POSITION PAPER

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Cefic position on the Revision of EU Legislation on hazard classification, labelling and packaging of substances and mixtures (CLP)

The EU chemical industry supports the goals of the Chemicals Strategy for Sustainability: ensure the chemicals are produced and used in a way that maximises their contribution to society including achieving the green and digital transition, while avoiding harm to the planet. We are ready to work with the EU institutions and Member State governments to deliver on the policy goals.

CLP, together with the REACH Regulation, is a cornerstone of the EU chemical legislation. Both CLP and REACH work hand in hand. Revising CLP means changing the foundation of one of the most comprehensive chemical legislations in the world. Changes to CLP will immediately cascade down to REACH, to product-specific EU legislation (e.g., cosmetics, biocidal and plant protection products, etc.) and will have an impact on the international Global Harmonised System of Classification and Labelling (UN GHS) from which CLP is derived.

We support most elements of the current European Commission's proposal for the CLP revision, which reflect experience gained until now and provide legal clarity for several topics, including the labelling responsibility for online marketplaces, the introduction of digital labelling for some elements of the labels, rules for reporting to poison centers, derogations from some labelling rules in specific cases, clarification on certain concentration limits and more transparency for classification and labelling inventory.

However, we also believe that the Commission's proposal in its current form will fall short of achieving one of its key objectives: strengthen and simplify the legal framework for chemicals.

In particular, the following elements raise concerns:

CLH – Harmonised Classification and Labelling (CLH) for groups of substances

One of the main aims of CLP is to determine whether a substance or mixture displays properties that lead to a hazard classification and, when this is the case, to label them as hazardous. The different label elements reflect the different hazards identified. In any case, the classification is the starting point for hazard communication.

It is the responsibility of the manufacturer or the importer placing a substance or mixture on the market to classify and label them according to the CLP rules (self-classification). In certain cases, the classification and labelling of hazardous chemicals is harmonised at European level. In first instance, it is done to ensure consistent hazard communication throughout the EU, as harmonised classification overrides self-classification for all market actors.

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In addition, harmonised classification of substances automatically triggers risk control measures under other pieces of chemicals legislation such as the cosmetics regulation, workers' protection legislation, plant protection products legislation, and more.

To speed up harmonised classification the Commission seeks to move away from a substance-by-substance approach and proposes to classify groups of substances based on 'similar classification' . The problem with this approach is that it assumes that substances having a similar molecular structure 'on paper' behave the same way in the real life and have the same impacts on health and environment, therefore deserve a 'similar classification'. This is an incorrect approach as structurally similar substances can have different behaviour and effects.

Therefore, the assessment of 'similarity' must be based on **a review of all available data** on the substances' physico-chemical, ecotoxicological and toxicological properties. This review must include a Weight of Evidence assessment across all relevant criteria for the hazard in question. Such an approach will help avoid over-classifying and over-regulating substances based on 'presumed' properties.

To ensure all CLH dossier submitters (e.g., Member States, Industry and – new proposal of the revision – the European Commission) apply the same scientific principles to justify similar classification, **there is a need for an ECHA guidance development that clarifies the scientific basis from which a harmonised classification for a group of substances can be derived and for a formal quality check mechanism, i.e. a conformity check, performed by ECHA** (as currently in place for a REACH Restriction dossier.

It is also important to note that the introduction of new hazard classes under CLP will increase the workload on authorities, industry and ECHA's committees, in particular the Risk Assessment Committee (RAC). Cefic is concerned that with such an increased workload, the quality of scientific assessments for substances on the EU market may decrease. To this end, **sufficient time should be given to allow for a thorough examination of each CLH dossier**, ensuring harmonised classifications are assigned where justified based on a comprehensive review of the weight of scientific evidence.

More generally, it is important that CLP reflects actual data in order to retain the integrity and value of the classification.

Multi-constituent substance definition

Both REACH and CLP apply the same definition of "substance". As the legal definition of a "substance" is rather general, REACH has put in place additional rules to identify and define substances in Annex VI Section 2, supplemented by guidance. According to them, substances are further categorised into:

- mono-constituents
- multi-constituents,
- UVCB substances (Unknown or Variable composition, Complex reaction products or Biological materials, like essential oils, petrochemicals, oleochemicals).

Detailed rules are laid out in the ECHA guidance for identification and naming under REACH and CLP and have been applied from the beginning across all REACH registrations. They are the foundation on which the assessment of substances is built.

The new proposal for CLP seeks to introduce a definition for multi-constituent substances for the purpose of clarifying classification rules for substances that contain impurities, additives or multiple components. **The introduction of this definition in CLP is both confusing and unnecessary as it is at odds with how multi-constituent substances have been identified under REACH.**

The REACH regulation has been in place for over a decade. The approach taken under REACH to define multi-constituent substances has been thoroughly vetted and implemented by industry and regulatory authorities alike, and it has provided a stable and reliable foundation for chemical regulation in the EU.

There is no need to introduce a new definition of multi-constituent substance for the purpose of clarifying classification rules. What is important is to clarify on a sound scientific basis when data on individual constituents (impurities, additives or constituents) prevail vs when data generated on the 'whole substance' can be used, and the CLP revision can do this without a new definition.

Multi-constituent substance and mixture classification rules – Annex I

Besides clarifying the rules for classifying substances and mixtures, the CLP revision proposes to create a new Annex I with specific rules for derogations to generic rules or for groups of substances, in case this is needed. These rules are not available yet. It is important for all actors placing chemicals on the market to have this clarity in time for re-classifying and re-labelling their products.

Formatting rules for labels

While the new provisions allowing the use of fold-out labels are welcomed, the new rules for formatting labels are too stringent and too specific, particularly those prescribing a minimum font size and spacing requirements. A slight increase in font size would increase legibility, but the proposed increase is unnecessary and impractical: it would make current label sizes unusable for the majority of products and would reduce the number of languages that can be placed on one label and thus, considerably limit flexibility. In addition, companies would need new or updated software's to manage those requirements.

In our view, specific formatting rules should be kept in the guidance document, as is currently the case.

Update of labels

The new CLP Regulation proposal requires labels to be updated within 6 months in case a new hazard class or a more severe classification needs to be assigned to a substance or a mixture, or when new supplemental information on the label is required. This timeline is too short and inconsistent with current practices which have proven adequate to allow re-design, re-printing of labels and re-labelling of packages. Consistent with current rules, we recommend that 18 months should be the timeline for all label updates - that is the normal timeline for ATP's when CLH becomes mandatory for specific substances.