CLP REGULATION REVISION – PUBLIC CONSULTATION

Cosmetics Europe represents the cosmetics and personal care industry in Europe. Ranging from antiperspirants, fragrances, make-up and shampoos, to soaps, sunscreens and toothpastes, cosmetics and personal care products play an essential role in all stages of our life. European citizens use cosmetic products as part of their daily lives, serving their essential needs and expectations. These needs and expectations drive our industry as well as delivering innovative products that enhance consumers' well-being and quality of life and boost their self-esteem.

Cosmetics Europe welcomes the opportunity to engage with the European Commission on the revision of the Regulation on the classification, labelling and packaging of substances and mixtures (the CLP Regulation).

Besides the comments already provided in reply to the Public Consultation, Cosmetics Europe would like to build and elaborate upon the answers to the questionnaire on 1) the scope of the CLP Regulation, 2) alternatives to animal testing, and 3) the impact and criteria of new hazard classes.

Overall, we believe that some of the questions included in the public consultation are challenging to provide meaningful input. For instance, some questions in Part I are consumers-oriented and therefore difficult to answer by business associations, representing the industry. Moreover, we want to point out the importance of differentiating among ingredients manufacturers and formulators of the finished products (ready for consumer use) in the questions. Finally, regarding the two questions on animal testing we find it important to clarify a few elements as responding to the questions would not be accurate enough to describe our position.

Executive Summary

- Cosmetic products in their finished state (ready for consumer use) should remain excluded from the scope of human and environmental hazard labelling under the CLP Regulation.
- Consumer information regarding the correct use and disposal of a finished cosmetic products should be addressed under the Cosmetic Products Regulation (CPR) which it is built on the real use and consumer's understanding of finished cosmetic products. The ongoing revision of the CPR provides an opportunity to extend, where necessary, the existing labelling provisions from human safety aspects to environmental aspects.
- Requirements for hazard labelling of finished cosmetic products would not deliver to consumers clear and easily understood product information. Additionally, they would neither improve the correct use and disposal nor would they drive consumer choice to safer and more sustainable cosmetic products. Such requirements would also go against established international practice under GHS and create barriers to trade.
- The introduction of new classification criteria should be consistent with Article 7 of the CLP Regulation and not lead to an increase of animal testing. The CLP revision is an opportunity for non-animal methods to find full regulatory acceptance for the classification of chemicals.
- Adoption of new hazard classes under the CLP Regulation before the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) would question the principle of harmonized approach under GHS. CLP – GHS alignment is critical. While introducing new hazard classes, it is important that the new classes are based on widely and internationally accepted definitions, supported by science.

- Real impact from CLP hazard classifications are 'automatic bans' triggered by some classifications in REACH and other sector legislations such as the CPR. Safeguards, such as exemption procedures, must be introduced both under REACH and sector-specific legislation such as the CPR to avoid unjustified bans of uses that are safe for consumers and the environment.
- Given that endocrine disruption is a mechanism of action and not an endpoint of toxicity, there is no scientific rationale for the addition of new Endocrine Disruptor (ED) hazard classes. An endocrine mode of action can already result in a hazard classification for a substance of Carcinogenic, Mutagenic or Reprotoxic (CMR). Thus, the addition of hazard classes for EDs may lead to duplication of classification.

1. Scope of the CLP Regulation

In its Inception Impact Assessment on the revision of the CLP Regulation, the European Commission has identified that the CLP Regulation may provide incomplete information about hazards to the environment due to exclusion of certain sectors from its scope.

We value the importance to provide hazard labelling in cases where the actual use and disposal of chemical products is unknown. Nevertheless, as further elaborated below, Cosmetics Europe believes that cosmetic products in their finished state (ready for consumer use) should remain excluded from the scope of human and environmental hazard labelling under the CLP Regulation.

Consumer information regarding the correct use and disposal of a finished cosmetic products should be addressed under the Cosmetic Products Regulation (CPR) which it is built on the real use and consumer understanding of finished cosmetic products. The ongoing revision of the CPR provides an opportunity to extend, where necessary, the existing labelling provisions from human safety aspects to environmental aspects. Such consistent approach on human and environmental aspects would ensure helpful and actionable information in terms of sustainable choice, safe use, and disposal. Requirements for hazard labelling of finished cosmetic products would not deliver to consumers clear and easily understood product information. They would neither improve the correct use and disposal nor would they drive consumer choice to safer and more sustainable cosmetic products.

It is important to note that finished cosmetic products are exempted from hazard labelling under the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Unilateral labelling by the EU would create a significant barrier to international trade, disadvantaging EU exports.

1.1. Hazard labelling is not relevant for finished cosmetic products as their use and disposal are pre-defined and they carry instructions/warnings that are relevant to this use

Hazard labelling is valuable in cases where the actual use and disposal of chemical products is not precisely known, allowing all actors in the value chain to be informed about the worst-case damage that can be caused and providing generic instructions for use/disposal.

Cosmetic ingredients and products in bulk form (large quantities, prior to filling in the final packaging) are fully included in the scope of CLP Regulation as – in this form – significant local release to the environment is a potential risk. Hazard information that targets trained professional workers is therefore useful.

The corresponding risks of cosmetic products in their finished state (ready for consumer use formulation in the final packaging) are significantly smaller than for bulk:

- Use and disposal are predefined and limited by the nature of the product;

- Packaging sizes are small;
- Products have undergone a mandatory safety assessment; and
- Products are labelled with relevant use instructions/warnings (CPR §3(b), §10.2, §19.1 (d,f), Annex I part B.2). See also section on safe disposal (1.2).

Accordingly, hazard labelling of finished cosmetic products would overstate and misrepresent their real-life risk and not provide consumers with additional useful and meaningful information on their use and disposal.

Indeed, several studies, including ECHA's, show the limited benefits of generic hazard labels compared to specific use-relevant instructions and warnings, such as those required in the CPR for each cosmetic product placed on the market. In particular, ECHA concluded that '*awareness-raising activities are needed to help consumers understand the labels. Consumers tend to rely on past experience with similar products and emotional drivers rather than pictograms*.' [1]

1.2. The combination of the CPR and REACH fully ensures safety of cosmetic products prior to placing on the market and there is no indication that the current CLP hazard labelling exemption of finished cosmetic products creates a safety problem for consumers and/or the environment

Safe use

The current combination of CPR and REACH completely addresses safety and quality aspects of cosmetic products prior to their placing on the market. For consumer safety, this is ensured by a full safety assessment done by a qualified safety assessor. This safety assessment considers the toxicological profile of all ingredients, their concentration and the consumer exposure arising from normal and reasonably foreseeable use of the product. For environmental safety, cosmetic ingredients are evaluated under REACH in an aggregate exposure that considers not only the cosmetic use, but all uses leading to environmental exposure.

Where necessary, the comprehensive safety assessments done under the CPR or REACH can already today mandate warning labels and use instructions. There is no indication of environmental problems due to wrong use or disposal of finished cosmetic products.

Additional hazard labelling is an inadequate tool to guide the safe consumer use of cosmetic products that have been assessed in detail for their safety and found to meet a 'high level of safety and protection'.

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[1] ECHA 2012 "Communication on the Safe Use of Chemicals": https://echa.europa.eu/documents/10162/17203/clp_study_en.pdf/33dd7bf1-93bc-4d30-8e8d-6f51d838851b

Purmehdi et al 2016, "The Effectiveness of Warning Labels for Consumers: A Meta-Analytic Investigation into Their Underlying Process and Contingencies," Journal of Public Policy & Marketing 36(1) DOI:10.1509/jppm.14.047
Meta analysis observing that "safe-use warnings elicit more favourable change [than moderation/cessation warnings]". Some suggested reasons are that safe use warnings relate to a more obvious and relevant threat, whereas a cancer warning is much more 'removed' (e.g. will the person live that long? they know unhealthy people who don't have cancer etc etc) (p23)

AISE study 2016/2017 "BREs - Better regulation & Safe use project"

'Almost 10 years after GHS implementation, consumer rarely check CLP/GHS labels on detergents, find the pictures and information confusing, and cannot distinguish the level of risk. Safe use icons better than precautionary statements.' https://unece.org/fileadmin/DAM/trans/doc/2017/dgac10c4/UN-SCEGHS-34-INF05e.pdf

Safe disposal

Today, there is no indication of any environmental problems or risks due to wrong disposal of finished cosmetic products that would benefit and/or be solved by introducing CLP hazard labelling.

For cosmetic products, use and disposal are similar scenarios. Cosmetic products are applied to the body and typically rinsed off, either immediately (e.g. shower gels, shampoos) or at the end of the day (e.g. face-creams, body lotion). Some products may also be wiped off after use and disposed of via solid waste. Once the product is used up, the empty packaging, including residues of unused product, will be disposed of via household waste. Therefore, the environmental fate of most cosmetic products is similar both during intended use and during disposal.

Any additional information deemed necessary regarding the correct use and disposal of a finished cosmetic products should be addressed under the CPR which it is built on the real use and consumer's understanding of finished cosmetic products. The ongoing revision of the CPR provides an opportunity to extend, where necessary, the existing labelling provisions to cover environmental aspects more comprehensively. A consistent approach on human and environmental labelling under the CPR would ensure helpful and actionable information in terms of sustainable choice, safe use, and disposal. Hazard labelling would not be useful to guide safe consumer use or disposal. On the contrary, precautionary phrases, e.g. to avoid release into the environment, would suggest that small amount could represent a risk to the environment and should not be rinsed down the drain. For products that are intended to be used under the shower (e.g. hair dyes, shampoos, hygiene products), this would send confusing messages to consumers on how to use/dispose the product.

1.3. Requirements for consumer information exist in the CPR that fully address consumer "right to know" about the presence of hazardous substances

Besides requirements regarding safe use/disposal (see above), the CPR provides also provisions to systematically inform consumers about the ingredients present in the product and, upon request, disclose the presence and concentration bands of any ingredient that is classified under the CLP with a physical, human, or environmental hazard:

- full ingredient labelling (CPR §19.1(g)); and
- obligation to provide, upon request, a list of all ingredients in a product that are classified for a chemical hazard, including their concentration range (CPR §21).

The information on the presence of hazardous substances that has to be provided under the CPR goes beyond the information provided on under the CLP regulation, which is limited to those substances that lead to the classification of the final mixture.

1.4. Environmental hazard labelling is not a useful indicator to steer consumer choice towards more sustainable products and may lead to an overall increase of environmental burden

Driving consumers to more sustainable cosmetic products will be comprehensively addressed under (upcoming) European Commission initiatives such as the Sustainable Products and Consumption package that includes comprehensive and relevant environmental labelling based on the Product-Environmental-Footprint (PEF) Methodology. Provisions can be implemented horizontally or via the framework of the CPR.

Additional CLP hazard information would not allow consumers to differentiate, with regard to sustainability, between products that already meet a similar high level of human and environmental safety, as set by the CPR and REACH regulations.

The presence of a specific classified ingredient is not necessarily indicative of the overall environmental sustainability of a cosmetic product, although it may be the sole driver of its hazard classification. If such hazard labelling would become a negative driver for consumer choice, it may even go against the objectives of the EGD. Without any consumer safety and environmental benefit, more sustainable products (concentrates, dry products) may disappear/not be marketed in the EU.

- For example, a concentrated cosmetic shampoo may require hazard labelling due to presence of a classified ingredient whereas a more diluted shampoo with the same ingredient would not require hazard labelling. Both products will lead to a similar environmental exposure during use and disposal (i.e. diluted rinse off in the shower). However, from an environmental sustainability perspective, the concentrate will likely have a smaller environmental footprint because it uses less resources and energy in transport and packaging.

Furthermore, the relatively frequent changes in CLP classification would require frequent changes of cosmetic packaging (including destruction of unused packaging), although the relevant risk-based safety information and use instructions are not changing.

Moreover, by being obliged to provide more information on label, we may jeopardise the overall consumer understanding and the possibility to have multi-lingual packaging.

1.5. Hazard labelling of finished cosmetic products is not aligned with the international practice under GHS and would disadvantage European cosmetic products traded outside of the EU

It is important to note that in every country where GHS is implemented, finished cosmetic products are exempted from hazard labelling. European cosmetic products are recognised globally for their safety and quality, as ensured by the CPR and REACH. The EU is the largest global exporter of cosmetic products (EUR 22.6 billion). Since hazard labelling of cosmetic products does not exist anywhere in the world, additional hazard labelling on EU exports would significantly and negatively impact their international perception and disadvantage them compared to the domestic products that do not require such labelling.

2. Alternatives to Animal Testing

Cosmetics Europe emphasises its full support for the ban on animal testing for cosmetics under the EU Cosmetic Products Regulation (1223/2009). The cosmetics and personal care industry has been at the forefront of developing alternatives to animal testing for regulatory safety assessment for more than 30 years, and believes the only way forward for the EU is to focus on the development and regulatory acceptance of non-animal testing methods. The protection of human health and of the environment is not in contradiction with animal welfare as alluded to the question 3 in the CLP public consultation questionnaire.

The introduction of new classification criteria will lead to new information requirements. These should be consistent with Article 7 of the CLP Regulation and not lead to an increase of animal testing. Indeed, a paradigm shift is necessary to move away from in-vivo testing as the gold standard. A lot of progress has been made on non-animal (eco)toxicology and risk assessment and we believe that the CLP revision is an opportunity for these methods to find full regulatory acceptance for the classification of

chemicals. An increase of animal testing, as a consequence of the proposed new hazard categories, should be assessed in an impact assessment.

Cosmetics Europe urges regulators to ensure an ethical and responsible approach and always consider the use of non-animal testing methods. Cosmetics Europe believes the only way forward for the EU is to focus on the development and regulatory acceptance of non-animal testing methods. We believe in an open scientific dialogue to advance this work with the cosmetics and personal care industry and all other relevant stakeholders through an appropriate collaborative platform.

3. Impact of new hazard classes & consequences to downstream users

Adoption of new hazard classes under the CLP Regulation before the UN GHS would question the principle of harmonized approach under GHS. This issue requires the World Trade Organization (WTO) notification since it could create a barrier to trade in EU, compared to the rest of GHS regions. CLP – GHS alignment is critical. While introducing new hazard classes, it is important that the new classes are based on widely and internationally accepted definitions, supported by science. The proposed changes to the CLP Regulation will have far-reaching consequences not only on the chemical sector but also the downstream sector.

Real impact from CLP hazard classifications are 'automatic bans' triggered by some classifications in REACH and other sector legislations such as the CPR. Safeguards, such as exemption procedures, must be introduced both under REACH and sector-specific legislation such as the CPR to avoid unjustified bans of uses that are safe for consumers and the environment.

3.1. Endocrine Disruptors

Given that endocrine disruption is a mechanism of action and not an endpoint of toxicity, there is no scientific rationale for the addition of new Endocrine Disruptor (ED) hazard classes. An endocrine mode of action can already result in a hazard classification for a substance of Carcinogenic, Mutagenic or Reprotoxic (CMR). Thus, the addition of hazard classes for EDs may lead to duplication of classification. Cosmetics Europe is in favour of the solution proposed by CEFIC in the April 2021 submission paper, "adding the reference to the endocrine mode of action to existing hazard classes capturing adverse effects, i.e., by adding a new EU Hazard Statements under CLP (and potentially under GHS)". For the environment, the same is valid for chronic toxicity and dangerous to aquatic organism endpoints where hazard classes already exist that include effects resulting from an endocrine mode of action.

Cosmetics Europe supports the adoption of the WHO definition of an endocrine disruptor where the three main criteria for identification are i) endocrine modes of action, ii) adverse effects in an intact organism, and iii) a causal link/relationship between the two. As a result, the addition of new hazard classes would certainly lead to a call for in vivo data when there is the need to prove that a substance falls in ED Category 1 or 2. Moreover, in light of the animal testing ban in place for the cosmetic sector, this could potentially lead to a loss of important ingredients which have already been safely used in cosmetics as well as those arising from new innovations. For instance, in vitro tools are available that can provide information on endocrine activity and therefore criteria (i) above; however, the tools themselves do not provide information on adverse effects and would identify endocrine activity in many substances that are not endocrine disruptors. Should these alerts arise, there would be no possibility to prove the absence of adverse effects in vivo.

The proposed ED hazard classes are solely based on hazard, however any endocrine disrupting activity in humans or the environment is dependent on the level of exposure and not only on hazard. Cosmetics Europe believes that there are thresholds for risks associated with EDs, thus the safety of EDs should not be evaluated independently of exposure. In this regard, two main elements should be considered during ED assessment, which are potency (the activity of a substance in terms of the concentration/amount required to produce a defined effect) and severity (the magnitude and/or nature of an adverse effect).

ED thresholds might also be applicable for the Environmental ED categories. If an adverse effect related to an endocrine mode of action is only observed for a substance at high concentrations (e.g. above the standard concentration of 1 mg/L), this effect should be considered not environmentally relevant. This is in line with the current classification systems (GHS and CLP Regulation) in which chronic effects (development, growth and reproduction) are considered of concern for the environment when observed at environmentally relevant concentrations, i.e. below or equal to 1 mg/L.

Should the new hazard classes for EDs be implemented, Cosmetics Europe fully supports the usage of New Approach Methodologies (NAMs) for the collection of supporting evidence. NAMs underlying Next Generation Risk Assessment (NGRA) can be appropriately used to exclude specific endocrine activity and thus, support the decision that ED properties in vivo are unlikely. However, the outputs of these NAMs are useful when interpreted in the context of exposure safety assessment to ensure that relevant exposures will not cause endocrine activity; they are not designed to fulfil the requirements for ED identification as stated by the WHO. In addition, should a substance be used in the cosmetic sector only and, without existing in vivo data from literature, fall in ED Category 2, the ability to demonstrate its safety using NAMs and NGRA in an exposure-led risk assessment should be permitted In general, in vitro assays associated with endocrine activity are known to have a high level of sensitivity and therefore an NGRA based on in vitro data only would result in a very conservative consumer safety assessment and a high level of protection for the consumer. Full dossiers following the NGRA framework for safety assessment should be evaluated in the context of downstream regulation, e.g., the CPR to acquire exemption for the test substance.

In addition to the scientific aspects, Cosmetics Europe strongly believes that the introduction of the proposed new ED hazard classes is unacceptable from an ethical perspective. As stated by the WHO definition, only adverse effects observed in vivo can lead to the characterization of a substance as ED. In light of the high rate of irrelevant positive results of in vitro screening assays, this would certainly lead to an unnecessary increase of animal usage. Cosmetics Europe would like to reiterate the importance of making use of the best scientific knowledge and data available. Blanket data requirements should be avoided and instead, a mechanistic approach, in the context of exposure, should be followed.

ENDS