

REACH

REACH Regulation (EC) No. 1907/2006 is designed to manage and control the potential hazards and risks to human health and the environment from the manufacture, import and use of chemicals within the EU and at the same time enhances the competitiveness of European industry by fostering innovation. REACH is an acronym for the Registration, Evaluation and Authorisation of CHemicals. A fourth stage of REACH is restriction.

The REACH Regulation gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances. Enterprises which manufacture or import more than one tonne of a chemical substance per year will be required to register it in a central database administered by the new European Chemicals Agency (ECHA).

The Agency, which is located in Helsinki, acts as the central point in the REACH system. ECHA runs the databases necessary to operate the system, co-ordinates the in-depth evaluation of suspicious chemicals and runs a public database in which consumers and professionals can find hazard information. The Agency manages and in some cases carries out the technical, scientific and administrative aspects of REACH so as to ensure consistency at Community level in relation to these aspects. The Agency provides the Member States and the Institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals covered by the Regulation.

The Regulation also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

REACH came into force on 1st June 2007 however the main titles of REACH were enforced as from 1st June 2008.

The following Legal Notices implement the requirements of this Regulation:

1. The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulations, 2008 (*LN 61/2008*)
2. Registration, Evaluation, Authorisation and Restriction of Chemicals Enforcement (E-REACH) Committee Regulations, 2008 (*LN 207/2008 - Commencement Notice LN 90/2009*)
3. Chemicals Co-ordinating Committee (Repeal) Regulations, 2008 (*under the Environment Protection Act*)

REACH & Registration

Manufacturers and importers of substances have a general obligation to submit a registration to ECHA for each substance manufactured or imported in quantities of 1 tonne or more per year per company (legal entity).

This obligation applies to substances as such and in mixtures. A special registration regime applies for substances in articles (e.g. manufactured goods such as cars, textiles, electronic chips). However, certain substances are exempted from registration under REACH.

Exemptions under REACH:

http://guidance.echa.europa.eu/chemicals_covered_en.htm

Failure to register means that the substance cannot be manufactured or imported.

Further information on registration of chemicals:

http://guidance.echa.europa.eu/registration_en.htm

REACH & Evaluation

There are three types of evaluation under REACH:

- Dossier evaluation performed by the European Chemicals Agency;
- Substance evaluation performed by a Member State: to clarify any grounds for considering that a substance constitutes a risk to human health or the environment;
- Member States can also evaluate registered intermediates.

Further information on evaluation:

http://guidance.echa.europa.eu/evaluation_en.htm

REACH & Authorisation

Substances of very high concern (SVHC) will be gradually identified in the 'Candidate list'. These substances may have very serious and often irreversible effects on humans and the environment. Substances on the Candidate List may subsequently become subject to authorisation by decision of the European Commission and thus will be included in Annex XIV of the REACH Regulation. Once included in that Annex, they cannot be placed on the market or used after a date to be set (the so-called "sunset date") unless the company is granted an authorisation.

Substances are added to the Candidate List by ECHA. The Candidate List will be regularly updated when more substances are identified as SVHC.

Candidate list:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

The identification of a substance as SVHC and its inclusion in the Candidate List is the first step of the authorisation procedure. Companies may have immediate legal obligations following such inclusion, which are linked to the listed substance on its own, in preparations and articles.

Immediate legal obligations:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_obligations_en.asp

Further information on authorisation:

http://guidance.echa.europa.eu/authorisation_en.htm

REACH & Restrictions

REACH foresees a restriction process to regulate the manufacture, placing on the market or use of certain substances, either on their own or in mixtures or articles, within the EU territory if they pose an unacceptable risk to health or the environment. Such activities may be limited or even banned, if necessary. The restriction is designed to manage risks that are not addressed by the other REACH processes or by other Community legislation.

From 1 June 2009, Annex XVII of the REACH Regulation replaced Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States, relating to restrictions on the marketing and use of certain dangerous substances and preparations.

Restrictions of cadmium in jewellery, plastics and brazing sticks

The European Commission has banned cadmium in all jewellery products, plastics and brazing sticks from December 2011. High levels of cadmium have been found in some jewellery articles, especially in imported imitation jewellery. Consumers including children risked being exposed to cadmium through skin contact or through licking. The new legislation prohibits the use of cadmium in all types of jewellery products, except for antiques. The Commission has also banned cadmium in all plastics as from December 2011. The ban will protect the environment by reducing cadmium pollution. The new rules also promote the recovery of PVC waste for use in a number of construction products.

Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium):

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:134:0002:0005:en:PDF>

and, related Corrigendum of 24 May 2011:

<http://eur->

[lex.europa.eu/Notice.do?val=573231:cs&lang=en&list=573231:cs,572982:cs.&pos=1&page=1&nbl=2&pgs=10&hwords=](http://eur-lex.europa.eu/Notice.do?val=573231:cs&lang=en&list=573231:cs,572982:cs.&pos=1&page=1&nbl=2&pgs=10&hwords=)

More information on restrictions of chemicals:

http://echa.europa.eu/reach/restriction_en.asp

Questions and agreed answers concerning the implementation of Annex XVII to REACH on the Restrictions on the manufacturing, placing on the market, and use of certain dangerous substances, mixtures and articles:

http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/restr-faq-may-2011_en.pdf

REACH & Waste

Under REACH, waste is not considered as a substance and therefore most obligations do not apply to waste. Nevertheless, suppliers of chemicals must show that risks can be properly managed also in the waste life cycle stage.

Once recovered substances cease to be waste, they are again subject to REACH obligations but can also benefit from a number of exemptions. The Commission developed draft guidance on REACH and waste and recovered substances, which was handed over to ECHA for integration into ECHA guidance in 2009. During 2009 - 2010, ECHA carried out the review of the waste and recovered substances guidance document, which it adopted in May 2010.

Guidance on waste and recovered substances - This document describes under which conditions legal entities recovering substances from waste can benefit from the exemption laid down in article 2(7)(d) of REACH and elaborates the obligation to share information in the supply chain as put forward in title IV of REACH.

http://guidance.echa.europa.eu/docs/guidance_document/waste_recovered_en.htm?time=1310380429

Further information:

Further guidance on REACH can be found on the ECHA website:

http://echa.europa.eu/home_en.asp

REACH Legal Text:

http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/index_en.htm

Fees & Charges:

http://ec.europa.eu/enterprise/sectors/chemicals/reach/fees/index_en.htm

Nanomaterials:

http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm

Guidance Documents:

http://guidance.echa.europa.eu/guidance_en.htm

REACH-Events:

http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm

For any other information or advice you can always contact the REACH helpdesk at the RAD-TRD at MCCAA via the following email: helpdesk.msa@msa.org.mt