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Our position

Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) revision

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Executive summary

In the European Commission's revision proposal for the Classification, Labelling and Packaging of substances and mixtures (CLP Regulation), the European Chemicals Agency (ECHA) and Member State Competent Authorities[1] (MSCAs) are set to play a crucial role. In order to ensure that ECHA and the MSCAs are able to navigate the increased workload and regulatory burden imposed by the introduction of new hazard classes, their resources must be increased. The introduction of these new classifications will also entail an expanded workload and considerations for business (eg re-design, research and development, identification of substances, reformulation, etc). Realistic transition periods (ie a minimum of 24 months), as well as a staged approach to label changes would ensure the regulation's operability. Finally, the introduction of digital labelling tools to communicate hazard and safety information to consumers and supply chain actors more comprehensively is a welcome addition for business, that we hope can only be expanded in time.

Issues	Recommendations
Harmonised classification process and ECHA resources	The European Chemicals Agency (ECHA) should be granted sufficient resources to properly navigate the added workload presented by the introduction of new hazard classes under CLP.
Assessment criteria	Grouping and definitions under CLP should align with the criteria set out in the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
Transition periods	The transition periods set out in the Regulation should leave businesses sufficient time to relabel and should not be less than 24 months.
Labelling and marketing provisions	Digital labelling tools should be used to communicate hazard and safety information to consumers and supply chain actors more comprehensively. Mandatory information for online sales should remain consistent with physical label information.

Introduction

The CLP Regulation aims to harmonise the communication of chemical substances and mixtures on the basis of the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The regulation presents specific criteria for substances and mixtures as well as rules on labelling and hazardous chemicals with the aim of protecting human health and the environment. Its provisions affect the activities of manufacturers, suppliers, importers and downstream users, making the clarity of its provisions and its proper implementation all the more crucial. The following recommendations aim to provide the clarity and workability that would make the CLP Regulation revision a success.

[1] Member states and competent authorities, European Chemicals Agency. Available at: https://echa.europa.eu/about-us/partners-and-networks/member-states-and-competent-authorities

Harmonised classification process and ECHA resources

The introduction of new hazard classes under the proposed revision of the CLP Regulation would increase the workload and regulatory burden on authorities, industry and ECHA's committees, in particular the Risk Assessment Committee (RAC). The European Commission's targeted impact assessment accompanying the relevant Delegated Act states that the new hazard classes could 'allow for the identification of around 2320 substances'. It also notes that over a 20-year period, 'dossier submitters […] would have to prepare additional 120 harmonised classification and labelling (CLH) dossiers per year […] and ECHA and RAC would have to process them'. This compares to a current rate of 50 CLH dossiers per year. There are concerns that with the increased workload, the quality of scientific assessments for substances on the EU market may decrease, undermining the CLP's core principles: identifying and communicating hazards based on accurate assessments and scientific evidence. To avoid such a scenario, ECHA's resources should be increased and its work better supported.

Additionally, the right of initiative now conferred on the Commission – and in turn, ECHA and RAC – might place a further burden on the agency's stretched resources and capacity. Because of this, the Commission must allow sufficient time for a thorough examination of each CLH dossier, ensuring harmonised classifications are assigned where justified, based on a comprehensive review of scientific evidence.

Beyond ECHA, there is also growing concern that the MSCAs' workload will become too heavy, affecting their ability to effectively scrutinise dossiers and increasing their susceptibility to political influence. It is therefore necessary to further strengthen the CLH process (Article 37) and reinforce the RAC opinion development process. Key proposals include better consultation opportunities on both the CLH dossier and the draft RAC opinion, formal opportunities for ECHA and RAC to involve independent experts on specific issues and detailed requirements around expertise for RAC membership.

Ensuring a thorough review of CLH dossiers is particularly important as the Commission moves to encourage additional grouping of substances for harmonised classification. This should not come at the expense of science-based assessments. For CLH dossiers covering groups of substances, dossier submitters should clearly identify relevant European Community and Chemical Abstract Service Registry numbers[2] (EC/CAS) and demonstrate the scientific justification for the proposed grouping approach. Considering the intrinsic complexity of grouping when applied to the classification process (please see below), this aspect of the CLH process should be subject to public consultation.

Grouping

While the rationale for proposing group classifications is to reduce workload for companies and authorities alike, it should not come at the expense of robust data on a substance's hazard profile. Grouping could result in hazards being defined solely on structural properties rather than the effect of the chemical on human health or the environment. While grouping can be a useful exercise to prioritise future classification, each substance should still be classified based on its own individual properties. From a scientific point of view, grouping for the purpose of determining a harmonised

[2] EC Inventory. Information on Chemicals. European Chemicals Agency. Available at: https://echa.europa.eu/information-on-chemicals/ec-inventory

classification and labelling under CLP should follow the same stringent criteria as the Read-Across Assessment under the Registration, Evaluation, Authorisation and Restriction of Chemicals regulation (REACH).[3]

Self-classification and the Classification and Labelling (C&L) Inventory

Conflicting notifications should be addressed as part of the CLP review. In the absence of means to address conflicting notifications, the notification provided by the registrant should be given priority. ECHA's earlier efforts to improve coordination between C&L notifiers have not delivered the expected benefits to either the authorities or inventory users. To this end, ECHA should be able to remove or refuse notifications that seem incorrect or unjustifiably inconsistent with information provided by the registrant. ECHA could also consider adding an option for submitters to flag notifications that are no longer active, eg due to divestures and discontinuations. This is a critical functionality for the workability and proportionality of the updated requirements and would allow companies to release resources for active submissions and avoid maintaining C&L Inventory notifications for chemistries that are no longer active. Information published by ECHA in relation to specific notifications could come at the expense of protecting confidential business information. The Commission and the co-legislators must exercise caution in this area.

Multi-constituent substances (MOCS)

As recognised by the substance definition in the CLP, REACH and GHS, no single substance is 100% pure. Introducing the definition of substances with more than one constituent in the CLP Regulation would be a paradigm shift, as all substances would eventually qualify as MOCS. This means that the new rules proposed for MOCS would affect all chemical substances produced, imported and placed on the market in the EU.

The different classes of substances defined in REACH represent the actual cases of products on the market and allow these substances to be tested as such. This testing includes all the known or unknown components which may have an impact on their toxicological profile. This is particularly important in cases where not all components can be identified; their effects are nevertheless included through testing. All components are therefore already considered when substances are tested to fulfil REACH requirements, and the data already cover the constituents' possible effects on human health or the environment. Consequently, MOCS definition undermines the GHS as well as the scientific basis for classifications in general. The proposed CLP revision should not deviate from existing REACH definitions for substances by introducing the proposed MOCS concept.

Transition periods and label changes

Businesses, as well as authorities, need realistic transition periods to implement any changes to CLP – both for major revisions of the hazard classes and criteria, and for periodic delegated acts. In this context, the differentiation between label changes for more severe classifications of six months and less severe classifications of 18 months seems arbitrary and is not based on the obligations linked to

[3] Read-Across Assessment Framework (RAAF), European Chemicals Agency. Available at: 614e5d61-891d-4154-8a47-87efebd1851a (europa.eu)

the application of such a change. In the event of changes in classification and labelling, the artwork re-design process alone takes approximately 12 months, in addition to identification/generation and evaluation of new data and any research and development work required to re-formulate products. Furthermore, considering the guidance documents for new hazard classes are still to be published, it is important that any transition period starts from the publication of this guidance.

Therefore, the Commission should consider a staged approach to label changes linked to the rationale. This should be clearly stated in the basic act and not in the guidance. In addition, the timeline for such a change needs to be better defined.

Changes to be considered could include:

- Change the deadline to update the label to 24 months, instead of six and 18 as currently proposed for different types of hazard classes.
- Reset the timeline to 24 months should further changes occur.
- Prescribe timelines for adaptations to technical progress for different actors in the supply chain, such as 15 months for suppliers and 24 months for downstream users/formulators.

It is important that substances already identified as endocrine disruptor or persistent, bioaccumulative and toxic/ persistent, mobile and toxic are thoroughly assessed for classification. The process to list a substance as a Substance of Very High Concern (SVHC) in REACH does not currently involve the RAC and the guidance documents for the new hazard classes recently introduced by the European Commission via delegated act. While this would concern few substances, it remains important that all substances are assessed in the same way by going through the same CLH process.

Some of the proposed provisions related to label design (eg font size) could lead to an overall increase in label size or packaging volume, and impacts on operations are expected to be significant due to additional re-labelling. This may prevent companies, in particular small and medium-sized enterprises, from including several languages on a single non-fold out label, which is the standard and by far the most cost-effective label type. This could hamper their ability to cover several markets with a single label, which would usually avoid unnecessary re-labelling of goods. This change would represent a dramatic cost increase for the industry without adding any tangible benefits to the end users. The CLP's current provisions and guidance, which focus on legibility and do not foresee an increase of the label font size with increasing packaging volume, are the best solution for the EU market and should not be changed. Co-legislators should also reconsider the requirements for white backgrounds, as they would make the use of recycled packaging more cumbersome and contradict current legislative efforts to increased circularity.

Digital labelling

Because they are voluntary, the digital labelling provisions introduced in the revision proposal cannot be enforced. Expanding the proposal to require digital labelling would allow the EU to make optimal use of digital tools to communicate more complete and up-to-date hazard and safety information to consumers and supply chain actors, in multiple languages and in a more prominent manner.

The CLP Regulation specifies that labelling information must be legible and visible on the packaging. Essential product safety information and instructions for use therefore need to be visible on or with the product.

Information to poison centres

The obligations to provide harmonised information to poison centres should only be imposed on the actors placing chemicals on the market, as they are best placed to do so. Similarly, only distributors placing chemicals on the market or rebranding/re-labelling mixtures should be expected to submit relevant information. A centralised and simplified database to update safety information to support economic operators further down in the supply chain would help comply with these obligations.

Advertisement and distance sales

The proposed text in Article 48 significantly expands the requirements to provide key label elements in the advertisement of hazardous substances and mixtures. Advertising materials (eg company websites, TV commercials, internet videos, customer presentations, brochures, etc) would have to be kept synchronised with product labels and updated in case of label changes impacting pictograms, signal words or hazard statements. The breadth of these requirements would, in practice, place an enormous administrative burden on value chain actors that advertise hazardous substances and mixtures, without scientifically increasing protection to human health and the environment.

In case of hazardous substances and mixtures for industrial and professional users, the end users are always provided with a safety data sheet (SDS). Therefore, it is not necessary to include key label elements in the advertisement of such products.

For consumer products, it is recommended that in lieu of including label elements in the advertisement, users could be asked to ‘read and follow label before use’. Such requests could also be made available online via digital tools. This would prevent consumers from becoming indifferent to omnipresent CLP label elements. It would significantly simplify the need to include the revised requirements in advertisement design and maintenance processes, as well as help build awareness about CLP labels’ relevance for safe use.

In the area of distance sales, there is concern about administrative burdens being increased unnecessarily in business-to-business (B2B) sales of hazardous substances and mixtures. The proposed Article 48a requires that a copy of a product label is included when hazardous substances and mixtures are offered through distance sales solution. However, the proposed provision does not account for the fact that industrial and professional users must be provided with a SDS. In this context, including a copy of a product label in B2B ordering systems does not improve human health and environmental protection. In fact, the label in such case would often be visible merely to the buying company's procurement agent, who has no relation to the way the purchased hazardous substances and mixtures are used by the purchasing company's employees.

Mandatory information for online sales should remain consistent with physical label information and customer experience in a brick-and-mortar shop. The European Commission should additionally provide clarity about what is considered an advertisement in comparison to an online offer.

Conclusion

The proposed revision of the CLP Regulation is an opportunity for the EU to develop harmonised classification requirements that would better protect human health and the environment. To ensure its implementation is successful, ECHA and MSCAs must have sufficient resources to ensure that hazards are identified and communicated on accurate and science-based assessments. Likewise, businesses and authorities need adequate transition times to adapt to changes made to classification and label requirements. Grouping and definitions under CLP should align with the criteria set out in REACH. Moreover, the requirements set out in the proposal on advertisement and distance sales would place considerable administrative burden on value chain actors, despite the SDS already serving the purpose of communicating the safety provisions of a product to the customer.