 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 (categories 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 (categories 1A, 1B and 1C)	✓	✓
Respiratory sensitisation (category 1)		✓
Aspiration hazard (category 1) *With the exception of substances or mixtures in aerosol form or if in container with sealed spray attachment if not classified for another hazard class triggering the requirement(s) for CRF or TWD*	✓	✓
Germ cell mutagenicity (category 2)		✓
Carcinogenicity (category 2)		✓
Reproductive toxicity (category 2)		✓
Flammable gases (including chemically unstable gases) (categories 1 and 2; categories A and B)		✓

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

14.4 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 an 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 the CLP Regulation 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 and section 5.4 of the *Guidance on labelling and packaging in accordance with the CLP Regulation*.

15. Safety data sheets

SDSs are an important communication tool in the supply chain. They help all the actors in the chain meet their responsibilities in relation to the management of risks arising from the use of substances and mixtures. The CLP hazard label and Section 2.2 of the SDS must be consistent.

The requirement to provide an SDS is set out in REACH Article 31 and Annex II to REACH[25] "Requirements for the compilation of safety data sheets".

The information given in the SDS 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 SDS for substances manufactured or imported at 10 tonnes or more per year.

15.1 When do you need to update?

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

- new knowledge on hazards becomes available;
- any of the other criteria listed in REACH Article 31(9) for which an SDS update is required (see the Guidance on compilation of safety data sheets for more details).

15.2 What do you need to update?

Any new or revised classification, including any changes of SCLs, M-factors or ATEs for substances, should be included in Section 2 (Hazard identification) and Section 3 (Composition / Information on ingredients) of your SDS. 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 SDS.

You will also need to review the other sections of your SDSs 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 SDSs and include any appropriate new or updated information.

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

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 CSR should be updated in line with any update of the SDS Section 7 (Handling and storage), Section 8 (Exposure controls/personal protection) or 13 (Disposal considerations)) or vice versa.

From 1 June 2015, REACH Article 31(3) (b) (amended by CLP Article 59(2)) changed to (new text in **bold**):

"The supplier shall provide the recipient at his request with an SDS 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) […]"

16. The classification and labelling inventory – notifying substances

16.1 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 C&L Inventory (CLP Article 42).

16.2 Who needs to notify?

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

- subject to registration under the REACH Regulation (≥ 1 tonne/year) and placed on the market (CLP Article 39(a));
- classified as hazardous under the CLP Regulation and is placed on the market, irrespective of the tonnage (CLP Article 39(b)); or
- classified as hazardous under the CLP Regulation and present in a mixture above the concentration limits specified in Annex I to 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 the REACH Regulation 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 section 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.

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

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

16.3 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 REACH;
- the identity of the substance, as specified in section 2.1 to 2.3.4 of Annex VI to REACH;
- the CLP classifications of the substance;
- where the substance has been classified in some but not all CLP hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive for non-classification;
- where applicable, SCLs, 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). However, you may classify your substance differently from another entry, provided that 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 section 7 of this guidance document). Please note that where an M-factor is not given in Part 3 of Annex VI to CLP 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 section 1.5 of the *Guidance on the Application of the CLP Criteria*.

16.4 What format must you use for notification?

Your notification must be in the International Uniform ChemicaL Information Database

(IUCLID) format. To send a notification dossier in the IUCLID format, you can either use the REACH-IT online dossier tool, or the downloadable version of IUCLID 6 (International Uniform Chemical Information Database) and submit your IUCLID dossier via the REACH-IT portal (CLP Article 40(1)).

To help you determine which route towards notification is best for you, and to find all the necessary information and links to the tools, go to the dedicated webpage of the ECHA website: https://echa.europa.eu/regulations/clp/cl-inventory/notification-to-the-cl-inventory.

Figure 3 below shows a screen shot from IUCLID 6.

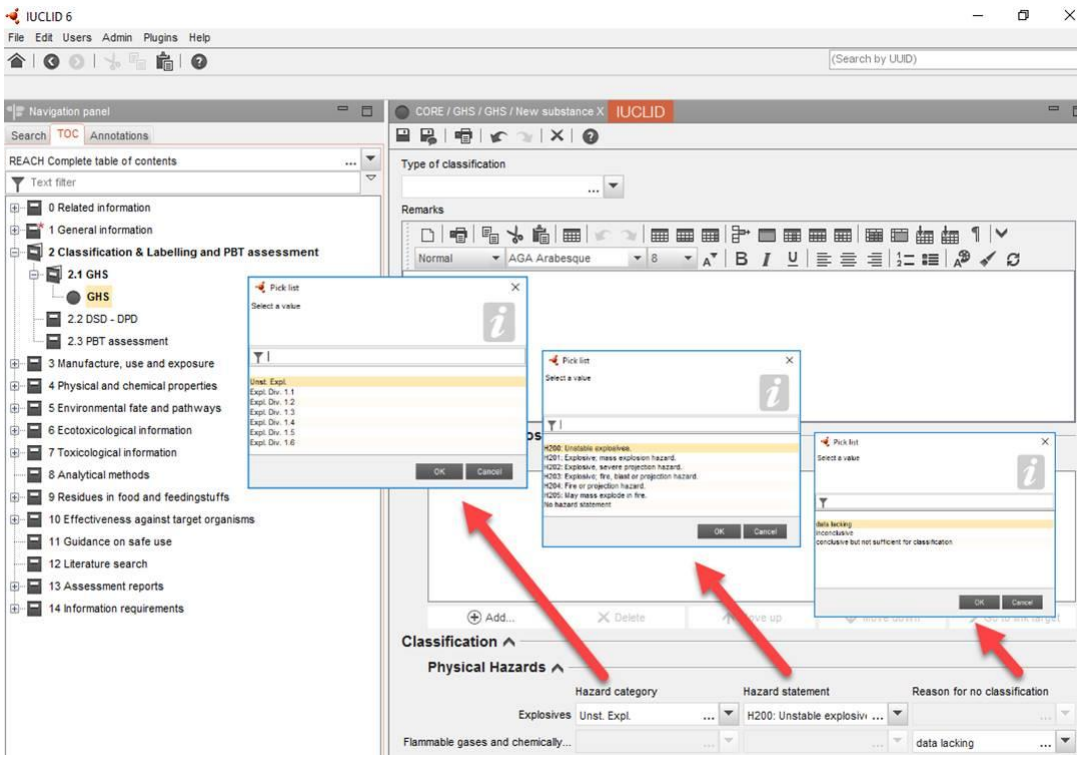

Figure 3 Screenshot from IUCLID 6

Figure 4 below shows a screenshot from the REACH-IT online dossier tool:

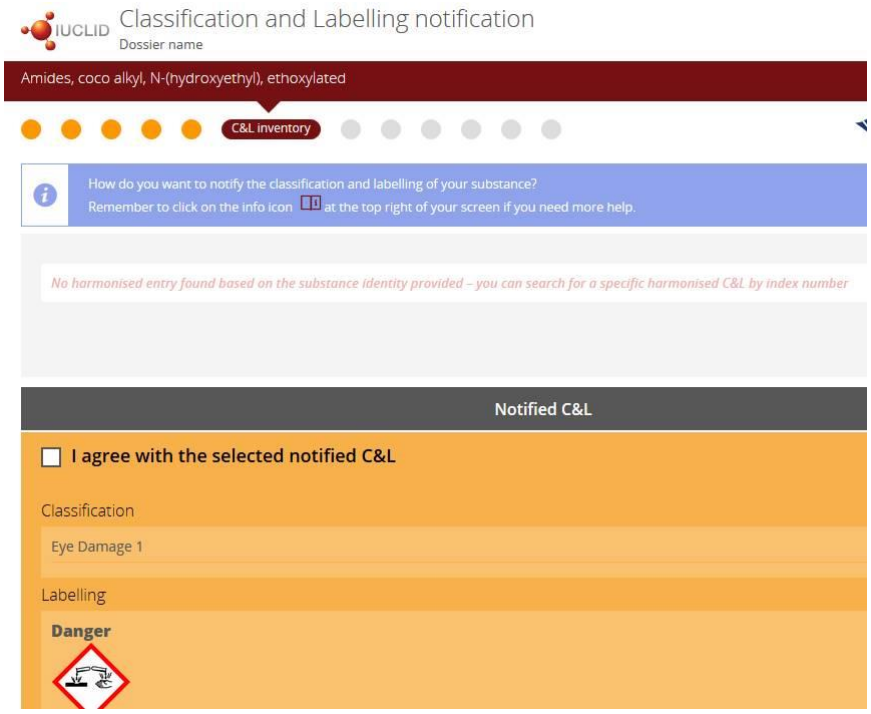

Figure 4 Screenshot from the REACH-IT online dossier tool

16.5 What happens next?

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

- whether there is a harmonised classification and labelling for the substance at Union level by inclusion in Annex VI to CLP;
- 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 the European Inventory of Existing Commercial Chemical Substances (EINECS); and
- the classification and labelling of the substance.

With regard to the name in IUPAC nomenclature for certain substances, 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.

17. New hazard information

17.1 You need to keep up to date with hazard information!

Under the CLP Regulation, 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."*

17.2 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 SDSs 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 for which you had previously submitted notification to the C&L inventory, you must notify the Agency of any such change (CLP Article 40(2)).

REACH	Chemical safety assessments and reports and SDSs will have to be updated when new information on hazards becomes available or when the classification and labelling change (REACH Articles 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 Articles 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 5.

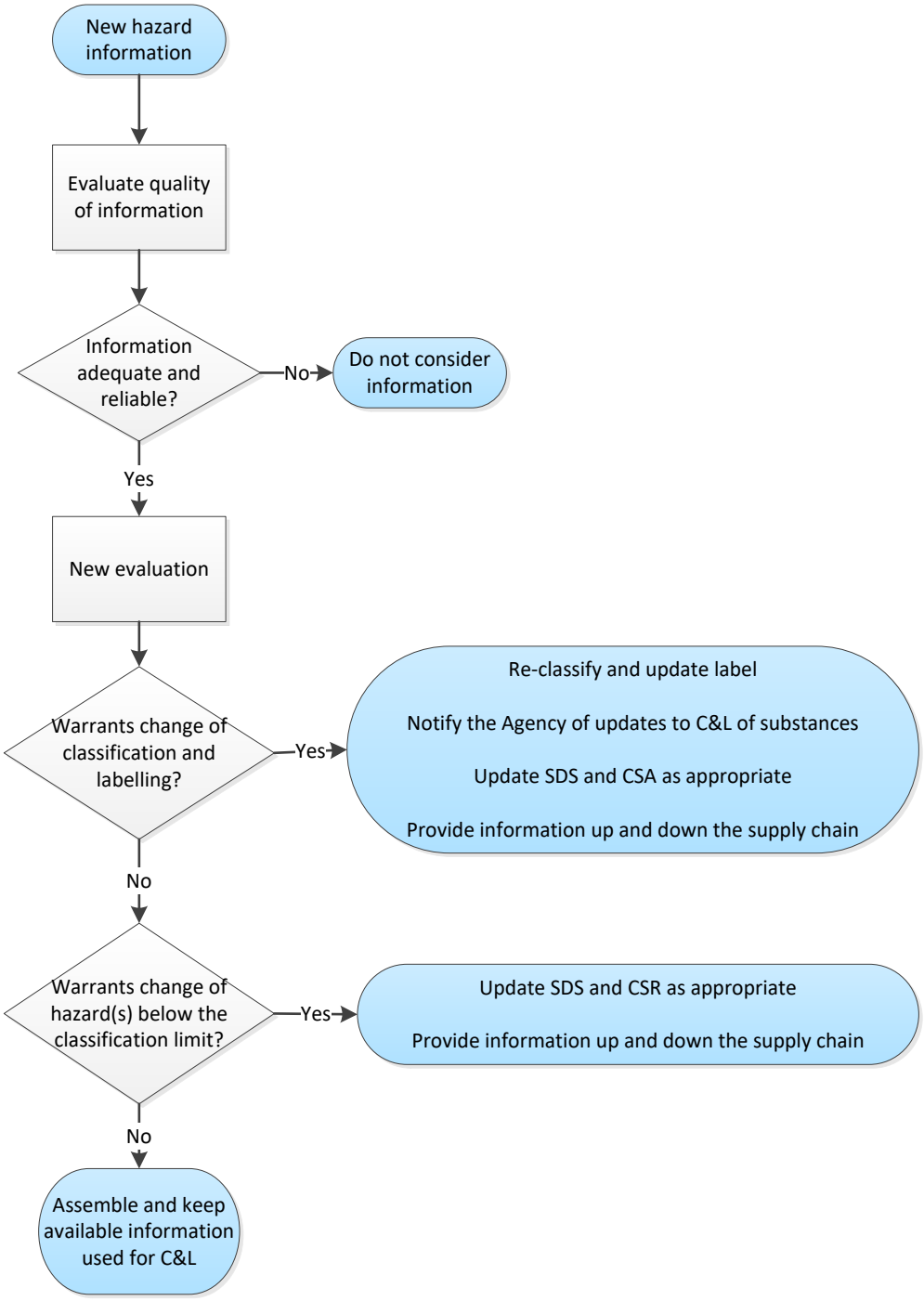

Figure 5 What to do about new hazard information

18. Request for use of an alternative chemical name

18.1 Introduction

Under the CLP Regulation, substances and mixtures placed on the market must be well identified (see section 12.6 of this guidance document on product identifiers). However, as a **manufacturer, importer** or **downstream user** you may be concerned that the disclosure on the label or SDS 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 you to submit a request to the Agency to use an alternative chemical name that 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'.

18.2 Who to submit the request to?

All requests for an alternative chemical name must be sent to the Agency (ECHA), 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 SDS of the mixture instead of the substance name.

If a request for use of an alternative chemical name was submitted to a Member State Competent Authority under the DPD and the request was approved before 1 June 2015, the use of the approved alternative chemical name is still allowed.

18.3 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 the necessary health and safety precautions to be taken and ensure that risks from handling the mixture can be controlled. It is up to the applicant to demonstrate that this is the case.

18.4 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 take a decision. Practical information is available on the dedicated webpage of the ECHA website at: https://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 from the date of submission of your request or, in case ECHA requires further information, from the date of receipt of such further required information. If ECHA raises no objections within these six weeks, the use of the requested name is deemed to be allowed.

19. Information records and requests

19.1 What record keeping regarding classification and labelling do the REACH and CLP Regulations require from you?

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 in section 2 of this guidance document).

REACH

The REACH Regulation requires you to assemble and keep available all the information necessary to carry out your duties under the REACH Regulation 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 Competent Authority/ies of the Member State where you are established or to the Agency (REACH Article 36).

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

19.2 Who 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 the CLP Regulation. 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 the CLP Regulation, or your registration under the REACH Regulation, 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[26]) to be responsible for receiving the information relevant for formulating preventative and curative measures, in particular for emergency health response. If you are an **importer** or

[26] A list of appointed bodies has been prepared and made available by the Commission at http://ec.europa.eu/growth/sectors/chemicals/poison-centres_en.

downstream user placing mixtures on the market**,** these bodies must receive from you the necessary information, *inter alia* on the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health and physical effects. The information you provide must include the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency (CLP Article 45 and Annex VIII) [27].

[27] See also the *Guidance on harmonised information relating to emergency health response*.

20. Proposals for harmonised classification and labelling

20.1 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 or for updating 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 that 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. When such a proposal is submitted by a manufacturer, importer or downstream user, it 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)[28].

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 section 22 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 to the update of an existing Annex VI entry (see section 7 of this guidance document). They must be submitted to the Agency.

20.2 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[29]). A Competent Authority may make such a proposal even for a hazard for which a 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 a harmonised classification and labelling already exists for that substance; on the other hand, if they have new information that may lead to a change in the harmonised classification and labelling of a substance, they 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 sensitisers, a justification demonstrating the need for action at Union level is required.

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

[29] 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.

20.3 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*.

The steps required for you to submit a proposal are summarised in Figure 6.

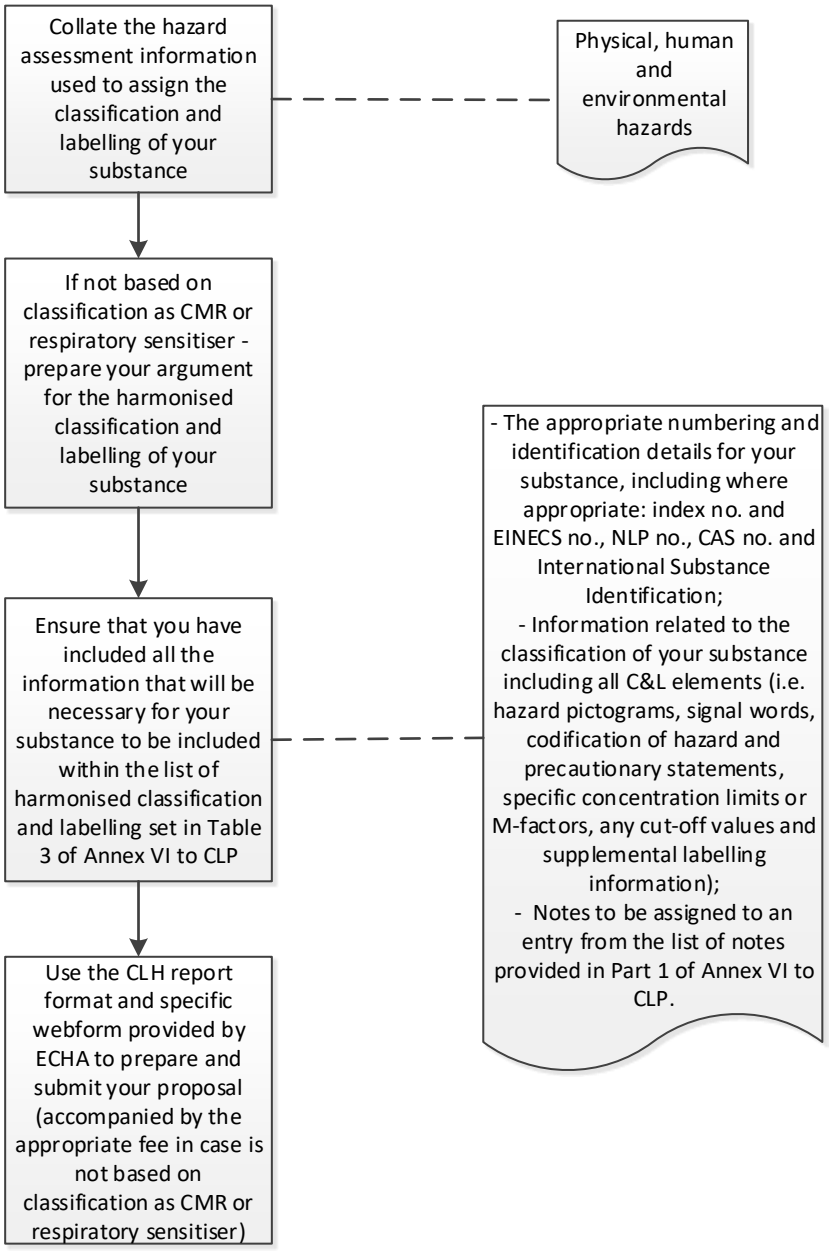

Figure 6 Steps required to prepare and submit a proposal

20.4 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 (https://echa.europa.eu/harmonised-classification-and-labelling-consultation), in a specified commenting form, where comments can be introduced by a specified deadline.

The Committee for Risk Assessment (RAC) of the Agency will form an opinion on a proposal for the harmonised classification and labelling of a substance within eighteen months (CLP Article 37(4)), and the Agency will then forward this opinion to the Commission. Should the Commission find that your proposal and justification are appropriate, it will propose to include your substance in Table 3 of Part 3 of Annex VI to CLP (which lists substances with a harmonised classification and labelling), together with the relevant classification and labelling elements and, where appropriate, the SCLs, M-factors and ATEs. The procedure to include a substance in Annex VI to CLP 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 7 (CLP Article 37).

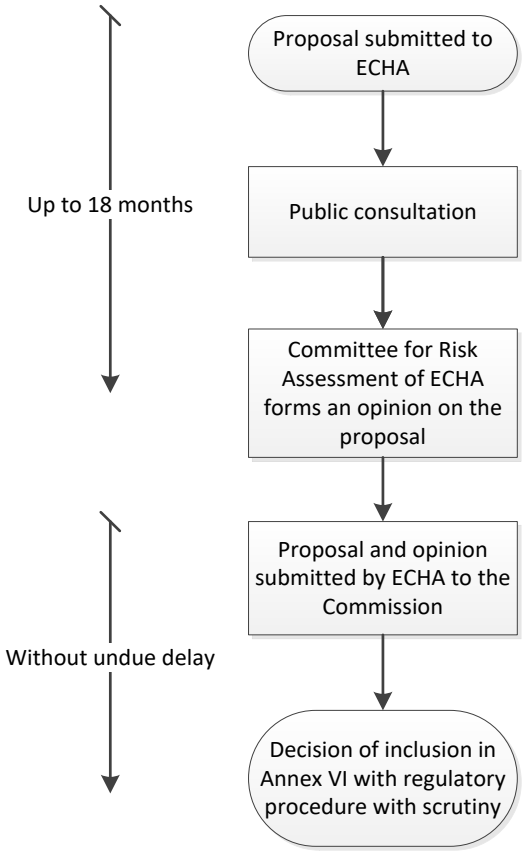

Figure 7 Process followed by the Agency and the Commission following the submission of a proposal for harmonised classification and labelling

21. Downstream legislation - an overview

21.1 Downstream legislation

Provisions under Union legislation other than the CLP Regulation (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 section 23 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 section 22 of this guidance document);
- Biocidal products: Regulation (EU) No 528/2012 (BPR) of 16 February 1998 (see section 22 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 might still refer to the previous directives on classification and labelling of substances and mixtures (preparations), i.e. DSD or DPD; they have been or are in the process of being amended accordingly over time to take account of the CLP Regulation. For summaries of some of the interactions between the CLP and REACH Regulations, the BPR and PPPR, see sections 22 and 23 of this guidance document.

The CLP Regulation 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 the CLP Regulation replaced those to the 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 the CLP Regulation replace those to the DSD. Insertion of general reference to the Test Methods Regulation (EC) No 440/2008, reference to CMR criteria under the CLP Regulation and concept of "dangerous" translated into CLP hazard classifications; the Directive was recast 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 the CLP Regulation 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 the CLP Regulation replace those to the DSD; concept of "dangerous" translated into CLP hazard classifications. The Directive was recast and on 13 August 2012 the new WEEE Directive 2012/19/EU entered into force[30].

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 the CLP Regulation, on 1 December 2010 or on 1 June 2015.

21.2 "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.

[30] The WEEE Directive is available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012L0019.

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.

22. Biocidal products Regulation, Plant protection products Regulation and interlinks with the CLP Regulation

The provisions of the CLP Regulation apply in full to any substance or mixture whose marketing and use are controlled by the BPR or the PPPR. However, the CLP Regulation 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 the CLP Regulation. 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 section 12 of this guidance document).

Substances that are active substances in the meaning of the BPR or the PPPR are normally subject to harmonised classification and labelling (see sections 7 and 20 of this guidance document), i.e. all hazard classifications and labelling elements will be harmonised. This is a difference compared to other substances, for which 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[31]. 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 update of the classification and labelling of your substance or mixture, you must do so in accordance with the provisions of the CLP Regulation (CLP Article 30) (see section 17 of this guidance document). However, should your substance or product (mixture) fall within the scope of the BPR or the PPPR and be 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)).

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

23. Obligations under REACH triggered by the classification of substances and mixtures

In general your obligations under the REACH Regulation 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 a substance or import it, on its own or in a mixture, at or above 10 tonnes per year, you are obliged to assess exposure and characterise the related risk for the preparation of the CSR in case this substance meets the criteria for classification (REACH Article 14);
- you must compile an SDS 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 substance in quantities between 1 and 10 tonnes per year that is likely to be classified as CMR category 1A or 1B according to the CLP Regulation, 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 SVHCs as new substances are subjected to the Authorisation process[32].

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

[32] More information is available on the dedicated webpage on the ECHA website: https://echa.europa.eu/substances-of-very-high-concern-identification-explained.

24. Joint submission of data and data sharing under REACH

Registrants for the same substance have the obligation under REACH to jointly submit data, including data for the purpose of classification and labelling, with limited exceptions (REACH Article 11(1) and (3)). Therefore, they must **agree on the classification and labelling of a substance** and consider where there is a difference between the potential registrants. It may indeed happen that a supplier classifies the same substance differently from another supplier, for example in case of impurity in one substance leading to a higher classification.

The CLP Regulation requires that the notifiers (under the CLP Regulation) and registrants (under the REACH Regulation) must make every effort to come to an agreed entry, i.e. to an agreed classification and labelling, to be included in the C&L inventory (CLP Article 41) where there are different entries for the same substance in the inventory.

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.

For more detailed information and guidance on joint submission of data and data sharing issues, please also refer to the *Guidance on data sharing*.

25. REACH guidance documents relevant to the CLP Regulation

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 understand and assess the hazards of your substance or mixture. The Agency has published a range of guidance documents (some of them being referred to in this guidance document) relating to the REACH Regulation, which are available to download from the Agency website: https://echa.europa.eu/guidance-documents/guidance-on-reach. Of particular relevance to the CLP Regulation are the guidance documents introduced here below.

Guidance on the compilation of safety data sheets

This guidance document assists industry in determining tasks and requirements to comply with in order to fulfil the obligations under REACH Article 31 (requirements for SDSs) and Annex II to REACH.

Guidance on registration

This guidance document gives clarification on the roles of "**manufacturer**" and "**importer**".

Guidance for downstream users

This guidance document gives clarification on the roles of "**downstream user**" and "**distributor**".

Guidance on requirements for substances in articles

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

Guidance on information requirements and chemical safety assessment

This guidance document gives advice on how to carry out certain steps that are common to hazard assessment under the REACH Regulation and classification, i.e.: where to find available information, how to assess collected data and 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 to F) and supporting reference guidance (Chapters R.2 to R.20). Part B contains concise guidance on hazard assessment. This covers information requirements on intrinsic properties of a substance under the REACH Regulation, 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 CSR and the extended SDS.

Guidance on data sharing

This document provides detailed information and guidance on data sharing and joint submission issues, e.g. the obligations of **registrants to share data** (see also section 24 of this guidance document).

Annex 1. Glossary

Terms used in this guidance document

Aerosol: aerosol dispenser, any non-refillable receptacle 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

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;

Differentiation: the distinction between hazard classes depending on the route of exposure or the nature of the effects;

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**;

Endpoint: any physico-chemical, biological or environmental effect, which can be measured under specific conditions;

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;

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;

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;

Hazard (sub-)category: the (sub-)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;

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;

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

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;

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;

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;

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 2. 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 section 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 find your way around the requirements of the CLP Regulation. Should you require more specific guidance on the application of CLP criteria to the classification of your substances and mixtures, please consult the *Guidance on the Application of the CLP Criteria*.

2. ***Guidance on labelling and packaging in accordance with the CLP Regulation*:** this document describes specific provisions for labelling and packaging of chemical substances and mixtures under Titles III and IV of the CLP Regulation. (see the *Guidance on labelling and packaging in accordance with the CLP Regulation*).

3. ***Guidance on harmonised information relating to emergency health response – Annex VIII to CLP*:** this document provides detailed guidance for companies on how to comply with their obligation under CLP Article 45 and Annex VIII to submit to the relevant national appointed bodies information on the hazardous mixtures companies place on the market (see the *Guidance on harmonised information relating to emergency health response* and ECHA's Poison Centres website at https://poisoncentres.echa.europa.eu/).

4. **Member State CLP/REACH helpdesks:** these are established in each Member State and are the points of contact for questions on the CLP and REACH Regulations (see 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: https://echa.europa.eu/web/guest/support/helpdesks.

5. **DG GROWTH website**: this internet website provides an overview and links to further information, including additional guidance at http://ec.europa.eu/growth/sectors/chemicals/classification-labelling/.

6. **DG ENV website**: this internet website provides an overview and links to further information, including additional guidance at http://ec.europa.eu/environment/chemicals/labelling/index_en.htm.

Annex 3. The UN GHS and the CLP Regulation

A.3.1. 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 UN 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.3.2. 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 implement in their own legislation only those hazard classes and categories which they consider relevant.

A.3.3. UN GHS categories not included in the CLP Regulation

Based on the building block approach, the CLP Regulation does not always include all hazard categories included in the UN GHS since they were not all part of the DSD, as shown in Table 14.

Table 12 Hazard categories included in the UN GHS but not in the CLP Regulation

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.3.4. Additional labelling and packaging rules

The CLP Regulation 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 the CLP Regulation and by transport legislation.

A.3.5. 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 section 22 of this guidance document.

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