

Brussels, 30 August 2022

Dear Mr Pinto Antunes,

I am writing to you regarding the ongoing revision of the Classification, Labelling and Packaging (CLP) Regulation to share key considerations from the European Chemical industry, ahead of the next regulatory steps.

Cefic supports the goals of the Chemicals Strategy for Sustainability (CSS), and we remain committed to work with the Commission to improve CLP, addressing the areas that require upgrading and proposing solutions that build on the current EU strong framework for regulating chemicals.

The revision of CLP may appear to be a technical matter, yet the impact of this reform is far-reaching and will be felt not only in the chemical industry but across all sectors relying on chemicals.

A Broader Approach

What is sometimes forgotten is that the changes in classification under CLP will automatically trigger restrictions and bans as foreseen by the generic approach to risk management (GRA) under the CSS. Already today, decisions taken under CLP lead to automatic bans and restrictions for which the Commission is powerless to intervene on (e.g., cosmetics, biocidal and plant protection products, etc.).

As many as 12,000 substances, out of 24,000 registered, are estimated to be affected by proposed changes to CLP and GRA, according to the Economic Analysis of the impacts of the Chemicals Strategy for Sustainability by Ricardo Energy&Environment. Unfortunately, we understand the Commission's Impact Assessment did not consider the impact of the changes on other sectoral legislation.

A request for clarification on the Delegated Act

A number of Member States and MEPs have raised concerns about the proposed delegated act on new hazard classes. Their concern is that this is an essential element, that should be dealt with under the ordinary legislative procedure. We are concerned that the politically sensitive matter of delegated act could slow down progress of the revision. We would be grateful if you could clarify whether and how this scenario could be avoided based on the conclusion of the Commission's Legal Service.

CLP, together with REACH, form the cornerstone of the EU chemicals legislation and the upcoming reform means changing the foundation of the most comprehensive chemical legislation in the world with impacts going beyond the chemical industry alone. The impact will depend on the scope, timing and phasing of upcoming changes to the two regulations, respectively and in combination. This is why launching both REACH and CLP reform in a package at the same time is something that could be considered indeed.

In the Annex we have detailed a few points, including practical suggestions and solutions.

We would appreciate the opportunity to have an exchange with you at your earliest convenience to further discuss these key aspects.

I am looking forward to hearing from you.

Sincerely yours,

Personal data

Personal data

Annexes to this letter:

Technical aspects for the proposal.

UN GHS first, then CLP?

Understanding the need for action, we believe that the EU needs to do much more to secure that the **proposed changes for new hazard classes will be agreed at the UN level (UN GHS)**. While it is possible for the EU to propose an update to UN GHS in line with the updated CLP, there is so far no guarantee that the EU proposal will be accepted by all parties (a previous attempt by the EU on PBT failed). A temporary divergence could then become a long-term deviation. **This is in contradiction with the 'G' and the 'H' of GHS**. A stand-alone CLP proposal will disrupt global value chains and contradicts the Strategic Approach to International Chemicals Management (SAICM) negotiations which calls for all countries to implement the global UN GHS classification. If the Commission is serious in its commitment to use the CSS to promote global standards, more needs to be done. Please be aware that EU REACH already regulates all substances that would be covered by new hazard classes under CLP (e.g. 57 substances have already been put on REACH Candidate List either for their endocrine disrupting properties, PBT/vPvB or high persistence and mobility properties).

Assessment criteria

For substances with Endocrine Disrupting properties, we call for **criteria that fully reflect the WHO (UN World Health Organisation) definition**, both for category 1 and for category 2 sub-divisions, taking into consideration the fact that the adverse effect should be a consequence of an endocrine mode of action, with corresponding evidence available.

As to the classification of mixtures, we ask for pragmatic concentration limits to be introduced, consistent with the classification of adverse effects (0.1% or higher, depending on the adverse effect which, in principle, should already be classified under CLP).

We support the PBT/vPvB criteria consistent with existing REACH requirements. However, we need a cautious approach for PMTs/vPvM. Several technical and policy discussions over the last two years showed the complexity of defining mobility criteria under CLP. Unlike bioaccumulation (B) assessment which includes a robust and definitive approach with enough discriminatory power, the same does not apply for mobility (M) assessment. Because of that, it should be **allowed to use additional data when assessing mobility**.

Transition periods

The introduction of new hazard classes **will require a reassessment of all existing data on all substances, as a basis to re-classify substances** (as applicable). Once substances are reclassified and relabelled, mixtures will have to be reclassified and relabelled in turn as well. The information on substances will be delivered to downstream users (mixture formulators) over a certain period. It is therefore essential to **introduce two successive transition periods for new hazard classes**, in line with the approach taken initially for CLP and later under the 2nd ATP to CLP when aquatic toxicity criteria were introduced: at least **two years for substances** and, as a second step, **at least three years for mixtures**.