

VdMi position paper on the Revision of EU's CLP Regulation

The EU's CLP Regulation in combination with the REACH Regulation are unique in such a form and extent worldwide. The collection of information on the hazard and potential risks from chemicals and the subsequent classification of substances and mixtures is a huge gain for protecting human health as well as the environment. Other countries already use these regulations as a blueprint for their own chemical regulations.

The effectiveness of the regulations as well as the archived benefit for health as well as environmental protection are unchallenged. While there are several aspects that may be improved, VdMi would like to stress that these refinements are also considered possible within the given legal framework. Instead of tightening the legal framework with the implementation of new hazard classes which contradict the GHS, the already existing possibilities should be exhausted first.

Implementation of new hazard classes: Undermining the GHS while other options are neglected

The CLP Regulation is the implementation of UN's GHS in the EU and as such it should never contradict the worldwide standard. A global system for the classification and labelling of hazardous substances ensures the harmonized communication of hazards and risks and as such has a high impact to the worldwide improvement of human health, environmental protection and occupational safety in particular. If the new proposed hazard classes would be implemented into CLP, the GHS would be undermining as an EU going this way all alone. Therefore, additional hazard classes should always be started in the GHS and be transferred to the CLP Regulation as a second step.

Furthermore, persistence, bioaccumulation or mobility are no reasons for concern in themselves. They are parameters to be included in a risk assessment as they influence the expected exposure to a specific substance. Therefore, there is no defined hazard solely based on these properties and thus no sufficient data basis for a classification. The proposed hazard classes PBT, PMT, vPvM, and vPvB should not be implemented.

Additionally, there are already means to handle hazardous properties based on mechanisms like endocrine disruption (ED) within the current CLP system. Thus, there are efficient ways to communicate such hazards. As a classification should always be based on an intrinsic substance property, ED – by itself – is inappropriate to serve as a hazard class. Thus, it should not be implemented as such; there are already means to handle such chemicals.

Extension of hazard communication: more complex hazard assessment does not facilitate hazard communication

Unfortunately, there is hardly any information on the proposed extension of the hazard communication for products which are currently outside the scope of the CLP Regulation. Therefore, no specific comments can be given. However, GHS and thus CLP cover the safe handling of substances and mixtures to be able to communicate hazards and give advice for safe handling throughout the supply chain. Mixtures and products falling under other regulations, e. g. the cosmetics or food additives, are subject to more restrictive assessments focusing on the specific exposure and require additional approval. Thus, the approved applications are specifically assessed and if deemed safe, additional labeling or warning statements according to CLP would contradict these specific safety assessments and only irritate and unsettle consumers.

The revision of hazard assessment of complex substances gives rise to many concerns. There are specific rules for the classification and labelling of mixtures, laid down in GHS and implemented within the CLP Regulation. "Complex substances" as described in the REACH Regulation was meant to facilitate the registration of mineral oil mixtures which consist of many different, yet chemically similar substances by nature. A transfer of such an approach to substances according to CLP is not necessary as there are ways and means to clearly communicate the hazard based on the hazard communication for mixtures. Mixing up the definitions of a substance and a mixture only leads to legislative uncertainties.

Additionally, the introduction of additional safety values does not fall under the scope of CLP. A harmonised risk assessment and corresponding risk management decisions are established under REACH as a first instance and specific regulations like e. g. OEL setting as a second step.

Process changes: no conglomeration of power and no mixing of CLP and REACH

In the classification process, the EU Commission has the responsibility to decide whether, or not a classification is the appropriate way to handle a concern. In case the Commission would be the submitter of the proposed harmonisation, consequently the Commission would need to assess and judge on their own proposal. Such a conglomeration of power in one body contradicts the fundamental principle of separation of powers. We doubt that an independent assessment of appropriateness beyond the submitters intention to harmonise can be assured if submission and assessment is in the same hand.

A simplification and reduction of administrative burdens would be welcome. However, the various fields of applications of chemicals also require no less various fields of expertise. Therefore, REACH was implemented as an independent regulation to deal with risk assessment of respective applications and implement appropriate measures, e. g. restrictions. CLP should be limited to the communication of hazards and not mixed with the responsibilities of REACH.

Far reaching consequences: CLP classification as trigger for other legislative actions

To assess the full impact of changes in the CLP Regulation, it should not be forgotten that many product specific legislations refer to CLP and the classification of substances and mixtures. Therefore, CLP should focus on the clear communication of hazards and advice for safe handling. Therefore, a substance should only be classified if – and only if – there is reasonable data verifying the intrinsic hazardous properties of this substance and no other means to communicate the hazard safely through the whole supply chain and to customers.

Additionally, due to the linkage between classifications and other legislation, there are already many, partially confusing obligations in place. The manpower to keep track of all responsibilities is already a huge burden for SMEs in particular. More and more complex classifications and links between respective regulations only increase the burden and thus, is a huge disadvantage for EU's industry and will lead to a decreasing number of SMEs in the end.

Contradictions to general aim of the Chemicals Strategy on Sustainability

Many of the proposed actions, especially the introduction of new, unjustified hazard classes, threaten the variety of chemicals available within the EU due to increasing numbers of classified substances. This is a huge innovation barrier while innovations are strongly needed to enable the transition towards a pollution and emission free economy. Bringing the EU industry in a disadvantage contradicts the aim for further resilience towards trading conflicts in sensible applications like e. g. pharmaceuticals. Additionally, new hazard classes contradict the GHS and thus, endanger the worldwide system of communicating hazards.

Especially the connection of CLP classifications to terms like 'essential use' and 'substance of concern' may be crucial. However, as long as there are not clear definitions for this terms industry has no planning security. As many consequences within the downstream legislation and further actions planned within the Chemicals Strategy for Sustainability cannot be assessed finally, a full impact assessment for VdMi's members is not possible.

Therefore, VdMi promotes

- No divergence from GHS
 - no hazard classes for non-hazardous properties which need to be taken into account in the risk assessment (persistence, mobility)
 - no additional hazard classes for substances that can already be handled within the current system (ED)
- No mixing of the responsibilities of CLP and REACH
 - no transfer of REACH's 'complex mixtures' to CLP's substance definition
 - no definition of safety values within CLP
- No mandate for the EU Commission to propose classifications
- Taking consequences of changes in the CLP Regulation for the downstream legislation into account

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