



# EU Chemicals Law

## Upcoming Developments in 2022

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# Introduction

## - New Emerging Regulatory Framework

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As environmental ambitions rise globally, the European Green Deal seeks to transform the European economy and society towards more sustainable models. In this context, the renewed environmental objectives of the EU will lead to significant changes to the chemicals management framework.

The Commission's Communication on the European Green Deal presents the overall vision and highlights the priority areas of action. Some of these priority areas are the transformation of the EU's industrial sector towards a clean and circular economy, reducing the use of pesticides in agriculture, and creating a toxic-free environment. All of these are highly relevant to the chemical industry. More specific communications apply this general vision to specific sectors, and list out regulatory changes to be undertaken.

The Chemicals Strategy for Sustainability is one of these specific communications. It further details measures to be taken to enact the EU's ambition of transitioning towards a toxic-free environment. These include amendments to both Regulation (EC) 1907/2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (known as the REACH Regulation) and Regulation (EC) No 1272/2008, on classification, labelling and packaging of substances and mixtures (known as the CLP Regulation). Changes also include several specific pieces of legislation (such as the Cosmetic Products Regulation, the Toy Safety Directive, and the Food Contact Materials Regulation).

The European Circular Economy Action Plan, another specific communication, sets out actions to implement the European Union's vision for a more sustainable and circular European economy. The sustainability of products is a critical issue in this regard. Regulatory initiatives in this area will address the presence of chemicals in product cycles, including through the review of Directive 2009/125/EC, establishing a framework for the setting of ecodesign requirements for energy-related products (the Ecodesign Directive).

## Key Developments

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- Proposed revisions to the REACH Regulation will affect the authorization and restriction regimes.
- Proposed changes to the CLP Regulation will introduce new hazard classes and hazard criteria.
- Some classes of hazardous chemicals will be proposed for categorization as Substances of Very High Concern (SVHCs).
- Changes to the Ecodesign Directive will enhance the attention given to Substances of Very High Concern in products.



# Legislative Changes and Effects on Businesses

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Many of the policy initiatives currently being proposed do not require legislative changes, and those that do are still in their early stages. This means that the European Commission is currently consulting stakeholders before publishing a legislative proposal to which the European Parliament and the Council of the European Union can propose changes. Therefore, information on the specifics of each legal change is not yet available. However, the current state of debate and the options under consideration can help companies anticipate future duties and better prepare for them.

Three proposals to be presented in 2022 will significantly change the legislative framework for chemicals in the European Union. Two of them are revisions of the existing overarching regulations (REACH and the CLP), while the third one seeks to address the nexus between chemicals and product legislation in a more coherent way.

## **REACH Revision**

A review of the REACH Regulation's performance by the European Commission showed that it was underperforming in terms of enforcement, complexity, and speed. Additionally, the Chemicals Strategy for Sustainability emphasises some issues that were not considered at the time of adopting REACH (this is especially the case of unintended mixtures).

According to the Commission's preliminary documents, the main changes to be applied to REACH concern the restriction and authorisation regimes and the extension of the generic approach to risk management.

It is still unclear what changes will be applied to the authorisation and restriction processes. Several options are being explored by the Commission, ranging from minor simplifying changes to removing authorisation or merging it with restriction.

As for the generic approach to risk management, it is an approach where hazard considerations lead to regulatory action on a general basis (for instance, banning the use of a certain class of chemicals in a certain type of products). Under this approach, the Commission will propose amendments to the necessary legislations to ensure that consumer products don't contain CMRs, endocrine disruptors, PBT/vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitisers or substances that affect specific organs. In this regard, the definition of essential uses – which is also under development – will be key in delimiting the remaining acceptable uses.

Finally, the Commission is seeking to step up overall enforcement of REACH, which includes enacting stricter border controls and enhancing coordination with Member State authorities.

The European Commission is currently holding consultations on the revision of the regulation. Once the period for stakeholder participation ends on April 15, 2022, the Commission will incorporate the feedback into its Regulation Proposal and present it to the European Parliament and Council of the EU, both of whom will have the opportunity to amend the text before its adoption. The Commission is expected to present its initial proposal by the end of 2022.

### **CLP Regulation**

A 2019 review of the CLP Regulation found room for improvement in several aspects, most notably the absence of criteria and labelling requirements for some hazards and the lack of clarity for some products currently not covered by the regulation.

Specific changes that will be proposed by the Commission include the introduction of new hazard classes and criteria to better address persistency, bioaccumulation, mobility, and toxicity. In the same vein, it will also propose the categorization of some classes of chemicals (endocrine disruptors, persistent, mobile, and toxic (PMT) and very persistent and very mobile (vPvM) substances) as Substances of Very High Concern (SVHCs).

Additionally, some labelling requirements for products currently not covered by the CLP Regulation might be introduced.





Consultations on the revision of the regulation have already been held, and the Commission is currently working to incorporate the feedback into its Regulation Proposal. The proposal is expected to be presented in 2022, followed by discussions at the European Parliament and Council of the EU, both of whom will have the opportunity to amend the text before adopting it.

Although the details of the proposal are not yet known, it is possible that new hazard classifications will require producers and importers to generate new data on their substances. Additionally, given that the classification under the CLP Regulation is used in many other sector-specific pieces of legislation, new duties under those regimes may also arise.

### **Sustainable Products Initiative**

Announced on March 30, 2022, The Sustainable Products Initiative (SPI) proposes changes to several pieces of product-based legislation, most notably the substitution of the Ecodesign Directive with a more extensive Ecodesign Regulation.

Currently, the Ecodesign Directive sets minimum energy-consumption requirements for energy-related products (such as refrigerators, electric motors or televisions and computer screens). The SPI propose enlarging the scope of the Ecodesign Directive to cover most products placed in the market. It will also expand the range of criteria on which minimal performance and information requirements can be set.

Relatedly, new rules and schemes to make products more circular have also been put forward in the SPI. These include enhanced availability of information on the chemical content of products, through the introduction of information and life-cycle tracking requirements, and potentially through limits on the presence of substances of concern in products.

The Commission's proposal will now have to be negotiated with the European Parliament and Council of the European Union, both of which will have the opportunity to propose amendments to the draft text.

While changes to the Ecodesign framework might not directly affect chemical importers, they remain highly relevant to the overarching vision for chemical governance in the EU and will play a key role in how EU markets evolve.

# Conclusion

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The new environmental vision of the European Union includes greater emphasis on the negative effects of chemicals for human and environmental health. Although specific proposed changes are still being finalized, there seems to be a clear direction towards a more restrictive approach to chemicals, stricter enforcement of current legislation, and greater attention to the presence of chemicals in products and material cycles.

Companies can benefit from improving compliance with current regulations. Additionally, there are important business opportunities to capitalize on for companies that meet the more stringent requirements under the upcoming legislation.

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- Toxicological assessment & Dossier updates
- Contract Study Management & Monitoring
- Compliance Verification & Certificates
- REACH & CLP compliant SDS & Extended SDS (eSDS) SDS translations in over 30 languages

## Know more about EU Chemicals Regulations

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The regulatory framework for chemicals in the European Union (EU) is highly developed and contains both overarching and sector- or product-specific pieces of legislation. The two fundamental blocks of chemical management in the EU are Regulation (EC) 1907/2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (known as the REACH Regulation) and Regulation (EC) No 1272/2008, on classification, labelling and packaging of substances and mixtures (known as the CLP Regulation).

REACH establishes the current framework for the manufacture, use, and import of chemicals in the EU. Its overall objectives are to improve the protection of human health and the environment, as well as boosting the competitiveness of the EU chemicals sector. It also aims at minimizing animal testing and prompting substitution of hazardous chemicals in the long run.

The CLP Regulation establishes common requirements for the classification, labelling and packaging of chemicals. It is the central piece of EU legislation for the hazard assessment of chemicals and REACH often regulates substances according to their classification under the CLP Regulations. Other specific pieces of legislation also use some CLP classifications, such as Regulation (EC) No 1107/2009, concerning the placing of plant protection products on the market, and Regulation (EU) No 528/2012, concerning the making available on the market and use of biocidal products.

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