Expert Briefing: What could the European Commission's plan to strengthen CLP mean for industry?

The Commission plans to adopt changes to the CLP Regulation to support the chemicals strategy for sustainability. Carla N Hutton, regulatory analyst at Bergeson & Campbell, and Karin F Baron, MSPH, senior regulatory consultant at the law firm, outline the measures being considered and their implications

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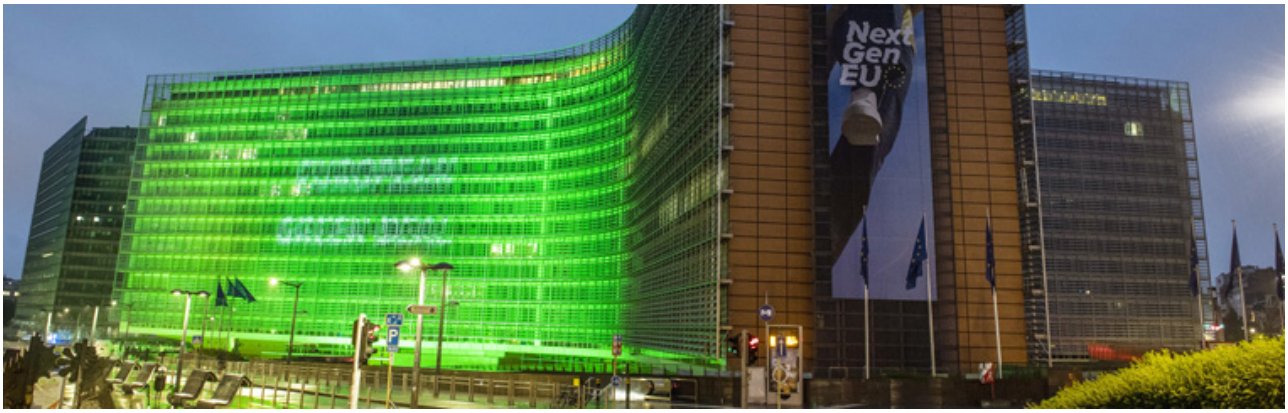

To help achieve the ambitious goals of the European Green Deal, the European Commission adopted the chemicals strategy for sustainability in October 2020. The strategy suggests that the Commission can address pressing human health and environmental concerns by reinforcing Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures – one of the EU's cornerstones for regulating chemicals.

The CLP Regulation sets forth the hazard identification and classification process for chemical substances and mixtures, how hazards should be communicated on labels, and the packaging requirements. According to the chemicals strategy, CLP can be strengthened by adding new hazard classes and criteria to address environmental toxicity, persistence, mobility and bioaccumulation. To achieve the goal of 'one substance, one assessment', the chemicals strategy calls on the Commission to ensure that CLP is the central legislation for hazard classification and allows the Commission to initiate harmonized classifications. This would include adding to CLP endocrine disruptors and substances that are persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB), and assessing the need for specific criteria for immunotoxicity and neurotoxicity endpoints.

The Commission held a public consultation in May 2021 on a roadmap concerning the proposed CLP revisions in the chemicals strategy. The roadmap describes three issues that the Commission intends to address, almost all through legislation amending CLP.

Firstly, according to the Commission, the current hazard criteria and labelling requirements are incomplete, such as the absence of requirements addressing the hazards posed by endocrine disruptors. CLP also fails to address the roles of different actors, including those involved in online sales.

Secondly, CLP in its current form hinders the free circulation of chemicals in the internal market, and poses an undue administrative burden. Companies cannot comply with CLP by using multilingual fold-out labels for typically sized packaging, or place mixtures in small containers on the market that meet the labelling requirements.

Thirdly, there are insufficient public resources, and the available resources may be used inefficiently because there is no mandate for the Commission or Echa to initiate classification dossiers or prioritise certain chemicals for classification.

The roadmap suggests possible non-regulatory solutions, such as additional guidance, technical assistance and financing more proposals for harmonised classification, as well as a number of possible amendments that would be made through legislation. The measures being considered include:

- introducing new hazard classes, such as for endocrine disruptors, and corresponding classification criteria;
- introducing labelling requirements for products that are currently outside the scope of CLP;
- clarifying the requirements to classify mixtures and some complex substances;
- introducing specific rules for online sales;
- allowing the submission of proposals for harmonised environmental and safety values for some substances;
- requiring importers and downstream users to submit information on substances classified for physical effects or health hazards to poison centres, and clarifying obligations for distributors to submit such information;
- introducing a mandate for the Commission to ask Echa to develop new harmonised classification and labelling (CLH) dossiers;
- allowing multilingual fold-out labels;
- introducing rules for labels where there is not enough space on the packaging;
- introducing a prioritisation mechanism to harmonise the classification of certain chemicals; and
- simplifying and reducing unnecessary administrative costs.

Adding new hazard classes and classification criteria, such as for endocrine disruptors, will require amending CLP, as well as introducing labelling requirements for products that are currently outside the scope of CLP. The roadmap does not provide more information about which "products currently outside the scope of CLP" are contemplated, but CLP does not apply to a variety of substances, including substances under customs supervision, non-isolated intermediates, or research and development (R&D) substances that are not placed on the market and are used under controlled conditions.

Amending CLP will be necessary to introduce a mechanism for the Commission to request that Echa develops new CLH dossiers, and to introduce a prioritisation mechanism to harmonise the classification of certain chemicals. Regulating online sales, allowing proposals for harmonised environmental and safety values, and requiring importers and downstream users to submit information to poison centres are other changes that will require amending CLP. Amendments will also be necessary to allow the use of multilingual fold-out labels and to create rules for labels where there is not enough space on the packaging.

Changes the Commission can make without amending CLP include revising current – or preparing new – guidance documents to clarify the requirements to classify mixtures and some complex substances, and enacting obligations for distributors to submit information to poison centres. Simplifying and reducing unnecessary administrative costs are actions that the Commission and Echa can take without amending CLP, although it is unclear what specific actions would achieve these goals.

The roadmap acknowledges that amendments such as adding new classes and classification criteria will have an economic impact on both EU and non-EU companies placing products on the EU market. Companies will have to review their products to determine whether the products are endocrine disruptors, PBTs or vPvBs. If their products fall into any newly added classes, then the companies will have to evaluate and classify the hazards and then revise the labels accordingly.

Given that the amendments to Annex II to the REACH Regulation – introduced by Commission Regulation (EU) 2020/878 of 18 June 2020 – began to apply on 1 January this year, and that they include provisions addressing endocrine disruptors, PBTs and vPvBs, companies that recently reviewed their substances and revised their safety data sheets (SDSs) may feel too familiar with this process. Adding endocrine disruptors, PBTs and vPvBs to CLP again introduces a major departure from the Globally Harmonized System (GHS) of classification and labelling of chemicals and the UN model. For multinational companies, it is easier to comply with GHS requirements than country-specific standards. With the EU's revisions to the SDS requirements in REACH and these likely CLP amendments, the EU is moving further from, rather than closer to, other countries' standards.

If CLP is amended to introduce labelling requirements for products that are currently outside its scope, the Commission and Echa will need to ensure that companies are aware of the new requirements. Once any amendments take effect, member state competent authorities will be responsible for enforcing the new requirements. To date there is no effective feedback loop to ensure consistent enforcement across member states.

For companies, an important factor will be how long companies have to comply with any new requirements, and whether they will be able to sell products that have already been labelled and packaged under the current requirements. The Commission amends CLP annually, updating CLH entries through an adaptation to technical progress (ATP). Other changes to the legal text of CLP may

also be implemented through an ATP, and the Commission may do so here. EU legislation and legislative amendments typically include transition periods, often of 18 months, allowing industry sufficient time to prepare.

According to the Commission's 'have your say' web page, it intended to hold a public consultation in the second quarter of 2021 on legislative proposals for a revision of both the enacting terms of, and the annexes to, CLP, but nothing has been announced yet. The Commission plans to adopt the revisions in the fourth quarter of 2021. Stakeholders should review and comment on the legislative proposals and monitor for further developments.

Carla N Hutton is a regulatory analyst with Bergeson & Campbell, where she monitors and researches global chemical regulatory and legislative developments and trends to inform and equip clients to respond to developing issues.

Karin F Baron, MSPH, is a senior regulatory consultant with Bergeson & Campbell and The Acta Group. Her practice areas include hazard and risk assessment and communication, industrial hygiene, and environmental health and safety (EHS) programmes, and the Globally Harmonized System (GHS) of classification and labelling of chemicals.

The views expressed in this article are those of the authors and are not necessarily shared by Chemical Watch. The author transparency statement can be seen here and here.

FURTHER INFORMATION

European Green Deal

Chemicals strategy for sustainability

Initiative details

Commission Regulation (EU) 2020/878, June 18, 2020

Have your say webpage