Helsinki, 2 June 2022

Agreed at RAC-61

Framework for RAC opinion development on substances for harmonised classification & labelling

This framework outlines the general principles and main elements of the process on the development of an opinion by the Committee for Risk Assessment (RAC) on proposals for harmonised classification and labelling (CLH dossiers) in accordance with Article 76(1)(c) of Regulation (EC) No 1907/2006 (the REACH Regulation) and with Article 37(4) of Regulation (EC) No 1272/2008 (the CLP Regulation)[1]. This framework also clarifies the roles and responsibilities of the different parties as well as their input throughout the process with the aim to further increase the overall efficiency and transparency.

This document replaces the previous RAC framework on processing proposals for harmonised classification and labelling agreed by RAC at its 21^{tst} meeting in June 2012. The framework is the reference document for processing CLH dossiers in RAC.

The process consists of:

- The registry of intentions to submit a CLH dossier;
- The submission of a dossier by a Dossier Submitter (DS) with a proposal to harmonise the classification and labelling for a substance as described in Article 37 of the CLP Regulation. RAC evaluates whether the proposal is justified by the data presented in the CLH dossier;
- An accordance check of the dossier performed by ECHA;
- A consultation of parties concerned: RAC assesses whether the proposal is justified by the data presented in the CLH dossier and considers comments and additional data submitted during the consultation;
- The development of an opinion by the appointed RAC rapporteur(s) on behalf of the Committee and supported where needed, by its standing Working Group;
- Adoption of the opinion by RAC within 18 months of declaring the dossier to be in accordance;
- Publication of the opinion on the ECHA website and its communication to the European Commission.

The party proposing classification and labelling, *i.e.* the Dossier Submitter, should provide relevant information according to Part II of Annex VI to the CLP Regulation supporting the proposal and a comparison with the classification criteria. RAC's role is to assess the proposal, taking into consideration the information and argumentation submitted in the

[1] Article 37(4) of the CLP Regulation states that: *"The Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission."*

dossier, during the consultation and relevant information submitted during any later targeted consultations with parties concerned with the proposal.

The process also requires a reasonable, appropriate, adequate and proportional investment of resources, while being fully transparent and giving fair opportunities for all parties concerned to make their views known and have their arguments examined and reacted to.

The main elements of the opinion development process are described below.

1. Roles of different parties

The opinion development process is underpinned by a clear separation of responsibilities, with distinct roles for the Dossier Submitter, RAC (including the RAC (co-)rapporteur) and the ECHA Secretariat.

The Dossier Submitter (DS)
The DS[2] has the burden of proof on the original proposal and as such is responsible for collecting and presenting the administrative, scientific and technical information for the proposed classification in the CLH dossier, and is requested to respond to any comments received during the consultation. The role of the DS is thus to ensure not only the compliance of the CLH dossier with the legal requirements but also that the dossier contains all relevant scientific information. In order to ensure that the integrity of the process is maintained, the information included in the dossier needs to be adequate in detail and content as well as being assessed for its reliability.

ECHA Secretariat (ECHA)
The role of the ECHA Secretariat is defined in Article 76(1)(g) of the REACH Regulation as follows: *'(…) shall work under the leadership of the Executive Director and provide technical, scientific and administrative support for the Committees and ensure appropriate coordination between them'*. The Secretariat runs the process for evaluating CLH dossiers and supports the rapporteurs and the Committee in their work of developing and adopting the opinions of the Agency.

RAC
Pursuant to Article 76(1)(c) of the REACH Regulation and to Article 37(4) of the CLP Regulation, RAC is responsible for delivering an opinion on the proposal presented by the DS taking into account the comments/data from parties concerned. The main role of RAC is to assess and adopt an opinion on the proposal. RAC is only required to ensure that relevant information submitted by the DS or any party during the consultation is taken into account; it is not obliged to take information received after the closure of the consultation into account. Accordingly, it is not RAC's role to systematically collect additional information to broaden or supplement the information basis. The CLH dossier submitted by the DS should by default be considered to contain all relevant information. However, this consideration needs to be balanced with the need to apply the expertise and knowledge of the RAC members to the assessment of the proposal and additional comments/data submitted during the consultation. This applies in particular to situations where an alternative interpretation of the same hazard data or proposals for a new hazard class is suggested.

[2] Pursuant to Article 37(1) and (2) of the CLP Regulation, a CLH dossier may be submitted by Member State Competent Authorities, manufacturers, importers or downstream users of a substance.

RAC (co-)rapporteur
In accordance with Article 87(1) of the REACH Regulation and Article 17 of the RAC Rules of Procedure, the Committee is required to appoint one of its members as rapporteur and may appoint a second member as co-rapporteur (both referred to as (co-)rapporteur in this document), which shall undertake to act in the interests of the European Union. The (co-) rapporteur is responsible for drafting, co-ordinating with the co-rapporteur and any members appointed by RAC in an *ad hoc* capacity to support the development of the opinion. They are also required to present their opinion on the classification proposal to RAC, with the support of the ECHA Secretariat.

RAC observers from stakeholder organisations (STOs)
In accordance with Article 85(4) of REACH and Article 6(6) of the Rules of Procedure RAC observers from accredited stakeholder organisations act as conduits between RAC and the parties concerned for information about RAC discussions. The procedure for involvement of accredited stakeholder organisations and their experts in the work of RAC on CLH substances follows the general Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees[3]

Parties concerned
Parties concerned have the right to comment on any proposal for CLH (Art 37(4) of the CLP Regulation). The opportunity to comment is provided via the consultation. On a case-by-case basis, where specifically requested by ECHA, additional targeted consultation with parties concerned may occur.

Commission (COM)
In accordance with Article 85(4) of REACH, representatives of the Commission (COM) are entitled to attend RAC meeting as observers. Pursuant to Article 37(5) of CLP, after RAC has adopted an opinion for a proposal, COM decides whether the CLH of the substance concerned should be included in Annex VI of the CLP Regulation.

2. Structure of the opinion

Pursuant to Article 37(4) of CLP, RAC adopts an opinion on any proposal submitted. The opinion is forwarded to the Commission. The opinion is accompanied by the background document (BD), i.e. an annotated version of the CLH proposal and the response to comments document (RCOM) from the consultation. During the drafting of the opinion RAC works with a document, which contains a table of the classification and labelling proposed by RAC (C&L table) and separate text boxes for those hazard classes that RAC is assessing during the opinion development process.

3. Input to the CLH process

The CLH dossier
The DS is responsible for ensuring that the CLH proposal (main part of the submitted CLH dossier) contains all relevant detailed study summaries and any other information that is available. The Dossier Submitter has the obligation to take REACH registration dossiers into

[3] https://www.echa.europa.eu/documents/10162/17091/admission_of_stakeholder_organisations_as_observers_en.pdf/51298e6b-1dda-4e23-88c3-7b96a6fc3e73?t=1622536575278

account in their CLH proposal and it is recommended that any relevant documentation produced for risk assessments of active substances in plant protection products (DAR) and/or biocidal products (CAR) or any studies planned are also taken into account in the CLH proposals.

Consultation and response to comments (RCOM)
All parties concerned may provide further information relevant to the substance under consideration during the consultation. This information may include, but is not limited to, published or non-published study results not included in the CLH report, alternative interpretation of the data in the CLH report, or any relevant comment on the CLH report.

The DS is then requested to provide responses to the consultation comments in a response to comments document (RCOM). RAC, through the (co-)rapporteurs, also provides its view in the same RCOM document, which is then published as an annex to the RAC opinion.

Input into the CLH process after the consultation
To ensure efficiency and proper administrative conduct on the one hand and meeting the 18-month process deadline for RAC to adopt an opinion[1] on the other hand, RAC will not be requested to consider further information after the consultation has been conducted, unless ECHA or the Committee specifically request further input. Whenever the ECHA Secretariat or RAC request additional information, the scope will be clearly defined and timelines for the submission of the information will be set. A request for additional information may have different forms, such as a targeted consultation, an expert meeting, or a paper on a specific topic.

Any information submitted to ECHA at a later stage may, in specific cases and at the discretion of the RAC Chair, be shared with the rapporteurs and/or RAC for information. However, as stated above, RAC is not obliged to take into account or respond to such information and certainly not within 10 calendar days prior to the respective CLH Working Group or RAC plenary meeting.

The approach to dealing with any new information submitted depends on the nature of that information. The RAC Chair and the ECHA Secretariat will screen the information. Considerations that may affect the use of new information are, e.g. the extent to which issues are raised which were not known at the time of the consultation, the relevance of the information for the opinion development and its potential impact on the classification and timelines.

Where the additional information was clearly announced during the consultation as being available (but e.g. confidential) or as on-going studies, these may be considered by RAC for the development of its opinion, in the event that they meet the criteria for such consideration and fit appropriately within the timelines.

4. Process tailoring

It is vital for the efficiency of the overall process that ECHA maintains the flexibility to adapt the process on a case-by-case basis depending on the complexity of issues within a proposal. The need for flexibility also applies to situations where data or compelling arguments are provided at the consultation.

Crucial, complex or potentially contentious issues may be identified in the dossier by the (co-)rapporteur in collaboration with the ECHA Secretariat. The need to involve the DS to

resolve these issues is decided on a case-by-case basis. Subsequent actions would involve, but are not limited to, additional targeted consultation on the dossier with parties concerned or even withdrawal of the dossier (and possible resubmission) by the Dossier Submitter.

RAC CLH working group
As provided for in the CLP Regulation and the Committee's Rules of Procedure, RAC is supported by a standing CLH working group, initiated in 2021, which pre-evaluates CLP proposals and makes recommendations to the plenary. The CLH working group operates under the RAC Rules of Procedure and is open to accredited stakeholder observers in a similar way to the plenary meetings of RAC.

Expert groups
In accordance with Article 76(2) and (3) of REACH and Article 18 of the Rules of Procedure RAC may establish expert groups. These can be groups consisting of RAC members and ECHA staff with special knowledge of a field of science or *ad hoc* groups with external experts for specific issues.

RAC discussions outside of the plenary sessions
In some cases a specific discussion outside of the context of the RAC plenary sessions may be needed aiming at preparing or clarifying issues for the RAC plenary sessions, e.g. an open rapporteurs` dialogue. This can be in the form of Webex meetings or via Interact consultations.

Consultation of parties concerned
All parties concerned are given the same opportunities to feed in additional information. The usual mechanism by which such consultation will occur is by consultation on the ECHA website.

The consultation of interested parties does not confer specific procedural rights on interested parties (e.g. a right to be heard), other that the right to submit information. ECHA is obliged to carry out one consultation only per opinion. There is no obligation to re-consult interested parties on comments/information received via the consultation. In exceptional cases further targeted consultation with those parties that have been identified as concerned with the proposal (e.g. through specific expert meetings, e.g. an open rapporteurs' dialogue, or written consultation), or a further consultation may occur. Written targeted *ad hoc* consultations may be launched on new information which is relevant, adequate and reliable and which is likely to impact significantly on the outcome of a classification proposal.

Co-ordination with EFSA
ECHA will coordinate with EFSA on the assessment of substances in Plant Protection Products, including on communication aspects, when the timelines for a substance which is in both the CLH and EFSA processes overlap.

5. Steps of the process

Intention

The CLH process begins when ECHA receives an intention to prepare a CLH dossier by an MSCA or manufacturer, importer or downstream user. Once the intention is received, a substance identity check is performed, after which ECHA publishes the intentions in the Registry of Intentions on its website.

Besides informing interested parties on the substances that are currently in the process, publishing the intentions for CLH aims to prevent situations in which two or more parties submit a proposal for the same substance at the same time. Moreover, anyone with information relevant to the proposed hazard classification for a substance may bring this to the attention of the party submitting the CLH proposal during the early stages of the process, or provide such information during the consultation.

Dossier submission

The CLH dossier is prepared by an MSCA or manufacturer, importer or downstream user and is submitted to ECHA. The dossier consists of the CLH report and any other supporting information, which is intended to be a 'stand-alone' document and must contain sufficient information to allow an independent assessment of physical, health and environmental hazards based on the information presented. The DS is advised to use the practical guide for the preparation and submission of a CLH dossier available on the ECHA website.[4]

The CLH report must not contain any confidential data as it will be subject to consultation. Furthermore, the DS should follow the policy for the publication of study author's names also available on the ECHA website[5]

Accordance check

During this stage, ECHA checks that the submitted CLH dossier is in accordance with the legal requirements of the CLP Regulation. More specifically, that the dossier includes the information needed for RAC to deliver an opinion on the classification proposed in the CLH dossier.

If the dossier is found to be in accordance, ECHA will start the consultation of the proposed CLH as presented in the CLH report on its website. Otherwise, the Dossier Submitter is asked to bring the dossier into accordance and to resubmit it.

Consultation

The consultation lasts for 60 days in which interested parties are invited to comment on those hazard classes for which data has been provided in the CLH dossier.

During the consultation, any comments received are published on ECHA's website.

Once the consultation closes, all the comments and attachments received are compiled and forwarded to the Dossier Submitter, inviting them to provide their response to the comments (RCOM). The compiled comments and non-confidential attachments are also published on the website at this stage.

RAC opinion development

The CLH dossier, the comments and attachments received, and the response of the Dossier Submitter following the consultation, are then forwarded to RAC for the drafting of its opinion.

The opinion on the CLH proposal has to be adopted by RAC within 18 months of receipt of a proposal that has been declared in accordance. For plant protection products ECHA endeavours to adopt the opinion within 13 months of receipt as required by the

[4] a715300e-c40e-b181-e1c2-7dc851eb7b62 (europa.eu)
[5] Microsoft Word - Policy for the publication of study authorˇs names.docx (europa.eu)

implementing Regulation (EU) 2020/1740. ECHA aims to reach adoption of each CLH opinion in RAC with one plenary meeting to spare before the process deadline.

The draft opinion prepared by the rapporteur(s) is the central document prepared by the Committee and any presentational material is secondary; ECHA has no obligation to circulate the latter in advance of meetings.

ECHA drafts a summary record of each meeting to reflect the decisions made on each case. However, it does not provide narrative minutes on the discussions. The summary record (report) of working group meetings is intended to communicate their recommendations concisely to the plenary and may be somewhat more detailed.

The role of plenary is to resolve remaining differences from the working group and to firm up on opinions for adoption. Members may request, within reason, to discuss particular aspects of any opinion in the plenary. It is not, however, the intention to repeat in-depth assessments where the working group made clear recommendations.

The RAC opinion and its annexes (the background document and the RCOM table) are published on ECHA's website once the opinion is adopted. The background document is based on the CLH report in which RAC evaluations are inserted. The RCOM contains the compiled comments received during the consultation and the responses by the Dossier Submitter and RAC.

ECHA sends the RAC opinion along with its annexes to the European Commission for its decision and publishes it on the ECHA website