REACH
Registration, Evaluation, Authorisation and Restriction of Chemicals

REACH - What is it?

REACH is the European Chemicals Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals. It has been in force since 2007 and aims to ensure a high level of protection for human health and the environment. It aims to ensure the free circulation of chemicals on the internal market while enhancing competitiveness and innovation. REACH is based on the principle that manufacturers, importers and downstream users take responsibility for their chemicals: They must ensure that the chemicals they produce and place on the market are used safely. REACH is considered one of the most stringent chemicals laws in the world.

Why REACH?

REACH builds on the experience gained from previous chemical legislation. Under the previous law, official authorities had to check the safety of chemicals. There was no systematic information available about most of the chemicals on the European market, i.e. on chemicals that had been in circulation before 1981. Manufacturers were only obliged to provide information when an evaluation by authorities had proven gaps in knowledge about the chemical, or there was evidence of potential harm to the environment or human health. The process turned out to be slow and cumbersome. REACH is intended to remedy this situation. Manufacturers and importers of chemicals must now provide information with the obligatory registration and carry out their own evaluations of associated risks. Chemicals may not be placed on the market without registration.

Implementation of REACH

Registration:
The core task of manufacturers and importers of chemicals is to evaluate chemical substances and register them with ECHA (European Chemicals Agency). Chemical registration takes place in three phases. The first phase ended in November 2010, the second phase ran until November 2013, and the third phase was to be completed in mid-2018.

1. Which substances have to be registered?

All substances manufactured in a volume of one ton or more per year and imported. If the substance is not registered, this means that it may neither be manufactured nor imported. For substances that had already been traded on the European market when REACH came into effect (phase-in substances), the implementation was to take place gradually. The registration deadlines are linked to the quantities per manufacturer/importer.

In concrete terms, this means:

For high-volume substances from 1000 t/a, CMRs from 1 t/a and substances dangerous for the environment with classification N, (R50-53) from 100 t/a, the obligation to register ended 3.6 years after entry coming into effect (i.e. on 1 December 2010).

For substances from 100 t/a the registration period ended 6 years after the coming into effect (01 June 2013).

For substances below 100 t/a, the registration period ended 11 years after entry into force (01 June 2018).

2. Which substances do not need to be registered?

A large number of substances on the market are not subject to REACH and are therefore exempt from registration.

These are in detail:

Radioactive substances, substances subject to customs control and non-isolated intermediate products; substances in waste; substances used in medicinal products or as food additives; substances under REACH Annex IV (e.g. water, certain sugars, natural oils, fatty acids); substances under REACH Annex V (e.g. certain reaction products, minerals, coal, crude oil, natural gas); already registered reimported or recovered substances; polymers (provisionally). Considered as already registered:

Active substances in plant protection agents and biocidal products; substances notified under Directive 67/548/EEC (Notification of New Substances).

Special rules apply to: product and process oriented research and development for isolated intermediates.

Evaluation:

The authorities' task is to evaluate company registrations. 5% of all registration dossiers are checked for quality. In addition, the authorities assess selected chemicals for substances of very high concern, and risks to humans or the environment. Substance evaluation is an important instrument of the REACH Regulation. The EU Member States are responsible for substance evaluation. In Germany, three higher federal authorities share this task:

The Federal Institute for Occupational Safety and Health (BAuA) is the coordinating body and responsible for protection at the workplace.

The German Federal Institute for Risk Assessment (BfR) is responsible for consumer and health protection.

The German Environment Agency (UBA) is responsible for environmental protection aspects.

During substance evaluation, the authorities check the registrations and substance safety evaluations of the responsible companies. They decide whether further investigations are necessary, whether the risk management measures described by the companies are appropriate or whether further regulatory measures are necessary to protect the environment or health. In 2012, the EU member states processed 36 substances for substance evaluation. Germany carried out five substance evaluations. In 2013 another seven from the new joint action plan.

Approval (Authorisation) and restriction:

With certain exceptions (e.g. pesticides), chemical substances are not subject to authorisation in the EU. REACH requires an authorisation requirement for substances of very high concern (SVHC). The authorisation requirement is primarily a general ban on use. Upon request, ECHA can issue an authorisation. For this purpose, the applicant must prove that the chemical's risks are controlled, or that the socio-economic benefit of the use is greater than the risk. There is also the possibility to prohibit or restrict the manufacture, placing on the market, or use of chemicals. Such regulation is called „Restriction".

What does authorisation mean?

Authorisation means the permission, regulated on a case-by-case basis, to handle a substance or object in a certain way. It is therefore an approval procedure.

What is the aim of the authorisation?

The aim of authorisation is to ensure that the risks posed by substances of very high concern are adequately controlled or that these substances are gradually replaced by suitable alternative substances or technologies, provided they are economically and technically viable. (Art.55). It is necessary for chemicals listed in Annex XIV of the REACH Regulation. With the inclusion in Annex XIV, an authorisation for each use must be applied for. The EU Commission decides on an authorisation. ECHA provides guidelines for the preparation of an application for authorisation.

Authorisation procedure

There is a complex process before being included in Annex XIV. As a first step, an EU Member State or ECHA proposes the inclusion in Annex XIV with the Annex XV dossier. ECHA publishes the dossier on its homepage and enables public commenting on the Internet. Comments and possible questions will be answered by the Member State or ECHA. ECHA then asks the Member State Committee whether the substance meets the criteria of very high concern. If the Committee unanimously confirms this, ECHA will include the substance in the list of substances that could be considered for inclusion in Annex XIV („Candidate List"). If the Committee does not vote unanimously, the EU's regulatory procedure (Council Decision 1999/468/EC of 28 July 1999, Art. 5 and Art. 7) shall apply.

With its inclusion in Annex XIV, the substance is subject to an authorisation requirement. On the one hand, this is intended to prevent or minimise as far as possible the substance's entry into the environment. On the other hand, the search for less dangerous alternative substances is to be expedited.

ECHA prioritises these substances on the candidate list in accordance with Article 58 of the REACH Regulation, and proposes the substances to the Commission for inclusion. The first recommendation was published by ECHA on 01 June 2009. It was recommended to include 5-tert-butyl-2,4,6-trinitro-xylene, 4,4′ diaminodiphenylmethane, the short-chain chlorinated paraffins (SCCPs), hexabromocyclododecane (HBCDD), bis(2-ethylhexyl)phthalate (DEHP), benzyl butyl phthalate (BBP) and dibutyl phthalate. These seven substances were listed in Annex XIV on xx.xx.2011. The substances listed in the second ECHA recommendation of 17 December 2010 were the next to be added. This list also included seven substances: diisobutyl phthalate (DIBP), diarsenic trioxide, diarsenic pentoxide, lead chromate, lead sulfo chromate yellow (C.I. pigment yellow 34), lead chromate molybdenum sulphate red (C.I. pigment red 104), tri-(2-chloroethyl)phosphate (TCEP) and 2,4-dinitrotoluene (2,4-DNT).

In addition to the authorisation procedure, the tried and tested instrument of restricting the manufacture and use of substances also continues to exist. A socio-economic analysis is to be included in the decision-making process in the future for both procedures. This analysis should help to make balanced decisions on the authorisation or prohibition of substances of concern that assess both the risks of a substance and the economic and social consequences of an intended regulation.

Responsible for implementation and compliance:

ECHA - European Chemicals Agency, Helsinki

Supported by the national authorities, in Germany:

BAuA - Federal Institute for Occupational Safety and Health, Dortmund

Source: German Environment Agency/vecco.de