

## WHAT IS REACH?

The European Union (EU) has, through its European Chemical Agency (ECHA), adopted regulation no.1907/2006, also known as the REACH (**R**egistration, **E**valuation, **A**uthorization and **R**estriction of **C**hemical Substances). This regulation became effective on June 1, 2007 and aims “to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances”.

## What is “CANDIDATE LIST”?

REACH requires all entities in the supply chain, exporting articles to the countries of the European Union, to identify the presence of Substances of Very High Concern (SVHCs). The Candidate List is a tabulation of such substances and the risk they pose. It is expected that the Candidate List will be updated periodically, at least annually.

In accordance with Article 33 of REACH regulation, suppliers of articles must communicate the presence of any Candidate List substances present in their product in a concentration of >0.1% by weight.

The first Candidate List of 15 substances was published on October 28, 2008. This list has been updated several times, with the latest update released on June 16, 2014. The updated SVHC Candidate List of 155 substances can be found at the URL below

<http://echa.europa.eu/candidate-list-table>

Companies manufacturing within or importing into the European Union 1000Kg/year or more of a substance on the candidate list must register the product with the European Chemical Agency (ECHA). Companies are also obligated to communicate the hazards of SVHCs to their employees and customers regardless of the quantity manufactured or imported. Synopses of all REACH requirements appear at the bottom of this document. For more comprehensive information and a better understanding of REACH regulation please visit the website of the European Chemical Agency (ECHA) and the European Commission at:

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

[http://ec.europa.eu/environment/chemicals/reach/reach\\_intro.htm](http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm)

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**REGISTRATION:** Companies have the responsibility of collecting information on the properties and the uses of substances that they manufacture or import at or above one tonne per year. They also have to make an assessment of the hazards and potential risks presented by the substance.

This information is communicated to ECHA through a registration dossier containing the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled.

Registration applies to substances on their own, substances in mixtures and certain cases of substances in articles. Chemical substances that are already regulated by other legislations such as medicines, or radioactive substances are partially or completely exempted from REACH requirements.

Registration is based on the "one substance, one registration" principle. This means that manufacturers and importers of the same substance have the obligation to submit their registration jointly. The analytical and spectral information provided should be consistent and sufficient to confirm the substance identity.

For substance registration a fee is usually charged.

**Authorisation:** The authorisation procedure aims to assure that the risks from Substances of Very High Concern are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the good functioning of the EU internal market.

Substances with the following hazard properties may be identified as Substances of Very High Concern (SVHCs):

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B in accordance with Commission Regulation (EC) No 1272/2008 (CMR substances)

- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII)

- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances

After a two-step regulatory process, SVHCs may be included in the Authorisation List and become subject to authorisation. These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation.

Manufacturers, importers or downstream users of a substance on the Authorisation List can apply for authorisation.

**Evaluation:** ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment.

Evaluation under REACH focuses on three different areas:

- Examination of testing proposals submitted by registrants
- Compliance check of the dossiers submitted by registrants
- Substance evaluation

Once the evaluation is done, registrants may be required to submit further information on the substance.

In line with Article 54 of the REACH Regulation, by 28 February of each year, ECHA has to publish a report on the progress it has made over the previous calendar year on its obligations in relation to evaluation. ECHA is specifically required to include recommendations to potential registrants to foster improvement in the quality of future registrations, in these reports.

**Restrictions:** Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market or use of a substance.

A restriction applies to any substance on its own, in a mixture or in an article, including those that do not require registration. It can also apply to imports.

A Member State, or ECHA on request of the European Commission, can propose restrictions if they find that the risks need to be addressed on a Community wide basis.

Anyone can comment on a proposal to restrict a substance. Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities. Comments are welcomed from the EU or beyond.

ECHA works with experts from the Member States to provide scientific opinions on any proposed restriction that will help the European Commission, together with the Member States, to take the final decision.