

Revision of the EU Regulation on classification, labelling and packaging of substances and mixtures

This briefing is one in a series of 'implementation appraisals', produced by the Ex-Post Evaluation Unit of the European Parliamentary Research Service (EPRS), on the operation of existing EU legislation in practice. Each briefing focuses on a specific EU law, which is likely to be amended or reviewed, as envisaged in the European Commission's annual work programme. 'Implementation appraisals' aim to provide a succinct overview of publicly available material on the implementation, application and effectiveness to date of an EU law, drawing on input from EU institutions and bodies, as well as external organisations. They are provided to assist parliamentary committees in their consideration of new European Commission proposals, once tabled.

SUMMARY

The European Union has been developing a policy on chemicals for more than 50 years. It employs legal regulation as the main policy instrument and aims to protect human health and the environment against the hazardous properties of chemicals, ensuring their free movement within the internal market, while also promoting competitiveness and innovation in the relevant industrial sector. Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (the CLP Regulation) is a key regulatory instrument of EU chemicals policy.

In 2020, in the context of the zero pollution ambition of the European Green Deal, the European Commission adopted a chemicals strategy for sustainability aimed at better protecting citizens and the environment and boosting innovation for safe and sustainable chemicals. The achievement of these objectives requires the revision of several pieces of EU legislation regulating chemicals, including the CLP Regulation. This briefing informs parliamentary decision-making by presenting findings on the implementation of the regulation.

Background

Chemicals are used extensively in daily life. They have an essential role in sectors, such as healthcare, energy, housing, mobility, and technology, which help maintain the high living standard and well-being of modern society. However, most chemicals have hazardous properties and could thus harm human health and the environment. Therefore, the EU has regulated chemicals and their use.

In October 2020, the European Commission published a [chemicals strategy for sustainability – towards a toxic-free environment](#), which is a key deliverable under the zero pollution ambition for a toxic-free environment of the 2019 [European Green Deal](#). The objectives of the strategy are to improve the protection of human health and the environment from hazardous chemicals, and to boost innovation for the development of safe and sustainable alternatives. It also aims to promote the EU industry as a global leader in the production and use of chemicals. The achievement of these objectives requires a revision of several pieces of EU chemicals legislation.



Legal framework

The EU policy on chemicals

The EU started regulating chemicals in the 1960s. In 1967, [Council Directive 67/548/EEC](#) (known as the Dangerous Substances Directive) was adopted. The directive harmonised the rules on the classification, packaging and labelling of chemical substances of the Member States of the then European Economic Community. A few more directives were adopted in the following decades.

In 2001, the Commission adopted a [white paper](#) entitled Strategy for a future chemicals policy. Its main objective was to ensure a high level of human health and environment protection, efficient functioning of the internal market and enhanced innovation and competitiveness in the chemical industry. This paved the way for the adoption of the two core pieces of EU legislation that directly regulate chemicals, namely [Regulation \(EC\) No 1907/2006](#) concerning the registration, evaluation, authorisation and restriction of chemicals (the REACH Regulation), which also established the European Chemicals Agency (ECHA), and [Regulation \(EC\) No 1272/2008](#) on classification, labelling and packaging of substances and mixtures (the CLP Regulation, in focus here).

The regulation of chemicals in the EU

The EU regulates chemicals in two phases – a 'hazard/risk assessment' phase followed by a 'risk management' (decision-making) phase.

'Hazard/risk assessment' phase

'Hazard' relates to the intrinsic properties of a chemical, while 'risk' examines the hazard against exposure and the probability of an adverse outcome (harm). The exposure to a chemical thus refers to how and in which concentration a human or another organism enters in contact with the chemical. The main steps in the risk assessment phase are: hazard identification (based on toxicity tests and other relevant data); dose (concentration) – response (effect) assessment; exposure assessment – exposure scenarios (based on models and measurements of the occurrence of the chemical); risk characterisation; and risk estimation.

The players involved in the 'hazard/risk assessment' phase are the industry, national competent authorities, and the relevant EU agency/authority (for example, ECHA is in charge of risk assessment under the REACH and CLP Regulations, and the Biocidal Products Regulation, while the European Food Safety Authority is in charge of risk assessment under the Plant Protection Products Regulation).

'Risk management' (decision-making) phase

Risk management measures are adopted against the identified hazards and/or assessed risks. These measures can range from (and involve a mix of) a total ban to any condition to the manufacture, use or placing on the market of chemicals (such as setting emission/concentration/migration limits, obligations to communicate hazards and risks, labelling requirements, obligations to use personal protection equipment, etc.)

Risk management measures are decided by public authorities at EU and national level. For example, under the CLP Regulation, the Commission is the risk manager for substances included in its Annex VI on harmonised classification and labelling (see details in section 'The CLP Regulation' of this briefing). Under the Plant Protection Products Regulation, the risk manager for the approval of active substances is the Commission, while the Member States' competent authorities are risk managers when products containing the active substance (already approved at EU level) are authorised for use at national level.

Source: [Swedish Chemicals Agency](#) and [European Commission](#).

The current EU policy on chemicals also includes:

- legislation regulating products containing chemicals (for example, [Regulation \(EC\) No 1935/2004](#) on food contact materials (the FCM Regulation), [Directive 2009/48/EC](#) on the safety of toys (the Toy Safety Directive), and the set of regulations on pesticides, namely [Regulation \(EC\) No 1109/2007](#) on the placing of plant protection products on the market (the Plant Protection Products Regulation) and the related [Regulation \(EC\)](#)

[No 396/2005](#) on maximum residue levels of pesticides in or on food and feed of plant and animal origin (the MRL Regulation) as well as [Regulation \(EU\) No 528/2012](#) concerning the making available on the market and use of biocidal products (the Biocidal Products Regulation);

- legislation regulating the conditions under which chemicals are manufactured, treated or used (for example, legislation on occupational health and safety (OSH) such as [Council Directive 89/391/EEC](#) on the introduction of measures to encourage improvements in the safety and health of workers at work (OSH Directive)), and;
- legislation containing provisions regulating chemicals (for example, [Directive 2010/75/EU](#) on industrial emissions (Industrial Emissions Directive, which covers emissions polluting the air, water and soil), [Directive 2000/60/EC](#) establishing a framework for Community action in the field of water policy (Water Framework Directive), [Directive 2008/98/EC](#) on waste (Waste Framework Directive).

The CLP Regulation

In line with the EU policy on chemicals, the objectives of the CLP Regulation are to ensure:

- a high level of protection of human health and the environment, and
- the free movement of substances, mixtures and articles.

The main instrument used by the CLP Regulation in meeting these objectives is harmonisation at EU level. In particular, the regulation defines uniform requirements for the classification, labelling and packaging of hazardous substances and mixtures. This is done in line with the United Nations' [Globally harmonised system of classification and labelling of chemicals](#) (UN GHS). In particular, companies¹ (manufacturers, downstream users, importers) are required to (self-)classify, label and package hazardous chemicals appropriately before placing them on the market.

In case a substance or a mixture meets the **classification** criteria defined by Annex I of the CLP Regulation, the hazards of the substance or the mixture are identified by assigning them:

- a certain hazard class (type of hazard) defining the nature of the hazard: physical (for example, flammable liquid), health (for example, acute toxicity, carcinogenicity) or environmental (for example, posing a hazard to the ozone layer or the aquatic environment), and
- a certain hazard category (level of hazard) defining the division of criteria within each hazard class, specifying hazard severity. The level of hazard is indicated by a label saying 'Warning' or 'Danger'.

The identified hazards of the substance or the mixture must be communicated to the users by means of labels. In particular, **labelling** informs the user of the hazard classification of the substance or the mixture. It alerts of hazards and of the need to manage the associated risks. The CLP Regulation lays down labelling requirements for: the supplier's identity; name of the substance or mixture and/or identification number; nominal quantity of the product in the package; hazard pictograms (graphic designs combining symbols and other visual elements); level of hazard (as mentioned above, signalled by the key words 'Warning' or 'Danger'); risk (signalled by phrases such as 'Fire or projection hazard', 'Fatal if swallowed'); safety (signalled by phrases such as 'Keep only in original container'; 'Protect from moisture'; 'Keep out of reach of children'). Manufacturers and importers are required to submit classification and labelling information for the substance(s) they are placing on the market to the Classification and Labelling Inventory (CLI). The CLI is regularly updated by the ECHA.

EU Member States, manufacturers, importers or downstream users may propose harmonised classifications and labelling (CLH) of chemicals with particularly serious hazards (for example, substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs), as well as respiratory sensitisers).² This is done to ensure adequate uniform risk assessment and risk management across the EU. Such 'harmonised' substances are included in Annex VI to the CLP Regulation.³ Non-

harmonised substances (i.e. outside the scope of Annex VI) must be self-classified by companies, and the industry is required to make every effort to reach a consensus on the classification of all substances.

The CLP Regulation also lays down requirements for the appropriate **packaging** of classified substances and mixtures. In particular, to ensure the safe supply of hazardous substances and mixtures, the packaging must prevent the contents from escaping, be made of materials that are resistant when in contact with the contents, be strong and solid and have sealable fastenings. Child-resistant fastenings and tactile warnings might be required in some cases.

Member States must establish bodies (commonly referred to as 'national poison centres') to receive information on the composition of hazardous mixtures (such as paints, detergents, adhesives). The suppliers of products containing hazardous chemicals must submit information to the poison centres for emergency health response needs.

The revision of the CLP Regulation

In December 2022, the Commission submitted a package revising the CLP Regulation. It consists of two proposals amending the regulation: i) a legislative [proposal](#) for revision to be adopted by the [European Parliament](#) and the Council of the EU via the ordinary legislative procedure, Article 294 of the Treaty on the Functioning of the European Union (TFEU); and ii) a [proposal](#) for a delegated act (a Commission delegated regulation) to be adopted via Article 290 TFEU. The latter proposal adds definitions and scientific and technical criteria to enable substances and mixtures with endocrine disrupting (ED), persistent, bio-accumulative and toxic for reproduction (PBT), very persistent and very bio-accumulative (vPvB), PMT and vPvM properties to be classified into established hazard classes. More specifically, the delegated act amends Annexes I, II, III and VI to the CLP Regulation. The proposals are accompanied by an [ex-ante impact assessment](#) (IA). They aim to: i) ensure that all hazardous chemicals, including those with ED, PBT, vPvB, PMT and vPvM properties, are classified adequately and uniformly across the EU; ii) improve the efficiency of hazard communication by making labels more accessible and understandable for users of chemicals, and provide companies with more flexibility, thereby reducing the administrative burden without lowering safety levels; (iii) making sure that the rules on chemical hazard classification and communication are applied by all relevant actors in the supply chain. The section below presents some of the findings made in relation to the implementation of the CLP Regulation.

European Commission

Fitness check of most relevant chemicals legislation (not REACH), and aspects of legislation applied to downstream industries

In 2019, the Commission published a [fitness check](#) of the EU chemicals legislation, the first ever 'comprehensive and cross-cutting' evaluation of what was already a 50-year-old EU policy. The check covers more than 40 pieces of EU legislation related to chemicals, with the exception of the REACH Regulation, and assesses what parts of it work well and what need improving to ensure the policy objectives are met and the regulatory burden is reduced. The findings of the fitness check are based on several externally prepared studies,⁴ among others. The check applied the methodology for ex-post evaluations prescribed by the EU Better Regulation [agenda](#), by using the standard set of criteria: relevance, effectiveness, efficiency, coherence and EU added value. The main findings on the implementation of the CLP Regulation against each evaluation criterion are presented below.

The fitness check notes that the original needs in terms of protecting human health and the environment from the risks of hazardous chemicals, enhancing the functioning of the internal market and promoting innovation and competitiveness, are still **relevant**. Therefore, these three core objectives⁵ of the EU policy on chemicals, which also apply to the CLP Regulation, remain relevant. The basic components and approaches to hazard/risk assessment and risk management

also continue to be relevant. The Commission notes, however, that science evolves and new data is available regarding links between exposure to hazardous chemicals and impacts on human health and the environment. In this context, a number of concerns have emerged over the past 10-20 years. As per 2019, these concerns had been addressed either partially or not at all by the EU legislation, and relate to: how to address the effects from combined exposure (to multiple chemicals by a single source or multiple sources) and how to better understand and address the impacts of hazardous chemicals on the environment, biodiversity and eco-system resilience. The Commission notes that action has been taken to improve the situation. Another concern is how to collect knowledge and better manage the risks related to the use of hazardous substances in articles, which is instrumental in the context of the EU's transition towards a circular model of production and consumption.

In the context of relevance, the fitness check also mentions that the general decision-making process of the EU chemicals policy has 'continuously improved', in line with the EU Better Regulation agenda. As regards the CLP Regulation in particular, all stakeholder groups⁶ consider that the CLH process has been 'well understood'. Furthermore, the process in its pre-regulatory phase (i.e. up until the ECHA Risk Assessment Committee (RAC) issues its opinion) is, in principle, seen by the stakeholders as transparent. However, the lack of communication between the companies (providing the data for the CLH dossier) and the national authorities can lead to a lack of clarity as to what information was taken on board during the CLH decision-making process. This is further exacerbated by the fact that the 'raw data/full studies' underlying an opinion or a CLH decision are not publicly available. Industry and non-governmental (NGO) stakeholders question the objectivity and predictability of the risk management (decision-making) phase, whenever it is a lengthy one. Industry stakeholders are concerned about transparency and stakeholders' involvement in the risk management (decision-making) phase.

In the context of **effectiveness**, the question is whether the objectives of the legislation are being met (or progress is being achieved) as a result of its implementation. The fitness check notes that, overall, the EU chemicals legislation is 'fit for purpose'. In particular, the legislation examined, including the CLP Regulation, ensures that these objectives are met.

As regards the policy objective concerning human health and environmental protection, the Commission notes that the EU chemicals legislation, including the CLP Regulation, has 'clearly led to significant benefits in terms of reduced and avoided negative health and environmental impacts for regulated hazardous substances'. However, exposure to hazardous chemicals continues to raise concern and requires further attention. Nevertheless, the fitness check notes that, where targeted EU policy and regulatory measures have been implemented, human and environmental exposure to many well-known individual hazardous chemicals has been reduced or minimised. The example of lead is highlighted. In particular, there is a noticeable reduction in the exposure of EU consumers – by 89 % between 1990 and 2011 – to lead in toys, paints, drinking water and petrol. This exposure reduction is attributed to a variety of risk-management measures implemented by Member States, 'at least in part due to EU legislation'. The substitution of substances hazardous to health and the environment with less hazardous solutions appears to be marginal; in any case, substitution by solutions less hazardous for the environment seems to progress better.

The EU chemicals legislation, including the CLP Regulation, has also 'clearly led to significant benefits' for the proper functioning of the internal market. In particular, it is assessed as 'instrumental' in ensuring the free circulation of chemicals within the internal market, thanks to the harmonisation of standards, requirements, risk management measures, labelling and the mutual recognition approach. This has reduced the barriers to trade in chemicals within the EU, which is growing. In particular, EU-level harmonisation has limited the application of potentially different national rules that not only have a limited territorial coverage but are also most probably only available in the relevant national language(s). The achieved level playing field across the EU has improved the functioning of the internal market. The fitness check notes that several directives regulating chemicals have been converted to regulations in order to address Member State authorities' and industry's demands for better harmonisation at the EU level. More specifically, the

CLP Regulation, which, as mentioned, was preceded by a directive, is assessed as providing the basis for consistent identification of properties of concern, which is subsequently used in hazard communication to downstream users in the supply chain, consumers and workers. Therefore, Member State authorities, the industry and civil society stakeholders broadly consider the CLP Regulation to be easier to apply than the directive preceding it, and thereby to contribute to the efficient functioning of the single market.

In terms of competitiveness, the fitness check notes that the achieved level playing field across the EU has enhanced the EU's competitiveness in this sector. The EU remains the world's largest exporting region and, despite the decline of its share in the global market,⁷ the EU chemicals industry 'remains internationally competitive'. The strong research base, high level of technological development and skilled workforce are highlighted as the main competitive advantages of the EU chemicals industry. The Commission notes further that in several areas the EU legislation on chemicals is the reference point for the development of international standards,⁸ which helps reduce potential 'trade frictions' and addresses cross-border chemicals-related issues. It is noted, however, that the enforcement of EU standards on imported products is an issue. In terms of innovation, the fitness check notes, however, that although the EU chemicals industry is often seen as a global leader in the field, there is no evidence that the EU chemicals legislation as such is either a major trigger of or a barrier to innovation for companies in general. Nevertheless, the CLP Regulation is highlighted as an instrument with a potential to stimulate innovation in substitutions of substances hazardous to the environment with less hazardous chemical or non-chemical solutions. In particular, hazard classification under the CLP Regulation triggers a number of legal obligations for the manufacturer (such as labelling and communication to downstream users and consumers), which creates an incentive for more cost-efficient substitution.

The fitness check also identifies issues that hamper the effective implementation of the CLP Regulation. A first issue relates to the data necessary for 'robust' hazard/risk assessment and risk management. Although the quality and availability of such data has improved, knowledge gaps remain. They have to do with exposure to hazardous chemicals, their use and impacts on humans and the environment, including on ecosystems' resilience and biodiversity. Furthermore, the uptake of non-animal test methods by the regulatory process is impeded by gaps in the available test guidelines. The lack of knowledge on substances contained in articles, highlighted above under the 'relevance' criterion, is of concern also in terms of effectiveness, especially in the context of shifting towards a circular model of production and consumption, which is a priority under the European Green Deal.

The communication of hazards and safety information to consumers is another issue hampering the effective implementation of the CLP Regulation. The level of understanding of certain labels and statements is 'relatively low'.⁹ This might be (in part) due to the excess of information on the label or duplication of the information on the label resulting from overlaps in the relevant legal requirements. It is thus difficult for downstream users and consumers to grasp the essential information on hazards. Missing information on consumer goods might also be problematic. For example, the lack of labelling requirements on the environmental hazards of cosmetic products affects consumers' possibility to make an informed choice; this is an issue also in terms of coherence. The fitness check concludes therefore that improvement and simplification are needed as regards the communication of hazards and safety information to consumers. Digital technologies (for example the use of QR codes on labels) may be helpful in this respect.

There are also effectiveness issues in relation to self-classification under the CLP Regulation, which, as explained above, is required when the substance is not subject to CLH but has hazardous properties. In particular, it is often the case that the same substance has been self-classified and registered in the CLI multiple times. This happens because the individual registrants were not able to negotiate an agreed entry, although, as mentioned earlier in this document, they are legally obliged to make every effort to do so. In addition, the reliability of some self-classifications is of concern. All this affects the value of the CLI as a hazard communication tool. The issue is further

exacerbated by the lack of a legal basis for ECHA actions, such as correcting or deleting mistakes; removing entries by companies that no longer exist or substances that are no longer marketed (or marketed in quantities below one tonne per year); or entering in direct contact with registrants with the aim to initiate a correction or obligation for the manufacturer or importer to check the quality of the notified information. Following the fitness check, it appears that, as of 2019, the ECHA and the Commission were looking into a number of ways to improve the situation.

Finally, yet importantly in terms of **effectiveness**, the Commission notes that Member State competent authorities' resources (human, financial, expertise) are limited, which leads to 'significant' challenges for the regulatory systems' overall effectiveness and efficiency. In particular, limited resources at national level affect enforcement activities such as inspections, market surveillance, monitoring and reporting. With relevance to the CLP Regulation, differences in the administrative organisation established by the Member States lead to differences in terms of the frequency of controls and inspections, different interpretation by Member States of the legislation and lack of guidance documents and/or harmonised analytical methods for testing. All of this affects the implementation of the CLP Regulation and other EU chemicals legislation (for example, on plant protection products and on food contact materials).

In terms of **efficiency**, the question is whether the costs and benefits stemming from the implementation of the EU legislation on chemicals, and more particularly its CLP aspects, are proportionate. The fitness check notes that it was not possible to give a direct answer to this question, but underlines that the implementation of the EU chemicals legislation has brought both significant benefits and costs. The main benefit drivers are the avoided suffering and premature deaths, healthcare costs, productivity losses (due to avoided lost working hours resulting from illness or premature death), remediation costs (including drinking water and wastewater treatment costs) and degradation of environmental services. While the main drivers of costs for the industry depend on the specific piece of legislation examined, they are generally linked to activities such as generation and maintenance of data on hazards, chemical uses and exposure; training of staff; the exercise of control, etc. The main costs for public authorities (at both EU and national level) are associated with their enforcement and monitoring activities.

The CLP Regulation was identified as one of the most efficient elements of the EU legislative framework on chemicals. In particular, it ensures hazard classification of a wide range of chemicals without creating a disproportionate administrative burden for public authorities. As regards benefits, it is noted that since 2008, the implementation of the CLP Regulation has led to benefits such as avoided healthcare costs and avoided productivity losses (lost working hours and income). These benefits result from the reduced number of poisoning incidents, cases of occupational skin and respiratory diseases and occupational cancers, and range from €217 million to €338 million per year. The fitness check assesses that the implementation of the CLP Regulation generates on-going annual regulatory costs for the EU industry ranging from €0.97 million to €1.7 billion. Enforcement costs at national level were impossible to quantify. ECHA's average costs for implementing the CLP Regulation – by providing guidance, running helpdesks, overseeing committees and forums, etc. – amount to approximately €2.57 million per year.

In the context of efficiency, the fitness check identifies a few implementation aspects that warrant improvements. A first issue concerns the 'substance-by-substance' approach, which is predominantly applied to risk assessment and risk management. While it is efficient in identifying the hazards of a specific substance and the risk from the situation in which it is used, in some cases it can limit the efficiency of risk assessment. Therefore, grouping approaches to identify and assess the risk associated with groups of chemicals with similar hazard and risk profiles are needed to speed up risk management and avoid 'regrettable substitutions'.¹⁰

Another efficiency issue concerns the risk of duplication of the work done by different EU agencies and committees providing hazard/risk assessment and scientific advice. The fitness check notes that their current setup could be simplified and their activities streamlined, which would generate

efficiency gains (such as avoiding the duplication of efforts) and more reliability (such as lower risk of potentially diverging outcomes of hazard risk assessments).

Although the various pieces of EU chemicals legislation analysed by the fitness check do not have entirely the same objectives, the approaches they apply to achieve their stated objectives are generally **coherent**. The CLP Regulation ensures the coherence of chemical hazard assessment and classification at EU level with developments at international level, notably the UN GHS. The regulation serves as a horizontal reference point for most of the EU chemicals and chemicals-related legislation and thus ensures a high degree of consistency of chemical hazard identification and classification.

The fitness check highlights inconsistencies for substances that have ED, PBT and vPvB properties, and substances fulfilling the classification criteria for specific target organ toxicity. These inconsistencies are the result of different risk management decisions taken under the different pieces of EU chemicals legislation. The potential benefits of introducing new hazard classes in the CLP Regulation – such as terrestrial toxicity, neurotoxicity, immunotoxicity, endocrine disruption, PBT and vPvB – need, as per 2019, to be assessed.¹¹

An issue in terms of coherence relates to vulnerable groups. In particular, the CLP Regulation does not refer to vulnerable groups, while pieces of EU chemicals legislation that do refer to vulnerable groups do not do it in a systemic way. For example, the PPP Regulation considers the following categories of people vulnerable: pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high pesticide exposure over the long term. Contrarily, the MRL Regulation considers children, the unborn, and vulnerable consumers to be vulnerable. This may potentially affect risk assessment and risk management. The fitness check warns though that the analysis 'did not come to a conclusion on the extent of the issue and if, in practice, risks to vulnerable populations are not sufficiently well addressed and managed because of these legislative gaps and inconsistencies'.

The fitness check assesses the **added value** of designing and implementing a chemical policy **at EU level** as high. As shown above, the harmonisation of chemicals legislation at EU level – of which the CLP Regulation is a main building block – is 'largely successful' in terms of its favourable effect on human health and environmental protection and the proper functioning of the internal market. The application of common rules and standards, coupled with the sharing of knowledge and resources across the EU, has led to 'significant positive economic, health and environmental impacts that would not have been possible to achieve on the basis of legislation at the Member State level alone'. The EU added value of the EU chemicals legislation, including the CLP Regulation, is also confirmed by the fact that, as mentioned, the EU standards serve as a reference point for the development of international standards.

Stakeholder consultation activities

The findings of the fitness check presented above are also based on a set of stakeholder consultation activities: an open public consultation (held between March and May 2016); an SME panel through the Enterprise Europe Network (held between May and July 2016); targeted interviews; stakeholder workshops conducted in the context of the externally prepared supporting studies; and two Eurobarometer surveys. The broad consultations gathered feedback¹² from the following stakeholder groups: national competent authorities in charge of implementation and enforcement; industry associations representing chemicals industry and downstream sectors (i.e. manufacturers and importers of chemicals, distributors of substances and mixtures, formulators), including small and medium sized companies; civil society organisations (such as NGOs in the field of environment, health and animal welfare); associations representing consumers; trade unions; academic and research bodies; and individual citizens.

Stakeholders were also consulted in the context of the Commission proposal for revision of the CLP Regulation. Stakeholders were first invited to send their feedback to the Commission's [inception](#)

[impact assessment](#) of the revision, published in May 2021. In support of the ex-ante IA accompanying the proposal for revision, the Commission collected stakeholders' feedback¹³ through an open public consultation (held between August and November 2021); a targeted stakeholder survey; three ad hoc meetings of the Competent Authorities for REACH and CLP ([CARACAL](#)) expert group (held in October and December 2021); and a set of interviews.

European Parliament

Resolutions of the European Parliament

In its [resolution](#) of July 2020 on the chemicals strategy for sustainability (adopted ahead of the Commission strategy of October 2020), the European Parliament welcomes the zero-pollution ambition for a toxic-free environment. It acknowledges the essential role of the chemicals sector in reaching the multiple targets of the European Green Deal, notably the zero-pollution ambition, climate neutrality, the energy transition, the promotion of energy efficiency and the circular economy, by offering innovative production processes and materials.

The European Parliament notes that studies commissioned by the Commission (including in the context of the fitness check discussed above) have identified important gaps in EU legislation on the safe management of chemicals, including inconsistencies at the level of sectoral legislation and insufficient implementation, and have outlined a broad set of measures that should be considered. It noted further that these gaps and inconsistencies require legislative action to ensure the effective protection of human health and the environment against the risks posed by chemicals. As regards the CLP Regulation in particular, the Parliament calls on the Commission to rapidly implement the recommendations of the fitness check and to introduce new hazard classes (for example, for EDs, terrestrial toxicity, neurotoxicity, immunotoxicity, PBTs and vPvBs) in the regulation and, in parallel, in the UN GHS.

The European Parliament also considers that the upcoming (as per July 2020) strategy should achieve coherence and synergies between the EU chemicals legislation (for example, the regulations on CLP, REACH, persistent organic pollutants, mercury, plant protection products, MRL, biocides, and the OSH legislation) and related EU legislation, including specific product legislation (for example, on toys, cosmetics, FCM, construction products, pharmaceuticals, packaging and single-use plastic products), general product legislation (for example on eco-design, eco-label, sustainable product policy), legislation on environmental compartments (for example on air, water and soil), and legislation on sources of pollution, including industrial installations (for example, the Industrial Emissions Directive and the Seveso III Directive¹⁴) as well as legislation on waste (for example, on the restriction of the use of certain hazardous substances in electrical and electronic equipment and end-of-life vehicles). The resolution calls for the strategy to be applied to significantly improve the implementation of the REACH Regulation with regard to registration, evaluation, authorisation and restriction, and for greater clarity on the REACH Regulation's interface with the OSH legislation and the CLP Regulation. The European Parliament stresses that the legislation on food contact materials (FCMs) should be revised in line with the CLP and REACH Regulations, in order to ensure a coherent, protective approach to the safety of materials and products that come into contact with food.

In its July 2020 resolution, the Parliament reaffirms its call made in a [resolution](#) of April 2019 on a comprehensive EU framework on EDs. In particular, it calls again for the adoption of a horizontal definition based on the WHO definition for suspected EDs as well as for known and presumed EDs in line with the classification of CMRs in the CLP Regulation; for data requirements to be revised accordingly; for the overall exposure of humans and the environment to EDs to be minimised effectively; for legislative proposals to be drawn up with a view to inserting specific provisions on EDs into the legislation on toys, FCM and cosmetics in order to treat EDs as CMRs; and for all the relevant legislation, including legislation on FCM, to be revised for the purposes of substituting EDs.

In a [resolution](#) of September 2018 on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation, the European Parliament 'calls on the Commission, with respect to the classification of waste streams, to clarify the correct interpretation of the CLP Regulation to prevent misclassification of waste containing substances of concern'.

Written questions of Members of the European Parliament

Since the entry into force of the CLP Regulation, Members of the European Parliament (MEPs) have submitted several written questions referring to various aspects of the regulation. Among others, the questions concern substances such as asbestos, titanium dioxide, synthetic amorphous silica and gallium arsenide. A 'European Toxicscore' on cleaning and disinfecting products (similar to the nutri-score labelling system applied in some Member States) has been [proposed](#) to facilitate EU consumers' reading and understanding of labelling. Essential oils have been a frequent issue in the questions put forward. An example is given below.

[Written question](#) submitted by Aldo Patriciello, Salvatore De Meo, Herbert Dorfmann, Massimiliano Salini, Fulvio Martusciello, Isabella Adinolfi, Lucia Vuolo, Andrea Caroppo (EPP/Italy) on 29 June 2022

The question refers to essential oils, which, according to the authors, are 100 % natural plant or fruit extracts derived through distillation or by squeezing the outer shell of the fruit. It is noted further that essential oils are classified as complex natural substances. It is stated that, in the context of the revision of the CLP Regulation, the Commission envisages that the hazardousness of these substances would be determined on the basis of their components, without assessing the substance as a whole. Owing to its natural origin, an essential oil consists of components that cannot be eliminated, as might be possible with, for example, a synthetic blend. Recent scientific data shows that the effects of an essential oil, assessed as a whole, differ markedly from the sum effects of its individual components. The safety of an essential oil therefore needs to be assessed on the basis of the essential oil as a whole, in order for regulatory measures to be proportionate. Against this background, the specific question is: can the Commission say whether it would be possible to analyse essential oils in their entirety when assessing hazards, rather than viewing them as a mere blend of their parts?

(Joint) [answer](#)¹⁵ given by Mr Breton on behalf of the Commission on 2 September 2022

In its answer, the Commission notes that under the CLP and REACH regulations, 'a chemical substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process'. As such, essential oils can be considered chemical substances under the applicable legislation. The Commission underlines that this approach is not expected to change under the forthcoming (as per September 2022) revisions. It is noted further that the revision of the CLP Regulation aims to complement existing hazard classes with new ones, and the Commission does not intend to derive a classification of a multi-component (complex) substance, such as lavender oil, based on the exhaustive hazard identification of all its components. In the context of the revision of both the CLP and REACH regulations, the Commission will continue to consult all relevant stakeholders about the possible impacts of the proposals, in particular for SMEs.

Citizens' enquiries and petitions

Individual EU citizens and their organisations are concerned about the impacts of chemicals on human health and the environment, including about different issues in the scope of the CLP Regulation and its implementation. For example, petitioners [alert](#) of incomplete or difficult-to-read labels developed as per the requirements of the CLP Regulation, and [request](#) the European Parliament to promote simple and clear information on EDs and suspected EDs on the labels of chemical products.

Council of the European Union

In March 2021, the Council adopted [conclusions](#) welcoming the chemicals strategy for sustainability. The document highlights that the synergistic application of the CLP Regulation and other relevant EU regulatory instruments (such as the REACH and Eco-label¹⁶ regulations, the Eco-design,¹⁷ Industrial Emissions, Waste Framework, Water Framework and OSH Framework directives, the sustainable products initiative) and relevant funds, is crucial for stimulating the production and use of chemicals, materials and products that are safe and sustainable already at the design stage. EU Member States' ministers recall the need to strengthen the EU legal framework in the area of EDs, which would make it possible to identify them swiftly in the framework of the CLP Regulation. Doing so would minimise exposure of humans and the environment to them, and ensure a high and coherent level of protection across legislation, especially for vulnerable population groups.

The Council stresses the need to involve the Member States closely in the development of the 'one substance, one assessment' approach and to maintain the Member States' rights under any legislation, in particular the REACH and CLP regulations, to initiate regulatory action. It also emphasises that this approach should not create delays in regulatory actions nor increase the administrative burden. The conclusions acknowledge that achieving the objectives and vision of the strategy requires changes to the relevant legislation, including the CLP and REACH regulations. The ministers underline the importance of the REACH Regulation for the risk assessment of chemicals and the central role of the CLP Regulation in the identification and hazard assessment of chemicals. In this context, the Council supports the announced strengthening of data requirements under the REACH Regulation, and the introduction of new hazard classes and criteria under the CLP Regulation, including for endocrine disruption and persistency in combination with either bio-accumulation or mobility, in order to address environmental concerns. The ministers request the Commission to promote the introduction, adaptation or clarification of criteria/hazard classes in the UN GHS in line with the intended revision of the CLP Regulation, in order to improve consistency, transparency and information exchange, and to level the playing field.

EU advisory bodies

In April 2021, the European Economic and Social Committee (EESC) adopted an [opinion](#) on the chemicals strategy for sustainability. The EESC supports the objective for a toxic-free environment and for ensuring that chemicals are produced in a way that maximises their positive contribution to society and reduces their impact on the environment. In order to facilitate the fulfilment of registration and regulatory risk management processes under the REACH and CLP regulations, the process should be simplified, or training for non-experts could be incentivised. The EESC notes the Commission's intention to propose new hazard classes and criteria in the CLP Regulation as a way to fully address environmental toxicity, persistency, mobility and bioaccumulation. It is important in this context that the evaluation of chemicals' adverse effects on the environment and the allocation of different hazard classes to chemicals be performed comprehensively and transparently. In particular, the classification criteria should be defined in detail in order to anticipate potential concerns about other products under development.

In May 2021, in relation to the chemicals strategy for sustainability, the European Committee of the Regions (CoR) adopted an [opinion](#) on safe and sustainable chemicals for a toxic-free environment in Europe's cities and regions. The CoR 'strongly' welcomes the strategy and calls for recognition of the importance of multilevel governance to link the goals and objectives of the chemicals strategy effectively to the green recovery of the EU economy. The opinion underlines that the national recovery and resilience plans represent an opportunity to use the potential of multilevel governance, including in implementing the chemicals strategy. Yet, attention has to be paid to a number of legal, financial and technical barriers faced by local and regional authorities in handling chemicals. The EESC notes the necessity of reviewing and strengthening the REACH and CLP

regulations, and their interface with the OSH legislation. Procedures under both regulations also need to be simplified.

ENDNOTES

- ¹ In general, the CLP Regulation applies to all industrial sectors. However, it does not cover radioactive substances and mixtures, cosmetics, medicines and certain medical devices, food and the transport of dangerous goods.
- ² However, only Member States can propose a revision of an existing harmonisation or submit proposals for CLH when the substance in question is an active substance contained in a plant protection/biocidal product.
- ³ Mixtures must always be self-classified before being placed on the market, as they are not subject to CLH.
- ⁴ Two 'key' studies were specifically prepared in support of the fitness check: a [study](#) on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation ('1st FC study') and a [study](#) supporting the fitness check on the most relevant chemicals legislation ('FC+ study'). The fitness check also used the findings of a [study](#) on cumulative cost assessment of the chemical industry ('CCA1 study') and a [study](#) on the cumulative health and environmental benefits of chemical legislation ('CuBA study'). All four studies were published in 2017.
- ⁵ These three objectives are defined by the Commission for the purposes of the fitness check. While the Commission wording does not exactly repeat Article 1 of the CLP Regulation – in particular, it does not mention enhanced innovation and competitiveness as an explicit objective of the regulation – it does correspond to the purpose and scope of the regulation.
- ⁶ The fitness check refers to the 'industry, NGOs, government authorities, other civil society representatives, etc.'.
- ⁷ It is noted that the decrease in the share of global sales mainly results from the relative growth in other parts of the world, such as China and India, which are served by their own production.
- ⁸ This concerns in particular EU competitors such as China, South Korea and India, which are introducing or aligning (as per 2020) their existing legislation to the EU regulatory model and standards for chemicals risk assessment and risk management.
- ⁹ In particular, 45 % of the respondents in the relevant Eurobarometer survey indicated that they are well informed about the potential dangers of chemicals in products.
- ¹⁰ 'Regrettable substitutions' are cases where a banned or restricted hazardous substance is substituted by a substance which is just as hazardous, or can be less toxic but with a greater release potential. Such substitutions are associated with costs for the industry and society in terms of health and environmental impacts.
- ¹¹ As a matter of fact, the impact of adding these new hazard classes has been assessed in the framework of the ex-ante impact assessment accompanying the proposal package for the revision of the CLP Regulation.
- ¹² A summary of the collected stakeholder views is available in Annex 2 to the fitness check.
- ¹³ A summary of the consultation activities is available in Annex 13 to the ex-ante IA (SWD(2022) 435 final, [part 3/5](#)).
- ¹⁴ [Directive 2012/18/EU](#) on the control of major-accident hazards involving dangerous substances
- ¹⁵ The Commission answer also addresses a similar priority written [question](#) submitted by a group of several Renew Members.
- ¹⁶ [Regulation \(EC\) No 66/2010](#) on the EU Ecolabel
- ¹⁷ [Directive 2009/125/EC](#) establishing a framework for the setting of ecodesign requirements for energy-related products

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