ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on the preparation of dossiers for harmonised classification and labelling

Version 2.0
August 2014

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Document History

Version	Comment	Date
n.a.	First edition	June 2007
n.a.	Please note that changes between the version published in June 2007 and that of May 2010 are not recorded in this document history.	May 2010
Version 2.0	Full revision of the guidance addressing structure and content. The whole guidance has been revised by correcting or deleting errors and inconsistencies and to reflect the progress achieved by the process development activities including the ECHA CLH related Workshops in February 2011 and January 2013 and/or CARACAL meetings. Furthermore, the revision reflects the efforts made to align CLH and Plant Protection products (PPP)/Biocide Products (BP) processes. The structure has been generally reviewed to render the document clearer and more readable. This entailed changing the order of existing sections and creation of new ones. Information already covered by newer manuals or falling under the scope of other guidance documents has been removed. In particular, text covering technical details about the CLH report format and IUCLID submission has been removed from the draft revised Guidance and will be covered in a new Data Submission Manual “How to prepare and submit a CLH dossier using the CLH report format and IUCLID”. The update includes the following: - Addition of reference to the relevant legal text to all section for consistency and improved clarity. - Update of subsection 2.1 by adding new relevant related documents and resources and removing obsolete references. - Update and transfer of subsection 3.2.1 on “Substance identification” to new Section 5 on “How to prepare a CLH dossier”. The detail on information requirements has been removed and instead a reference to Part 1, Annex VI to CLP has been added. - Addition of new subsection 3.3 to specify the legal requirements for the format to be used for the preparation of the CLH dossier. - Revision of subsection 3.4 to provide more and up-to-date information on the substances for which a CLH dossier can be submitted, identifying separately requirements related to new entries and to revisions of existing entries and roles of the different actors. - Addition of new subsection 3.4.4 on the possibility to submit CLH dossier for group entries. - Revision and transfer of subsection 4.2 on “The Registry of Intentions” to new Section 5 on “How to prepare a CLH dossier”. - Revision of subsection 4.3 and inclusion of the updated subsection on the justifications to propose changes to existing	August 2014

	entries and harmonised classification for hazard classes/differentiations other than CMR and respiratory sensitisation. - Original Section 4 split into two new sections: Section 4 on the overview of the process and Section 5 on how to prepare a CLH dossier. - Creation of new subsections in Section 5 to provide specific information also on active substances in BP and in PPP in relation to the creation of CLH dossiers for those substances. - Deletion of subsection 4.6 on “Classification based on impurities”. The interpretation of the regulation is under discussion and guidance on the issue needs to be further agreed and developed. - Revision of original subsection 4.7 to reflect the progress achieved by the process development activities and the development of new templates and IT tools. - Transfer of original subsection 4.9 on “What should an MSCA do if it considers that a CLH dossier is not appropriate?” to new Section 9. - Revision of original Section 5 (now Section 6) to reflect the progress achieved by the process development activities. In particular, the difference between “required” and “recommended” revisions, which may be requested by ECHA following accordance check, has been introduced. The role of quality of dossiers in RAC opinion development has been clarified. - Creation of new Section 7 on the alignment of the CLH process with the processes under PPPR and BPR. The information provided in this section aims to align the review processes for active substances in BP and the peer review evaluation of active substances in PPP with the CLH process. - Reduction of original Section 6 (now Section 8) by eliminating the out-of-date subsection 6.2.	

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Abbreviations

ATP	Adaptation to Technical Progress (in this guidance “ATP” refers to an ATP to the CLP Regulation)
BD	Background document
BP	Biocidal Product(s)
BPC	Biocidal Products Committee
BPD	Biocidal Products Directive; 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
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
CAR	Competent Authority Report (for active substances in biocidal products)
CLH	Harmonised Classification and Labelling
CLH dossier	Dossier consisting of a CLH report and a technical dossier in IUCLID, containing a proposal for harmonised classification and labelling of a substance (see also ‘CLH report’)
CLH proposal	Proposal for harmonised classification and labelling of a substance
CLH report	Report prepared according to a template provided by ECHA and containing all information relevant for the harmonised classification proposal, including substance identification, relevant data on the substance, evaluation and discussion of the data, a comparison with the CLP criteria and a conclusion on classification
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
CMR	Carcinogenicity, germ cell mutagenicity, reproductive toxicity
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DAR	Draft Assessment Report (for active substances in plant protection products)
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
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EEA	European Economic Area
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ESR	Existing Substance Regulation
EEC	European Economic Community
EC	European Commission
EU	European Union
Fee Regulation	Commission Regulation (EU) No 440/2010 of 21 May 2010 on the fees payable to the European Chemicals Agency pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
IARC	International Agency for Research on Cancer
IUCLID	International Uniform ChemicaL Information Database
IUPAC	International Union of Pure and Applied Chemistry
M-factor	Multiplying factor
MSCA	Member State Competent Authority
NONS	Notification Of New Substances
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic
PPP	Plant Protection Product(s)
PPPR	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
(Q)SAR	(Quantitative) Structure-Activity Relationships
RAC	Committee for Risk Assessment

RAR	Renewal Assessment Report
RCOM	Response to Comments
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
RoI	Registry of Intentions
RMS	Rapporteur Member State (for active substances in BP and PPP)
SCL	Specific Concentration Limit
SIEF	Substance Information Exchange Forum
vPvB	Very Persistent and very Bioaccumulative
WHO	World Health Organisation

In this document, text cited from the CLP and REACH Regulations is indicated in green boxes.

1. Introduction

Regulation (EC) No. 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the CLP Regulation) entered into force on 20 January 2009. Title V of the CLP Regulation contains provisions for submission of proposals for harmonised classification & labelling.

The CLP Regulation specifies that Member State[1] Competent Authorities[2] (MSCAs) as well as manufacturers, importers or downstream users may submit proposals for harmonised classification and labelling (CLH proposals) of substances to the European Chemicals Agency[3] (ECHA) (Article 37, CLP).

Such proposals would normally pertain to any of the carcinogenicity, germ cell mutagenicity and reproductive toxicity (CMR) or respiratory sensitisers hazard classes[4] (and differentiation(s)[5] within the hazard class where applicable), but also to any other hazard classes or differentiations on a case-by-case basis if justification for action at EU level is provided in the proposal (Article 36(1) and (3), CLP). CLH proposals must be submitted to ECHA in the form of a dossier (hereinafter referred to as 'CLH dossier') prepared in accordance with the requirements of the CLP Regulation (see Section 3.3). The provisions of Title V of the CLP Regulation on the harmonisation of classification and labelling also apply to active substances in plant protection products (PPP) and biocidal products (BP), regulated by Regulation (EC) No 1107/2009 (the PPPR) and Regulation (EU) No 528/2012 (BPR), respectively (Article 36(2), CLP). With regard to these substances, the harmonisation of classification and labelling should normally apply to all hazard classes.

The hazard classes and categories in this document refer to those specified in the CLP Regulation. CLH dossiers received by ECHA after 1 January 2014 should not contain a classification proposal according to DSD. Until 1 June 2015, substances must also be classified according to the criteria in the Dangerous Substances Directive (DSD) (Article 61, CLP). However, considering the time it takes from submission of a CLH dossier until the Committee for Risk Assessment (RAC) forms an opinion on the proposed classification and the Commission includes the classification in an entry in Part 3, Annex VI, CLP, the opinions adopted by RAC will only cover classification according to the CLP Regulation.

2. About this guidance

This document provides guidance for MSCAs and manufacturers, importers and downstream users on how to prepare a CLH dossier under the CLP Regulation. The relationship between this guidance and other guidance documents relevant to both the CLP and the REACH Regulations, as well as the possible contribution of other activities under the REACH Regulation

[1] 'The Member States' refers to the Member States of the European Union (EU). In addition, the European Free Trade Association (EFTA) states that are signatories to the European Economic Area (EEA) agreement (these are currently Iceland, Liechtenstein and Norway) have incorporated the CLP Regulation into their national legislation, and hence references in this guidance to 'the Member States' should be read to include Iceland, Liechtenstein and Norway.
[2] 'Competent Authority' means the authority or authorities, or bodies established by the Member States to carry out the obligations arising from the CLP Regulation.
[3] The European Chemicals Agency (ECHA) is an EU body established for managing REACH and ensuring the consistency of its implementation throughout the EU. It is central to the implementation of both the REACH and the CLP Regulation. ECHA, through its secretariat and specialised committees, provides Member States and the institutions of the EU with scientific and technical advice on questions relating to chemicals falling within its remit.
[4] 'Hazard class' means the nature of the physical, health or environmental hazard and these are set out in detail in Annex I, Part 2, 3 and 4, to the CLP Regulation.
[5] 'Differentiation' means distinction within hazard classes depending on the route of exposure or the nature of the effects (Article 2 (33), CLP).

to the CLH dossier, is also described in this guidance. This guidance gives an overview of the general process for the preparation of a CLH dossier, as well as information on the different steps in the preparation of a CLH dossier and information about the processing of the dossier once it has been submitted to ECHA. There is also information on how the process for harmonised classification and labelling can be aligned with the processes for approval, renewal and review of active substances under the BP and PPP legislations (see Section 7) and information on transitional arrangements (outlined in Section 8).

2.1. Links to supporting documents and web pages

This guidance document is complemented by other supporting documents. Each of the supporting documents mentioned below is accessible via the ECHA website (http://www.echa.europa.eu). Please note that the relevant Data Submission Manual and the CLH report format were being finalised at the time of the publication of this Guidance. They will be made available at the link indicated soon after August 2014. Links to relevant web pages on the ECHA website, as well as other guidance or supporting documents, are given below.

1. Guidance documents and formats related to the CLP Regulation and the CLH process:
   - Guidance on the basic features and procedures of the CLP Regulation can be found in the *Introductory guidance on the CLP Regulation* (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp).
   - Detailed guidance on how to use relevant available information for classification purposes is provided in the *Guidance on the Application of the CLP Criteria* (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp).
   - Technical instructions on how to prepare a CLH dossier, including where and how to fill in the required information in the CLH report and in the IUCLID dossier and how to submit it to ECHA, can be found in the *Data Submission Manual "How to prepare and submit a CLH dossier using the CLH report format and IUCLID"* (http://www.echa.europa.eu/web/guest/regulations/clp/harmonised-classification-and-labelling).
   - Guidance on substance identification can be found in the *Guidance for identification and naming of substances under REACH and CLP* (http://echa.europa.eu/guidance-documents/guidance-on-reach).
   - The CLH report format can be found here: http://www.echa.europa.eu/web/guest/regulations/clp/harmonised-classification-and-labelling.

2. Other supporting documents that may be of relevance for the preparation of CLH dossiers:
   - Guidance on how to report robust study summaries can be found in *Practical Guide 3 "How to report robust study summaries"* on the ECHA website at: http://echa.europa.eu/practical-guides. It should be noted that the level of detail to provide for each hazard class (or differentiation(s) within a hazard class where applicable) is outlined in the CLH report format.
   - Practical guides that could be of relevance when drafting a CLH dossier, *e.g.* on how to report *in vitro* data, weight of evidence, QSARs, read-across and category approach, can also be found on the ECHA website at: http://echa.europa.eu/practical-guides.
   - A *IUCLID Getting started guidance* as well as a *IUCLID End User manual* (with detailed technical guidance on how to prepare the technical dossier in IUCLID) are available on the IUCLID website: http://iuclid.eu/index.php?fuseaction=home.documentation&type=public#technical manual.
   - *Guidance on information requirements and chemical safety assessment, Chapter*

R.6: QSARs and grouping of chemicals can be found on the ECHA website at: http://echa.europa.eu/guidance-documents/guidance-on-reach

3. Links to relevant web pages:

- The latest version of IUCLID can be downloaded from the IUCLID website: http://iuclid.eu/index.php?fuseaction=home.iuclidHome
- CLP legislation on the ECHA website: http://echa.europa.eu/web/guest/regulations/clp/legislation
- CLH related information on the ECHA website: http://echa.europa.eu/web/guest/regulations/clp/harmonised-classification-and-labelling
- Registry of Intentions (RoI) web page: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions
- Web form for submitting an intention to the RoI: http://echa.europa.eu/web/guest/support/clh
- Web form for submitting the CLH dossier: http://echa.europa.eu/web/guest/support/clh
- Public consultation web page: http://echa.europa.eu/web/guest/harmonised-classification-and-labelling-consultation
- Committee for Risk Assessment web page: http://echa.europa.eu/web/guest/about-us/who-we-are/committee-for-risk-assessment
- Biocidal Products Committee web page: http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee
- C&L Inventory and notification process: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/notification-to-the-cl-inventory
- Dissemination web site for registered substances: http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances
- EFSA website (pesticides section): http://www.efsa.europa.eu/en/panels/pesticides.htm

3. Scope and legal basis

3.1. Harmonised classification and labelling

Harmonised classification and labelling for a substance means that a decision to classify and label[6] the substance in a particular hazard class (or, where applicable, differentiation(s) within a hazard class), has been taken at EU level. The harmonised classification and labelling is included as an entry in Part 3 of Annex VI to the CLP Regulation. A harmonised classification, including any specific concentration limits[7] (SCLs) and/or Multiplying (M-)factor(s)[8] of a

[6] The labelling elements to be included in the list of harmonised classification and labelling of hazardous substances in Part 3, Annex VI, CLP, are specified in Annex VI, Part 1, 1.1.2.2, CLP. Precautionary statements are not harmonised and need to be determined by the manufacturer, importer or downstream user of the substance. For substances that are included in an entry in Part 3 of Annex VI, CLP and are also subject to self-classification (according to Title II, CLP), the label should include the hazard pictogram corresponding to the most severe hazard category for each relevant hazard class (Article 26(2), CLP).

[7] 'Specific concentration limits' are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous (Article 10(1), CLP).

substance must be used by all suppliers of that substance within the EU.

This means that self-classification of a substance must be performed only for those hazard classes or differentiations which are not yet included in an Annex VI entry for the substance. For hazard classes (or, where applicable, differentiation(s) within a hazard class) not covered by an entry in Annex VI to the CLP Regulation, suppliers are responsible for the classification and labelling before placing the substance on the market (Article 4(3) CLP). This means that for substances placed on the market that meet the criteria for classification in one or more of those hazard classes (or differentiation(s) within a hazard class where applicable), a self-classification must be conducted. Self-classification must also be conducted for substances that are not placed on the market but are subject to registration according to the REACH Regulation. The self-classification must be conducted by manufacturers, importers and downstream users of the substance in accordance with the criteria for classification as laid out in Annex I to the CLP Regulation (Article 1(1)(b), CLP). Guidance on how to carry out the self-classification can be found in the *Introductory guidance on the CLP Regulation* and in the *Guidance on the application of the CLP Criteria* (for links, see Section 2.1). Special provisions apply in cases where only a minimum classification[9] for a substance exists for one or more hazard classes or where specific notes have been added to the entry in Annex VI, CLP (1.1.3, Part 1, Annex VI, CLP).

Articles 36 and 37 of the CLP Regulation give the specific provisions for the procedure for CLH proposals. They provide information on who can submit a proposal, for which substances a proposal can be submitted as well as for which hazard classes, or differentiations within a hazard class, a proposal can be submitted. There is also information on the format to be used for the proposal, the timelines within which a decision has to be taken as well as specific cases where the proposal is to be accompanied by a fee.

3.2. Who can submit a CLH proposal?

Article 37, CLP

Procedure for harmonisation of classification and labelling of substances

1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits or M-factors, or a proposal for a revision thereof.
   [...]
2. A manufacturer, importer or downstream user of a substance may submit to the Agency a proposal for harmonised classification and labelling of that substance and, where appropriate, specific concentration limits or M-factors, provided that there is no entry in Part 3 of Annex VI for such a substance in relation to the hazard class or differentiation covered by that proposal.
   [...]
3. Where the proposal of the manufacturer, importer or downstream user concerns the

[8] 'M-factor' means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present (Article 10(2), CLP).

[9] For certain hazard classes, including acute toxicity and STOT repeated exposure, the classification according to the criteria in DSD does not correspond directly to the classification in a hazard class and category under the CLP Regulation. In these cases, the harmonised classification in Annex VI to CLP must be considered as a minimum classification. Minimum classification for a category is indicated by the reference * in the column "Classification" in Table 3.1., Annex VI, CLP (Section 1.2.1, Annex VI, CLP).

harmonised classification and labelling of a substance in accordance with Article 36(3), it shall be accompanied by the fee determined by the Commission in accordance with the regulatory procedure referred to in Article 54(2).
[…]

A CLH proposal, including SCLs and/or M- factors where appropriate, can be submitted by an MSCA or by a manufacturer, importer or downstream user of a substance established in any of the Member States (Article 37, CLP). These submitters are henceforth referred to as the 'dossier submitter' in this guidance document. It should be noted that an 'Only Representative'[10] (Article 8, REACH) cannot submit a proposal for harmonised classification and labelling according to the CLP Regulation. However, a manufacturer, importer or downstream user may authorise a representative to submit a CLH dossier on their behalf. Further instructions on how to do this are given in the Registry of Intentions (RoI) and CLH dossier submission web forms (see links in Section 2.1).

An MSCA may submit a CLH proposal, including SCLs or M-factors where appropriate, for a new entry in Annex VI to CLP as well as for a revision of a current entry in that Annex.

Manufacturers, importers or downstream users of a substance may submit a CLH proposal for a substance if there is no current entry in Part 3 of Annex VI to CLP for that substance for the specific hazard class(es) or differentiation(s) covered by the CLH proposal. If a substance is already included in Annex VI, a manufacturer, importer or downstream user may only submit a proposal directly to ECHA for those hazard classes or differentiations that are not included in the existing entry. For further information on the provisions for manufacturers, importers and downstream users, please see section 3.4.3.2.

A manufacturer, importer or downstream user cannot submit a CLH proposal for a substance that is considered as an active substance in the meaning of the BP or PPP legislations (Article 36(2), CLP).

3.3. Which format must be used for the CLH proposal?

The format of the CLH proposal, as well as the procedure for harmonised classification and labelling of substances is defined in Articles 36 and 37 of the CLP Regulation. In particular, in Article 37(1) reference is made to Part 2, Annex VI concerning the format for a CLH proposal.

ANNEX VI, CLP

PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING

[…]

A dossier for harmonised classification and labelling shall contain the following:
— Proposal
The proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed.
— Justification for the proposed harmonised classification and labelling
A comparison of the available information with the criteria contained in Parts 2 to

[10] A natural or legal person established outside the EU who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into the EU may by mutual agreement appoint a natural or legal person established in the EU to fulfil, as his only representative, the obligations on importers under Title II of REACH (Registration of substances).

5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) No 1907/2006.

— Justification for other effects at Community level

For other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of Directive 91/414/EEC[11] or Directive 98/8/EC[12].

Any CLH proposal submitted to ECHA must be prepared in the format of a 'CLH dossier'. A specific CLH report format has been developed by ECHA, with the intention of streamlining the process whilst assisting dossier submitters and RAC by ensuring that all relevant information is included. The format is the same for all the dossier submitters. Any CLH dossiers submitted to ECHA must consist of:

i. a 'technical dossier' created in IUCLID[13] (see Section 5.4.1.2); and
ii. a 'CLH report' attached to it (see Section 5.4.1.1).

When preparing the technical dossier, the dossier submitter should ensure that the latest version of IUCLID is used. The latest version of IUCLID can be found on the IUCLID website (see link in Section 2.1).

The CLH report must be prepared in the CLH report format as provided by ECHA on the ECHA website (see link in Section 2.1).

Further details on how to prepare the dossier are provided in Section 5.4.

3.4. For which substances can a CLH dossier be submitted?

3.4.1. General provisions

In principle, CLH dossiers can be submitted to ECHA for any substance (or group of substances) within the scope of the CLP Regulation, irrespective of the tonnage manufactured or imported. An MSCA, manufacturer, importer or downstream user can decide to prepare a CLH dossier at their own initiative, taking into account Section 3.2 "Who can submit a CLH proposal?".

A CLH dossier, according to the CLP Regulation can only be submitted for a substance[14], or a group of substances, and not for a mixture[15]. As alloys are considered mixtures for the purposes of the CLP Regulation (Article 2(27), CLP), CLH dossiers cannot be submitted for alloys.

[11] (This footnote is not part of the legal text) It should be noted that with effect from 14 June 2011, Directive 91/414/EEC has been repealed by Regulation (EC) No 1107/2009.
[12] (This footnote is not part of the legal text) It should be noted that with effect from 1 September 2013, Directive 98/8/EC has been repealed by Regulation (EU) No 528/2012.
[13] IUCLID is the international standard database for capturing, managing and exchanging data on properties of chemicals.
[14] According to Article 2(7) of CLP "Substance" means *a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any 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*.
[15] According to Article 2(8) of CLP "Mixture" means *a mixture or solution composed of two or more substances*.

3.4.2. New entries

3.4.2.1. Substances other than active substances in BP or PPP

Article 36, CLP

Harmonisation of classification and labelling of substances

1. A substance that fulfils the criteria set out in Annex I for the following shall normally be subject to harmonised classification and labelling in accordance with Article 37:

   (a) respiratory sensitisation, category 1[16] (Annex I, section 3.4);
   (b) germ cell mutagenicity, category 1A, 1B or 2 (Annex I, section 3.5);
   (c) carcinogenicity, category 1A, 1B or 2 (Annex I, section 3.6);
   (d) reproductive toxicity, category 1A, 1B or 2 (Annex I, section 3.7).

[…]

One of the main objectives of CLH is to focus on substances and hazards of highest concern (Recital 52, CLP). Since CMR and respiratory sensitisation are the hazard classes of greatest concern, ECHA recommends that dossier submitters systematically assess all CMR and respiratory sensitisation (category 1A and 1B) hazard classes for any type of substance. The dossier submitter can then draw conclusions on whether or not the substance fulfils the criteria for classification in these hazard classes (Part 3, Annex I, CLP). If the dossier submitter does not assess all CMR and respiratory sensitisation hazard classes in the dossier, it is recommended to add a brief reasoning as to why a particular hazard class was not assessed. The reasoning could be, for example, that no data are available for that specific hazard class.

Harmonised classification and labelling for hazard classes other than CMR and respiratory sensitisation may be proposed on a case-by-case basis if it is justified that action is needed at EU level (Article 36(3), CLP) (see Section 4.2). For a CLH dossier submitted by an MSCA covering hazard classes other than CMR and respiratory sensitisation, no fee is to be paid. However, if a CLH proposal submitted by a manufacturer, importer or downstream user concerns the harmonised classification and labelling of a substance in accordance with Article 36(3), CLP, *i.e.* hazard classes or differentiations other than CMR or respiratory sensitisation, it must be accompanied by the required fee (Article 37(3), CLP). The fee to be paid to ECHA is laid down in the Fee Regulation[17].

3.4.2.2. Active substances in BP or PPP

Article 36, CLP

Harmonisation of classification and labelling of substances

[…]

2. A substance that is an active substance in the meaning of Directive 91/414/EEC[18] or

[16] (This footnote is not part of the legal text) The 2nd ATP to CLP amended the differentiations for respiratory sensitisation to include category 1A and 1B.
[17] The Fee Regulation (Regulation (EU) No 440/2010) is a separate Commission Regulation on the fees payable to ECHA in accordance with CLP Regulation.
[18] (This footnote is not part of the legal text) It should be noted that with effect from 14 June 2011, Directive 91/414/EEC has been repealed by Regulation (EC) No 1107/2009.

Directive 98/8/EC[19] shall normally be subject to harmonised classification and labelling. For such substances, the procedures set out in Article 37, paragraphs 1, 4, 5 and 6 shall apply.

[…]

CLH dossiers for active substances in the meaning of the BP and PPP legislations can only be submitted directly to ECHA by an MSCA (Article 36(2), CLP). The CLH dossier is normally submitted by the Competent Authority established to implement the obligations under CLP in the same Member State as the Rapporteur Member State (RMS) preparing the Draft Assessment Report (DAR) or Competent Authority Report (CAR) for the active substance. For more information on the alignment of the processes for approval, renewal and review of active substances in BP and PPP with the CLH process, see Section 7.

For active substances in the meaning of the BP and PPP legislations, CLH dossiers should normally address all hazard classes and differentiations unless there is already an existing entry in Annex VI to CLP (see Section 3.4.3 and 5.4.1.1). A specific justification that action is needed at EU level is not required for such active substances in BP and PPP.

As a consequence, any CLH dossier for active substances in BP and PPP for which there is no current entry in Annex VI, CLP, should include the relevant available information related to all hazard classes and differentiations covered by the CLP Regulation, including those for which, based on the evaluation on existing data, no classification is proposed. For hazard classes where the criteria for classification are not fulfilled, the conclusion in the CLH dossier should state the reason why no classification is warranted (*e.g.* either 'data lacking', 'inconclusive', or 'conclusive but not sufficient for classification' as specified in Annex VI, 4.1. of the REACH Regulation, or any of the other options given in the CLH report format).

The MSCA should submit a CLH dossier for active substances in the meaning of the BP and PPP legislations to ECHA, even if the conclusion of the assessment is that no classification according to the CLP Regulation is justified. If RAC concludes that no classification is warranted for any hazard class, an opinion will be adopted but it will not lead to an entry in Annex VI to CLP.

3.4.3. Revision of an existing entry in Annex VI

3.4.3.1. MSCAs

CLH dossiers proposing a revision or removal of a specific hazard class and/or differentiation, and/or an SCL and/or M-factor, from an existing entry in Annex VI to the CLP Regulation, or removal of the entire entry, can only be submitted directly to ECHA by an MSCA (Article 37(1), CLP).

A revision or deletion of an existing entry can be justified in the event that new data has become available since the harmonised classification was agreed. The new data could, for example show that classification in a different category and/or differentiation is justified, or that a classification is no longer justified since the substance no longer fulfils the classification criteria. It could also be that due to changes in the classification criteria in the CLP Regulation, a revision of the current harmonised classification may be justified or that classification is no longer appropriate based on the new criteria.

[19] (This footnote is not part of the legal text) It should be noted that with effect from 1 September 2013, Directive 98/8/EC has been repealed by Regulation (EU) No 528/2012.

It should be noted that a CLH proposal for a substance for which an entry in Annex VI already exists, but where the proposal addresses only hazard class(es) or differentiation(s) that are not covered by the current entry, is not considered a revision but a new proposal (*i.e.* falls under the case addressed in Section 3.4.2).

Any CLH dossier with a proposal for revision of an existing entry in Annex VI to CLP, should include information on the current entry, the proposed revisions as well as information on what the resulting entry in Annex VI would be. For technical details on how to fill in the CLH dossier, refer to the *Data Submission Manual "How to prepare and submit a CLH dossier using the CLH report format and IUCLID"* (see link in Section 2.1). If the relevant information is available to the dossier submitter, ECHA also recommends including a short summary of what was the basis for the current entry.

The dossiers proposing revisions to Annex VI entries need only focus on the specific hazard classes that are proposed to be revised. If one or several of the CMR and respiratory sensitisation hazard classes were not assessed in the past when the current harmonised classification was adopted and included in Annex VI, it may be considered (in line with Article 36(1), CLP) that these are included in the updated dossier, in addition to the hazard class(es) for which the revision is proposed. The process for updating Annex VI entries is the same for active substances used in BP and PPP as for other substances, and hence CLH dossiers proposing a revision of an existing entry for active substances in BP and PPP do not need to include data on all hazard classes but only data relevant for the revision proposal.

The substance identity that is included in the existing entry should be used. If a change to the substance identity is proposed, the dossier submitter should contact ECHA via the Classification functional mailbox (classification@echa.europa.eu) before submitting the CLH dossier.

If the substance is part of a group entry, this should be indicated, and the CLH dossier should clearly indicate how the existing entry will be affected and which substance(s) of the group entry are to be revised, as well as what the new entry would look like (also see Section 3.4.4).

Any CLH dossiers with a proposal for revision or removal of an existing entry should clearly explain how the new information supports the proposed revision. The hazard classes and/or differentiations in the existing entry in Annex VI to CLP that are not covered by the proposal for revision and/or removal will not be affected.

If an MSCA receives a CLH proposal from a manufacturer, importer or downstream user of a substance that has information that could lead to a revision of a current entry for that substance in Annex VI to CLP, it is up to the MSCA to decide whether or not it is justified to submit a CLH dossier proposing a revision to ECHA. In order to avoid duplication of work, there is a system in place by which an MSCA can check whether another MSCA has been approached by the same manufacturer, importer or downstream user. For more information on this, the MSCA can contact ECHA via the Classification functional mailbox (classification@echa.europa.eu). For further details, see Section 3.4.3.2.

3.4.3.2. Manufacturer, importer and downstream user

Article 37, CLP

Procedure for harmonisation of classification and labelling of substances

[…]

6. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of a substance in Part

3 of Annex VI shall submit a proposal in accordance with the second subparagraph of paragraph 2 to the competent authority in one of the Member States in which the substance is placed on the market.

[…]

A manufacturer, importer or downstream user cannot submit a CLH dossier proposing a revision or removal of a specific hazard class and/or differentiation, and/or an SCL and/or M-factor, from an existing entry in Annex VI to the CLP Regulation, or the removal of an entire entry directly to ECHA (Article 36(2), CLP). If the manufacturer, importer or downstream user has information that could lead to a revision of an existing entry in Annex VI to CLP, as specified above, they must instead submit a CLH proposal (in line with Article 36(2), CLP) to the MSCA in one of the Member States in which the substance is placed on the market (Article 37(6), CLP). The MSCA will then decide if, based on the new information, it is appropriate to prepare a CLH dossier and submit it to ECHA in order to revise the existing harmonised classification. There is a system in place in which an MSCA can check whether another MSCA has been approached by the same manufacturer, importer or downstream user, in order to avoid duplication of work.

If a manufacturer, importer or downstream user has information that could lead to an addition of hazard classes and/or differentiations to the already existing entry, they can prepare a CLH dossier and submit it to ECHA. Information on the existing entry as well as information on what the resulting entry in Annex VI, CLP, would look like should then be included in the CLH dossier. The CLH dossier should only include information relevant for the new hazard classes (or differentiation(s) within the hazard class where applicable) in these cases and only the new hazard classes and differentiations will be considered by RAC.

3.4.4. CLH dossiers for group entries

Section 1.1.1.5, Annex VI, CLP

Entries for groups of substances

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

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

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

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

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

It is possible to submit a CLH dossier for a group of substances (Section 1.1.1.5, Annex VI, CLP). In these cases, the classification and labelling requirements will apply to all substances that are part of the group. The identity of the group and the scope of the resulting entry in Annex VI to CLP need to be clearly indicated in the CLH dossier.

If the aim is to have all substances included in the same entry (*i.e.* a group entry), one CLH dossier including all substances can be submitted. If, however, the aim is to have the CLH proposal resulting in several entries, one dossier per entry should be submitted.

Before submitting a CLH dossier for a group of substances, the dossier submitter is strongly advised to discuss with ECHA the most appropriate way to prepare the dossier.

If a dossier submitter has information that would lead to the removal of one or more of the substances included in an already existing group entry in Annex VI, CLP, it is recommended that the dossier submitter contacts ECHA via the Classification functional mailbox (classification@echa.europa.eu) before submitting the CLH dossier.

4. Overview of the process

The following sections explain in detail the different steps in the process up to the inclusion of the harmonised classification and labelling in Part 3, Annex VI to the CLP Regulation. The flowchart (Figure 1) gives an overview of the process for preparing a CLH dossier, indicates the parties involved and the steps in the processing of the dossier once it has been submitted to ECHA.

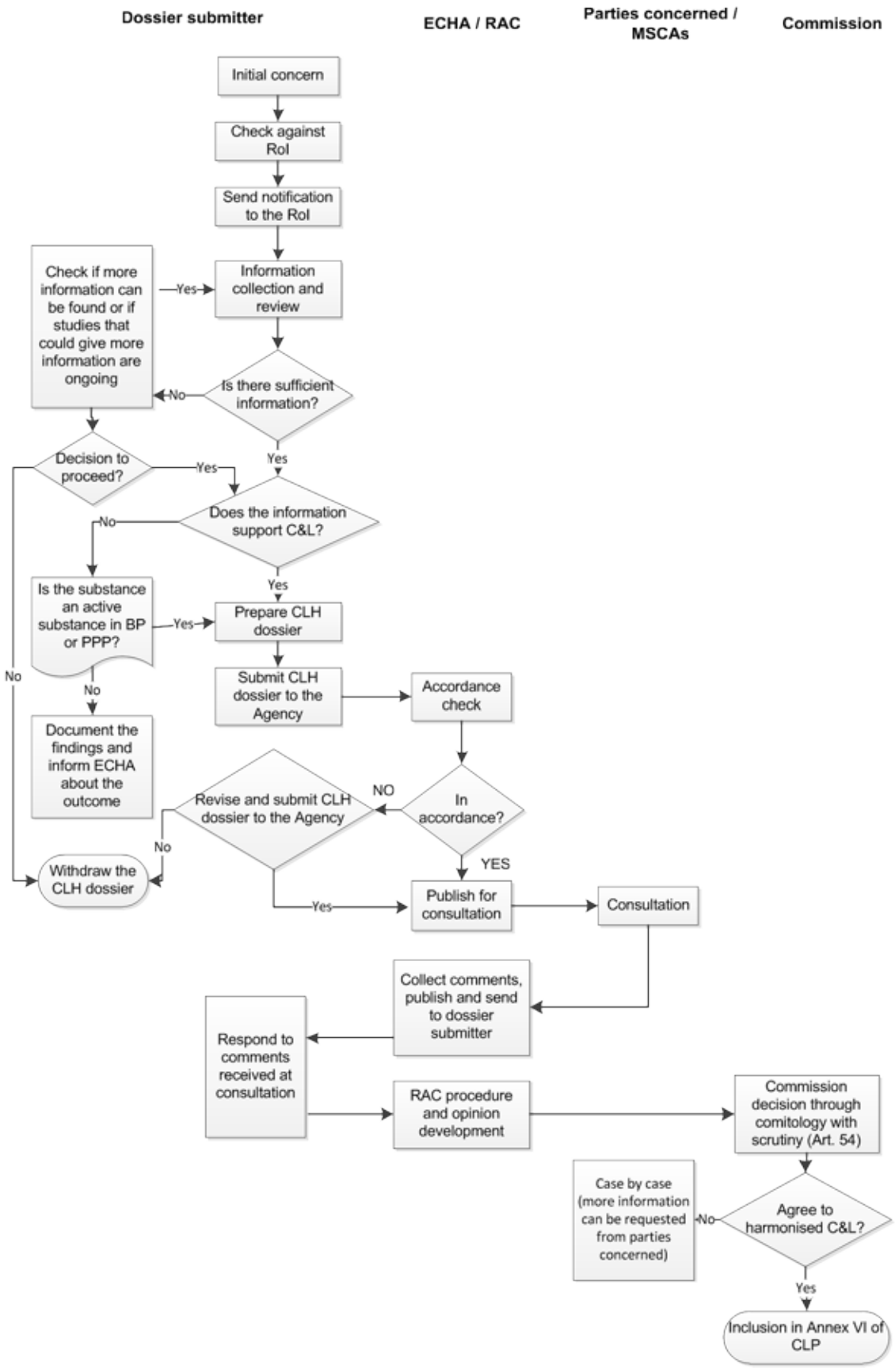

Figure 1: Overview of the preparation and further processing of a CLH dossier

4.1. Possible reasons to initiate the preparation of a CLH dossier

4.1.1. Possible reasons for an MSCA to prepare a CLH dossier

An MSCA may have several reasons for deciding to prepare a CLH dossier. For example, an MSCA may:

- carry out a substance evaluation under the REACH Regulation and conclude that the substance is a CMR substance or respiratory sensitiser, or that classification and labelling in another hazard class (or differentiation(s) within a hazard class where applicable) may be justified; and/or
- carry out an evaluation on an active substance in BP or PPP (for alignment with the CLH process, see Section 7); and/or
- discover that new information is available that could justify a revision of a current harmonised classification and labelling of a substance, *e.g.* via a registration submitted in accordance with the REACH Regulation; and/or
- receive a proposal and/or dossier from a manufacturer, importer or downstream user which has new information that could lead to a change in the current harmonised classification and labelling (Article 37(6), CLP); and/or
- discover that there are different self-classifications notified in the Classification and Labelling (C&L) Inventory[20] for the same substance and there are indications that the notifiers are unable to come to an agreement despite every effort having been made to do so; and/or
- discover that the data may no longer support the conditions on which a minimum classification has been applied to an existing entry (1.2.1, Annex VI, CLP); and/or
- discover that the classification and labelling criteria in the CLP Regulation have changed for a particular hazard class and application of the new criteria would lead to different classification and labelling for a substance with an existing entry in Part 3, Annex VI, CLP.

This list of examples is not exhaustive and an MSCA may have other reasons for preparing a CLH dossier.

4.1.2. Possible reasons for a manufacturer, importer or downstream user to prepare a CLH dossier

A CLH dossier can be prepared and submitted to ECHA by a manufacturer, importer or downstream user of a substance (non-exhaustive list):

- if it is concluded that the substance fulfils the criteria for classification in any of the CMR or respiratory sensitisation hazard classes/differentiations;
- if a harmonised classification and labelling in another hazard class/differentiation than CMR and respiratory sensitisation is considered justified (also see Section 4.2);
- if it is discovered that there are different self-classifications notified in the C&L inventory for the substance, and there are indications that the notifiers are unable to come to an agreement despite every effort being made to do so.

As described in Section 3.4.3, CLH dossiers proposing revision and/or removal of part of or an

[20] The C&L Inventory is a database established and maintained by ECHA according to Article 42 of CLP. It contains basic classification and labelling information on notified and registered substances. It also contains the harmonised classifications in Annex VI to the CLP Regulation. The obligations for the information to be included in the notification to the C&L Inventory are set out in Article 40, CLP.

entire entry included in Annex VI to the CLP Regulation, cannot be submitted directly to ECHA by a manufacturer, importer or downstream user. If a manufacturer, importer or downstream user has new information that justifies such a proposal, they must instead submit a CLH proposal (in line with Article 36(2), CLP) to the MSCA in one of the Member States in which the substance is placed on the market (Article 37(6), CLP).

4.2. Justification demonstrating the need for action at EU level

Article 36, CLP

Harmonisation of classification and labelling of substances

[…]

3. Where a substance fulfils the criteria for other hazard classes or differentiations than those referred to in paragraph 1 and does not fall under paragraph 2, a harmonised classification and labelling in accordance with Article 37 may also be added to Annex VI on a case-by-case basis, if justification is provided demonstrating the need for such action at Community level.

In adopting the CLP Regulation and the REACH Regulation, the legislators decided that the resources of the authorities would be best spent on those hazard classes and differentiations of highest concern, *i.e.* the CMR and respiratory sensitisation hazard classes/differentiations. Harmonised classification and labelling for hazard classes/differentiations other than CMR and respiratory sensitisation can be proposed, if a justification demonstrating the need for action at EU level is provided (Article 36(3), CLP). Such justification is not required if the substance is an active substance used in BP and/or PPP for which normally all hazard classes should be addressed in the CLH report (Article 36(2), CLP). For more information on the hazard classes to be addressed in a CLH proposal for revision of a current entry, see Section 3.4.3.1.

Examples of acceptable justifications demonstrating the need for action at EU level:

- a change in an existing entry is considered justified due to new data becoming available after the current harmonised classification was agreed;
- a change in an existing entry is considered justified due to changes in the CLP classification criteria;
- a change in an existing entry is considered justified due to a new interpretation and/or evaluation of existing data;
- differences in self-classification between different notifiers in the C&L Inventory and/or between different registration dossiers are discovered, and notifiers are not able to agree;
- the dossier submitter disagrees with the current self-classification by the notifiers and/or registrants;
- harmonised classification is relevant for other legislation or processes;
- where there is a harmonised classification entry in Annex VI to CLP containing a minimum classification and it is concluded that a refinement of the classification based on new available data is justified (for more information, refer to CA/8/2013, version 2, CARACAL 12).

The justification that a harmonised classification and labelling is needed for hazard classes/differentiations other than CMR and respiratory sensitisation should clearly indicate why the dossier submitter considers that there is a need for action at EU level. This information should be inserted in the relevant section of the CLH report (technical details on

how to insert the information can be found in the *Data Submission Manual "How to prepare and submit a CLH dossier using the CLH report format and IUCLID"*, see link in Section 2.1).

5. How to prepare a CLH dossier

5.1. The Registry of Intentions

When an MSCA or manufacturer, importer or downstream user has decided to prepare a CLH dossier, the first step is to make a notification to the Registry of Intentions (RoI). Notification to the RoI should be done via a web form on the ECHA webpage. A link to the notification web form can be found in Section 2.1. The RoI is a list held by ECHA containing information from parties who intend to submit a CLH dossier to ECHA. The RoI is published on the ECHA website and should be checked before starting to prepare a CLH dossier. The aim of the RoI is to allow interested parties to be aware of the substances for which dossier submitters intend to submit CLH dossiers and in that way facilitate timely preparation of the interested parties for commenting later in the process. In addition, if interested parties have relevant information that they wish the dossier submitter to be aware of, they can contact the party preparing the dossier.

Submitting an intention to the RoI is not mandatory, but it is highly recommended, as it will help ECHA as well as MSCAs, industry and other stakeholders to plan for the pending submission of the CLH dossier.

The RoI is divided into three sections: current (active) intentions, submitted dossiers and withdrawn dossiers. The RoI hence allows potential dossier submitters to see if any party (MSCA or manufacturer, importer or downstream user) is currently preparing a CLH dossier for the substance, if a dossier for the same substance has already been submitted, or if another party has worked on a CLH dossier for the specific substance in the past and withdrawn it.

Before submitting an intention to the RoI, Annex VI of the CLP Regulation (available on the ECHA website) should be checked to make sure that there is not already an existing harmonised classification for the substance in that specific hazard class/differentiation and category. Please note that the substance could be covered by an existing 'group entry' (see also Section 4.4). The most recent consolidated version of the CLP Regulation and each subsequent Adaptation to Technical Progress (ATP) published in the Official Journal, but not yet included in the consolidated version of the CLP Regulation, are available on the 'CLP Legal text' web page on the ECHA website (for link see Section 2.1). In addition, the published RAC opinions on CLH for substances not yet included in an ATP should be checked to establish that there is not an opinion already adopted for the same substance and in the same hazard class/differentiation and category. In this way, duplication of work can be avoided, and co-operation between submitting parties can be coordinated when preparing CLH dossiers.

Submitting an intention to the RoI will be helpful for the dossier submitter as ECHA can perform a check of the substance identity before the CLH dossier is submitted. ECHA will inform the dossier submitter of the outcome of this check and can advise on how potential issues can be dealt with. If any revisions are proposed, the dossier submitter can contact ECHA via the Classification functional mailbox (classification@echa.europa.eu) for further clarification, if needed. The dossier submitter can also discuss with ECHA any other issues where ECHA may be able to provide support already at this stage, and this in turn will increase the likelihood of having a CLH dossier that is in accordance at first submission (see Section 6.1 for more information on the 'Accordance check'). Submitting an intention to the RoI will also allow ECHA to plan its work and the work of RAC in advance, which will in turn make the processing of the CLH dossier more efficient.

A correct substance identity and description is essential for the further development and processing of a CLH dossier. Dossier submitters are therefore encouraged to provide as much detail as possible on the substance itself, the state and/or form(s) if relevant and any impurities and/or other constituents of the substance in the RoI (for more information, see Section 5.2.1). If the dossier submitter does not have all the relevant information when submitting an intention to the RoI, and this information becomes available during the preparation of the CLH dossier, or if the scope (*e.g.* the classification proposed) of the dossier changes, the dossier submitter can update the RoI by contacting ECHA via the Classification functional mailbox (classification@echa.europa.eu).

The dossier submitter should include the information listed on the RoI web page in their intention (see link to the RoI web page in Section 2.1).

Any confidential information included in the intention must be flagged as such and will then not be included in the RoI.

5.2. Information collection

In order to propose a harmonised classification and labelling of a substance, information about the substance needs to be collected. According to Part 2 of Annex VI to the CLP Regulation and as outlined in the subsequent sections, for all dossiers any relevant information from registration dossiers must be considered for the preparation of a CLH dossier. Active substances manufactured and imported for use only in BP and in PPP are regarded as registered when they meet the criteria set out in Article 15 of the REACH Regulation.

Article 15, REACH

Substances in plant protection and biocidal products

1. Active substances and co-formulants manufactured or imported for use in plant protection products only and included either in Annex I to Council Directive 91/414/EEC (*) or in Commission Regulation (EEC) No 3600/92 (*), Commission Regulation (EC) No 703/2001 (*), Commission Regulation (EC) No 1490/2002 (*), or Commission Decision 2003/565/EC (*) and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.
2. Active substances manufactured or imported for use in biocidal products only and included either in Annexes I, IA or IB to 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 (*) or in Commission Regulation (EC) No 2032/2003 (*) on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

* Please check the REACH Regulation for full legal references.

Thus, CLH dossiers for such active substances must take into account the hazard information included in the CAR, DAR and/or RAR (Renewal Assessment Report), respectively.

In addition, other available information may be used. Potential information sources that can be used are further outlined in the sections below.

Normally the (robust) study summaries provided in registration dossiers, including DARs, CARs and RARs, will contain sufficient detail for preparing a CLH dossier. However, there may be cases when the dossier submitter has to refer to the full study reports, where available, in order to obtain all the information needed. This has to be decided case-by-case, and depends on the level of detail provided in the registration dossier.

5.2.1. Substance identification

Clear and accurate reporting of the substance identity (including the state and/or form(s) if relevant) in the CLH report is crucial for several reasons.

Firstly, once the substance identity has been established, this provides the basis for the Annex VI entry for the substance. Details of the information that will be listed for each entry in the list of harmonised classification and labelling (*i.e.* Table 3.1 and 3.2, Annex VI, CLP) are given in Section 1.1, Part 1, Annex VI, CLP.

Secondly, a correct substance identity (including the state and/or form(s) if relevant) is important for the public consultation of the CLH dossier (see Section 6.2) to ensure that all interested parties are aware of the correct substance identity (including the state and/or form(s) if relevant) of the substance for which the CLH dossier is submitted, and for which the consultation is launched.

In order for RAC to draw up a robust opinion, available information on substance identity (including the state and/or form(s) if relevant) of the tested substance used in the different physicochemical and (eco-) toxicological studies is important. The CLH report should therefore address the relevance of the tested substance(s) to the substance for which inclusion in the list of harmonised classification and labelling is proposed. Impurities, additives and minor components are normally not mentioned in the list of harmonised classification and labelling unless they contribute to the classification of the substance (Section 1.1.1.4, Annex VI, CLP). Nevertheless, this information should be included, if considered relevant, as it can provide important information for RAC in their opinion development. If only a particular state and/or form of the substance is to be harmonised, this needs to be clearly stated in the CLH report and robustly justified.

If any questions on substance identity arise during the preparation of the dossier, the dossier submitter is encouraged to contact ECHA via the Classification functional mailbox (classification@echa.europa.eu) before the CLH dossier is submitted. If a correct substance identity is established before the CLH dossier is submitted, this will help the dossier submitter to prepare the dossier. A correct substance identity in the CLH dossier already at first submission will also make the further processing of the dossier more efficient.

More information on the details to be provided related to substance identity and how to insert the information in the CLH report and the technical dossier in IUCLID can be found both in the CLH report format and *Data Submission Manual "How to prepare and submit a CLH dossier using the CLH report format and IUCLID"* (see links in Section 2.1).

5.2.2. Substances other than active substances in BP and PPP

The information basis available to a dossier submitter when preparing a CLH dossier will, for example, depend on whether a REACH registration dossier has been submitted to ECHA for that particular substance.

A registration dossier must be submitted for all substances manufactured or imported in

quantities of one tonne or more per year, unless the substance is explicitly exempted from registration under the REACH Regulation. The registration dossiers must be submitted in IUCLID format via the REACH-IT system made available by ECHA, and consist of a technical dossier and, depending on the tonnage band of the substance, a Chemical Safety Report (CSR).

The CSR documents the Chemical Cafety Assessment (CSA) which has to be performed for substances manufactured or imported in quantities of ten tonnes or more per year. The CSA must include an assessment of physicochemical properties, a human health hazard assessment, as well as an environmental hazard assessment. It should also include a conclusion on the classification and labelling for each hazard class, as well as for differentiation(s) within a hazard class where applicable.

Any relevant information provided in the registration dossier (IUCLID and CSR) must be taken into account by the dossier submitter when preparing a CLH dossier (Part 2, Annex VI, CLP). Some of this information may also be available through the ECHA dissemination web site for 'Registered substances' (see link in Section 2.1).

Further information can be generated as a result of dossier or substance evaluation under the REACH Regulation. Under the compliance check, which is part of the registration dossier evaluation at ECHA, registrants may be required to submit information needed to bring the registration dossier(s) to compliance with the requirements under the REACH Regulation. Following examination of testing proposals, which is another part of dossier evaluation, more information may need to be generated and submitted.

As mentioned in Section 4.1.1, an MSCA can decide to prepare and submit a CLH dossier as a result of a substance evaluation. Substance evaluation is the procedure by which an MSCA evaluates all the registration dossiers for a specific substance. As an outcome of the substance evaluation, further information may be requested to clarify risks from substances (Article 46, REACH). After the generation and submission of any requested information, conclusions will be drawn and documented by the MSCA. The relevant information retrieved under this evaluation should be used when preparing the CLH dossier.

5.2.3. Active substances in BP

Active substances used in BPs are subject both to evaluation under the BPR and to harmonised classification and labelling under the CLP Regulation.

Before a BP can be placed on the market, an authorisation is required, and the active substances contained in the BP must have been previously approved. Exceptions to this principle are BP containing active substances under the so-called 'review programme'. These can be placed on the market while awaiting the final decision on the approval. Provisional product authorisations can be granted for products containing new active substances that are still under assessment.

For new active substances in BP, companies have to apply for approval by submitting a dossier to ECHA. The applicants have the responsibility to provide dossiers with all relevant information on their active substance(s). An evaluating MSCA is appointed for each active substance, and this MSCA is responsible for carrying out the validation, and subsequently the evaluation, of the dossiers submitted by the applicants. The responsible MSCA will perform an evaluation of the information submitted within one year of the validation of an application. During the evaluation process, the applicant may be requested to provide additional information if the evaluating MSCA considers that more information is necessary.

If the active substance is a candidate for substitution[21], a public consultation will be launched. This gives third parties the opportunity to submit relevant information, including information on alternative substances.

The result of the evaluation from the MSCA, in the form of a CAR, will be forwarded to ECHA's Biocidal Products Committee (BPC), which must prepare an opinion within 270 days. This opinion will serve as a basis for the decision-making by the European Commission and the Member States.
A similar process takes place for the renewal of the approval of an active substance in BP.

For active substances in BP that fulfil the criteria in Article 15 of REACH and consequently are regarded as registered, the dossier submitter must consider the hazard information included in the CAR in the CLH report. Where no CAR is yet available, the dossier submitter must consider the hazard information to be included in the CAR.

The aim is to align the two processes, *i.e.* the review process for active substances in BP and the CLH process. To achieve this, deadlines for the coordination between the two processes have been defined. For further details on this, see Section 7.

5.2.4. Active substances in PPP

Active substances used in PPP are subject both to evaluation under the PPP legislation and to harmonised classification and labelling under the CLP Regulation.

For the evaluation of these substances under the PPP legislation, a DAR or RAR is prepared by the appointed RMS. The DAR or RAR is then submitted to the European Food Safety Authority (EFSA) who performs an evaluation.

A similar process takes place for the renewal of the approval of an active substance in PPPs.

For active substances in PPPs, which fulfil the criteria in Article 15 of REACH and consequently are regarded as registered, the dossier submitter must consider the hazard information included in the DAR or RAR in the CLH report. Where no DAR or RAR is yet available, the dossier submitter must consider the hazard information to be included in the DAR or RAR.

The aim is to have the two processes, *i.e.* the evaluation process for active substances in PPP and the CLH process, aligned. To achieve this, deadlines for the coordination between the two processes have been defined. The processes can only be aligned if the information in the DAR or RAR is the same as in the CLH dossier. Therefore, the CLH dossier for PPP active substances should contain the information from the relevant parts of the DAR or RAR to be submitted to EFSA. For further details on this, see Section 7.

5.2.5. Other available information

In addition to using information from registration dossiers (including the CAR, DAR and/or RAR for active substances in BP and PPP), other available information may be used when preparing the CLH dossier (Part 2, Annex VI, CLP).

Other useful information sources, in particular for substances not (yet) registered, can for example be databases and published literature such as scientific journals and books. Also EFSA

[21] An active substance is considered as a candidate for substitution if any of the conditions specified in Article 10 (1) of the BPR are met.

conclusions and DARs for substances where the DAR has been submitted to EFSA but where the use of the active substance has not been approved can be used. Consultation with external stakeholders may also be an important way for a dossier submitter to obtain additional information. The dossier submitter should decide upon the need for consultation and the resources and time to be allocated to consultation activities. However, dossier submitters are encouraged to engage interested parties in the development of the dossier as early in the process as possible. This will facilitate the timely collection of the necessary information and will contribute to the transparency and representativeness of the CLH dossier.

Information generated under internationally recognised chemical programmes may exist, for example reviews performed under the preceding EU legislation (*e.g.* Regulation (EEC) No 793/93), by OECD, WHO, IARC, ECETOC, or by Member States. These reviews can be useful for identifying the available information. Studies may also be available in the literature (*e.g.* published peer-reviewed journals) or in research reports. Epidemiological data and experience on the effects in humans, such as occupational data and data from accident databases may exist. Mechanistic data related to the potential Mode of action (MoA) of the substance can also be used, if available and relevant. A more detailed search of the literature could help to identify relevant information where there are significant gaps in any available reviews, or where there are no reviews.

When using this kind of information it is recommended that the primary sources of information, for example the full study reports, if available to the dossier submitter, should be reviewed, particularly for the studies considered as key studies. Information from secondary sources, for example reviews, should be considered on a case-by-case basis, and there should be a high confidence in the robustness of the approach used to review the information from the secondary source.

For further information see for example Chapter 10 in the *Introductory guidance on the CLP Regulation* (see link in Section 2.1) where guidance on information sources and gathering is provided.

5.2.6. Information on related substances and from (Q)SARs

Information on structural analogues may also be relevant and useful when preparing the CLH dossier (Sections 1.3 and 1.5, Annex XI, REACH). The dossier submitter must then explain how this information relates to the substance for which the CLH dossier is prepared and for which classification is proposed. A justification for the use of information from other substances and the way in which it supports the proposed classification must be provided. For further information, please see Section 2.1.

5.2.7. Substances undergoing testing

It may be the case that the substance is undergoing testing, for example as a consequence of a testing proposal included in the registration dossier. If this testing is considered to be of potential relevance for the proposed harmonised classification and labelling it must be carefully considered whether to proceed with the CLH dossier or to await the result of the testing. In the event that dossier submitters decide to proceed with the preparation of the dossier, they should indicate that testing on the substance in question is currently being performed and when the test results will be available. Testing proposals related to registration dossiers and decisions on these are made available on the ECHA website. A dossier submitter can also contact the relevant industry to request information on planned testing.

5.2.8. Supporting information

In addition to studies directly related to the specific hazard class(es) (and differentiation(s) within a hazard class, where applicable) that are proposed for classification in the CLH dossier,

other information may be useful to give a better understanding of the properties of the substance. For example, for health hazard classification, physicochemical data and toxicokinetic data can form the basis for a better understanding of the behaviour of the substance in the body and the (adverse) effects related to other hazard classes. Data from repeated dose toxicity studies may give supporting evidence for hazard classes such as carcinogenicity and reproductive toxicity. For environmental hazard classification, knowledge of physicochemical properties such as water solubility, stability data, hydrolysis data, molecular weight and size information is important. These should only be treated as examples, and which information to consider as supporting information needs to be decided on a case-by-case basis. The dossier submitter must make clear for which purpose the information is included (see also Section 5.4).

5.3. Review of the available information and comparison with the classification criteria

When the available information on the substance (and related substances if appropriate) has been collected, the information available for each of the relevant hazard classes needs to be reviewed in order to determine:

- Which information is relevant, adequate and reliable?
- Is there sufficient information to evaluate against the classification criteria and to come to a conclusion on classification?
- Is there a need to search for more information?
- Are there ongoing studies that can result in useful information? (see also Section 5.2.7)

The dossier submitter may also wish to consult external experts. This may be especially useful and important where there are data gaps, where the available information is less consistent and/or when the evaluation of the data is difficult.

The relevant available information should be systematically evaluated in order to derive a classification. The information should be compared with the criteria for classification, as specified in Annex I to the CLP Regulation, for each hazard class or differentiation within the hazard class, and a decision should be made as to whether the substance meets the criteria for classification. In the CLH report, the dossier submitter should clearly describe the relevant information. The dossier submitter should also include an analysis and discussion of the information, a comparison of the information against the classification criteria and a conclusion on classification for each relevant hazard class (and differentiation, if applicable).

In some cases the classification decision may be straightforward, requiring only an evaluation of whether the substance gave a positive or negative result in a specific test that can be directly compared with the classification criteria. In other cases, for example where the criteria cannot be applied directly to the relevant information, a weight of evidence approach may be used (Section 1.1.1, Annex I, CLP and Section 1.2, Annex XI, REACH). Expert judgement may be needed to consider for example dose/response relationships, equivocal results and results from non-standard tests, and to conclude on whether the results of a particular test meet the criteria laid down in Annex I to the CLP Regulation.

Even where a full dataset is not available, sufficient information may be available to classify according to the criteria. When there is not enough information from each single source to conclude on whether the classification criteria are met, there may be evidence from several sources of information that, if using a weight of evidence approach and expert judgment, is sufficient to draw a conclusion.

Detailed guidance on how to use relevant available information for classification purposes is provided in the *Guidance on the application of the CLP Criteria (*see link in Section 2.1).

5.4. Preparation and creation of the CLH dossier

This section gives an overview of how to prepare and create a CLH dossier. A Data Submission Manual is available giving detailed technical guidance on how to insert the information into IUCLID, how to fill in the CLH report and how to create the final CLH dossier (*Data Submission Manual "How to prepare and submit a CLH dossier using the CLH report format and IUCLID"*, see link in Section 2.1).

5.4.1. Structure of a CLH dossier

As noted in Section 3.3, the CLH dossier submitted to ECHA must consist of a technical dossier (prepared in IUCLID, see Section 5.4.1.2) and a CLH report attached to it (see Section 5.4.1.1). The CLH report must be prepared in a format specified by ECHA and this format can be downloaded from the ECHA website (see link in Section 2.1). The information to include in the CLH report and in the technical dossier, respectively, is described in the subsections below.

5.4.1.1. The CLH report

The CLH report format to be used when preparing the CLH report is provided by ECHA and can be found on the ECHA website (see link in Section 2.1). In the CLH report, the relevant available information should be systematically evaluated in order to derive a classification and the report should provide a concise and comprehensive overview of the scientific evidence. The information should be compared with the criteria for classification for each hazard class, or differentiation within the hazard class, and a conclusion should be drawn as to whether the substance meets the criteria for classification or not.

The CLH report should be a 'stand-alone' report since, in accordance with the legal requirements, it will be subject to a public consultation (see Section 6.2). This means that it should provide sufficient information to make an independent assessment of the physical, health and environmental hazards based on the information presented. The CLH report should not contain any confidential information, but confidential information should instead be provided in the IUCLID technical dossier in the relevant sections where the confidential information should be flagged accordingly, and the justification for declaring the information confidential should be included. If considered appropriate, a separate confidential annex to the CLH report can be provided. The annex should then be attached to Section 13 of IUCLID, and flagged as confidential (see Section 5.4.1.2). If confidential information is provided in the IUCLID technical dossier or in a separate annex, this should be indicated in the CLH report and a reference to where the information can be found should be given.

Part 2 of Annex VI, CLP, states that "*For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used*". MSCAs have access to registration dossiers via REACH-IT and can use the information from these dossiers when preparing a CLH dossier. The CLH report will be published by ECHA on its website for comments by parties concerned. It will also be used as a basis for RAC to prepare its opinion and the background document (BD), which in turn will be used by the European Commission for its decision-making. For these reasons it is important that the dossier submitter includes all information relevant for the classification proposal in the CLH report.

Technical details on how to fill in the IUCLID technical dossier and the CLH report can be found in the *Data Submission Manual "How to prepare and submit a CLH dossier using the CLH*

report format and IUCLID" (see link in Section 2.1).

All available information on the substance that is considered adequate, reliable and relevant for the proposal should be inserted in the CLH report. The dossier submitter should reflect carefully on which information to provide. It may be that RAC rapporteurs, during the accordance check of the dossier, request clarification on part of the information provided if they consider this necessary in order to prepare an opinion on the proposed classification. For active substances in BP and PPP, CLH dossiers proposing a completely new entry should address all hazard classes and differentiations, and hence relevant information on all hazard classes, and differentiations within a hazard class, where applicable, should be included in the CLH dossier, regardless of whether a classification is proposed or not. For the hazard classes and differentiations where no classification is proposed, a justification of why the classification criteria are not considered to be fulfilled should be included. Note that dossiers proposing revisions or deletions of (a) hazard class(es) in an already existing Annex VI entry, or dossiers proposing addition of new hazard classes and/or differentiation(s) to an existing Annex VI entry, need only contain information related to the specific hazard class(es) for which revision or addition is proposed.

As mentioned in Section 5.2.8, there may also be other information, not directly related to the proposed classification that is considered relevant for the understanding of, and as support for, the proposed classification.

Key hazard information in the CLH report must be clearly presented and there should be a clear reference to the original source of information included in the CLH report, unless the reference or part of the reference is confidential (see Section 5.4.1.2 regarding justification of confidentiality claims).

In some cases, information that is included as supporting data for harmonised classification in a particular hazard class or differentiation, *e.g.* reproductive toxicity, might indicate classification for a hazard class or differentiation for which harmonised classification is not being proposed, *e.g.* repeated dose toxicity. The dossier submitter must make clear for which purpose the information is included.

ECHA recommends to also include a short description of the (main) uses of the substance in the CLH report, as this information is useful for the purposes of the public consultation on the ECHA website.

It should be noted that only the CLH report will be published for public consultation. The full CLH dossier, including the CLH report and the technical dossier (described in the following Section 5.4.1.2) in IUCLID, will be made available only to RAC and to MSCAs for their consideration and comments.

5.4.1.2. The technical dossier

The technical dossier must be prepared in IUCLID. The technical dossier is created starting from a substance dataset, which is the core information in IUCLID. A new substance dataset in IUCLID needs to be created for each substance for which a CLH dossier is going to be submitted. The substance dataset is the 'raw data layer' in IUCLID into which all information must be inserted (Section 4.1 in the *IUCLID End user manual*; see link in Section 2.1).

The substance dataset must contain data related to the substance, including:

- Substance identity: Information on substance identity is crucial for evaluation of the CLH dossier and for the entry in Annex VI to the CLP Regulation. Sections 1.1 and 1.2 of the substance dataset in IUCLID should always be filled in and should include the IUPAC name or chemical name, CAS number, EC number, registration number for the registration

dossier which was used as a source of information (if available), molecular and structural formulae (if applicable), as well as the purity of the substance and any impurities (see Section 5.2.1) and the state and/or form(s); and

- Information on classification and labelling according to the CLP Regulation in Section 2.1 of the substance dataset in IUCLID, including the reasons for no classification for hazard classes, and differentiations, for which no classification is proposed.

If confidential information is provided, it must be flagged as confidential in the technical IUCLID dossier, including a justification why the information is considered confidential (Article 10(a)(xi) and Article 119(2), REACH and Article 4, Regulation (EC) No 1049/2001[22]).

A dossier submitter can also include endpoint study records with robust study summaries[23] or study summaries for the studies considered relevant for the proposed classification. These (robust) study summaries can be included under the relevant Sections (4 to 7), in the substance dataset. It is however not mandatory to provide the (robust) study summaries in IUCLID, but all information considered relevant for the classification proposal must be included in the CLH report (see Sections 5.4.1.1). For more information on how to fill in (robust) study summaries in IUCLID, please see Sections 4.2.2, 4.7.1 and 4.7.7 in *IUCLID End user manual* (see link in Section 2.1).

5.4.2. Creation of the CLH dossier in IUCLID

When all relevant information has been included in the CLH report, the finalised report must be attached to Section 13 of the substance dataset in IUCLID. The report must be attached both as a word file to enable commenting and editing in the subsequent processing, and as a PDF file to be used for the public consultation on ECHA's website. It is recommended to attach also other documents considered relevant for the classification proposal, *e.g.* Risk Assessment Reports, DARs, CARs, RARs or other references used. Any attachments containing confidential information should also be attached. When all information has been included in the substance dataset, a CLH dossier must be created by using the dossier creation functionality of IUCLID.

The final CLH dossier submitted to ECHA is read-only and hence ECHA cannot make any changes to it. If a revision of the CLH dossier is needed (*e.g.* resulting from feedback from the accordance check; see Section 6.1), the dossier submitter needs to make the changes in the IUCLID substance data set and the CLH report, respectively. Thereafter the revised CLH report should be attached to the revised substance dataset in IUCLID, and a new CLH dossier should be created.

For further guidance on how to create the CLH dossier in IUCLID, see the *Data Submission Manual "How to prepare and submit a CLH dossier using the CLH report format and IUCLID"* (see link in Section 2.1).

6. Processing of the submitted CLH dossier

When the CLH dossier has been created, it should be submitted to ECHA for further processing. Detailed guidance on how to submit the dossier to ECHA via the submission web form can be found on the ECHA website and in the *Data Submission Manual "How to prepare and submit a CLH dossier using the CLH report format and IUCLID"* (see link in Section 2.1). After the submission, the dossier submitter will receive a confirmation that ECHA has received the dossier and a submission number, which should be used in all further communication with

[22] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents

[23] A robust study summary is a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report (Article 3 (28) of REACH).

ECHA on the dossier. If no confirmation is received, the ECHA Classification unit should be contacted through the functional mailbox (via the e-mail address indicated in the web form, see link in Section 2.1). After the CLH dossier has been submitted, the procedure follows timelines set by ECHA for the different steps, notably:

- accordance check;
- public consultation;
- response to comments; and
- opinion development by RAC.

According to Article 37(4) of CLP, RAC must adopt an opinion on any CLH proposal submitted within 18 months of the receipt of the proposal. The 18 months deadline is counted from the date when the dossier that is considered to be 'in accordance' was received by ECHA (Article 37(4), CLP).

More information on each step is provided in the subsections below.

6.1. Accordance check

For each CLH dossier submitted to ECHA, one rapporteur, and possibly a co-rapporteur, from RAC will be appointed. The ECHA Secretariat will perform the accordance check of the CLH dossier, with support from the rapporteur(s) who have the opportunity to submit their observations on the dossier.

The purpose of the accordance check is to ensure that the dossier has been prepared in accordance with the legal requirements (Article 37, CLP), that it includes all the information needed for RAC to consider the classification proposed in the CLH dossier and to deliver an opinion, and that the information is correctly presented in both the CLH report and the technical dossier in IUCLID.

The dossier submitter will be informed of the outcome of the accordance check, and if the CLH dossier is considered to be 'in accordance', ECHA will issue a formal letter of receipt with the date from which the 18 months deadline for RAC to issue an opinion is derived. The 18 months starts on the date when a CLH dossier that is considered to be in accordance with the legal requirements is submitted to ECHA. Furthermore, ECHA will publish the CLH report on the ECHA website for consultation by parties concerned (see Section 6.2).

In the accordance check report, the findings are divided into 'required revisions' and 'recommended revisions'. The required revisions must be addressed before the CLH dossier can be accepted for further processing. The recommended revisions are additional findings that, if addressed, will improve the quality of the dossier. It is highly recommended to address also these revisions before resubmitting the CLH dossier, as the recommended revisions address concerns about the content of the dossier that might hamper the successful evaluation of the classification proposal and even in reaching the opinion if not addressed.

If the CLH dossier is considered to be 'not in accordance', *i.e.* if the accordance check specifies required revisions, the dossier submitter should revise the dossier according to the required revisions stated in the accordance check report and resubmit it to ECHA. However, if the dossier submitter cannot implement the required changes, they should contact ECHA via the Classification functional mailbox (classification@echa.europa.eu) or consider withdrawing the dossier.

If the dossier submitter decides to revise the dossier, they are recommended to provide ECHA with an expected date for re-submission, if possible.

After the dossier submitter has revised the CLH dossier it should be resubmitted to ECHA via the web form on the ECHA website (see link in Section 2.1) for further processing. If the CLH dossier is found to be in accordance with the legal requirements after the revisions, ECHA will start the public consultation of the CLH report on its website.

6.2. Public consultation and response to comments

During the public consultation, which is open for 45 days, parties concerned (*e.g.* industry, Member States, other stakeholders and the general public) are invited to comment on the CLH dossier. All hazard classes for which the dossier submitter has provided an appropriate information basis, and which have been assessed against the classification criteria, will be open for comments during the public consultation. The comments from the public consultation are published regularly during the public consultation on the ECHA website to increase transparency. After the public consultation, the comments received will be collected by ECHA and sent to the dossier submitter who will be asked to provide, within a set deadline (normally 42 days), a response to the comments (RCOM). The RCOM must then be returned to ECHA. No revisions must be made to the original CLH dossier, but the response to all comments, including any corrections and/or revisions to the CLH dossier, should instead be addressed in the RCOM. ECHA will then forward the CLH dossier and RCOM to RAC, including the rapporteur(s), for the consideration of the RAC members (and observers from stakeholder organisations) and to allow the rapporteur(s) to begin to formulate an opinion.

6.3. The RAC opinion

The minimum requirements for the content of the RAC opinion on a CLH proposal are laid down in the CLP Regulation (Article 38(1), CLP). The RAC opinion may be adopted either by consensus or by simple majority. The RAC opinion, including minority positions where relevant, the final BD, the comments submitted during the public consultation with the RCOM from the dossier submitter and from the rapporteur(s), are forwarded to the European Commission to support the subsequent decision-making process (see Section 6.4).

For all substances, RAC will evaluate only those hazard classes that were open for comments during public consultation (*i.e.* all hazard classes for which the dossier submitter has provided an appropriate information basis, and which have been assessed against the classification criteria; see Section 6.2). RAC will not gather information and/or data on, or evaluate, any other hazard classes during the opinion development.

For active substances in BP and PPP, RAC will evaluate the hazard classes for which a classification was proposed, as well as other hazard classes where no classification was proposed but where an appropriate assessment and conclusion was included in the CLH dossier. This means that RAC evaluates also the dossiers where classification is not proposed. Any CLH dossiers proposing revision or removal of existing entries in Annex VI to CLP should be treated in the same way for active substances in BP and PPP as for other substances.

The RAC opinion (including any minority positions where relevant), the BD and the RCOM are published on ECHA's website.

More information on RAC, including the 'Framework for RAC opinion development on substances for harmonised classification & labelling', can be found on the RAC web page on the ECHA website (see link in Section 2.1).

6.4. European Commission decision

Article 37, CLP

Procedure for harmonisation of classification and labelling of substances

[…]

5. Where the Commission finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it shall, without undue delay, submit a draft decision concerning the inclusion of that substance together with the relevant classification and labelling elements in Table 3.1 of Part 3 of Annex VI and, where appropriate, the specific concentration limits or M-factors.

   A corresponding entry shall be included in Table 3.2 of Part 3 of Annex VI subject to the same conditions, until 31 May 2015.

   That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 54(4).

   […]

The European Commission considers whether the harmonisation of the classification and labelling of the substance concerned is appropriate, taking the RAC opinion into account. If the Commission finds it appropriate, it prepares a draft decision concerning the inclusion of the substance in Table 3.1 of Part 3 of Annex VI to the CLP Regulation (Article 37(5), CLP). The draft decision also includes the relevant classification and labelling elements and, where appropriate, the SCLs and/or M-factors. The decision is adopted in accordance with the regulatory procedure with scrutiny (by the European Parliament) referred to in Article 54(3) of the CLP Regulation. The minimum content of this decision is described in detail in the CLP Regulation (Article 38, CLP).

6.5. Inclusion of the harmonised classification and labelling in Annex VI to CLP

Part 3 of Annex VI to the CLP Regulation contains the lists of harmonised classification and labelling of hazardous substances. Table 3.1 lists the harmonised classification and labelling of hazardous substances according to the criteria in the CLP Regulation whilst Table 3.2 lists the harmonised classification and labelling of hazardous substances based on the criteria in the DSD[24]. When a decision on a new harmonised classification or a revision or deletion of an existing harmonised entry has been adopted according to the above-mentioned procedure, these lists are amended accordingly. The legal procedure for including a new or revised entry, or for deleting an already existing entry, in Part 3, Annex VI to CLP is via the inclusion in an ATP to the CLP Regulation. The ATPs are updates to the CLP Regulation (Article 53, CLP). They are published in the Official Journal of the European Union, and enter into force on the 20th day

[24] From 1 December 2010 until 1 June 2015, substances must be classified in accordance with both the CLP Regulation and the DSD, but must be labelled only according the CLP Regulation. From January 2014 onwards, RAC opinions only address classification according to the CLP Regulation.

after their publication. However, a certain period of time, usually 18 months, is given to allow for a transitional period for implementation for manufactures, importers and downstream users of the substance concerned. The harmonised classifications may be applied voluntarily before that date. The information listed for each entry can be found in Part 1 to Annex VI to the CLP Regulation.

7. Alignment of the CLH process with the processes for active substances under the BP and PPP legislations

7.1. Active substances in BP

The review process for active substances in BP and the CLH process should be aligned. To achieve this, deadlines for the coordination between the two processes have been defined, as outlined below. In addition, in order to make the alignment of the processes possible, normally the MSCA responsible for CLH matters in the same Member State as the one acting as RMS for the evaluation, should submit a CLH dossier for this active substance. Annex II of the Regulation 1451/2007 contains an overview of the active substances to be examined under the so-called 'review programme' including the RMS performing the evaluation.

If the substance is an active substance under both the BPR and PPPR, and different MSCAs are responsible for the two processes, it is recommended that only one CLH dossier is submitted, and it is then important that the CLH dossier contain all relevant information from both the CAR and DAR. Also other relevant information should be considered and included in the CLH dossier, if available (see 5.2.5).

It is highly recommended that the dossier submitter for the CLH dossier submits a notification to the RoI, to allow other parties to see that preparation of a CLH dossier for the substance is on-going (see Section 5.1).

The role and tasks of the BPC and of RAC are clearly defined in the BPR, in REACH and in the CLP Regulation and by the rules of procedure of the two Committees. Although the processes under the responsibility of the two Committees are covered by different Regulations, there is a relationship between the approval of active substances in BP (under the responsibility of the BPC) and the harmonised classification and labelling process (under the responsibility of RAC). For example, the approval (or renewal of the approval) of the active substances and the identification of candidates for substitution are based also on the classification according to CLP criteria. There are also certain exclusion criteria described in the BPR, and active substances meeting these exclusion criteria will not be approved. The criteria include substances classified as CMRs Category 1A or 1B according to the CLP Regulation; endocrine disruptors; persistent, bioaccumulative and toxic (PBT) substances; and very persistent and very bioaccumulative (vPvB) substances. Derogations are foreseen, in particular when the active substance may be needed on the grounds of public health or of public interest when no alternatives are available.

For these reasons, strategies to ensure the best possible alignment of the two processes for new and existing active substances have been considered.

The 'review programme' concerns the review of all existing biocidal active substances (*i.e.* substances on the market on 14 May 2000 for use as active substance in a BP).

The 'review programme' includes the following deadlines for coordination between the CLH process and the review process:

- For existing active substances for which the draft CARs have not yet been submitted, the CLH dossier should be submitted as soon as possible after the hazard evaluation of a substance has been conducted, and at the latest at the same time as the draft CAR is sent to ECHA by the evaluating MSCA. For existing active substances, no draft CAR will be accepted by ECHA if this has not been done.
- If it is suspected that the active substance might fulfil the exclusion/substitution criteria it is highly preferable, and therefore strongly recommended, that the MSCA submits the draft CAR only when RAC has given its opinion on classification. If the substance is classified as CMR Category 1A or 1B this should be taken into account in the draft CAR before submission.
- For draft CARs already submitted to the European Commission before 1 September 2013, MSCAs should send the appropriate CLH dossiers as soon as possible to ECHA.
- For new active substances (*i.e.* active substances placed on the European market for use in BP from 14th May 2000 until 1st September 2013; Article 3(e), BPR) the same principles apply; however, in these cases ECHA will accept all the CARs even when a CLH dossier has not yet been received.
- Concerning new active substances under BPR (Article 7) (*i.e.* substances for which a CAR will be submitted to ECHA after 1 September 2013), MSCAs are strongly recommended to submit the CLH dossiers in advance of the submission of the CAR (ideally at least 2-3 months before). This will allow the alignment of the CLH process with the approval process for the active substance in BP.

7.2. Active substances in PPP

The evaluation of active substances in PPP and the CLH process should be aligned. In order to make the alignment of the processes possible, normally the MSCA responsible for CLH matters in the same Member State as the one acting as RMS for the evaluation, should submit a CLH dossier for this active substance.

A list of the active substances under the approval and the renewal processes (*i.e.* active substances which are already approved but are under reassessment since the approval has expired) can be found at:
http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection.

If the substance is an active substance under both the BPR and PPPR, and different MSCAs are responsible for the two processes, it is recommended that only one CLH dossier is submitted, and it is then important that the CLH dossier contain all relevant information from both the CAR and DAR. Also other relevant information should be considered and included in the CLH dossier, if available (see 5.2.5).

It is highly recommended that the dossier submitter for the CLH dossier submit a notification to the RoI, to allow other parties to see that preparation of a CLH dossier for the substance is on-going (see Section 5.1).

It should be noted that the timely adoption of the harmonised classification and labelling by RAC is highly relevant for the approval decision on the active substance (for further information, see the downstream consequences of classification set out in Annex II to the PPPR). It is therefore of utmost importance that the evaluation process and the CLH process run in parallel, and that the adoption of the CLH opinion by RAC, and the EFSA conclusion on the evaluation, occur as close as possible to each other time-wise.

Considering the deadlines defined in the legal text (CLP Regulation and PPPR, respectively) this will only be possible if the CLH dossier is submitted to ECHA around three months before the submission of the DAR/RAR to EFSA by the RMS. Accordingly, the time needs and resources should be planned and coordinated by the MSCA(s) involved. The CLH dossier should be

submitted as early as possible to ECHA, and ideally, the RAC opinion should be available before the EFSA conclusion on the DAR or RAR is finalised in order to allow for a proper consideration of the outcome of the RAC conclusion in the peer review process.

8. Transitional provisions

The CLP Regulation (Article 61, CLP) specifies the transitional provisions that affect the classification, labelling and packaging of hazardous substances and mixtures previously covered by DSD and DPD. From 1 December 2010 until 1 June 2015, substances must be classified in accordance with both DSD and the CLP Regulation, but labelled and packaged only in accordance with the CLP Regulation. Considering that new adopted harmonised classifications will not be included in the Annex VI to the CLP Regulation until after the transitional period ends on 1 June 2015, the CLH dossiers should no longer include classification according to DSD criteria.

9. What can an MSCA do if it considers that a CLH dossier is not appropriate?

For active substances in BP and PPP, a CLH dossier should be submitted to ECHA also where it is concluded that the substance does not fulfil the criteria for classification in any hazard class (see Section 3.4.2.2 for further information). For other substances, there may be cases where an MSCA carries out work to prepare a CLH dossier but concludes at some point that there is no need to progress with the work, *e.g.* because it is concluded that the substance does not fulfil the criteria for classification as CMR, respiratory sensitisiser or other hazard classes. In this case, the conclusions may be documented since it is important that the work that has already been undertaken is not lost but is made available for future work on that substance.

It is up to the MSCA to decide how much of the work that they have done needs to be documented, and this can be done on a case-by-case basis. The documentation could be, for example, information they have inserted into the IUCLID substance dataset, and/or the (draft) CLH report with the appropriate conclusions that led the MSCA to stop further work on the dossier. The beneficial outcome would be that the work undertaken by one MSCA is made known and available to ECHA (and other MSCAs upon request to ECHA) so that the process works efficiently and without undue duplication of work. In the RoI on the ECHA website the withdrawn intentions are also listed, including information on which MSCA made the intention (under ‘Withdrawn intentions and withdrawn submissions’). This information would allow a potential future dossier submitter to contact the previous MSCA in order to make use of the work already undertaken on a particular substance. If an MSCA wants to submit this kind of documentation, they can contact ECHA via the Classification functional mailbox (classification@echa.europa.eu).

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