

## Fact file: the REACH Regulation

### What is it?

Regulation EC 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH). Adopted 18 December 2006.

### When does it take effect?

Entered into force on 1 June 2007. As a regulation it applies directly in all 27 EU member states without need for domestic implementing legislation.

### What does it do?

- ★ Reverses responsibility for assessing chemical risks onto manufacturers and importers, rather than regulators.
- ★ Introduces a “no data, no market” provision, prohibiting manufacture or placing on EU market of substances for which registration risk-assessment data packages have not been submitted. Owners of data are entitled to compensation for 12 years from others referring to their data.
- ★ Data generally must be derived under Good Laboratory Practice standards. Data generated through other international schemes such as OECD and High Production Volume will be admissible.
- ★ Requires specific authorisation for sale or use of substances that meet criteria identifying them as being of “very high concern”, listed in Annex XIV. First priority list of substances recommended for authorisation due by 1 June 2009.
- ★ Creates a publicly available candidate list of substances potentially earmarked for authorisation. This could be available as early as 1 June 2008.
- ★ Encourages data sharing for each substance under a “one substance, one registration” rule, with penalties for those who opt out.
- ★ Makes it mandatory to share data derived from vertebrate animal testing in order to minimise the amount of such testing necessary.
- ★ Creates a European Chemicals Agency (ECHA), established in Helsinki since 1 June 2007, to oversee implementation of the Regulation (<http://echa.europa.eu>)
- ★ Enables member states to restrict the manufacture, use or placing on the market of substances “when there is an unacceptable risk to human health or the environment... which needs to be addressed on a Community-wide basis”.
- ★ Allows ECHA and member states to carry out checks on registration data dossiers submitted

by industry and to evaluate priority substances more fully.

### To whom and what does it apply?

- ★ EU manufacturers and importers of substances whether on their own or in preparations.
- ★ Downstream users of registrable substances who will need to identify their uses to suppliers.
- ★ Between 30,000 and 100,000 substances.
- ★ Roughly 1,500 substances are thought likely to meet criteria making them “substances of very high concern”. Some 900 are known to exist already and another 600 are predicted to be identified as data for them are generated to meet the requirements of REACH.
- ★ Provisions on classification and labelling, authorisation and restrictions are applicable to all substances manufactured or placed on the EU market regardless of volume if dangerous
- ★ Registration requirements apply to substances manufactured or imported in quantities above one tonne per year. Registration is applicable per legal entity, which means that larger companies may register several times for each of their manufacturing or importing sites.
- ★ New substances and any that fail to be accepted as “phase-in” substances must meet registration requirements under REACH with immediate effect. The data to be submitted depend on the tonnage being produced or imported.
- ★ Substances that are proven to have been placed on the EU market or manufactured in the EU at least once in the 15 years prior to entry into force of the Regulation are eligible for “phase-in” registration deadlines, providing they are pre-registered (free of charge) in a six-month window from 1 June to 1 December 2008.

#### The extended deadlines are:

by 30 November 2010 for substances produced or imported in quantities above 1,000 tonnes per year;  
 by 31 May 2013 for substances above 100 tonnes per year; by 31 May 2018 for substances above 1 tonne per year.

- ★ A requirement to produce a chemical safety report containing risk management measures applies to substances manufactured or imported above ten tonnes per year per registrant.

#### Substances in articles are required to be:

- ★ registered if the substance is present in quantities above one tonne per producer or importer per year and the substance is intended to be released under normal conditions;

- ★ notified to ECHA if the substance meets criteria requiring it to be authorised and is on the candidate list for authorisation. This applies only if it is present in quantities above one tonne per producer or importer per year and the substance is present in those articles above a concentration of 0.1% weight by weight. It does not apply if the producer or importer can exclude exposure to humans or the environment during normal conditions of use including disposal and supplies appropriate instructions for safe use of the article.

### What are the exemptions?

- ★ Radioactive substances.
- ★ Substances on their own or in preparations that are under customs supervision.
- ★ Non-isolated intermediates (on-site and transported intermediates are only partially exempt).
- ★ Carriage of dangerous substances or preparations.
- ★ Waste.
- ★ Substances identified by member states for defence purposes.
- ★ Annex IV list of substances for which risks are considered to be well known, eg limestone.
- ★ Annex V list of substances for which registration is deemed to be inappropriate.
- ★ Substances that are registered under REACH, exported and then re-imported.
- ★ Substances that have been registered, used and that are subsequently recovered.
- ★ Polymers do not have to be registered or evaluated (but polymer producers or importers must register the monomers and additives used in producing the polymer).
- ★ Substances manufactured or imported in limited quantities solely for product and process-orientated research and development are exempted from registration for the first five years if notified. ECHA can impose conditions on their use and extend the exemption for a maximum of five years (a ten-year maximum for medicinal and veterinary product and process development).

### What other EU legislation remains in force? (non-exhaustive list)

- ★ 99/45/EC Dangerous Preparations Directive.
- ★ 91/155/EEC Safety Data Sheets Directive.
- ★ 91/414/EEC Plant Protection Products Directive and 98/8/EC Biocidal Product Directive (authorised active substances deemed to be already registered under REACH).

 [Full text of REACH Regulation](#)

- ★ 89/391/EC Directive on workplace health and safety.
- ★ 96/61/EC Directive on integrated pollution prevention and control.
- ★ 2000/60/EC water framework Directive.
- ★ 2004/37/EC protecting workers from exposure to carcinogens and mutagens.
- ★ 76/768/EEC Directive on testing involving vertebrate animals.

#### Laws that are supplemented by REACH:

- ★ human and veterinary medicinal products.
- ★ food additives.
- ★ cosmetics.
- ★ flavouring in foodstuffs.
- ★ additives in animal feedstuffs.
- ★ products used in animal nutrition.
- ★ EU chemical export/import control legislation.
- ★ some national legislation.

### When will reviews take place?

#### By 1 June 2008

Commission to review requirements for chemical safety report and exempted substances listed in Annexes IV and V.

**1 December 2009** Commission to review Annex XIII, setting criteria to identify substances that are persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB).

**1 June 2012** Commission to review scope of Regulation to avoid overlap with other EU legislation and the rules governing ECHA.

**1 June 2013** Commission to decide whether endocrine-disrupting substances should be barred for authorisation by demonstration of adequate control.

**1 June 2014** Commission to decide whether chemical safety reports should be produced for substances manufactured or imported below 10 tonnes per year that are carcinogenic, mutagenic or reproductive toxins (CMR).

**1 June 2019** Commission to decide whether chemical safety reports should be produced for all substances below 10 tonnes per year; whether companies should advise consumers of the presence of dangerous substances in articles other than those already identified as substances of very high concern; whether acceptable non-animal testing alternatives are available for substances produced or imported in quantities from 10-100 tonnes per year.

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Dave Buckland, Corporate Regulatory Affairs Manager, Akzo Nobel NV

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- ✦ Technical guidance available and being developed under the REACH implementation projects (RIPs).
- ✦ The forthcoming Globally Harmonised System (GHS) of chemicals classification and labelling.
- ✦ How to put together an intelligent testing strategy that minimises data requirements.
- ✦ How to select REACH consultants and testing laboratories.

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