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VdMi Position on the introduction of new hazard classes in the CLP Regulation

EU's CLP Regulation together 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.

As the CLP Regulation is EU's implementation of the worldwide standard GHS, it ensures harmonized communication of hazards in worldwide trade. Nevertheless, the EU Commission proposed the introduction of several new hazard classes. Such an implementation would undermine the suitability of GHS as a common reference. Furthermore, the scientific justification for the hazard of some of the proposed classes as well as reasonable criteria for specific properties are lacking.

Our key remarks and messages:

- No divergence from GHS to ensure worldwide harmonized communication of hazards
- Handling of ED effects already possible with current CLP Regulation
- No persistence-based hazard classes due to insufficient justification and questionable criteria

Introduction of five new hazard classes proposed

The Chemicals Strategy for Sustainability was published on 14th October 2020¹ as part of the EU Green Deal. It includes 54 actions including the revision of the CLP Regulation and the implementation of new hazard classes. Overall, five new classes are proposed for

- endocrine disruptors (ED),
- persistent, bio-accumulative, and toxic substances (PBT),
- very persistent and very bio-accumulative substances (vPvB),
- persistent, mobile, and toxic substances (PMT), and
- very persistent and very mobile substances (vPvM).

Undermining the GHS and jeopardizing a worldwide standard

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 on 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 validity of GHS would be undermined as the EU would be embarking down this pathway

¹ See Press Release, Chemicals Strategy for Sustainability and corresponding Annexes available for [download](#).

independently. To avoid this scenario, additional hazard classes should always be started at the level of the GHS and be transferred subsequently to the CLP Regulation as a second step.

Insufficient justification of the proposed hazard classes

Endocrine Disrupting activity (ED) describes a mechanism, not an intrinsic substance property. As CLP Regulation shall only cover intrinsic properties, ED – by itself – is inappropriate to serve as a hazard class. At the same time, the effects on human health caused by ED mechanisms are already covered by the current CLP Regulation. Additionally, a separate hazard class would result in the obligation to perform more animal tests which is highly unethical if no additional benefit is gained. But the means to identify and communicate such hazards already exist under CLP.

The introduction of ED as a separate hazard class would therefore bring no additional benefit to the communication of potential hazards and the protection of human health. The one-sided modification of the worldwide standard GHS would be unjustified.

The other four proposed classes focus on persistent substances. With the exemption of the “mobility” parameter, they are based on criteria which are already subject to data requirements under REACH.² However, REACH introduced these requirements to enable the appropriate and safe handling of such substances and avoid effects on the environment. As many substances registered under REACH also occur naturally, Annex XIII clearly states that it is only applies for organic substances.³ Therefore, these requirements may often be waived for inorganic materials.

Mobility and bioaccumulation appear to describe opposing characteristics⁴ and there is a risk that most substances fulfilling the persistence criterion will also possess one of these two properties. As there is no need for intrinsic toxic properties to trigger classification for very mobile or very bioaccumulating substances, the number of substances falling under these four new classes may be high.

Therefore, many substances will be classified although, neither persistence, mobility nor bioaccumulation pose a hazard and are a reason for concern as such. These are parameters to be included in a risk assessment as they influence the expected exposure to a specific substance. This is already accounted for under the REACH Regulation. Additional classification based on these parameters would not offer any advantage. Moreover, as there is no defined hazard solely based on these properties, there is no sufficient justification for the creation of such hazard classes. Without a clearly defined hazard and with exposure control already in place, the implementation of these proposed classes would only weaken the hazard communication and again compromise the worldwide standard without additional benefit.

Conclusion

As ever with the publication of a first draft, several aspects in the implementation of the proposed hazard classes are still open for discussion, including threshold values for the criterion of the mobility and therefore the impact of this implementation cannot be fully assessed. However, should these new classes be introduced as currently proposed, a vast amount of classified substances can be expected. Whilst the intention of the EC is aligned with its policy on Sustainability, communicating properties such as bioaccumulation and mobility through CLP and presenting them as hazardous is clearly inaccurate. Some of these substances’ characteristics are already evaluated as part of the REACH process, and any additional properties, such as mobility, should be evaluated according to a similar procedure and be associated with clearly

² See e.g. presentation given by Sylvain Bintein „The Chemical Strategy for Sustainability and the implementation of the PMT/vPvM criteria“ given at 26th March 2021 in the *Third PMT Workshop* organized by UBA and NGI, and CARACAL documents available on [CIRCABC](#).

³ See REACH Regulation (EC No. 1907/2006), Annex XIII.

⁴ Both values are typically derived from the octanol-water partition coefficient K_{ow} but describe opposing phenomenon: mobility describes the ability to pass barriers by resisting separation processes which means the possibility to spread while bioaccumulation describes aggregation of a substance in one compartment due to missing of transport or degradation possibilities.

established standard test methods so users of such substances can make informed decisions in line with their ethos.

While further consequences will arise from the classification itself, the justification for the classification would be highly questionable. As a result, hazard communication would be weakened. Additionally, the variety of chemicals available within the EU would be threatened. This poses a huge innovation barrier at a time when innovation is strongly needed to enable the transition towards a pollution and emission-free economy. Placing the EU industry at a disadvantage contradicts the goals of the Chemicals Strategy for Sustainability and may lead to a shift of production to countries with lower protection levels. As a result, environmental pollution may even increase.

However, the most critical aspect of the implementation of the proposed hazard classes would be the undermining of the GHS. Due to this worldwide standard, hazard communication improved tremendously in all countries. Spin-offs or sectorial regulations contradicting the general standard will work against this success.

Therefore, VdMi promotes

- no divergence from GHS
 - worldwide standard must not be subverted
 - implementation of new hazard classes should always be agreed at GHS level first, and then be transferred to CLP
- no introduction of ED as hazard class
 - options for handling of ED effects are already possible within the current CLP Regulation
 - no unnecessary animal testing
 - no additional benefit for hazard communication
- no introduction of persistency-based hazard classes
 - insufficient justification and description of the hazard
 - meaningless criteria for many substances occurring naturally

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