

REACH

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Background: Regulation (EC) No 1907/2006 – Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a regulation of the European Union (EU), adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals. In doing so, it promotes alternative methods for the hazard assessment of substances to reduce the number of tests on animals. This regulation went into force in 2007 and its provisions have been phased-in over 11 years.

The REACH regulation places responsibility on industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and to register the information in a central database in the European Chemical Agency (ECHA) in Helsinki. The Agency is the central point in the REACH system: it manages the databases necessary to operate the system, co-ordinates the in-depth evaluation of suspicious chemicals and is building up a public database in which consumers and professionals can find hazard information.

The regulation calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

One of the main reasons for developing and adopting the REACH Regulation was that many substances have been manufactured and placed on the market in Europe for many years, sometimes in extremely high amounts, and yet there is insufficient information on the hazards that they pose to human health and the environment.

Regulation: REACH applies to all chemical substances, commercial and household, including cleaning supplies, paints, and articles such as clothes, furniture, and electrical appliances. There are no companies across the EU that are not impacted by this regulation.

REACH impacts on a wide range of companies across many sectors, even those who may not think of themselves as being involved with chemicals. In general, under REACH you may have one of these roles:

- **Manufacturer:** If you make chemicals, either to use yourself or to supply to other people (even if it is for export), then you will probably have some important responsibilities under REACH.
- **Importer:** If you buy anything from outside the EU/EAA, you are likely to have some responsibilities under REACH. It may be individual chemicals, mixtures for onwards sale or finished products.
- **Downstream users:** Most companies use chemicals, sometimes even without realizing it, therefore you need to check your obligations if you handle any chemicals in your industrial or professional activity.
- **Companies established outside the EU: If you are a company established outside the EU, you are not bound by the obligations of REACH, even if you export their products into the customs territory of the EU. The responsibility for fulfilling the requirements of REACH, such as registration, lies with the importers established in the EU, or with the only representative of a non-EU manufacturer established in the EU.**

REACH places the burden of proof on companies. To comply, companies must identify and manage the risks linked to the substance they manufacture and market in the EU. If the risks cannot be managed, authorities can restrict the use of substances in different ways.

There are four parts to the implementation process:

- Registration
- Evaluation
- Authorization
- Restrictions

Registration: All manufacturers and importers of chemicals have a general obligation to submit a registration to the European Chemicals Agency for each substance manufactured or imported in quantities of 1 ton or more per year per company. In the registration dossier, they must identify the risks that are linked to the substances they produce and market and indicate how these risks are managed. This obligation applies to substances as such and in mixtures. A special registration regime applies for substances in articles (e.g., manufactured good such as cars, textiles, electronic chips). Without registration, substances cannot be manufactured or imported into the EU.

Evaluation: ECHA (European Chemicals Agency) and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing

proposals and to clarify if a given substance constitutes a risk to human health or environment. Extensive information on the evaluation process, procedures and on the final decisions, as well as recommendation to registrants and the annual evaluation reports can be found on ECHA's website (<https://echa.europa.eu/>).

Authorization: Substances of very high concern will be gradually identified and placed on a Candidates list. Once on that list, they cannot be placed on the market or used unless the company is granted an authorization.

Restrictions: REACH includes a restriction process for certain substances of very high concern if they pose an unacceptable risk to health or the environment. Such substances may be limited or even banned, if necessary. The restriction is designed to manage risks that are not addressed by the other REACH processes or by other legislation.

Author's Note: The preceding article is intended to summarize the EU legislation called REACH. For more detailed, up-to-date, information, I would suggest you consult the ECHA website: <https://echa.europa.eu/>.



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