

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 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 RAC working procedure on processing dossiers for harmonised classification and labelling agreed by RAC at its 11th meeting in May 2010. The framework is considered the reference document for processing CLH dossiers in RAC and is complemented by separate detailed workflow procedures for an efficient handling of CLH dossiers.

The opinion development process begins with the submission of a CLH dossier by a dossier submitter (DS) with a proposal to harmonise the classification and labelling (C&L) for a substance as described in Article 37 of the CLP Regulation. RAC assesses whether the proposal is justified by the data presented in the CLH dossier and considers comments and additional data submitted during public consultation (PC). At the end of the process, RAC delivers an opinion on the proposal submitted by the DS (point of reference: CLH proposal on which the PC was carried out) taking into account the comments/data from parties concerned).

The party proposing the C&L, *i.e.* the DS or a commenting party proposing a different classification, 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 dossier, during the PC and information submitted during targeted consultations with parties concerned with the proposal, that are relevant to 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 (DS), RAC (including RAC (co-)rapporteur) and the ECHA Secretariat.

The Dossier submitter (DS)

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.*"

The DS² 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 PC. 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.

ECHA

For the purpose of this framework, ECHA refers to the ECHA Secretariat and its Committees, including RAC.

ECHA Secretariat (ECHA-Sec)

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*'.

RAC

Pursuant 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 not required to ensure that relevant information other than the information submitted by the DS or any party during PC is taken into account. Accordingly, it is not RAC's role to systematically collect additional information to broaden or supplement the information basis as 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 public 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.

RAC (co-)rapporteur

In accordance with Article 17 of the Rules of Procedure, RAC is requested 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, coordinating and presenting 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 stakeholder organisations (STOs) act as conduits between RAC and the parties concerned for information about RAC deliberations. Their main role in the CLH process is, therefore, to contribute to the appropriate information flow from ECHA and RAC to the stakeholders. The procedure for involvement of STO in the work of RAC on CLH substances follows the general RAC procedure for admission of STO³ with the exception that sub-section 4.3 of it will not apply in this framework given that parties concerned have an opportunity to comment during the opinion development process. This means that experts of any parties concerned have equal chances to provide their input to the CLH process

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.

³ "RAC procedure for admission to the work of RAC of regular and sector-specific observers from the stakeholder organisations and their experts" http://www.echa.europa.eu/documents/10162/13579/rac_pfa_sto_en.pdf

during PC and in some cases also after PC during targeted consultations of parties concerned (see as well section 4 below).

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 PC. 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 meetings 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 normally consists of the opinion itself, the background document (BD) and the response to comments document (RCOM). During the opinion forming process RAC works with a document, which contains a table of the classification and labelling proposed by RAC (C&L table) and 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 report contains all relevant detailed study summaries and any other information that is available. The DS has the obligation to take registration dossiers into 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.

Public consultation (PC) and response to comments (RCOM)

All parties concerned may provide further information relevant to the substance under consideration at the PC. The information submitted during PC includes, 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 comment on the CLH report.

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

Input into the CLH process after PC

To ensure efficiency and proper administrative conduct on the one hand and meeting the legal 18-month deadline for RAC to adopt an opinion¹ on the other hand, RAC will not be requested to consider further information after the PC has been conducted, unless ECHA or RAC specifically request further input. Where the additional information was clearly announced during the PC as being available (but e.g. confidential) or as on-going studies, these will be considered by RAC for the opinion development, in the event that they meet the criteria for such consideration.

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 PC. Since ECHA is responsible for administering the opinion development process, ECHA must also exercise its discretion where additional flexibility is needed and drive the tailoring of the process.

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 would be decided case-by-case. Generally subsequent actions would involve, but are not limited to, either additional targeted consultation with parties concerned with the dossier or withdrawal of the dossier (and possible resubmission) by the dossier submitter.

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. This can be in the form of Webex meetings or via Newsgroups in CIRCABC or similar means.

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 public consultation. At that point in time parties concerned will be requested to identify themselves also in case they do not plan to submit comments to the proposal.

In exceptional cases further targeted consultation with those parties that have been identified as concerned with the proposal (e.g. through specific expert meetings or written consultation), or a further public consultation may occur.