



REACH

Registration, Evaluation, Authorization and Restriction of Chemicals

What is REACH?

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. REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to ECHA how the substance can be safely used, and they must communicate the risk management measures to the users. If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones. **REACH stands for Registration, Evaluation, Authorization and Restriction of Chemicals. It entered into force on June 1, 2007.**

How does REACH work?

REACH establishes procedures for collecting and assessing information on the properties and hazards of substances. Companies need to register their substances and to do this they need to work together with other companies who are registering the same substance. ECHA receives and evaluates individual registrations for their compliance, and the EU Member States evaluate selected substances to clarify initial concerns for human health or for

the environment. Authorities and ECHA's scientific committees assess whether the risks of substances can be managed. Authorities can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a use or make it subject to a prior authorization.

What is REACH's effect on companies?

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/EEA, you are likely to have some responsibilities under REACH. It may be individual chemicals, mixtures for onwards sale or finished products, like clothes, furniture or plastic goods.

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. You might have some responsibilities under REACH.

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 European Union. The responsibility for fulfilling the requirements of REACH, such as pre-registration or registration lies with the importers established in the European Union, or with the only representative of a non-EU manufacturer established in the European Union. As a practical matter, however, importers will be looking up their supply chain for the necessary information so they may register.

What is an article?

An article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition (Article 3(3)). ECHA guidance applied this definition to show a product made up of many parts to be interpreted as ONE article. Dissenting member states did not agree and made their own interpretation of “once an article, always an article.” This led to a requested ruling from the European Court of Justice (ECJ).

The question posed to the ECJ was “Where an **article** within the meaning of [the REACH regulation] is composed of several elements which themselves meet the definition of **article** given by the regulation, are the obligations resulting from Article 7(2) and Article 33 of the regulation to apply only with regard to the assembled article or with regard to each of the elements which meets the definition of **article**?”

The court ruling issued in **September 2015** provided that “the classification as an article remains applicable to any object meeting the criteria in Article 3(3) of the REACH Regulation and forming part of the composition of a complex product unless, following a production process, that object becomes waste or ceases to have the shape, surface or design which is more decisive in determining its function than its chemical composition.” The ruling aligned with the original dissenting member states opinions.

What contents of an article trigger reporting obligations under Reach?

Substances fulfilling one or more of the criteria in Article 57 may be identified as Substances of Very High Concern (SVHC). If a substance on the candidate list is contained in an Article it will trigger obligations under REACH if

- The substance is present at or above a concentration of 0.1% weight, and
- The total amount of the substance present in ALL articles imported and/or produced in the EU by that producer or importer in articles that meet the % requirements above or importer exceeds 1 tonne per year. (Note for goods made outside the EU, the importer must add all articles, including those from other non EU manufacturers to determine if the aggregate is met. It is NOT based on the aggregate produced by the non EU manufacturer to various EU customers).

Notification is based on the substance, not the article, and so a single article may trigger multiple notifications for each substance that meets the above criteria. The calculations are made separately for each substance in a given article.

Are there exemptions for certain substances?

If the substance in question has already been reported and registered for the same use (meaning in that specific article) it is exempt from further notification requirements.

A substance is also exempt from exposure if the producer or importer can exclude exposure to humans during normal or reasonably foreseeable conditions of use and disposal.

Why is REACH a concern for pool equipment and hot tub manufacturers?

Any pool product that meets the above criteria and is imported to the EU is affected by REACH. Because the term “article” was initially interpreted to refer only to a finished product, hot tubs were excluded from the requirements under REACH. Because all components are now considered separate articles, Hot Tubs are now affected, along with any other product that contains a component which meets the above criteria. This does not mean an OEM cannot sell their product within the European Union, but their EU customer/importer is now required to give notification of all substances contained in any of the articles/components which meet the above criteria.

What steps should my company take now?

Each OEM supplier should be reviewing the definition of articles as provided in “Article 3 (3) – Definitions – of the Regulation (EC) No. 1907/2006 (REACH)”, as there are exemptions from REACH the registration requirement. The source information can be found in the data available in the material safety datasheets (MSDS) of the raw materials. For example, fiberglass roving doesn’t contain substances of very high concern (SVHC) referring to the published list by European Chemical Agency (ECHA), updated on June 20, 2016, beyond the threshold concentration of 0.1% weight, but on the other side resins would fall under requirements needing compliance/declaration.

Does the ruling mean my company may be in immediate non-compliance?

The ruling was an interpretation of the regulation and not a change in the regulation itself, meaning there is no phase-in period. However, the European Enforcement Forum is actively cross-training on best practices for enforcement of substances of very high concern (SVHC) in articles through 2016 with a commitment to targeted enforcement in 2017.

Therefore, non-compliance with REACH may have a grace period of enforcement, but member states may still enforce when their interpretation has always been clear.

What do I need to do to be compliant?

If you import or produce products in the EU, then you are required to comply. If you distribute products to the EU, your customers will be looking to you for the necessary product information. For each subcomponent of the assembled article, you need a declaration/report from the supplier indicating which articles of that subcomponent contain at or over 0.1% candidate substances. Of those substances, which of them are SVHC compounds and at what concentration? What are the human exposure possibilities from that article and how is it to be disposed of at end of life?

OEMs then need to collate this information from all of their suppliers into a single document as well as final product exposure information. Then create safety information for use of the article. OEMs need to make this report available to distributors immediately as well make the report/information available within 45 days of a request by a consumer.

How do I determine if substances in articles need to be registered or not?

Guidance can be found at the following links and using the graphic that follows:

July 2016 draft guidance:

https://echa.europa.eu/documents/10162/13643/peg_sia_guidance_en.pdf/fe8f10c8-bbdf-430c-af7d-315d2f7be7ac

Webinar slides and recording: <http://assentcompliance-1.hs-sites.com/webinar-recap-reach-draft-guidance>

Nutshell guidance:

https://echa.europa.eu/documents/10162/13632/nutshell_guidance_csa_en.pdf

<https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/guidance-in-a-nutshell>

Other links of interest:

<http://echa.europa.eu/regulations/reach>

<http://echa.europa.eu/regulations/reach/understanding-reach>

<http://echa.europa.eu/addressing-chemicals-of-concern>

