Regulatory context for harmonised classification and steps to be followed by the RMS

PSN meeting

11 November 2025

European Chemicals Agency

The CLP Regulation (EC) No 1272/2008

→ A substance which is either self-classified or included in Annex VI to CLP following the harmonised classification (CLH) process is subject to
- labelling requirements
- requirements arising from downstream regulations

→ Self-classification mandatory based on available data by Manufacturer, Importer or Downstream User (MIDU)
- Can lead to different self-classification

→ Harmonised classification legally binding in all EU

CLP revision

- → Published on 20 November 2024 the Official Journal (OJ), available at: Regulation - EU - 2024/2865 - EN - EUR-Lex
- → New hazard classes in the Delegated Regulation 2023/707, available at: Delegated regulation - 2023/707 - EN - EUR-Lex
- → The updated CLP regulation aims to protect better EU workers, consumers and the environment from hazardous substances, mixtures and articles.
- → It also strengthens the internal market of chemicals, paving the way for a more competitive and sustainable chemical industry.

CLH is an agreement of classification and labelling at EU level

→ Legally binding - obligatory to be used by every MIDU of the substance within the EU

→ Focus on substances which are of most concern:

- Carcinogenic (C), Mutagenic (M), Reproductive toxicants (R)
- Respiratory sensitisers (RS)
- New: ED HH and ENV, PBT, vPvB, PMT and vPvM

→ Other hazard classes can be harmonised on a case-by-case basis – 'justification' needed

CLH for pesticides

→ Active substances used in PPP are subject both to evaluation under the PPP Regulation and to CLH under the CLP Regulation.

→ For the evaluation of these substances under the PPP legislation, a DAR or RAR is prepared by the appointed RMS. The DAR or RAR is then submitted to EFSA who performs an evaluation.

→ The aim is to have the two processes, i.e. the evaluation process for active substances in PPP and the CLH process, aligned. To achieve this, deadlines for the coordination between the two processes have been defined.

- Goal is to start the consultation in parallel.

Commission Implementing Regulation 2020/1740

Article 11(9)

- → The RMS shall … submit a proposal to …[ECHA] …to obtain an opinion on a harmonised classification of the active substance at least for the following hazard classes:
- → (a) explosives;
- → (b) acute toxicity; (c) skin corrosion/irritation; (d) serious eye damage/eye irritation; (e) respiratory or skin sensitisation; (f) germ cell mutagenicity; (g) carcinogenicity; (h) reproductive toxicity; (i) specific target organ toxicity – single exposure; (j) specific target organ toxicity – repeated exposure;
- → (k) hazardous to the aquatic environment.

The CC and ACC processes when a submission is made parallel to ECHA and EFSA

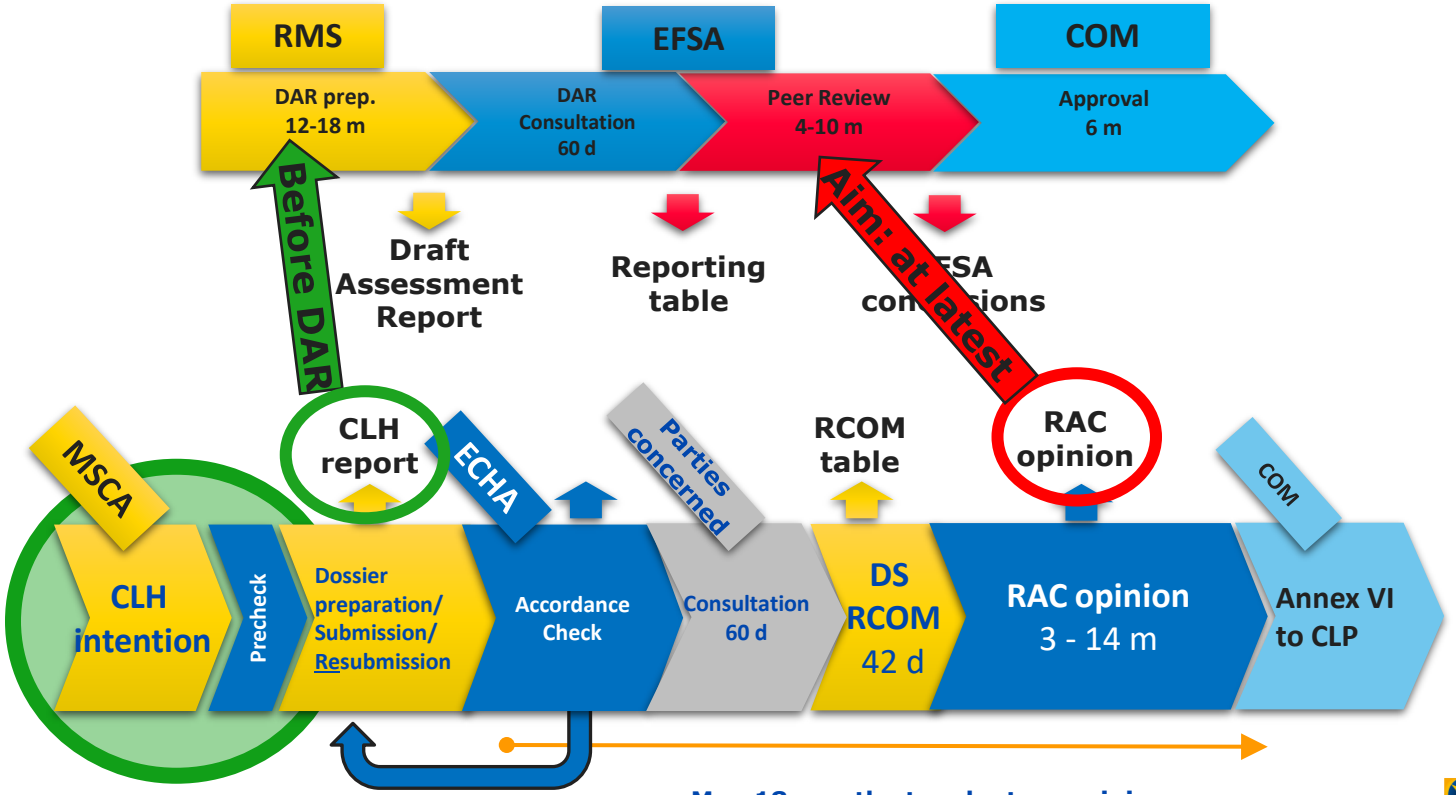
Main reasons:

→ CLH impacts the approval process (exclusion criteria)
- RAC opinion before EFSA concludes the review process

→ Avoid conflicts in opinions (REACH Art. 95)
- consistent information basis in the two processes

→ Efficient use of resources, e.g. preparation of CLH/DAR by MSCAs and avoid overlapping discussions when possible (e.g. C&L discussions at the expert meetings?)

Alignment - Parallel processes



Main challenges in CLP and PPP alignment

→ All the steps are defined by legal deadlines for PPP approval
- Low flexibility
- The EFSA conclusions adoption may occur 4-10 months after the DAR consultation
- The decision on the PPP approval may occur between 10-16 months after the DAR consultation

→ The deadline for the adoption of the CLH opinion is 18 months once the CLH dossier is in accordance with the CLP Regulation

Submission of an intention or a proposal for harmonised classification and labelling (CLH) of a substance, in accordance with the CLP Regulation (EC) 1272/2008

→ ECHA Website
- Checking in practise how to submit a classification proposal via form at ECHA's website

→ Registry of CLH intentions until outcome – ECHA
- Show RoI where all CLH process related cases can be found (from intention onwards)

Thank you

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