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Revision of the CLP Regulation

This factsheet was developed as part of a series on evolving European Union chemical policies.

SUMMARY

- The European Union Chemical Hazard Classification, Labeling, and Packaging (CLP) Regulation aims to protect health and the environment while facilitating the free movement of substances, mixtures, and articles. It aligns with the UN's Globally Harmonized System (GHS) and mandates harmonized classifications, hazard assessment, and hazard communication in the supply chain. The European Commission's 2022 work program included plans to revise the CLP as part of the EU Chemicals Strategy for Sustainability.

- The CLP Revision package put forward by the Commission in December 2022 is comprised of two pieces of legislation:

    - **A Delegated Act** that added new hazard classes and associated substance classification criteria and entered into force in April 2023.
    - **A legislative proposal** that seeks to improve hazard identification, classification, and communication, and address legal loopholes. Trilogue negotiations resulted in a provisional agreement in December 2023 and the plenary vote is scheduled for the second April 2024 session.

- The new hazard classes will have significant upstream and downstream implications because the CLP Regulation is the basis for much of the EU's downstream chemical policy. This will have additional implications intertwined with the Generic Risk Management Approach (GRA), leading to automatic restrictions on certain chemicals of concern in specific product categories.

BACKGROUND & CONTEXT

The EU, through the Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008), requires companies to classify, label and package their chemicals before placing them into the market, to ensure that the risks that chemicals pose are indicated throughout the supply chain. The objective is to protect workers, consumers, and the environment, and to allow for free movement of substances, mixtures, and articles.

The CLP Regulation outlines legally binding hazard identification and classification rules, and specific criteria for labelling, including pictograms, signal words, and standard statements addressing hazards, prevention, response, storage, and disposal. Additionally, it establishes general packaging standards to guarantee the safe distribution of hazardous substances and mixtures. Importantly, it implements the classification criteria and labelling rules agreed upon at the UN level (the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)) into law. While leveraging GHS is not unique to the EU, the EU takes on more hazard classes than other jurisdictions globally and leverages these hazard classes for the purpose of restriction and chemical substitution further up and down the supply chain. As such, changes to the CLP Regulation have ripple effects across EU chemicals management.

DESCRIPTION

Despite its overall success, some weaknesses and gaps in the CLP were identified that prevented consumers, companies, and authorities from fully benefiting from protection against the dangers posed by hazardous chemicals. Building on these weaknesses and current scientific understanding, the CLP Revision package was proposed by the Commission on December 19, 2022. It is composed of two different pieces of legislation that undergo separate procedures: a legislative proposal to amend the CLP (Art.294 TFEU) that follows the Ordinary Legislative Procedure and a proposal for a Delegated Act (Art. 290 TFEU) complementing the CLP revision, which was taken through comitology.
The legislative proposal for a revision of the CLP aims to address three issues:

1. **Properly identifying and classifying hazardous chemicals:** EU legislation lacks harmonized criteria for identification, and the quality of information on classified substances is often poor, with many incorrect or outdated classifications and inconsistencies in classifications within the European Chemicals Agency's (ECHA's) inventory.

   The proposed regulation prioritizes the five new hazard classes introduced by the Commission's Delegated Act (see below) for harmonized classification and labelling (CLH), alongside carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitization. It also mandates the inclusion of substances with endocrine disrupting (ED), persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) properties in the list of harmonized entries in CLP Annex VI. The European Commission is provided the authority to mandate ECHA or the European Food Safety Authority (EFSA) to develop harmonized classification and labeling proposals, allowing for multiple substances to be addressed simultaneously.

   Provisions also exist to increase transparency in CLH proposals, to address diverging self-classifications and to address 'multi-constituent substances,' where assessment based on individual constituent data would be required (such as CMR, ED, and others) unless specific CLP provisions apply.

2. **Optimizing the communication of chemical hazards:** The proposed regulation outlines minimum label formatting standards to enhance label readability, including font size and spacing requirements, and allows for broader use of fold-out labels. It introduces rules for voluntary digital labeling, restricting digital-only elements to non-essential information, with specific requirements for accessibility and privacy. Certain chemicals supplied without packaging would be exempt from labeling requirements, such as fuel at filling stations and very small packaging. The text establishes regulations for selling hazardous substances or mixtures in refillable containers, including labeling requirements, packaging standards, supplier availability, and staff training.

3. **Addressing non-compliance:** High levels of non-compliance on imported chemicals and online sales were identified in a chemicals fitness check. To tackle these, the proposal mandates that EU-based suppliers must ensure that substances or mixtures meet regulatory requirements before placing them on the market, including for distance sales. The proposal also includes added requirements around hazard pictograms and statements, as well as requirements for distributors like re-labelers and re-branders to submit relevant information under certain circumstances.

The Delegated Act issued by the Commission further tackles concerns about the lack of comprehensiveness in the identification and classification of hazardous chemicals as well as the fact that the current CLP regulations do not require manufacturers to identify certain critical hazards. It adds new hazard classes to Annex I of the CLP Regulation and defines the specific criteria for the classification of substances under these new hazard classes:

- Endocrine disrupting (ED) to human health or the environment
- Persistent, bioaccumulative and toxic (PBT)
- Very persistent and very bioaccumulative (vPvB)
- Persistent, mobile and toxic (PMT)
- Very persistent and very mobile (vPvM)

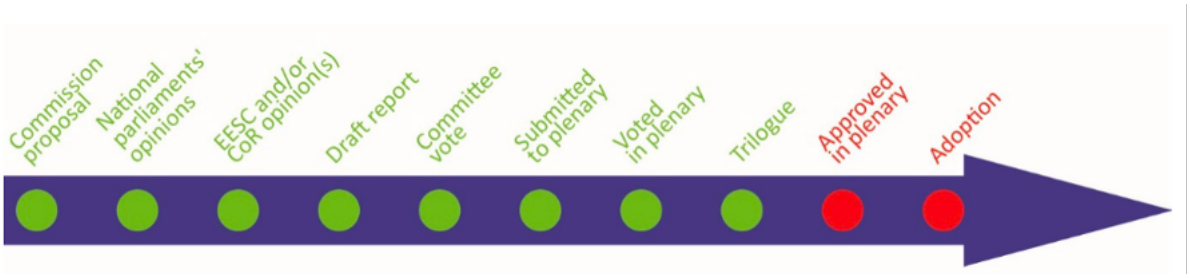
Before the Delegated Act, ED and PBT/vPvB properties were only identified through REACH or specific regulations for plant protection products and biocides, while PMT/vPvM properties were only identified via REACH.

The current CLP Regulation exemptions (focused mainly on health and allowing for the exclusion of certain substances and mixtures) will remain intact.

CURRENT STATUS

The proposed Delegated Act was scrutinized by the European Parliament and the Council. The Regulation was published in the EU Official Journal on March 31, 2023, entering into force on April 20, 2023.

The revised legislative proposal amending the CLP Regulation is following the Ordinary Legislative Procedure. On December 5, 2023, the Parliament and the Council reached a provisional agreement on the file, including the exemption of substances extracted from plants or plant parts and not chemically modified from certain regulations. Within five years, the Commission must present a scientific report on these substances. The deal sets deadlines for including substances identified as ED, PBT, or vPvB in Annex VI. The agreement also includes rules for label formatting and advertisements. ECHA's resource allocation for CLP implementation will be addressed, and enforcement authorities will be required to follow up on non-compliance reports. The Commission will evaluate alternative classification methods and may amend Annex II based on evaluation outcomes. The agreement was endorsed by relevant committees and awaits formal adoption by the co-legislators. The plenary vote, the final step in the process, is planned for April 23, 2024 (see timeline below).



CLASSIFICATION IN THE CONTEXT OF SPECIFIC VS. GENERIC RISK APPROACHES

There are two basic approaches to risk management often used in combination in the EU chemicals policy (the laws, regulations, directives, and standards governing the management, registration, evaluation, authorization, and restriction of chemicals within the EU): one based on specific risk assessment and the other based on generic risk considerations.

The GRA automatically triggers predefined risk management measures (e.g. packaging requirement, communication requirement, restrictions, bans, etc.) based on the hazardous properties of chemicals and generic considerations of their exposure. For example, certain substances are automatically

banned from cosmetics and toys if they fall into specified hazard categories. In contrast, the Specific Risk assessment Approach (SRA) applies measures based on the outcomes of assessments that evaluate both hazards and potential exposure scenarios for humans and the environment to the substance/mixture.

Risk management measures are based on the hazardous properties of the chemical determined under CLP, without the need or possibility to assess and take into account specific exposure levels for a specific situation or use. As such, the GRA-based approach would affect substances and mixtures reclassified for new hazard classes.

IMPLICATIONS

The biggest implication of the CLP revisions is that **the new hazard classes could automatically trigger new regulatory action** through REACH, especially if/once the GRA is implemented. As mentioned before, because the EU leverages the CLP Regulation as the basis for their downstream chemical policies, a large number of substances may eventually be subject to either authorizations or restrictions. Despite the need for businesses to invest to comply with the new rules, the industry is likely to benefit from the provisions, particularly SMEs.

A strength of the CLP Regulation is that it is based on the **United Nations' Globally Harmonized System (GHS)**. However, the Delegated Act includes classes and rules that are still not agreed on at the UN level, introducing inconsistencies between the CLP and GHS. That said, the EU submitted a proposal in 2022 to work on unaddressed hazard classes in the 2023-2024 GHS Work Programme and it will chair a newly formed UN informal working group to develop global criteria for the newly adopted hazard classes that will hopefully be incorporated into the new revised edition of the GHS that may be expected in 2025.

According to the impact assessment accompanying the revision, the introduction of new hazard classes to the CLP Regulation is generally strongly supported by stakeholders despite the temporary challenge of a lack of global classification harmonization that complicates legal certainty in the manufacturing and trade of substances and products.

For factsheets and more information on European Chemicals Policies, please visit www.sustainablechemistrycatalyst.org/eu-chemical-policy.

AUTHORS

This factsheet was developed through a collaboration between:

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