

Regulatory compliance: REACH

Producers and importers may have obligations under REACH, the EU's principal regulation on chemicals. This document provides guidance on who needs to respond to the regulation and how.

What is REACH?

REACH is the primary EU Regulation on chemicals. REACH stands for: Registration, Evaluation, Authorisation and restriction of Chemicals. The regulation aims at ensuring a high level of protection of human health and the environment as well as the free movement of substances on their own, in preparations and in articles, while enhancing competitiveness and innovation.

The Regulation (EC) No 1907/2006 was adopted on 18th December 2006 and entered into force in 2007 and repeals a patchwork of EU and national regulations on chemicals by a single text. The European Chemical Agency (ECHA), based in Helsinki, oversees the implementation of the regulation together with the European Commission. REACH allows to assess hazards posed by chemical substances and develop risk management options which are then adopted by the European Commission. To assess hazards and manage risk, several tools are available under REACH.

Obligations for importers of final articles

Based on the REACH processes, producers or importers of final articles might have obligations. This will depend on several factors, notably whether the final article is produced in or outside the EU, and on the chemicals used in the final article. This section will look at situations that could reflect the position of most FTA members. In all cases communication obligations still apply, you can find more information [here](#).

1. The company produces final articles in the EU/EEA

A company producing final articles in the EU/EEA has limited responsibility but still needs to comply with restrictions that could apply to the product. The company is also not allowed to use substances subject to authorisation, unless it has applied for an authorisation for this specific use.

If the company producing in the EU/EEA imports substances or mixtures from outside the EU, those substances must be registered in the EU, if they are not then the responsibility to register them falls on the importer of the substance. **If a substance is not registered, it is not allowed on the EU market** (no data, no market principle).

Communication obligations apply to companies producing in the EU/EEA.

2. The company produces final articles outside the EU/EEA and imports them on the EU/EEA market

A company producing or importing final articles in the EU/EEA has limited responsibility but still needs to comply with restrictions that could apply to the product. The company is allowed to use substances subject to authorisation in the production process but has to notify the European Chemical Agency if it imports articles containing Substances of Very High Concern (SVHCs) at a concentration higher than 0.1% per article.

The European Chemical Agency has updated its guidance document on requirements for substances in articles, which can be found [here](#).



3. The company is a retailer that sells articles produced in or outside the EU/EEA to final consumers

A company that only sells final articles to consumers does not have to comply with any of the registration or notification obligations. However, under Article 33, retailers have a duty to communicate the presence of SVHCs in a concentration above 0.1% per weight by weight to a consumer upon request. This information shall be provided, free of charge, within 45 days of receipt of the request and should be sufficient to allow safe use of the article including, as a minimum, the name of that substance.



Communication on chemicals in supply chains

REACH puts the burden of proof concerning the safety of chemical substances and their use on the manufacturers, importers and downstream users. Communication in the supply chain is therefore a key element to achieving the safe use of chemicals.

Downstream users, such as manufacturers of articles, receive information for hazardous substances and mixtures in Safety Data Sheets (SDS) which may also have exposure scenarios in annexes if the substance is manufactured in quantities of over ten tonnes per year.

Downstream users should identify and apply recommended measures in the SDS to adequately control risk. It is also the responsibility of downstream users to inform suppliers when risk management measures identified in the safety data sheet are not appropriate.

Resources

You can find the text of the REACH Regulation (EC)1907/2006 by following this [link](#). Annexes are regularly updated and can be found [here](#).

The list of substances subject to authorisation (Annex XIV) can be found [here](#) and all restrictions adopted in the framework of REACH can be found [here](#).

ECHA provides guidance document on key aspects of REACH, follow the links below for more information on relevant guidance documents for FTA members:

[Guidance on requirements for substances in articles](#)

[Guidance for Downstream Users](#)

Overview of the main downstream user obligations under REACH:

- Identify the appropriate measures described in the safety data sheets you receive and apply them.
- If you receive an exposure scenario, or information sourced from one, check whether your current use is covered and whether you comply with the conditions described in it.
- If your use is not covered by an exposure scenario, communicate with your supplier with the aim of having your use covered by an exposure scenario, or take another action.
- Contact your suppliers if you have new information on the hazard of the substance or mixture, or if you believe that the risk management measures communicated to you are not appropriate.
- If you place substances or mixtures on the market (e.g. you are a formulator), or are a producer of articles, provide appropriate information to your customers to enable safe use.
- Comply with the obligations related to the authorisation or restriction of the substance that you use. Relevant information and conditions to be complied with are indicated by your supplier, usually in the safety data sheet.

Source: *Guidance for downstream users, Version 2.1, European Chemical Agency, October 2014*

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