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Eurocolour Position on the Proposal for a Regulation amending the CLP Regulation

On 19 December 2022, the European Commission published the proposal for a Regulation amending the Regulation on Classification, Labelling and Packaging of Chemicals (CLP). The CLP Regulation implements the internationally valid Globally Harmonised System (GHS) of the United Nations in the European Union (EU). Overall, the EU has succeeded in creating an efficient single market for chemicals.

The revision of the CLP Regulation was announced as a key part of the Chemicals Strategy for Sustainability. According to the EU Commission, there are some gaps in relation to hazard communication and the hazard identification of substances and mixtures. These are intended to be addressed by the current draft.

Our key remarks:

- The proposed approach to the classification of multi-constituent substances contradicts the UN GHS and will lead to severe problems in implementation with very limited benefits. We request that the introduction of the definition of multi-constituent substances should be withdrawn.
- We have concerns that the harmonised classification of substance groups will lead to inadequate classification, if the members of the group are not clearly identified and validated with respect to the hazard being assessed.
- Instead of creating more bureaucratic burdens, we argue for closing the Classification and Labelling Inventory and focusing on the harmonised Classification and Labelling (Annex VI) and the joint Classification and Labelling from REACH registrations, as this information is of higher value and reliability.
- We strongly criticise the EU's unilateral deviations from the UN GHS as they will create major challenges for the entire chemical industry and will lead to trade barriers and legal uncertainties. We question the need for these actions.

Definition and classification of "multi-constituent substances"

The introduction of the so-called "multi-constituent substances" in Article 2, which were previously referred to as "more than one constituent substances" (MOCS), will lead to legal uncertainties as to the correct treatment of substances and mixtures. They are intended to follow the same classification rules as mixtures. As a consequence, the whole multi-constituent substance shall be classified if any of its constituents is classified and is present in concentrations equal to or higher than the threshold for mixture classification, even if data on the substance for the same endpoint do not support the classification.

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The proposed definition and classification of “multi-constituent substances” will cause severe problems in implementation as it is inconsistent with existing definitions in several respects:

- It collides with **the general substance definition in Article 2 of the CLP Regulation** and in Article 3 of the REACH Regulation, which includes necessary additives and impurities from the production process. This definition reflects the actual status of chemical products on the market. As there is almost no mono-constituent substance with 100% purity, the proposed definition will affect virtually all chemicals under REACH and will have a correspondingly high impact that is not sufficiently assessed.

- It is not aligned with the **requirements on substance identity under REACH**, which for good reasons distinguish between UVCB’s[1], mono-constituent[2] and multi-constituent substances[3]. Considering all these groups together under a single group is a step back from the aim of creating these definitions: the recognition that these are substances with important differences in their characterisations. In particular for UVCBs, an approach based on single components is hard to implement, as UVCB’s are substances for which single components may be unknown and inseparable.

- It **undermines the UN GHS**, which also includes necessary additives and impurities from the production process in the substance definition. Furthermore, section 1.3.2.3.1 (a) clearly states that if information on a mixture is available, a classification decision should always be based on this data. The EU CLP Regulation should not contradict the global standard, otherwise it will create legal uncertainty and trade barriers for European companies.

The different aligned regulations mentioned above form the basis for placing the products on the market. Therefore, studies performed on substances to fulfil the information requirements e. g. of REACH registration consider all known or unknown components of a chemical and therefore also the potential hazards for human health and environment. The CLP amendments would require an adaptation within the REACH Regulation and thus formally pre-empt the REACH revision without fully considering the impact on this Regulation, for example whether additional studies on "mono-constituent" substances might be triggered. In any case, harmonisation between the two regulations should be maintained. There is no need to introduce a new definition of multi-constituent substance for the purpose of clarifying classification rules.

The introduction of the definition of multi-constituent substances should be withdrawn due to the many associated problems and the limited benefit.

Changes in the Harmonised classification (CLH) procedure

We have concerns about the harmonised classification of groups of substances. The permitted grouping criteria should be clearly defined as established under REACH. In addition, each member of a group should be identified by its CAS number, or other numeric identifier.

[1] UVCB = substances of Unknown or Variable composition, Complex reaction products or Biological materials.
[2] Mono-constituent substances: one main constituent ≥ 80 % and impurities in concentration < 20 %.
[3] Multi-constituent substances: a reaction mass of main constituents each between ≥ 10 – < 80 % and impurities in concentrations < 10 %.

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Grouping based on mere structural similarity or reactive groups, especially if the members of the group are not clearly identified and validated with respect to the hazard being assessed, may lead to inadequate classification or overclassification.

We have reservations about the Commission's right to initiate the CLH process itself, as the initiator and the assessing body are now identical. In addition, following the amendments to Article 37(5), it is no longer clear whether or not the EU Commission has to review the appropriateness of a proposed harmonised classification and labelling, which was a final assessment step after receiving the RAC opinion in the process.

In our view, both would reduce the integrity of an independent evaluation process and increase the possibility of politically motivated bans on substances and entire classes of substances. There is no need to change the right to initiate the procedure. The bottleneck in the CLH process is the capacity of the Scientific Risk Assessment Committee (RAC), not the lack of regulatory bodies entitled to submit a proposal. Acceleration of the process could be more easily achieved by providing the RAC with adequate resources.

Label update deadlines for changed classification

We would like to object to the change of the current label update requirements in Article 30 to a fixed period of six months when a substance or mixture needs to be assigned a new hazard class or more severe classification or when new additional information is required on the label. This period is too short and inconsistent with current practice, which has proven to be sufficient to allow for reprinting of labels and re-labelling of packaging at each stage of the supply chain, rather than an unrealistic deadline for the whole supply chain. The current provision provides the necessary flexibility. Currently, a new or changed entry in the harmonised classification and labelling has a transition period of 18 months. This would also be a more realistic timeframe for updating the labelling.

Classification and Labelling Inventory

With the proposed amendments, the name of the notifier will be published for transparency reasons and justifications for a less severe classification have to be made. We do not support the disclosure of company names as this information will be used by third parties for market analysis and other commercial purposes. This could even endanger R&D activities and innovations by EU companies. In addition, it will trigger a lot of unnecessary communication along the supply chains. Further information requirements for the inventory will lead to more bureaucracy without any beneficial effects regarding safety communication.

The proposed justification of deviation from the most severe classification in the inventory is not workable, as any change in the most severe classification will render any justifications provided so far meaningless.

Instead of increasing the administrative burden, the objectives of promoting transparency and knowledge of the hazards of substances can be better achieved by focusing the Classification and Labelling Inventory on the harmonised Classification and Labelling (Annex VI) and the joint Classification and Labelling from REACH registrations. This information is of higher value than the notifications kept in the inventory database, which may already differ for the same substances and do not claim to be up to date. There is a high number of erroneous or obsolete

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classifications of substances, as well as diverging classifications for the same substance in the Classification and Labelling Inventory. Additional (and extended) notification duties in Articles 40(1), 40(2) and 42(1) will not add value.

The substance-by-substance check of each individual hazard class of each notification for divergence is time-consuming and will lead to questionable results that will be outdated anyway with the next submission of another notifier. In order to reduce unnecessary bureaucracy, we are in favour of shutting down the Classification and Labelling Inventory, as it is not a valuable or reliable source of information on hazard classification and may even provide incorrect and outdated information.

Missing harmonisation with UN GHS

The definition of multi-constituent substances, as well as the unilateral introduction of the new hazard classes in the EU via delegated act in parallel to the start of discussions about introduction of those hazard classes into the UN GHS, will bring major challenges for the entire chemical industry and will lead to trade barriers and legal uncertainties. Although the EU Commission announced to have submitted a proposal for new work on unaddressed hazard classes in the GHS work programme, there will be a transition period of several years with non-harmonised GHS requirements in the EU compared to the rest of the world. Final harmonisation between UN GHS and EU CLP is by no means assured.

It is in the utmost interest of industry to maintain the harmonisation that has been achieved and not to disregard the work of the UN GHS Expert Committee by unilaterally introducing new hazard classes and classification procedures without consulting the UN. The UN GHS discussions and an agreement need to take place before a final introduction into EU CLP.

We strongly criticise the EU's unilateral deviations from the UN GHS and question the necessity of these actions.

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About Eurocolour:

Eurocolour e. V. is the umbrella association for the manufacturer of pigments, dyes, fillers, frits, ceramic and glass colours and ceramic glazes in Europe.