# **REACHing Out**

## The REACH Regulation and New Developments for Chemicals at a Glance

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The increased political focus on climate and environmental protection has a particular impact on trade with chemicals. In an amendment to the REACH Regulation at the end of 2024, the European Commission banned the use of certain chemicals due to the risk of contamination. In this part of our ESG Briefing series, we provide an overview of the key provisions of the REACH Regulation and its latest amendments.

### What is the REACH Regulation?

The <u>REACH Regulation</u> is the European Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. It is a comprehensive regulatory instrument for chemicals that obliges manufacturers, importers and users of chemicals to collect information on chemical substances and assess their risks. Its main objective is the general and far-reaching improvement of chemical safety for humans and the environment in the European Union. Due to its high level of detail and wide scope of application, it is regarded as one of the strictest regulatory frameworks for the handling and trading of chemicals in the world.

#### **Registration Obligations**

Chemical substances that are manufactured or imported in quantities of one tonne or more per year must be registered in a central database managed by the <u>European Chemicals Agency</u> (*ECHA*). Without registration, the substance may neither be manufactured nor placed on the European market (so-called "no data, no market" principle). A technical dossier containing a range of information on the chemical must be submitted as part of the registration process. This includes, *inter alia*, information on the manufacturer or importer, the identity of the substance, the use of the substance and the classification of the substance.

#### **Effects of REACH on the Supply Chain**

In addition to the registration obligations of the manufacturer or importer vis-à-vis the ECHA, there are also various information obligations in the relationship between the supplier and the recipient of a substance. In many cases (e.g. if the substance is classified as hazardous according to the <u>Chemicals Regulation</u>), the supplier must provide the recipient with a safety data sheet containing detailed information on the substance. Mandatory sections to be included are, for example, possible hazards, measures in case of accidental release, handling and storage as well as physical and chemical properties.

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#### **Authorisation and Restrictions**

In addition to the registration obligation, an authorisation obligation applies to the substances of very high concern (*SVHCs*) listed in Annex XIV of the REACH Regulation. The authorization process aims to properly control the risks posed by such substances and progressively replacing them with suitable alternatives. In general, authorization is a prerequisite for placing SVHCs on the market. While applications for authorisation must be submitted to the ECHA, it is the responsibility of the EU Commission to decide on authorisations. Authorisation shall be granted if the risks posed by the use of the substance to human health or the environment are adequately controlled. Furthermore, it may be granted if it can be shown that the socio-economic benefits outweigh the risks and if there are no suitable alternative substances or technologies.

For certain dangerous substances, restrictions on the manufacture, placing on the market and use apply. Restrictions serve to prevent an unacceptable risk to human health or the environment arising from substances of very high concern. Restrictions may include, a limitation on the use or even the prohibition of substances to be placed on the market.

#### What's New?

The European Commission has recently restricted the use of undecafluorohexanoic acid (*PFHxA*) and *PFHxA*-related substances under the *REACH* Regulation (see <u>press release</u>). These chemicals qualify as per- and polyfluoroalkyl substances (*PFAS*) which, as so-called "forever chemicals", cannot be broken down in the natural environment. They are viewed particularly critical due to their high mobility in water against the background of numerous cases of soil and water contamination. The restriction bans the use of *PFHxA* chemicals in food packaging, consumer textiles and shoes, consumer mixtures and cosmetics, among other things. The regulations will start to apply from 10 October 2026.

#### **Consequences in Case of Non-Compliance**

If the various obligations under the REACH Regulation are violated, there is a risk of severe consequences. Infringements relating to the core obligations such as authorisation, registration or chemical safety reports are punishable by imprisonment of up to five years or a considerable fine.

BLOMSTEIN is closely following developments in connection with the REACH Regulation. Florian Wolf, Ramona Ader, Ines Florinde Horn and Hanna Sophie Kurtz will be happy to answer any questions you may have about the potential impact on your company.

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