

ECHA-15-FS-02-EN

ECHA and the EU's legislation on chemicals

Improving the safe use of chemicals



The EU has the world's most ambitious legislation to ensure the safe use of chemicals.

As a result of this legislation (REACH and CLP), the chemical industry has made previously unseen amounts of information available on the chemical substances in use throughout Europe. This information relates to the impact of chemicals on human health and environment, and also on how to use them safely.

The Biocidal Products Regulation improves the functioning of the biocidal products market in the EU. The Prior Informed Consent Regulation controls the export and import of certain hazardous chemicals.

The European Chemicals Agency (ECHA) implements these four pieces of legislation for the protection of human health and the environment.

REACH

REACH stands for the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **ch**emicals.

Chemicals cannot be used in Europe unless they have been registered. To date, European manufacturers and importers have registered the most hazardous chemicals and those produced in large volumes. Lower volumes have to be registered by 2018. Any new chemicals have to be registered before they are manufactured or placed on the market.

ECHA receives and evaluates individual registration dossiers for their compliance with the law, and the EU Member States evaluate selected substances to clarify any concerns they may have for human health or for the environment.



REACH places the responsibility for chemical safety on industry but it also brings opportunities for innovation.

Information on chemicals freely available

ECHA publishes the information from the chemical registration dossiers on its website – with the exception of commercially confidential data. The website provides information on the substance itself, its hazards, and guidance on how to use it safely. The amount of information is constantly increasing, making it a unique source of information on chemicals in the world.

Manufacturers and importers use the information to ensure the safe use of chemicals. They communicate safety information to users who can then identify the risks in the work place and apply the most efficient risk management measures. Consumers can use the information to find out more about chemicals in the products they buy.

The information is used by authorities to identify chemicals that need additional controls or restrictions because of their hazards. Also national enforcement authorities use the information from registration dossiers when they make onsite inspections and check that proper risk management measures are in place.

Sharing information to avoid unnecessary testing on animals

Companies that manufacture the same chemical have to work together to exchange information. This exchange of information is required by law to avoid unnecessary testing on animals and to minimise costs for companies. Where data does not exist, testing on animals must only be done as the last resort and therefore, alternative methods of assessing the hazards of chemicals are encouraged.

Furthermore, when industry proposes to test a chemical on vertebrate animals, ECHA publishes the proposal on its website. Anyone with relevant information on the proposed test on the substance can submit it to ECHA. If such information is identified, the testing on animals can be avoided.

Managing substances of concern

REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks posed by the substances they manufacture and market in the EU.

They have to demonstrate to ECHA how the chemical can be used safely, and they must communicate the risk management measures to the users of the chemical.

If the risk management recommended by industry in a registration dossier is not considered sufficient, the EU can take steps to further control the risks of the chemical, for example by restricting its use or by requiring companies to get prior authorisation before using it.

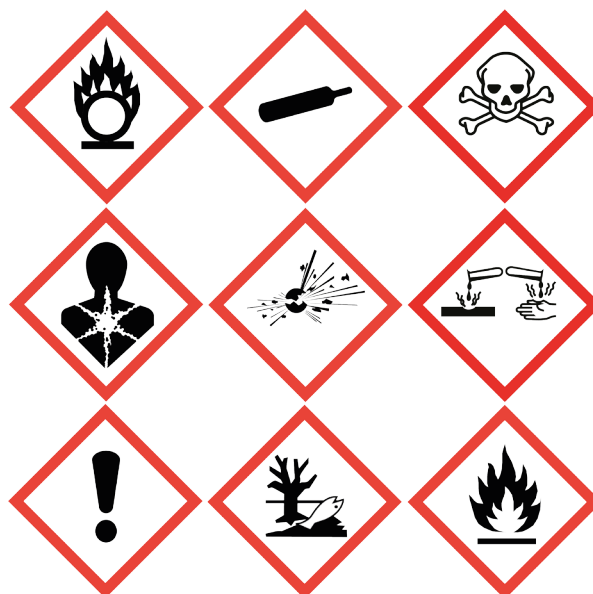
Substances that may have serious effects on human health and the environment can be identified as substances of very high concern (SVHCs), and added to the Candidate List. As a next step, these substances can move to the Authorisation List. This means that, after a given date, companies will not be allowed to place the hazardous substance on the market or to use it, unless they have prior authorisation to do so. The authorisation process aims to substitute these SVHCs with safer alternatives.

CLASSIFICATION AND LABELLING

The EU Regulation on the Classification, Labelling and Packaging of substances and mixtures (CLP) also aims to protect human health and the environment as well as enable the free movement of substances throughout Europe. It integrates the chemical classification criteria of the United Nations' Globally Harmonised System into EU law.

Companies need to notify ECHA of the classification and labelling that they use for their substances. ECHA has received millions of these notifications for more than 100 000 substances. The notification is done for all substances that need to be registered under REACH.

Member States and industry can propose that the classification and labelling of a hazardous substance should be harmonised across the EU. This harmonised classification then ensures that all companies are providing their customers with the same information. An opinion from ECHA's Committee for Risk Assessment, preceded by a public consultation, forms the basis for the European Commission's decisions on harmonisation.



The Classification, Labelling and Packaging Regulation introduces new pictograms.

BIOCIDAL PRODUCTS

Biocidal products are used to protect humans and animals from pests and harmful micro-organisms. They include, for example, insect repellents, wood preservatives and disinfectants.

The Biocidal Products Regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment. The most hazardous active biocidal substances are assessed before approval and the biocidal products containing them are also assessed before they are authorised to be placed on the market. This is to reduce the number of carcinogens, mutagens and toxic substances on the market. If the active substance is identified as one which should be substituted by something less hazardous, it can only be authorised in a biocidal product if no safer alternatives are available.

All biocidal products must get authorisation before they can be placed on the market. Producers of biocidal products can apply for a product authorisation in one country or for an authorisation that covers all EU Member States.

PRIOR INFORMED CONSENT

The regulation on Prior Informed Consent sets guidelines for the export and import of hazardous chemicals. It implements, within the European Union, the Rotterdam Convention to control hazardous chemicals and pesticides in international trade. It places obligations on companies who wish to export these chemicals to non-EU countries. Receiving countries are informed in advance when hazardous chemicals are about to enter their country. They can then reject the import.

SCIENTIFIC EXPERTISE AND REGULATORY EXCELLENCE

ECHA's scientific committees bring together experts from all EU Member States. The Committee for Risk Assessment and the Committee for Socio-economic Analysis prepare ECHA's opinions related to the risks of substances and the socio-economic impact of risk management actions on hazardous chemicals.

The Member State Committee provides opinions and resolves differences of opinion among Member States. The Biocidal Products Committee prepares opinions under the Biocidal Products Regulation.

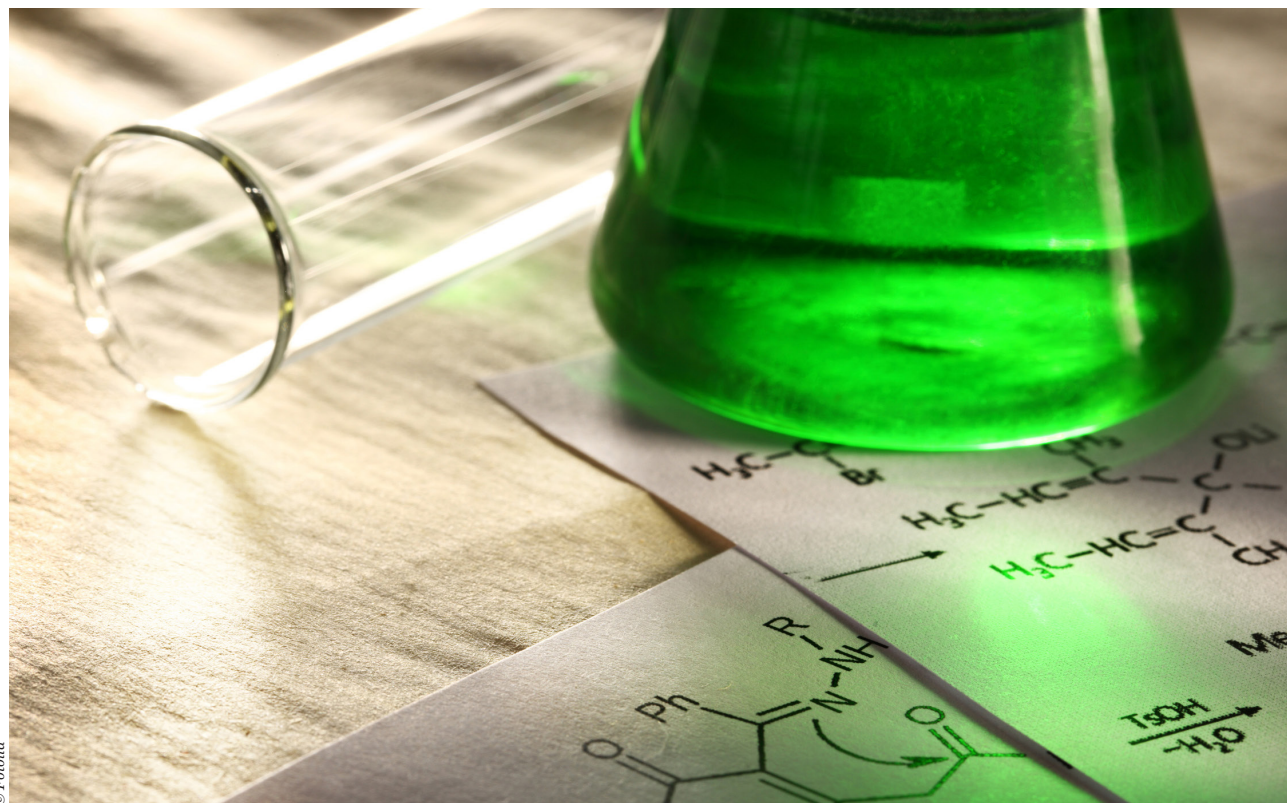
The Forum for the Exchange of Information on Enforcement coordinates the enforcement of the legislation on chemicals across Europe.

SUPPORTING INDUSTRY

ECHA supports industry by publishing information and guidance in 23 EU languages. The Agency provides Helpdesk services together with the EU/European Economic Area Member States and organises events, workshops and webinars.



echa.europa.eu/regulations



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