EU Consultation: Revision of EU legislation on hazard classification, labelling and packaging of chemicals

European Association of Chemical Distributors (Fecc)
Contact : Pierre Germain, Technical & Regulatory Affairs Manager (pge@fecc.org)

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Fecc, European Association of Chemical Distributors in Europe, welcomes the opportunity to provide feedback on the open EU COM public consultation on the Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixture (CLP) and would like to draw attention to the following:

- **Label requirements**

The chemical trade has its function in the procurement of raw materials for the chemical industry, including imports from non-EU countries. It benefits from a high degree of harmonization of the UN GHS with the CLP regulation. The planned introduction of new hazard classes and labeling will lead to considerable additional work for the industry and also make trade outside the EU more difficult. We expect this to continue for years as harmonization with the UN GHS cannot be achieved within a few months. Especially if you have to assume that at the end of the consultations at UN level, there will most likely be new pictograms and H phrases that will then replace the EUH phrases that were introduced at great expense. This leads to a renewed burden on the industry, which is mainly characterized by small and medium-sized companies. Introduced systems for creating safety data sheets and labeling programs have to be adapted again. We would expect more foresight here and would like to point out again at this point that the planned introduction should be reconsidered and postponed. Even without new hazard characteristics, a high level of protection for people and the environment can already be achieved with the existing elements.

- **Introduction of mandatory formatting rules**

Fecc reject the proposed changes in Annex I, Sections 1.2.1.4 and 1.2.1.5.
From the point of view of our industry, the following difficulties arise, but also an additional organizational effort, which in the end does not make any significant gain for the readability of the label content, especially in the area of professional and industrial users.

1. Existing label sizes and formats that have been established for years must be completely redesigned - generates high costs;
2. Larger label formats must be selected - which, for example, then no longer fit on existing adhesive bridges on IBCs;
3. New labels must be pre-tested and approved to meet durability and weather resistance requirements;
4. The requirement for a white background would mean that e.g. paper sacks, plastic sacks or bottles (e.g. PET) in red, brown, blue or other colors as currently used in the industry can no longer be pre-printed and a change of color or the printing would lead to significant follow-up costs;
5. Due to the font sizes, no multilingual labels can be attached to the containers and packaging. Further additional labels have to be created and kept available, which leads to additional costs for material and storage;
6. Changed label formats may mean that new label printers must be purchased that can print the new formats.

- **Digital labelling**

Fecc has called for labelling requirements that are end-user relevant. The current proposal imposes many requirements on companies and does not introduce any of the benefits of digitalisation. The use of digital means to communicate some (non-mandatory) CLP information is an obvious answer to the current challenge of squeezing ever-increasing amounts of regulatory-related text onto current physical labels with limited space.

The introduction of a fixed 6-month time limit for label changes for both a substance and a mixture is far too short for downstream users. The existing 18-month time limit linked to a harmonised classification under the ATP procedure already poses considerable challenges for our members. In addition, the lack of coherence between the CLP legislation and other regulatory frameworks (e.g. those covering biocides, cosmetics, detergents…) with respect to the definition of 'placing on the market' continues to be a major issue when it comes to the relabelling of products already in the supply chain. This could be resolved by aligning with the definition found within the BPR etc, which refers to 'first making available'

- **Multi-constituent substance and mixture classification rules, multi-constituent definition**

Fecc supports that 'multi-constituent substances' shall be classified following the same classification, labelling, and packaging rules as 'mixtures'. However, we would like to emphasise that consistency between the CLP Regulation and the REACH Regulation is crucial. The multi-constituent substance definition as proposed includes identified impurities and additives, this is in contradiction to the substance definition in the REACH Regulation and the Plant Protection Regulation, which encompass identified impurities and/or additives. Best practice can be found in ECHA's 'Guidance for identification and naming of substances under REACH and CLP', identifying mono-constituent, multi-constituent and UVCB substances. The guidance acknowledges for substances with one constituent a purity of >= 80% a main component, impurities from the production process as well as additives for stability included as needed.

Additionally, we urge for consistency with the rules for classification of mixtures. UN GHS, being the basis for the CLP legislation that when test data is available for the complete mixture, this should be the basis for classification only thereafter bridging to similar mixtures or individual ingredients should take place. For multi-constituent substances, valid test data on the multi-constituent substance should be used as a first priority, in the same way that is used for mixtures.

- **CLH – Harmonised Classification and Labelling, grouping of substances**

Fecc welcomes the grouping of substances which alleviates the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances and in line with the reduction of unnecessary animal testing.

However, grouping methodology needs to be based on sound scientific principles.
For instance, structural similarities should not be the sole criteria for grouping substances and resulting in similar classifications but instead, a minimum of data requirements (i.e., physico-chemical properties, ecotoxicology and toxicology data) needs to be presented to defend the rationale for grouping substances. Fecc is therefore highly supportive to support ECHA in a NEW guidance development on grouping of substances in a pragmatic and consistent science-based approach. In addition, Fecc is recommending that any substance subjected to a grouping needs to be clearly identified by a unique identification number (e.g. CAS number and physical parameters as per the REACH guidance.

Fecc is concerned about the downstream consequences a non-scientific, arbitrary grouping could cause. Substances which are safely used could be heavily restricted and/or banned in consumer products only because they are part of a group of substances, which is targeted for a CLH, based on the presence of a single substance that has been classified as such. Finally, we suggest the possibility to remove (or add) a substance from a substance group based on any new conclusive scientific element.

- **Weight of Evidence Assessment**

The Weight of Evidence assessment is a fundamental part of the hazard assessment in UN GHS. Building an assessment on all available data is not only good scientific practice, for some hazard classes a classification can only be decided on a Weight of Evidence basis. Especially where a hazard classification will be based on the evaluation of several criteria as in PBT/vPvB and PMT/vPvM assessment, it is crucial to consider all available information to assess if a classification is really warranted. Fecc therefore calls for strengthening the Weight of Evidence assessment and to make it a mandatory part for any classification.

- **Article 37**

Fecc welcomes the initiative but has concerns about the proposal to automatically transfer regulatory decisions from other legislations into harmonized classifications in CLP annex VI as these conflict with the EU CSS principle: “one substance, one assessment”.

For active substances in plant protection products, we are concerned that since their EFSA decision, new data might be available which would need to be taken into account to ensure the harmonized classification according to CLP principles is granted during this transfer of regulatory decisions across regulations.

- **Poison center notifications - Addition for conditions for submission update**

The additional requirement to submit a poison center notification update “*when there are other changes to a mixture placed on the market which are relevant for the emergency health response…*” is considered to be too vague and leaves a lot of room for interpretation. Thus, additional update requirements would need to be specified in more detail. Generally, the conditions for a submission update as currently specified in the CLP are considered to cover all aspects relevant for an emergency health response.

To access the Fecc's response on the EU Commission's website, please click here.