

11 April 2023

ECHA's input to the CLP Revision

Background

On 19 December 2022 the European Commission proposed a revised Regulation on classification, labelling and packaging of chemicals (CLP) and introduced new hazard classes for endocrine disruptors and other harmful chemical substances that persist and either accumulate or remain mobile in the environment, with the aim to better protect people and the environment from hazardous chemicals.

Press release

https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7775

There are two changes ongoing

- 1) An ordinary legislative procedure¹ amending the CLP regulation to, among other issues, address
 - The right for the Commission to develop classification proposals or mandate ECHA/EFSA to do so. Currently, only Member States or industry can initiate such proposals.
 - Improved communication of chemical hazards, including online, through simpler and clarified labelling and advertising requirements.
 - Changes to the information in the classification and labelling inventory.
 - Clarifications on the bridging principles for mixtures and the tiered approach for mixture classification.
 - Extending the scope of the mixture rules to substances where there is more than one constituent (MOCs).
 - Poison centres notifications.
- 2) A [delegated act](#)² was published on 31 March 2023, introducing new hazard classes to the Annexes of CLP

There are new hazard classes for

- Endocrine disrupting chemicals (ED HH, ED ENV)
- Persistent, Bioaccumulative and Toxic (PBT) or very persistent and very bioaccumulative (vPvB) chemicals
- Persistent, Mobile and Toxic (PMT) or very persistent and very mobile (vPvM) chemicals

¹ <https://www.europarl.europa.eu/olp/en/ordinary-legislative-procedure/overview>

² https://commission.europa.eu/law/law-making-process/adopting-eu-law/implementing-and-delegated-acts_en

ECHA input

ECHA was involved in all stages of the development of the proposals and provided support to the Commission on many aspects in terms of clarifying the need to intervene with legislative change and the cost/benefit analysis but also in terms of providing technical and scientific support based on our knowledge and experience.

Some key areas where ECHA provided significant support are described below:

New hazard classes and associated criteria

These new hazard classes are the result of extensive scientific discussions and ECHA provided significant input in developing and refining the criteria. The addition of these hazard classes will help to centralise and consolidate hazard assessment and is a key step towards one substance, one assessment.

The work on this area continues with the need to provide and update the CLP guidance³. Given that the new hazard classes have some history in other processes such as SVHC, BPR and PPP there is a need to closely collaborate with other regulators and stakeholders in developing this guidance and also in developing the CLH process to assess and confirm such hazards. ECHA support is also needed and is ongoing in discussions on the inclusion of the new hazard classes in GHS.

Commission's right of initiative

This amendment to the regulation will allow the Commission to initiate proposals for harmonisation of classification and labelling. This will help to relieve some of the burden on Member States and should facilitate improved prioritisation and swifter action by allowing agencies to support this work when there is a particular need.

Substances with more than one constituent (MOCs)

ECHA, informed by discussions at the MOCs working group of Member State competent authorities, provided input in support of extending the mixture rules to MOCs (substances with more than one constituent) with the aim to ensure appropriate classification of MOCs while avoiding additional animal studies.

The proposal contains an option for derogations from this general rule. The amended article stipulates that a derogation may apply if listed in an Annex to the CLP regulation. ECHA support is expected to be needed in developing any such derogations in future.

Clarifications on the bridging principles

ECHA, informed by discussions at a Forum working group of enforcement authorities, provided input to improve and remove unclarity in the application of the tiered approach for mixture classification, in particular in context of using bridging principles for classification of mixtures and how this relates to the weight of evidence determination. Overall, these clarifications will help industry to self-classify mixtures in accordance with the legislation and also help to make the work of enforcement authorities more effective.

³ <https://echa.europa.eu/guidance-documents/guidance-on-clp>

Changes to the classification and labelling inventory

ECHA provided extensive input regarding the information it holds from industry self-classifications and updated the Commission on plans to improve the user experience and usefulness of the C&L inventory in the near future. ECHA also advised the Commission on the effectiveness and feasibility of the various policy options for legislative changes to improve information in the classification and labelling inventory.

Poison centres notifications

ECHA advised on the proposal which included adding a more robust legal basis for ECHA's role in receiving and processing notifications and adding distributors as notifiers for PCN data. ECHA also provided other technical input to improve Annex VIII to the CLP regulation.

Improved communication on chemical hazards via labelling

ECHA advised the Commission on various options based on our experience gathered over many years of helpdesk queries on labelling.