Harmonisation of Classification and Labelling

1. Purpose

This procedure describes the process of harmonisation of classification and labelling (CLH), as set out in Title V of the Regulation on classification, labelling and packaging of substances and mixtures (Regulation (EC) No 1272/2008, CLP). Article 37 of CLP is the legal basis for the harmonisation of classification and labelling of substances.

The outcome of the process is an opinion issued by the Committee for Risk Assessment (RAC) on a proposed classification and labelling. The final opinion is published on the ECHA website and forwarded to the European Commission (COM). Subsequently, the COM takes the final decision to include a new entry or to revise an existing entry in Annex VI to CLP.

The procedure describes the main elements of handling of CLH dossiers submitted to ECHA. The procedure shall ensure that:

- legal requirements and deadlines are respected;
- responsibilities are unambiguously defined for all relevant activities;
- communication and co-operation with the dossier submitter (DS), the RAC, the parties concerned and the COM are well defined, consistent and transparent;
- scientific consistency and quality of the RAC opinion is monitored.

2. Scope

This procedure starts with the notification of intention (NoI) submitted by the DS, to inform about a planned CLH proposal for a specific substance/group of substances, or with a submission of a CLH dossier without prior NoI. It ends with ECHA's publication of an adopted RAC opinion on its website, which is then forwarded to the COM. ECHA supports the COM in the inclusion, revision or deletion of the CLH into Annex VI to the CLP.

3. Description

The classification and labelling of hazardous chemicals is harmonised to enhance management of hazardous substances and mixtures throughout the European Union. Member States, manufacturers, importers or downstream users may propose harmonised classification and labelling for substances. Article 37 of CLP sets out the procedure applicable to the different actors and conditions under which CLH can be proposed. The parties concerned have an opportunity to comment on the proposal.

The procedure on Prevention and Management of potential Conflicts of Interest (PRO-0067) is applied throughout the process and is applicable to the ECHA staff involved in handling the CLH dossier (CLH team). The CLH team manages the CLH process and it is further described in the WIN-0228 *CLH - Handling intentions to submit a CLH dossier and processing of a CLH dossier until adoption of RAC opinion*.

In the following, the main elements of the CLH process are described.

3.1. Intention

The DSs are encouraged to send a NoI via a specific web form, informing ECHA of an intention to prepare a CLH dossier. This is to avoid a possible duplication of work, if there is more than one potential DS for the same substance, and to transparently inform any party of a planned action to prepare a proposal for a harmonised classification.

The CLH team updates the public Registry of Intentions (RoI) whenever (a) a NoI about a CLH dossier is received or updated, (b) a CLH dossier is submitted without a NoI or (c) a NoI or submission of a CLH dossier is withdrawn.

The CLH team verifies the scope of the proposed CLH.

Once a NoI is received, ECHA's chemistry unit checks the substance identity and proposes the substance(s) name(s) which the DS should use when preparing the CLH dossier.

3.2. Dossier submission and accordance check

The Chemistry unit checks the submitted dossier against the information requirements related to the identification of the substance as set out in Article 38(1)(a) of CLP.

The dossier is further checked for accordance with regard to the legal requirements of the CLP regulation, as well as to the recommendations provided in the *Guidance on the preparation of dossiers for harmonised classification and labelling* and in the *Practical guide: How to submit a CLH dossier*. In addition, the CLH team may recommend revisions aimed to support RAC in drawing a conclusion on the proposal.

The CLH team provides the accordance check report to the DS and to RAC. If the CLH dossier is not in accordance with CLP, the DS must address the shortcomings before resubmission or decide to withdraw the proposal. This process is repeated until the CLH dossier is concluded to be in accordance with CLP.

The process deadline for the adoption of an opinion pursuant to Article 37(4) of the CLP is 18 months and starts when the submitted dossier is in accordance with the CLP. Should a fee apply for proposals submitted by manufacturers, importers or downstream users, the start of the 18-month deadline is either the date when this fee is received by ECHA or when the dossier is found to be in accordance with CLP, whichever is later.

If the DS decides to resubmit the dossier, they communicate the estimated resubmission date to the CLH team (default within 2 months). The CLH team monitors whether the deadline is feasible and offers support to the DS where necessary.

3.3. Consultation

When the CLH proposal is deemed to meet legal requirements, the CLH team launches the consultation of the CLH proposal on the ECHA website, to allow the parties concerned to submit comments within the agreed deadlines.

After the consultation ends, the CLH team publishes the received non-confidential comments on the ECHA website and sends a letter to the DS requesting their responses to the consultation comments in a RCOM document. Confidential information received during the consultation is provided to the RAC and the DS, provided that the DS is a competent authority.

3.4. Developing the RAC opinion

The CLH team requests the Rapporteur(s) (RAP) appointed by RAC to prepare the draft of the opinion on the CLH proposal (taking into account the comments and scientific information received during consultation, including any responses provided by the DS). The CLH team agrees with the RAP on the schedule for the development of the draft opinion.

As soon as the RAP prepares the draft of the opinion, the CLH team is notified and check the document for its consistency and completeness.

The draft opinion is then subjected to a consultation for the RAC members (RAC consultation) to provide written comments. Depending on the outcome of the RAC consultation, the RAP may revise the draft opinion.

3.5. Adoption of the RAC opinion and follow-up

RAC examines in a RAC-CLH working group the available information for all hazard classes proposed, including 'no classification'. RAC may consider other categories of the hazard class proposed for the classification of the substance as being more appropriate. Depending on the outcome of the RAC-CLH working group, the RAP may revise the draft opinion.

The RAC opinion may be adopted either in a RAC plenary meeting or through a written procedure.

The RAP revises the opinion according to RAC's discussion and conclusion, if relevant, and notifies the CLH team, which conducts an editorial check, proof-reading and formatting of the final opinion.

The final opinion consists of (1) the Opinion as adopted by RAC, (2) the Background document (Annex 1 to the opinion), which includes the proposal of the DS, the opinion of RAC, including any in depth analyses and supplementary information and (3) the RCOM completed by the DS and RAC (Annex 2 to the opinion) as well as the non-confidential attachments received during the consultation.

The CLH team publishes the opinion on ECHA website and sends it (including its Annexes and attachments) to the COM for decision making for inclusion in Annex VI to the CLP.

3.6. Supporting the COM in decision making on harmonised C&L

ECHA compiles the agreed CLH opinions in the table format used in Annex VI to the CLP and regularly provides it to COM and provides advice to COM as needed during this process as needed.

4. Flowchart

N/A

5. Definitions

Term or abbreviation	Definition
C&L	Classification and Labelling
CLH	Harmonised Classification and Labelling
CLH dossier	Dossier proposing harmonised classification and labelling (contains the CLH report as well as any annexes, appendices or attachments to the CLH report)
CLH team	Harmonised classification and labelling Team, composed of Scientific Dossier Managers, RAC Secretariat and Assistants (as defined in WIN-0228)
DS	Dossier Submitter
MSCA	Member State Competent Authority
NoI	Notification of Intention
RAC	Committee for Risk Assessment
RAP	RAC Rapporteur(s) or Co-Rapporteur(s)
RCOM	DS's and the RAC's response to comments from a consultation
RoI	Registry of Intentions
COM	European Commission

6. Records

Record name	Security level	Comments
Notification of Intention	Internal	Intention received, the acknowledgement of receipt of the intention and communication exchanged with DS at intention stage, including, if any, requests to withdraw the intention
CLH team nomination and check of conflict of interest	Internal	
CLH dossier	Internal	CLH report and annexes
Letter of appointment of RAP	Internal	
Signed declarations of conflict of interest and commitment of RAP	Internal	
Accordance check decision	Internal	(Letter to the DS with the outcome of the accordance check and its annexes) 1. ECHA Secretariat report; 2. CLH tables; 3.

Record name	Security level	Comments
		Annotated CLH dossier, 4. Report on confidential information
Consultation documents	Internal	Letter to the MSCA for consultation comments, Letter to the DS requesting to provide responses to the consultation comments, Original comments and scientific information received during consultation, RCOM submitted by the DS and RAC.
RAC opinion	Internal	Draft versions of the opinion and the RAC comments received on the draft version, the final RAC opinion including Annex 1 "Background Document" and Annex 2 "RCOM" including appendices such as detailed study summaries provided during consultation or outcome of any consultation of parties concerned. In the event there is a revised CLH report submitted after consultation, it will be included as an appendix to Annex 2.
Communication of the RAC opinion to the COM	Internal	Includes also communication exchanged with the COM and the CLH tables compiled by the CLH Team.

7. References

Associated document code	Document name
(EC) No 1272/2008	Regulation on classification, labelling and packaging of substances and mixtures (CLP Regulation)
ECHA-14-G-02-EN	Guidance on the preparation of dossiers for harmonized classification and labelling
N/A	Working procedure for the appointment of rapporteurs and co-rapporteurs by RAC and SEAC for application for authorisation, restriction dossiers and dossiers for harmonised classification and labelling
CA/45/2013	CARACAL paper on information received after consultation period
ED/32/2010	Tasks, duties and powers of the Data Protection Officer and the Data Controller

8. Annexes

N/A