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Guidance on the preparation of dossiers for harmonised classification and labelling

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Abbreviations

BD	Background document
BP	Biocidal product(s)
BP 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
C&L inventory	Classification and labelling inventory
CAR	Competent Authority Report (for active substances in biocidal products)
CLH dossier	Dossier with proposal for harmonised classification and labelling
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
CMR	Carcinogenicity, germ cell mutagenicity, reproductive toxicity
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
EC	European Community
ECETOC	European centre for ecotoxicology and toxicology of chemicals
ECHA	European Chemicals Agency (The Agency)
EEA	European Economic Area
EFTA	European Free Trade Association
EINECS	European Inventory of Existing Commercial chemical Substances
ELINCS	European List of Notified Chemical Substances

ESR	Existing Substance Regulation
GCL	Generic concentration limit
IARC	International Agency for Research on Cancer
IR/CSA assessments	Guidance on information requirements and chemical safety
M-factor	Multiplying factor
MSCA	Member State competent authority
NONS	Notification of new substances
OECD	Organisation for Economic Cooperation and Development
PPP	Plant protection product(s)
PPP Directive	Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (will be repealed by Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the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, from 14 June 2011. Transitional provisions will apply as set out in Article 80 of Regulation (EC) No 1107/2009)
(Q)SAR	(Quantitative) structure-activity relationships
RAC	Committee for Risk Assessment
RAR	Risk 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
RS	Respiratory sensitiser
(R)SS	(Robust) study summary
SCL	Specific concentration limit
SIEF	Substance Information Exchange Forum
SMILES	Simplified molecular input line entry specification
Substance ID	Substance identity

TC C&L	Technical Committee on Classification and Labelling
The Agency	European Chemicals Agency (ECHA)
WHO	World Health Organisation

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[1]. Title V of the CLP Regulation contains provisions for submission of proposals for harmonised classification & labelling.

The CLP Regulation specifies that Member State[2] competent authorities (MSCAs) as well as manufacturers, importers or downstream users may submit proposals for harmonised classification and labelling of substances to the European Chemicals Agency[3] (ECHA, hereinafter referred to as 'the Agency'). Such proposals would normally pertain to either of the carcinogenicity, germ cell mutagenicity and reproductive toxicity (CMR) or respiratory sensitisers (RS) hazard classes and/or differentiations[4], but also to any other hazard classes and/or differentiations on a case-by-case basis if justification for action at European Community level is provided in the proposal. The dossier for submitting a proposal for harmonised classification and labelling (hereinafter referred to as 'CLH dossier') shall be prepared in accordance with the requirements of the CLP Regulation. 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) that are regulated by Directive 91/414/EEC[5] (PPP Directive) and Directive 98/8/EC (BP Directive), respectively. With regard to these substances the harmonisation of classification and labelling shall apply to all hazard classes and/or differentiations.

[1] Title XI of the REACH Regulation has been deleted with effect from 20 January 2009. Title VII repeals Directives 67/548/EEC (Dangerous substances directive, DSD) and 1999/45/EC (Dangerous preparations directive, DPD) with effect from 1 June 2015. Transitional provisions apply as laid down in Articles 61 and 62 of the CLP Regulation.

[2] "The Members States" refers to the 27 Member States of the European Union (EU). Once 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, references in this guidance to "the Member States" should be read to include Iceland, Liechtenstein and Norway.

[3] The European Chemicals Agency (ECHA) is a European Community body which was established for the purpose of managing REACH to ensure consistency throughout the European Community. 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 European Community with scientific and technical advice on questions relating to chemicals which fall within its remit.

[4] Differentiation is a distinction depending on the route of exposure or the nature of the effects.

[5] Will be repealed by 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, from 14 June 2011. Transitional provisions will apply as laid out in Article 80 of Regulation (EC) No 1107/2009.

2. About this guidance

This document provides technical guidance for MSCAs and manufacturers, importers and downstream users on preparing a CLH dossier under the CLP Regulation. The relationship between this guidance and other guidance documents relevant to both the CLP and the REACH Regulation is described, as well as the possible contribution of other activities under the REACH Regulation to the CLH dossier. It gives an overview of the general process for the preparation of a CLH dossier, as well as detailed information on the different steps in the process of preparing a CLH dossier, and information about the processing of the dossier once it has been submitted to the Agency. There is also information on transitional arrangements outlined in Section 6 of this guidance document.

This guidance document does not provide information on the notification to the Classification & Labelling (C&L) Inventory (cf. Article 40 of the CLP Regulation). Detailed information and guidance on the notification process can be found on the Agency's website (http://echa.europa.eu/reachit/inventory_notification_en.asp).

2.1. Links to other guidance documents

This guidance document provides overall guidance for the preparation of CLH dossiers and is complemented by other guidance documents. In the text it is indicated when to refer to other relevant guidance. Each of the guidance documents mentioned below is accessible via the Agency's website (http://www.echa.europa.eu):

- 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/clp/clp_help_en.asp; ECHA, 2009).
- 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/clp/clp_help_en.asp; ECHA, 2009).
- Guidance on how to gather information, how to evaluate the relevant available information *etc.* can be found in Guidance on information requirements and chemical safety assessment (http://guidance.echa.europa.eu; IR/CSA, ECHA 2008).

The relevant parts of the latter for preparing a CLH dossier are mainly found in:

Volume 2 (Part F, Chemical Safety Report);

Volume 3 (Chapters R.2, Framework for generation of information on intrinsic properties, R.3, Information gathering, R.4, Evaluation of available information and R.6, QSARs and grouping of chemicals);

Volume 4, (Endpoint specific guidance for physicochemical properties and human health); and

Volume 5-6 (Endpoint specific guidance for environment and toxicokinetics).

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

- Guidance on substance identification (substance ID) can be found in Guidance for identification and naming of substances under REACH (http://guidance.echa.europa.eu/; INS, ECHA 2007).
- Please note that this document has not been updated after the adoption of the CLP Regulation. Guidance given in this document, including its suitability for classification and labelling, may therefore not be fully consistent with the CLP criteria.
- A User manual with detailed technical guidance on how to prepare the technical dossier in IUCLID 5 and how to prepare the CLH report (available on the Agency's website under http://echa.europa.eu/publications_en.asp as soon as published)
- Further guidance on the use of IUCLID 5 (*e.g.* IUCLID 5 End user manual and IUCLID 5 Getting started guidance) can be found on the IUCLID 5 Documentation website (http://iuclid.echa.europa.eu/index.php?fuseaction=home.documentation&type=public).
- Guidance on the detail of information for robust study summaries (RSS) to be provided in the IUCLID 5 technical dossier can be found in the Practical guidance on How to report robust study summaries (ECHA 2010). This guidance is available on the Agency's website (http://echa.europa.eu/publications_en.asp; under Practical guides).
- A User manual with technical guidance on how to submit a dossier via REACH-IT is available at: http://echa.europa.eu/reachit/supp_docs_en.asp.

3. Scope and legal basis

3.1. Harmonised classification and labelling

"Harmonised classification and labelling" in this context means that a decision to classify and label a substance in a particular hazard class and/or differentiation has been taken at the European Community 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 (SCLs) and/or Multiplying (M-)factor(s) of a substance shall be used by all suppliers of that substance within the European Community. This means that self classification of a substance shall be performed only in cases where no harmonised classification for a specific hazard class or differentiation is yet included in Annex VI to the CLP Regulation (Article 4(3)). Special provisions apply in cases where only a minimum classification for a substance exists for one or more hazard classes; see Section 1.2.1 of Annex VI to the CLP Regulation. For hazard classes and/or differentiations not covered by an entry in Annex VI to the CLP Regulation, suppliers are responsible for the classification before placing the substance on the market (Article 4(3) of the CLP Regulation) (see also Guidance on the application of the CLP criteria; see Section 2.1 for link).

3.2. Legal basis for proposals on harmonised classification and labelling of substances

Proposals for harmonisation of classification and labelling of substances are governed by Article 37 of the CLP Regulation which provides that:

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.

The proposal shall follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.

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.

The proposal shall be drawn up in accordance with the relevant Parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 and it shall follow the format set out in Part B of the Chemical Safety Report of section 7 of that Annex. It shall contain the relevant information provided for in Part 1 of Annex VI to this Regulation. Article 111 of Regulation (EC) No 1907/2006 shall apply.'

3. Where the proposal of the manufacturer, importer or downstream user concerns the 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).

Further, Part 2 of Annex VI to the CLP Regulation:

'lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling.

The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 shall be used for the methodology and format of any dossier.'

The CLH dossier shall consist of a technical dossier (in IUCLID 5) and a CLH report attached to it. The structure of a CLH dossier is further explained in Section 4.7.1.

3.2.1. Substance identification

Article 38 (1(a)) of the CLP Regulation states that:

"1. Any opinion referred to in Article 37(4) and any decision according to Article 37(5) shall at least specify for each substance:

(a) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI to Regulation (EC) No 1907/2006"

Sections 2.1 to 2.3.4 of Annex VI to the REACH Regulation, 'Identification of the substance' specifies these requirements as follows:

2.1. Name or other identifier of each substance

2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)

2.1.2. Other names (usual name, trade name, abbreviation)

2.1.3. EINECS or ELINCs number (if available and appropriate)

2.1.4. CAS name and CAS number (if available)

2.1.5. Other identity code (if available)

2.2. Information related to molecular and structural formula of each substance

2.2.1. Molecular and structural formula (including Smiles notation, if available)

2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)

2.2.3. Molecular weight or molecular weight range

2.3. Composition of each substance

2.3.1. Degree of purity (%)

2.3.2. Nature of impurities, including isomers and by-products

2.3.3. Percentage of (significant) main impurities

2.3.4. Nature and order of magnitude (… ppm, … %) of any additives (e.g. stabilising agents or inhibitors)"

Therefore, when preparing a CLH dossier, the dossier submitter should provide sufficient information to enable the substance to be unequivocally identified. If, however, it is impossible due to technical reasons or it does not appear to be necessary to provide information on one or more of the abovementioned items, the reasons should be clearly stated. The provided information should be presented consistently in both the IUCLID 5 technical dossier and the CLH report. Once unequivocal substance ID has been established, this ID provides the basis for the Annex VI entry for this substance. Annex VI, Part 1, section 1.1 to the CLP Regulation specifies the information listed for each entry in the list of harmonised classification and labelling (i.e. Table 3.1 and 3.2 of Annex VI).

No confidential information should, however, be included in the CLH report as this will be made publicly available, but should instead be provided only in the technical dossier in IUCLID 5 where it should be flagged as confidential. If confidential information is provided in the technical dossier, this should be mentioned in the CLH report and a summary should be provided indicating whether and how this information is considered to be relevant for the classification proposal.

In order for RAC to draw up a robust opinion, available information on substance ID of the tested substance used in the different physicochemical and (eco-) toxicological studies is important. The CLH report should address the relevance of the substance ID of the tested substance(s) to the substance ID of 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 significantly to the classification of the substance (Annex VI, Part 1, point 1.1.1.4. of the CLP Regulation).

The Agency will conduct the substance ID check as a part of the accordance check (see Section 5.1) which will be sent to the dossier submitter[6] and, if any revisions are proposed to the CLH dossier, the dossier submitter can contact the Agency for further clarification if needed. It is recommended that information on substance ID is already included in the Registry of Intentions (see Section 4.2) as this will allow the substance ID check to be started at an early stage. The dossier submitter can then already discuss the substance ID with the Agency before the CLH dossier is submitted.

3.3. Who can submit a CLH dossier?

A proposal for harmonised classification and labelling, including SCLs and/or M-factors, if 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 under the conditions laid down in Articles 37(1), (2), (3) and (6) of the CLP Regulation. They are referred to as the dossier submitter in this guidance document.[6]

[6] "Only Representatives", as defined in the REACH Regulation, cannot submit a proposal for harmonised classification and labelling according to the CLP Regulation.

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

3.4.1. General provisions

A proposal for harmonised classification and labelling shall normally[7] be submitted for a substance fulfilling the criteria for classification set out in Annex I to the CLP Regulation in one or more of the following hazard classes and/or differentiations (Article 36(1) of the CLP Regulation)[8]:

- Carcinogenicity, Category 1A, 1B or 2;
- Germ cell mutagenicity, Category 1A, 1B or 2;
- Reproductive toxicity, Category 1A, 1B or 2;
- Respiratory sensitisation, Category 1.

Harmonised classification and labelling for other hazard classes and/or differentiations than CMR and RS may be proposed on a case-by-case basis if it is justified that action is needed at European Community level (Article 36(3) of the CLP Regulation) (Section 4.8). Proposals for harmonised classification for other hazard classes and/or differentiations submitted by a manufacturer, importer or downstream user shall be accompanied by a fee laid down in a separate regulation[9] determined by the Commission (Article 37(3) of the CLP Regulation).

Proposals for harmonised classification and labelling according to the CLP Regulation can only be submitted for substances, and not for mixtures. As alloys (Article 2(27) of the CLP Regulation) are considered to be mixtures for the purposes of this Regulation, proposals for harmonised classification and labelling cannot be submitted for alloys.

It is also possible to submit a CLH proposal for a group of substances provided that the identity of each substance is clearly indicated and a rationale as to why the substance belongs in the group is given in the CLH report. Furthermore, a substance may have different impurity profiles, which might lead to different hazards and consequently different classification and labelling. In the technical dossier in IUCLID 5 (Section 1.2) different impurity profiles for a substance and different classifications, if appropriate, for each impurity profile can be provided. Before submitting a CLH proposal for a group of substances, the dossier submitter is advised to contact and discuss with the Agency in order to decide, on a case-by-case basis, the most appropriate way to prepare the proposal.

3.4.2. Active substances in plant protection and biocidal products

For active substances in PPP and BP, proposals for harmonised classification and labelling normally address all hazard classes and differentiations. These proposals can be made without a specific justification that action is needed at European Community level (Article 36(2), 37(1), (4), (5) and (6) of the CLP Regulation and Section 4.8).

As a consequence, any proposal for harmonised classification and labelling for active substances in PPP and BP 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. If an

[7] An MSCA, manufacturer, importer or downstream user can decide to prepare a proposal for harmonised classification and labelling at their own initiative.
[8] The hazard classes and categories in this document refer to those specified in the CLP Regulation. However, until 1 June 2015 proposals for harmonised C&L should also include the classification in accordance with the DSD criteria (Section 6.1).
[9] A fee Regulation for the CLP Regulation is currently under preparation by the Commission.

active substance does not fulfil any of the criteria for classification, no proposal for harmonisation needs to be submitted.

Proposals for classification of active substances in PPP and BP can only be submitted by an MSCA (Article 36(2) of the CLP Regulation).

3.4.3. Revision of an existing entry in Annex VI

Proposals for revision or removal of a specific hazard class and/or differentiation from an existing entry in Annex VI to the CLP Regulation or removal of the entire entry can only be submitted by an MSCA (Article 37(1) of the CLP Regulation).

When information is available demonstrating the need to revise a specific hazard class and/or differentiation of an existing harmonised entry in Annex VI to the CLP Regulation, a CLH dossier with a proposal for a revision of the entry may be submitted to the Agency. The proposal should include information on the current entry, the proposed revisions as well as information as to what the resulting entry in Annex VI would be. If the current entry is part of a group entry, this should be indicated.

It could also be that due to changes in the classification criteria, the CLP Regulation may trigger classification for certain hazards which were not required by DPD or DSD.

If a manufacturer, importer or downstream user has information that could lead to a revision of the harmonised classification and labelling of a substance, he should submit a proposal to the MSCA in one of the Member States in which the substance is placed on the market (Article 37(6) of the CLP Regulation). The MSCA will then decide if it is appropriate to prepare a CLH dossier and submit it to the Agency in order to revise the existing harmonised classification.

The work of MSCAs and the Agency (including its Committees) should focus on substances of the highest concern with regard to human health and the environment. Hence, CLH proposals which aim at harmonising ‘no classification’ for a substance should not be submitted to the Agency. However, for active substances in PPP and BP it may be the case that a submitted CLH dossier also consists of proposals for ‘no classification’ for one or several hazard classes and/or differentiations since a full harmonisation is foreseen for these substances (Article 36(2) of the CLP Regulation).

However, if information is available on a substance that is already classified (and included as an entry in Annex VI to the CLP Regulation) and this information shows that the criteria for classification are no longer fulfilled, an MSCA may submit a proposal for removal of a specific hazard class and/or differentiation from an entry or removal of the entire entry.

The proposal for revision and/or removal of an entry should only include information related to those hazard classes and/or differentiations which are either not yet covered by the existing entry or need to be revised based on the information available. The proposal shall also include a justification of how the new information supports the proposed revision. Existing harmonised classifications included in Annex VI to the CLP Regulation, in hazard classes and/or differentiations that are not covered by the proposal for revision and/or removal, will not be affected.

4. How to prepare a CLH dossier

4.1. 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 Annex VI to the CLP Regulation. The flow chart (Figure 1) gives an overview of the process for preparing a CLH dossier, indicates the parties involved in each step and the steps in processing of the dossier once it has been submitted to the Agency.

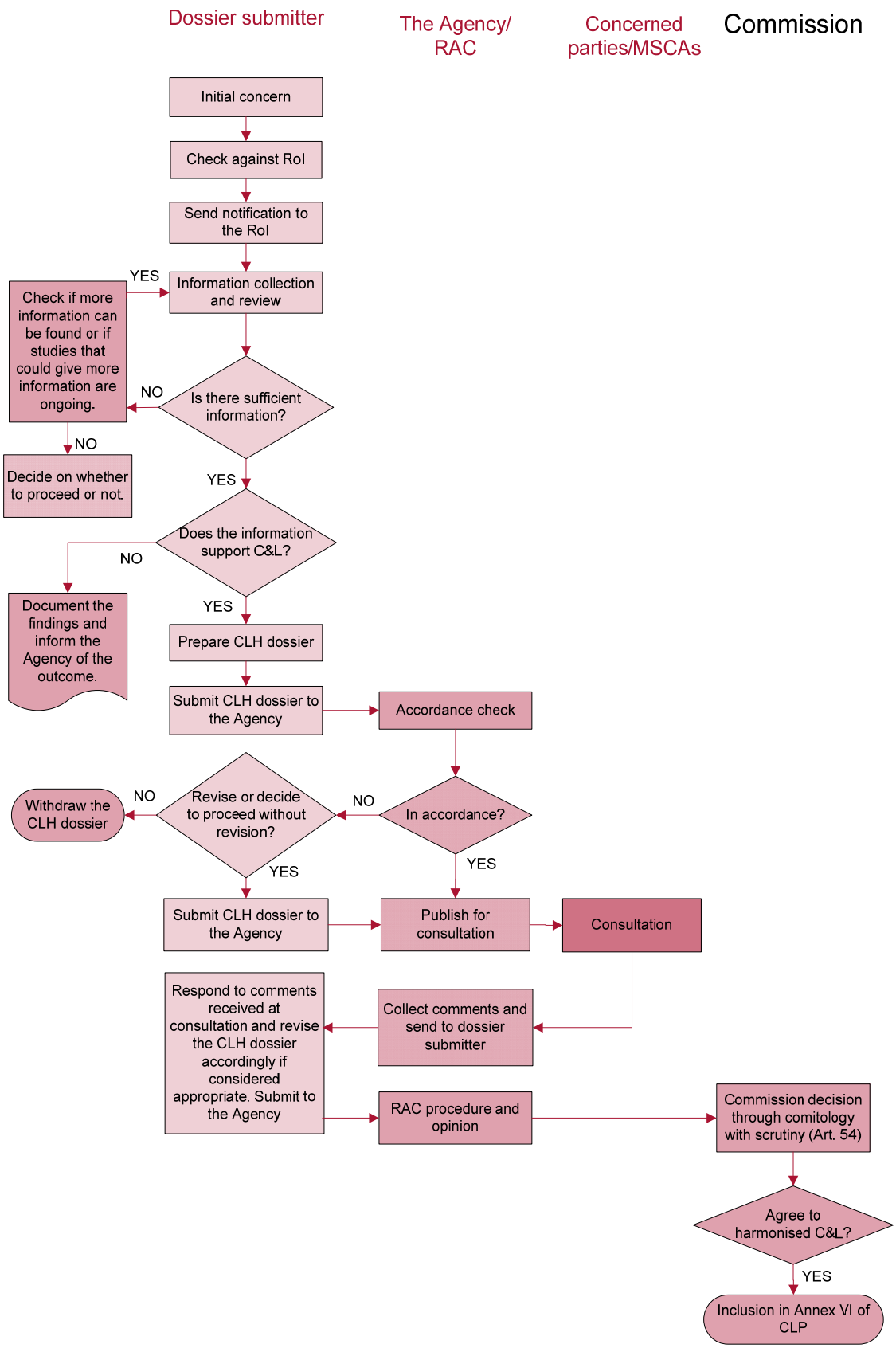

Figure 1: Overview of the preparation and further processing of a CLH dossier

4.2. The Registry of Intentions

The Registry of Intentions (RoI) is a list held by the Agency containing information from parties who intend to submit a CLH dossier to the Agency. The RoI is published on the Agency's website (under ECHA CHEM) and should be checked before starting to prepare a proposal to avoid two parties submitting a CLH dossier for the same substance at the same time. Annex VI to the CLP Regulation (on the Agency's website under CLP - Classification) should also be checked to make sure that there is not already an existing harmonised classification for the substance in that specific hazard class and/or differentiation and category.

When a potential dossier submitter intends to prepare a CLH dossier for a specific substance, it is recommended to inform the Agency in advance, as this will both inform MSCAs, industry and other stakeholders on the intention and allow all parties to prepare for the forthcoming discussions. It is suggested to send the information well in advance of the intended submission date in order to allow sufficient time for planning the processing of the dossier by the Agency and the Committee for Risk Assessment (RAC).

The dossier submitter should include the following information in their intention to the RoI:

- Name of the dossier submitter;
- Information on the substance (IUPAC name, EC number, CAS number and purity range);
- Information on impurities (including IUPAC name, EC number, CAS number and concentration range for each), if appropriate and available;
- Information on which hazard classes and/or differentiations the proposal concerns; and
- Expected date of submission.

Any confidential information included in the RoI shall be flagged as such and will then not be included in the part of RoI that is publicly available.

It should also be indicated whether it is an active substance in PPP or BP, and whether the substance is subject to transitional arrangements (Sections 6.2 and 6.3).

It is essential for the further development and processing of a CLH dossier that the substance is identified and described correctly. Potential dossier submitters are therefore requested to provide as much detail as possible on the substance itself and any impurities and/or other constituents of the substance (see Section 3.2.1). In case uncertainties arise before the dossier is submitted, dossier submitters from industry can refer to their national helpdesks for advice.

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

4.3.1. Possible reasons for an MSCA to initiate the preparation of a CLH dossier

There are several potential reasons for an MSCA to initiate the preparation a CLH dossier. For example an MSCA:

- Carries out a substance evaluation under the REACH Regulation and concludes that the substance is a CMR or RS or that classification and labelling in another hazard class and/or differentiation may be justified;
- Discovers that new information on an already classified substance is available, *e.g.* via a registration submitted in accordance with the REACH Regulation, that could justify a revision of the current harmonised classification and labelling;
- Carries out an evaluation on an active substance in PPP or BP and the evaluation shows that the classification criteria are met;
- Receives information from a risk assessment carried out by a regulatory body outside the EU which concludes that the substance is a CMR or RS or that classification and labelling in another hazard class and/or differentiation may be justified;
- Receives a proposal (Article 37(6) of the CLP Regulation) from industry which has new information that could lead to a change in the current harmonised classification and labelling;
- Receives information from someone in industry who is about to start manufacture of a substance that may be a CMR or RS substance, but who does not intend to submit a proposal for harmonised classification and labelling; or
- Discovers that there are different entries in the Classification and Labelling (C&L) inventory[10] for the same substance and there are indications that the notifiers cannot agree despite every effort being made to come to an agreement.

4.3.2. Possible reasons for a manufacturer, importer or downstream user to initiate the preparation of a CLH dossier

If a harmonised classification for a substance exists and is included in Annex VI of the CLP Regulation, this classification must be followed and no self-classification shall be done for the specific hazard classes and/or differentiations included in that entry (Article 4(3) of the CLP Regulation). If no harmonised classification for a hazard class and/or differentiation exists as an entry in Annex VI, and if the substance meets the criteria for classification in one or more of those hazard classes and/or differentiations, a self-classification shall be done for substances that are placed on the market. Self-classification shall also be done for substances that are not placed on the market but are subject to registration or notification according to the REACH and the CLP Regulation, respectively. The self-classification shall be done by manufacturers, importers and downstream users[11] of the substance (Article 1(1) of the CLP Regulation) in accordance with the criteria for classification as laid out in Annex I to the CLP Regulation.

If it is concluded that the substance is a CMR or RS or that classification and labelling in another hazard class/differentiation may be justified, a CLH dossier may be prepared and submitted to the Agency in order for RAC to give its opinion on a harmonised classification of the substance (for more information see Section 3). As described in Section 3.4.3, proposals for revision and/or removal of part of or an entire entry included in Annex VI to the CLP Regulation, can only be submitted to the Agency by an MSCA. If a manufacturer, importer or downstream user has new information that

[10] The C&L inventory is a database established and maintained by the Agency. 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 of the CLP Regulation.

[11] According to the provisions laid down in Section 4.1.3 of Annex VI to DSD, a manufacturer, distributor or importer is obliged to submit all relevant information indicating that the substance is a CMR substance to the Member State in which the substance is placed on the market. This Directive will be repealed with effect from 1 June 2015.

justifies such a proposal, this information shall instead be submitted to the MSCA in one of the Member states where the substance is placed on the market.

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; see Section 2.1 for links).

4.4. 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 shall be considered for the preparation of a CLH dossier. In addition, other available information may be used. Potential information sources are further outlined in the subsections below (see 4.4.1 to 4.4.5).

The information available to a dossier submitter when beginning the preparation of a CLH dossier will, for instance, depend on the status of the substance following the provisions of the REACH Regulation regarding if and when the substance has to be registered, and this may have an influence on the development of the dossier. For example, depending on the tonnage level in which the substance is manufactured or imported or the classification of the substance, different registration deadlines apply to the so-called 'phase-in substances' (Article 23 of the REACH Regulation).

4.4.1. Registration dossiers

Unless explicitly exempted under the REACH Regulation, a registration dossier shall be submitted for all substances manufactured or imported in quantities of one tonne or more per year. If there is more than one registrant for a substance, most parts of the dossier, including the classification and labelling and the (R)SS for relevant hazard classes and differentiations as required in accordance with Annexes VII-XI to the REACH Regulation, should be submitted in a joint dossier unless companies demonstrate their need to submit parts individually. The registration dossiers shall be submitted in IUCLID 5 format via the REACH-IT system made available by the Agency, and shall consist of a technical dossier and, depending on the tonnage band of the substance, a chemical safety report (CSR). The information that shall be included in the technical dossier for registrations is stated in Articles 10 and 12 of the REACH Regulation and the minimum required information depends *e.g.* on the quantity manufactured or imported per year (for detailed information on information requirements, see Annexes VII-XI to the REACH Regulation).

For substances manufactured or imported in quantities of ten tonnes or more per year, the chemical safety assessment (CSA) has to be documented in the form of a CSR which shall be attached to the registration dossier. Any relevant information provided there can also be used when preparing a CLH dossier. The CSA shall include a human health hazard assessment, including an assessment of physicochemical properties, and an environmental hazard assessment. It should also include a conclusion on the classification and labelling.

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 the Agency, registrants may be required to submit information needed to bring the registration(s) in compliance with the requirements

under the REACH Regulation. Following examination of testing proposals, which is another part of dossier evaluation, more information may have to be generated and submitted.

As mentioned in Section 4.3.1 a substance evaluation can be an initiator for an MSCA for preparing a proposal for harmonised classification and labelling. Substance evaluation is the procedure by which an MSCA evaluates the registration dossiers. As an outcome of the substance evaluation, further information may be requested to clarify risks from substances (Article 46 of the REACH Regulation). 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.

4.4.2. Other available information

In addition to using information from registration dossiers, other available information may be used (Part 2 of Annex VI to the CLP Regulation).

Information required for other regulatory purposes, *e.g.* from data submitted under the PPP and BP Directives, concerning active substances in PPP and BP, can be used for the CLH dossier. Other useful information sources, in particular for substances not (yet) registered under the REACH Regulation, can for instance be databases and published literature such as scientific journals, books *etc.* Also consultation with external stakeholders may 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, they 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 European Community legislation (*e.g.* Regulation (EEC) No 793/93), by OECD, WHO, IARC, ECETOC, or by Member States (eChemPortal: http://webnet3.oecd.org/echemportal). These reviews can be useful to identify the information that is available. New studies may be available in the literature or in new research reports. Epidemiological data and experience on the effects in humans, such as occupational data and data from accident databases may exist. 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 where 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 for the proposal. There should be a high confidence in the robustness of the approach used to review the information from the secondary source.

For each (R)SS provided in IUCLID 5, the reliability of the information source used should be indicated using the Klimisch score (see R.2.2.1.2 in IR/CSA, Chapter R.2, Guidance on the application of the CLP Criteria and IUCLID 5 End user manual; see Section 2.1 for links).

For further information see IR/CSA (Chapters R.2 and R.3) and Introductory guidance on the CLP Regulation (see Section 2.1 for links) where guidance on information sources and gathering is provided.

4.4.3. 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 of Annex XI to the REACH Regulation). The dossier submitter will then need to explain how this information relates to the substance being assessed, how this justifies the use of the information and in what way it supports the proposed classification.

Guidance on the use of information from structural analogues, *e.g.* using (qualitative or quantitative) structure-activity relationships ((Q)SARs), read-across approach and grouping of substances, is provided in the IR/CSA (Chapter R.6) and Guidance on the application of the CLP Criteria (see Section 2.1 for links).

4.4.4. Substances undergoing new 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 thought to be of relevance for the proposed harmonised classification and labelling it should be carefully considered whether to proceed with the CLH dossier or to await the result of the testing. In case a dossier submitter has decided to proceed with the preparation of the dossier, he should indicate that testing on the substance in question is currently being performed. Testing proposals and decisions on these will be made available on the ECHA website. If there is no registration dossier on the substance, this information will not be available. A dossier submitter can also contact the relevant industry to retrieve information on planned testing.

4.4.5. Supporting information

In addition to studies directly related to the specific hazard class(es) and/or differentiations that the proposal concerns, 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 certain physicochemical properties such as water solubility, stability data, hydrolysis data, molecular weight and size information is important. These should only be seen as examples, and which information to consider as supporting information needs to be decided on a case-by-case basis.

4.5. 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 needs to be reviewed in order to determine:

- Which information is relevant, adequate and reliable?

- Is there sufficient information to allow a conclusion to be drawn on the proposed classification?
- Is there a need to search for more information?
- Are there ongoing studies that can result in useful information?

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

The relevant available information should be systematically evaluated in order to derive a classification. The information shall be compared with the criteria for classification 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 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 of Annex I to the CLP Regulation and Section 1.2 of Annex XI to the REACH Regulation). Expert judgement may therefore be needed to decide 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 for classification according to the criteria specified in Annex I to the CLP Regulation[12]. 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 which, if using a weight of evidence approach, is sufficient to draw a conclusion.

Further guidance on the subsequent evaluation of available information is given in IR/CSA (Chapter R.2., R.4 and R.7) and 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 Section 2.1 for links).

[12] And Annex VI to the DSD until 1 June 2015 (Section 6.1).

4.6. Classification based on impurities

Article 10(1) of the CLP Regulation provides that:

'Specific concentration limits and generic 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.'

Furthermore, Article 11(1) of the CLP Regulation lays out that:

'Where a substance contains another substance, itself classified as hazardous, whether in the form of an identified impurity, additive or individual constituent, this shall be taken into account for the purposes of classification, if the concentration of the identified impurity, additive or individual constituent is equal to, or greater than, the applicable cut-off value in accordance with paragraph 3.'

This means that if there is a harmonised classification for a substance, included as an entry in Annex VI to the CLP Regulation, and that substance is present in another substance as an identified impurity, additive or individual constituent in concentrations at or above the SCL or generic concentration limit (GCL), this other substance should be classified as hazardous accordingly. If a substance, for which a harmonised classification included as an entry in Annex VI exists, is present in another substance in the form of an identified impurity, additive or individual constituent in concentrations at or above the relevant cut-off value, this shall be taken into account for the purpose of classification. The wording "taken into account" should be understood as meaning that when the substance is present above the cut-off value in a mixture, this substance should be considered in the calculation and rationale to determine the potential classification of the corresponding mixture based on the scientific evidence available.

However, a proposal for harmonised classification shall not be submitted for the substance in which the classified substance is present if this substance in itself does not fulfil the criteria for classification.

If there is no harmonised classification for the impurity, additive or individual constituent, but only a self-classification, a proposal for harmonised classification can be submitted (see Section 3). As pointed out in Section 4.8, priority for harmonised classification should be given to those hazard classes and differentiations of highest concern, *i.e.* the CMR and RS hazard classes/differentiations.

4.7. Preparation and creation of the CLH dossier

This section gives an overview of how to prepare and create a CLH dossier. A User manual gives detailed guidance on how to insert the information into a IUCLID 5 substance dataset, how to create the CLH report and how to create the final CLH dossier (see Section 2.1 for link).

4.7.1. Structure of a CLH dossier

The CLH dossier shall consist of a technical dossier (prepared in the format of IUCLID 5) and a CLH report attached to it. The CLH report should be prepared in a format specified by the Agency to be downloaded from the Agency's website. The information

to include in the technical dossier and the CLH report, respectively, is described in the subsections below. Basically, the format used for preparing the CLH report is the same for every potential dossier submitter, including MSCAs and manufacturers, importers and/or downstream users.

For MSCAs, the proposal for harmonised classification and labelling shall follow the format set out in Part 2 of Annex VI to the CLP Regulation stating, among other things, that relevant parts of Sections 1, 2 and 3 of Annex I of the REACH Regulation shall be used for the methodology and format for any dossier. The dossier shall contain the relevant available information provided in Part 1 of Annex VI to the CLP Regulation (Article 37(1) of the CLP Regulation).

For manufacturers, importers or downstream users, the proposal shall be drawn up in accordance with the relevant parts of Sections 1, 2 and 3 of Annex I to the REACH Regulation. The format should follow that for Part B of the CSR (Point 7 in Annex I of the REACH Regulation). The dossier shall contain the relevant available information provided for in Part 1 of Annex VI to the CLP Regulation. Article 111 of the REACH Regulation, which states, among other things, that the Agency shall specify and make available the formats and software packages for submissions to the Agency, shall apply (Article 37(2) of the CLP Regulation).

4.7.1.1. The technical dossier

The technical dossier shall be prepared in IUCLID 5, which is the international standard database for capturing, managing and exchanging data on properties of chemicals. The technical dossier is created starting from a substance dataset, which is the core of information in IUCLID 5. The substance dataset is the 'raw data layer' in IUCLID 5 into which all information shall be inserted (Section 4.1 in IUCLID 5 End user manual; see Section 2.1 for link).

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

- Substance ID: Information on substance ID is crucial for evaluation of the CLH proposal and for eventual inclusion in Annex VI to the CLP Regulation. Sections 1.1 and 1.2 of the substance dataset in IUCLID 5 shall always be filled in and must include the IUPAC name or chemical name, CAS number, EC number, registration number (if available), molecular and structural formulae (if applicable), purity and impurities (see Section 3.2.1);
- Information on classification and labelling in Sections 2.1 and 2.2 in the substance dataset in IUCLID 5; and
- Endpoint study records with RSS (for the studies considered as 'key studies') and SS (for the studies not considered as 'key studies') under the relevant Sections 4 to 7 in the substance dataset. The available information on identity of the tested substance should be included for each (R)SS (see also Section 3.2.1).

An endpoint study record contains the information related to one study. It provides a template with predefined fields and free text prompts, which helps the user to summarise a study. These include for example flag fields for specifying the study result type (e.g. "experimental study" or "read-across based on grouping of substances (category approach)"). See also Section 4.2.2 of the IUCLID 5 End user manual. An RSS is a detailed summary of the objectives, methods, results and conclusions of a full study report and should provide sufficient information to make an independent assessment of the study, minimising the need to consult the full study report (Article 3(28) of the REACH Regulation and Sections 4.2.2.3, 4.7.1 and 4.7.7 in IUCLID 5 End user manual). Guidance on the detail of information for RSS to be provided in the

IUCLID 5 technical dossier can be found in the Practical guidance on How to report robust study summaries (ECHA, 2010). This guidance is available on the Agency's website (under PUBLICATIONS).

A new substance dataset in IUCLID 5 needs to be created for each substance for which a CLH dossier is going to be submitted. For hazard information that has not previously been submitted to the Agency, an RSS shall be included in the relevant section of the technical dossier in IUCLID 5 (Part 2 of Annex VI to the CLP Regulation). MSCAs have access to registration dossiers via REACH-IT and can use the information from these dossiers when preparing a CLH dossier. If the hazard information has been submitted to the Agency before, reference can be made to that information (*e.g.* RSS from a submitted registration dossier), but MSCAs can also decide to copy relevant RSS from existing registration dossiers, or to fill in the relevant available information in the new substance dataset manually. This may require that they have access to the full study report. It should be noted that a IUCLID dossier is a read-only snap-shot of the raw data which does not allow editing of data copied from the dossier.

Industry does not have the same access to registration dossiers via REACH-IT as MSCAs. Hence, they will not be able to use the data from registration dossiers unless they are the owner of the registration dossier from which the relevant information is to be used. In this case the importer or manufacturer has the substance dataset in IUCLID 5 available for subsequent creation of the CLH dossier. If the potential dossier submitter is part of the same Substance Information Exchange Forum (SIEF) the substance dataset can be requested from the lead registrant. The latter also applies to downstream users, who may either fill in the data from existing registration dossiers manually or request the relevant information from the registrant of the substance of concern.

When the hazard information has not previously been submitted to the Agency, the dossier submitter must fill in all relevant available information on the substance, and related substances if appropriate, manually. In some cases transitional arrangements apply regarding the information required to be filled into the substance dataset in IUCLID 5. These arrangements are outlined in Sections 6.2 and 6.3 of this guidance document.

4.7.1.2. The CLH report

In the CLH report (created using the CLH report format) 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 shall be compared with the criteria for classification 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.

The CLH report should be a 'stand-alone' report by which is meant that it should provide sufficient information to make an independent assessment of various physical, toxicological and ecotoxicological hazards based on the information presented. In case the substance has already been discussed in the past, an overview of the history related to previous discussions and agreements (including relevant international evaluations and reviews) on the hazard identification of the substance should be included. It should not contain any confidential information, but confidential information should instead be given in the IUCLID 5 technical dossier in the corresponding chapters and should be flagged accordingly as confidential. If considered appropriate, a confidential addendum can be provided. The addendum should then be attached to

the relevant section of IUCLID 5 and accordingly flagged as confidential. In the CLH report it should be indicated in the appropriate section(s) whether there is relevant confidential information included in the technical dossier related to a specific issue, and in which section the information can be found.

The CLH report will be published by the Agency 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 may be used by the Commission for its decision-making.

The CLH report format provided by the Agency includes also an explanatory version with guidance on which information to fill in and from where the information can possibly be extracted (e.g. reference is given to relevant sections of the IUCLID 5 technical dossier or to relevant parts of the assessment reports prepared for active substances in PPP or BP). The CLH report shall comply with the criteria for the CSR report (Section 4.7.1).

4.7.2. Where to provide information

Overall, the CLH dossier shall contain (Part 2 of Annex VI to the CLP Regulation):

- A proposal, with the identity of the substance(s) concerned and the harmonised classification and labelling proposed; and
- A scientific justification for the proposed harmonised classification and labelling. This justification should include a comparison of the available information with the criteria contained in parts 2 to 5 of Annex I to the CLP Regulation; and
- A justification that action is needed at European Community level for other hazard classes and/or differentiations than CMR and RS, unless the substance is an active substance in PPP or BP (Section 4.8).

It is recommended to also include a short description of the (main) uses of the substance in the CLH report as this information is needed for the purposes of the public consultation on the Agency's website.

All available information on the substance that is considered adequate, reliable and relevant for the proposal should be inserted into the substance dataset in IUCLID 5. The dossier submitter should reflect carefully on which information to provide. It may be that RAC during the accordance check of the dossier requests clarification of part of the information provided if they consider this necessary to give an opinion on the proposed classification. For active substances in PPP and BP, proposals for harmonised classification and labelling normally addresses all hazard classes and differentiations, and hence information on all hazard classes and/or differentiations should normally be included in the CLH dossier, regardless of whether a classification is proposed or not. For the hazard classes where no classification is proposed, a justification of why the classification criteria are not considered to be fulfilled shall be included.

The key information related to the proposed classification and labelling should, in addition to in the substance dataset in IUCLID 5, be provided in the CLH report. However, 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. Hence, the dossier submitter should carefully consider whether to provide such information only in the technical dossier in IUCLID 5 or additionally also in the CLH report.

When preparing the CLH report, the dossier submitter should consider the IR/CSA guidance (Part F; see Section 2.1 for link) as the level of detail in the CLH report is required to be consistent with the level of detail specified for the CSR (Annex I specifications of REACH to be followed). Key hazard information in the CLH report must be clearly presented and justified and must be traceable back to its sources.

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 should make clear for which purpose the information is included ('key study', 'supporting study' *etc*.; Section 4.2.2.3 in IUCLID 5 End user manual; see Section 2.1 for link) and for which hazard classes and/or differentiations harmonised classification is being proposed.

It should be noted that it is only the CLH report that will be published for the public consultation. The full CLH dossier, including the CLH report and the technical dossier in IUCLID 5, will be made available to the MSCAs for their consideration and commenting.

4.7.3. Creation of the CLH dossier in IUCLID 5

The finalised CLH report shall be attached to the substance dataset in IUCLID 5 (in Section 13). The report shall be attached both as a word file to enable commenting and editing in the further process, and as a PDF file to be used for the public consultation on the Agency's website. Other documents considered relevant for the proposal, *e.g.* Risk Assessment Reports (RARs), other references used and attachments containing confidential information may also be attached. When all information has been included in the substance dataset a CLH dossier shall be created by using the dossier creation functionality of IUCLID 5. The final CLH dossier to be submitted to the Agency is read-only and hence no changes can be made to it.

If a revision of the CLH dossier is needed (*e.g.* resulting from feedback from the accordance check; Section 5.1), any changes need to be made in the IUCLID 5 substance data set, and thereafter a new CLH dossier has to be created.

For further guidance on how to create the CLH dossier in IUCLID 5, see User manual (see Section 2.1 for link).

4.8. Justification demonstrating the need for action at Community level

The primary reason for proposing a harmonised classification and labelling is that harmonisation is necessary to ensure adequate risk management throughout the European Community. In adopting the CLP Regulation, and before that, 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 RS hazard classes/differentiations. Harmonised classification and labelling for other hazard classes/differentiations than CMR and RS can be proposed, but the proposal shall then include a justification demonstrating the need for action at European Community level (Article 36(3) of the CLP Regulation) unless the substance is an active substance used in PPP and BP, in which case no justification is needed.

One example of when a harmonised classification and labelling in other hazard classes and/or differentiations may be justified is when the proposed self-classifications for a substance differ between registration dossiers and/or notifications. This would then result in different entries in the C&L inventory for that substance and a proposal for harmonised classification and labelling can be submitted. The Commission might provide further examples and guidance on acceptable justifications demonstrating the need for Community action.

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

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

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, RS or other hazard classes and/or differentiations. 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.

It is up to the MSCA to decide how much of the work that they have done needs to be documented, and this will be done on a case-by-case basis. The documentation could be for example information they have inserted into the IUCLID 5 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 the Agency and other MSCAs so that the process works efficiently and without undue duplication of work. The Agency's website lists the withdrawn intentions and specifies the submitting MSCA (under ECHA CHEM – RoI – withdrawn intentions). 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.

5. Processing of the submitted CLH dossier

The finalised CLH dossier should be submitted to the Agency for further processing. Detailed guidance on how to submit the dossier to the Agency via REACH-IT can be found on the Agency's website (see Section 2.1 for link). After the submission, each dossier submitter will receive a confirmation that the Agency has received the dossier and a submission number which should be used in all further communication with the Agency on the dossier. Then the procedure follows timelines set by the Agency for the different steps, notably accordance check, public consultation, response to comments, first draft opinion and final opinion.

5.1. Accordance check

For each CLH dossier submitted to the Agency, one rapporteur and possibly a co-rapporteur from RAC will be appointed. The rapporteur(s), supported by the Agency Secretariat, will perform the accordance check of the dossier. The purpose of the accordance check is to ensure that the dossier has been prepared in accordance with the requirements as specified in the legal text and by the Agency. In other words, that it includes all the information needed for RAC to discuss the proposal and to deliver an opinion, and that the information is correctly presented (see Section 4.7.2) in both the CLH report and the technical dossier in IUCLID 5. The dossier submitter will be informed of the outcome of the accordance check, and if the proposal is considered to be 'in accordance' the Agency will issue a formal letter of receipt with the date from which the 18 months deadline for RAC to issue an opinion is derived. Furthermore, the Agency will publish the CLH report for consultation by concerned parties and MSCAs.

If the dossier is considered to be 'not in accordance', the dossier submitter can decide to either:

- Revise the dossier according to the comments and recommendations received in the accordance check report and resubmit it to the Agency;
- Request the Agency to proceed with the proposal without any revisions; or
- Withdraw the proposal.

However, the second option could substantially prolong the process in RAC as RAC via its rapporteur(s) will have expressed concerns about the content of the dossier which might hamper the successful evaluation of the proposal and reaching of an opinion. In any case, the dossier submitter should inform the Agency about their intentions on how to proceed. If the dossier submitter decides to revise the dossier they should also provide the Agency with an expected date for re-submission, if possible.

After revision, the CLH dossier should be re-submitted to the Agency for further processing and the CLH report will be published for public consultation on the Agency's website. The Agency will issue a formal letter of receipt with the date from which the 18 months deadline for RAC to issue an opinion is derived (Article 37(4) of the CLP Regulation).

5.2. Public consultation and response to comments

During the public consultation, which is open for 45 days, concerned parties (*e.g.* industry, Member States, the general public and other stakeholders) are invited to comment on the proposal. The comments from the public consultation will be collected by the Agency and sent to the dossier submitter who will be asked to provide, within a set deadline, a response to comments (RCOM) and to revise the CLH dossier (including the CLH report) if appropriate. The RCOM and the revised CLH dossier shall then be returned to the Agency. The Agency will then prepare a draft BD and forward this to RAC, including 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.

5.3. The RAC opinion

RAC shall adopt an opinion on CLH proposals sent to the Agency within 18 months of receipt of a proposal (Article 37(4) of the CLP Regulation). The minimum requirements for the content of this opinion are laid down in the CLP Regulation (Article 38(1)). The RAC opinion on the proposal 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 possibly those from the rapporteurs, are forwarded to the Commission to support the further decision-making process.

The RAC opinion, minority positions where relevant, the BD and RCOM are published on the Agency's website.

5.4. Commission decision

The Commission shall consider whether the harmonisation of the classification and labelling of the substance concerned is appropriate, taking the RAC opinion into account. In justified cases, it shall prepare 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) of the CLP Regulation). The draft decision shall also include the relevant classification and labelling elements and, where appropriate, the SCLs and/or M-factors. The decision shall be adopted in accordance with the regulatory procedure with scrutiny (by the European Parliament) referred to in Article 54(4) of the CLP Regulation (referring to the so-called Comitology procedure under Decision 1999/468/EC, 'comitology procedure'). The minimum content of this decision is described in detail in the CLP Regulation (Article 38).

The information that will be listed for each entry can be found in Part 1 to Annex VI to the CLP Regulation.

During the period for which the transitional provisions apply (Section 6.1) a corresponding entry shall be included in Table 3.2 of Part 3 of Annex VI to the CLP Regulation.

6. Transitional arrangements

6.1. Transitional provisions

The CLP Regulation (Article 61) specifies the transitional provisions that affect the classification, labelling and packaging of hazardous substances and mixtures previously covered by DSD and DPD. By way of derogation, substances may be classified, labelled and packaged in accordance with the criteria of the CLP Regulation before 1 December 2010. Substances shall be classified, labelled and packaged in accordance with the criteria specified in Annex VI to DSD until 1 December 2010. From 1 December 2010 until 1 June 2015 substances shall be classified in accordance with both DSD and the CLP Regulation, but labelled and packaged in accordance with the CLP Regulation. The CLH dossiers shall therefore, until 1 June 2015, in addition to the proposed classification according to CLP criteria, also contain the proposed classification according to DSD criteria.

6.2. Substances where a harmonised C&L has been agreed by the Technical Committee on Classification and Labelling and hand-over dossiers

The Technical Committee on Classification and Labelling[13] (TC C&L) at Directorate General Joint Research Centre (DG JRC) adopted during 2006 and 2007 final recommendations for classification and labelling of 87 substances which due to legal considerations have not been included in the 1st ATP to the CLP Regulation. These should nevertheless be considered for future inclusion in Annex VI to the CLP Regulation.

Special arrangements apply for these substances, and also for the so called 'hand-over dossiers' (*i.e.* dossiers that concern substances from the review of existing substances under the Existing Substance Regulation (ESR) and Notification of new substances (NONS) programmes) as well as other substances for which classification proposals were submitted to the TC C&L, but for which discussions were not finalised. The same format as specified in Section 4.7 should be used, but it has been agreed with the MSCAs that the CLH dossier for these substances does not need to include the RSS in IUCLID 5 as long as similarly detailed summaries of the studies are provided in the CLH report. However, information on substance ID and Classification and labelling (Sections 1.1, 1.2, 2.1 and 2.2 in the substance dataset) has to be included in IUCLID 5 as usual. A justification for action at Community level (see Section 4.8) should be provided for classification proposals in hazard classes and/or categories other than CMR and RS, unless the substance is an active substance in PPP or BP for which no such justification is needed. A comparison with the classification criteria both according to DSD and the CLP Regulation should also be made. The translation table in Annex VII to the CLP Regulation should not be used to translate classification proposals according to DSD into classification proposals according to the CLP Regulation.

[13] In the TC C&L, proposals for harmonised classification and labelling submitted by MSCAs for substances to be included in Annex I to DSD were discussed. All conclusions reached by the TC C&L were recommendations to the Commission for possible inclusion in an ATP of DSD.

6.3. Active substances in plant protection and biocidal products

For the submission of a CLH dossier the format and software that shall be used is IUCLID 5. In addition to the format, the information requirements of the CLH proposal are also specified, which was not the case under the previous legislation (DSD). Under DSD, for proposals for classification of active substances in PPP and BP, relevant parts of the Draft Assessment Report (DAR) and Competent Authority Report (CAR), were submitted by the MSCAs to the TC C&L. In order to facilitate the change-over to the new system using IUCLID 5, an interim solution for the submission of CLH proposals for these substances has been agreed between the Agency, the Commission and the MSCAs. This interim solution can be followed when submitting CLH dossiers for active substances in PPP and BP.

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