Harmonisation of Classification and Labelling

1. Purpose

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

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

The procedure described hereafter includes handling of CLH dossiers submitted to ECHA by the dossier submitter (DS) proposing the CLH (CLH dossiers) and any additional support to the COM. The procedure shall ensure that:

- legal requirements and deadlines are respected;
- responsibilities and decision-making are unambiguously defined for all relevant activities;
- communication and co-operation with the 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

The procedure begins with a notification of intention (NoI) submitted by the DS, to propose a CLH for a specific substance, or with a reception of a CLH dossier without prior NoI. The procedure ends when ECHA has published an adopted RAC opinion on its website, forwarded the RAC opinion to the COM and supported the COM in the inclusion, revision or deletion of the CLH into the Annex VI to the CLP.

3. Description

The classification and labelling of hazardous chemicals is harmonised to enhance adequate management of hazardous substances and mixtures throughout the European Union. Member States, manufacturers, importers or downstream users may propose a harmonised classification and labelling of a substance. The parties concerned have an opportunity to comment on the proposal. Harmonised classification and labelling is mandatory for the suppliers of respective substances.

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 is formed to manage 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 it is in accordance with the CLP Regulation* and WIN-0229 *- CLH dossier - from proposal in accordance to adoption of RAC opinion*.

The CLH process may be generally divided into seven phases, which may be further divided into various steps.

3.1. Intention

Step 1 – Receiving an 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, and to provide the parties concerned with the time to prepare for public consultation (PC). If a NoI is received, the CLH team sends an acknowledgement of receipt to the DS and informs the DS about the publication of the intention.

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 or (c) a NoI or submission of a CLH dossier is withdrawn.

Step 2 – Verification of scope and proposal

The process coordinator nominates the CLH team and verifies the scope of the proposed CLH.

The SID team proposes the substance name which the DS should use when preparing the CLH dossier.

3.2. Pre-submission activities

Step 3 - Launch process for the appointment of RAC rapporteur(s) (RAP)

The RAP appointment process should start when the intention to submit a CLH dossier was included in the RoI and the expected date of submission is approaching. CLH team seeks volunteers who would act as RAP for the CLH dossier, according to the *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.*

Step 4 – Support to the DS

The CLH team offers support to the prospective DS in compiling the CLH dossier, as appropriate.

3.3. Dossier submission and accordance check

Step 5 – CLH dossier submission

When the DS submits a CLH dossier (in IUCLID format), the CLH team sends an email of acknowledgement of receipt to the DS.

The CLH team distributes the CLH report and its attachments to the RAP for information and sets an indicative timetable for the completion of the subsequent steps.

Step 6 – SID and accordance check

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

After reception of the CLH dossier by ECHA, the dossier is checked for accordance with regard to the legal requirements of the CLP, as well as to the recommendations provided in the *Guidance on the preparation of dossiers for harmonised classification and labelling*. In addition, the CLH team may recommend revisions aimed to support RAC in drawing a conclusion on the proposal.

The RAP may examine, on a voluntary basis, the quantity and quality of the information presented in the CLH dossier and may provide observations in a separate report. If available, the RAP observation report is included in the accordance check report as a separate annex.

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 shall address the shortcomings before resubmission. This process is repeated until the CLH dossier is concluded in accordance with CLP (see Step 7).

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

Step 7 – Resubmission and re-examination of the CLH dossier

If the CLH dossier is not found in accordance, the DS addresses the required revisions before resubmission. The DS may choose not to resubmit a dossier that was concluded not in accordance with CLP. In this case the CLH team updates the status of the substance to *withdrawn*, and the process stops.

If the DS decides to resubmit the dossier, the CLH team agrees with the DS on a resubmission date for the revised CLH dossier. The CLH team monitors whether the deadline is feasible and offers support to the DS where necessary.

A resubmitted dossier is examined again by the CLH team, in order to determine if it meets legal requirements. If the resubmitted dossier still does not meet legal requirements, the CLH team contacts the DS to discuss further necessary improvements.

3.4. Public Consultation

Step 8 – Launch the public consultation (PC)

When it is concluded that the CLH proposal meets legal requirements, the CLH team launches the PC on the ECHA website, to allow the parties concerned to submit comments within the agreed deadlines. The CLH team informs RAC about the launch of the PC.

Step 9 – Dissemination of PC comments

After the PC ends, the CLH team publishes the received non-confidential comments on ECHA website and sends a letter to the DS asking for responses to the PC comments. Confidential information is provided to the RAC and the DS, provided that DS is a competent authority.

Step 10 – RCOM preparation and response

The DS is requested to respond in writing to the comments in the RCOM document. Subsequently, the RAP provides their view on the comments submitted during PC and on the responses to comments by the DS. The RCOM is finalised and published as the Annex 2 to the RAC opinion.

3.5. Developing the RAC opinion

Step 11 – Draft opinion preparation

The CLH team requests the RAP to prepare the first draft opinion on the CLH proposal, taking into account the comments and scientific information received during PC, 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 first draft of the opinion, it is forwarded to the CLH team. The CLH team checks the document for its consistency and completeness.

Step 12 – RAC consultation

The draft opinion is then subjected to RAC consultation. Depending on the outcome of the RAC consultation, the RAP may revise the draft opinion.

3.6. Adoption of the RAC opinion and follow-up

Step 13 – Adoption of the opinion

RAC examines the available information for all hazard classes proposed, including 'no classification' as the starting point but may consider other categories for the classification of the substance as being more appropriate.

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

Step 14 – Finalise work on the adopted opinion

The RAP revises the opinion according to RAC's discussion and conclusion, if relevant, and forwards it to CLH team, which ensures 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 dossier submitter and the conclusion of RAC and (3) the RCOM completed by the DS and RAC (Annex 2 to the opinion) as well as the attachments received during consultation.

Step 15 - Forward the opinion to the COM and publish it on ECHA website

The CLH team sends the final opinion of RAC (including the Annex 1, Annex 2 and any other attachments) to the COM for decision making and publishes it on ECHA website.

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

Step 16 - Supporting the COM in decision making on CLH

The CLH agreed by RAC is compiled in a table format used in the Annex VI to the CLP and forwarded to COM once a year..

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 in a IUCLID format (contains the CLH report as an attachment)
CLH team	Harmonised classification and labelling Team, composed of Scientific Dossier Managers, RAC Secretariat and Assistants (as defined in WIN-0228)
DS	Dossier Submitter
Dynamic Case	Case management application
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 PC
RoI	Registry of Intentions
CoRAP	Community rolling action plan

Term or abbreviation	Definition
COM	European Commission
PC	Public consultation
SID team	Team from Substance identification Unit

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	IUCLID file, CLH report and annexes, acknowledgement of receipt of CLH dossier
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. RAC Rapporteurs' observation report; 4. Report on confidential information
Public Consultation documents	Internal	Letter to the MSCA for PC comments, Letter to DS requesting to provide responses to the PC comments, Original comments and scientific information received during PC, 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 I "Background Document" and Annex II "RCOM" including appendices such as detailed study summaries provided during PC or outcome of any consultation of parties concerned. In the event there is a revised CLH report submitted after PC, it will be included as an appendix to Annex II.

Record name	Security level	Comments
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
Regulation (EC) No 1272/2008	Regulation on classification, labelling and packaging of substances and mixtures (CLP Regulation)
ECHA-10-G-03-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 public consultation period
ED/32/2010	Tasks, duties and powers of the Data Protection Officer and the Data Controller

8. Annexes

N/A