

WHAT IS EU-REACH?

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1 June 2007.

REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

In principle, REACH applies to all chemical substances; not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles such as clothes, furniture, and electrical appliances. Therefore, the regulation has an impact on most companies across the EU.

To comply with the regulation, companies have to identify and manage the risks linked to the substances they manufacture and market in the EU and submit dossier information to the European Chemicals Agency (ECHA). ECHA can restrict the use of substances if the risks cannot be managed.

Registration Process

To minimize animal testing and data fees for each registrant, REACH encourages data sharing among all registrants by the joint submission of registration data to the ECHA. The main principle of REACH is "one substance, one registration".

During a joint submission process, one of the members among the manufacturers of same chemicals nominate himself as the lead registrant. The lead registrant or the REACH consortium will do most of the work such as data collection, development of the technical dossier and the Chemical Safety Report (CSR), and submission of the joint registration dossier to the ECHA. Other co-registrants only need to pay the lead registrant or consortium a fee to refer to the joint registration dossier and then prepare the individual part of the registration dossier in IUCLID6.

SVHC substances

Substances fulfilling one or more of the criteria defined in Article 57 of the EU-REACH Regulation are identified as "Substances of Very High Concern" (SVHC) and placed in the "candidate list for authorization." The candidate list is reviewed twice a year. Currently, it comprises 224 substances.

WHAT ARE YOUR OBLIGATIONS UNDER EU REACH?



Manufacturers

- ✓ Provide information to authorities
- ✓ Advise your customers on how to use your chemicals safely
- ✓ Comply with the registration process
- ✓ Provide extended safety data sheets to your customers
- ✓ Use the appropriate hazard labels on your products
- ✓ Grant access to information to your own workers and their representatives



Importers

- ✓ Import from a non-EEA country – the same responsibilities as manufacturers (e.g. substance registration)
- ✓ Import of hazardous substances or SVHC – comply with additional specific labelling and packaging requirements
- ✓ Import of SVHC substances for use in articles - provide sufficient information to your customers to allow safe use of the product



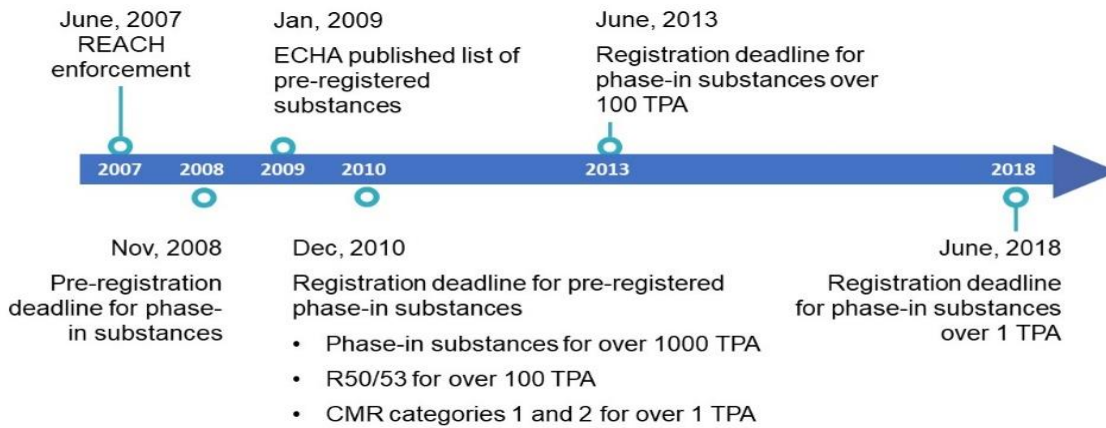
Only Representatives

- ✓ The same obligations as an importer and additional requirements specific to the role as an only representative



Downstream users

- ✓ Some responsibilities might apply to downstream users under EU REACH



How can Only Representative (OR) help you:

REACH requires all companies manufacturing or placing a substance on the EU market in quantities greater than 1 TPA to register with the ECHA. For non-EU companies, registration may be submitted via an EU-based Only Representative (OR) who registers on their behalf. Benefits of appointing an OR include relieving the obligations of the importers, avoiding dependency on a single importer to access the EU market, and gaining advantages compared to other non-EU suppliers. Here is a list of compliance obligations that an OR can assist with:

- Submission of registration data (company identity, annual tonnage, etc.) to the ECHA through REACH-IT.
- Representing the non-EU company in SIEF/Consortium after pre-registration and keeping them informed of the latest progress of the SIEF/Consortium.
- Preparation of the Technical Dossier (robust study summary)
- Preparation of Safety Data Sheets (SDSs) or distribution of SDSs along the supply chain.
- Communication with the EU importers and regulatory authorities and issuance of necessary documents to ensure REACH compliance.
- Preparation of Chemical Safety Assessments
- Provide compliance training and advice

OBLIGATIONS RELATED TO SVHC SUBSTANCES:

- Importers and producers of articles will have to notify the ECHA if their article contains SVHC. Suppliers of substances on the candidate list must also provide their customers with a safety data sheet (SDS).
- Suppliers of articles containing a candidate list substance above a concentration of 0.1 % (weight by weight) will also need to notify the Substances of Concern in Products (SCIP) database under the waste framework Directive.



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