

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OR REACH (Registration, Evaluation, Authorisation and restrictions of Chemicals) Regulations 2007.

The EU chemical safety regime

The new European chemicals legislation, REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals) came into force on 1 June 2007 and with it the new European Chemicals Agency (ECHA) started operations in Helsinki.

REACH applies to any business which manufactures, imports, distributes, sells or uses chemicals throughout the supply chain. REACH obligations could therefore potentially fall upon any business of any size in any part of the UK.

REACH requires the registration over a period of 11 years of some 30,000 chemical substances in use today, which will be co-ordinated by ECA. This process will fill information gaps on chemical hazards and the risk management measures to ensure safe use.

Which chemicals are involved?

Manufacturers and importers of substances on the European Inventory of Existing Commercial Chemical Substances (EINECS) will have to pre-register those substances. Of these, only substances manufactured or imported in volumes starting at 1 tonne need to be registered.

Remember that only substances must be pre-registered and then registered, articles and preparations do not – but the substances they contain potentially should be!

The EINECS list is available as a reference to this Guide, or the EC official version can be searched online.

The more extensive EU database of all known substances (ESIS) is also available free of charge and includes classification, packaging and labelling data, with safety and risk phrases.

It is not possible for the Commission to provide an exact list of all substances that will be registered as the EC does not have knowledge of the precise tonnage of all the substances on the market. It will be left to industry (including importers) to decide if they want to continue the production or marketing of all these EINECS substances.

Some substances are exempted from REACH altogether. These are:

- wastes
- radioactive substances
- non-isolated intermediates
- substances under customs supervision
- substances necessary for the interests of defence.

Implementation

The basic components of the REACH regime are set out below:

- established on 1 June 2007, the ECHA will become fully operational on 1 June 2008
- companies will begin **on-line submission of pre-registrations and registration dossiers** from 1 June 2008. This pre-registration phase ends on 1 December 2008, and is intended to encourage data sharing and help minimise any additional testing requirements
- **registration** on a central database of all substances which any individual company manufactures or imports into the EU in quantities greater than 1 tonne per year. There are special arrangements to phase in registration for substances currently manufactured or on the market, based on tonnage
- **dossier evaluation** – registration requires a technical dossier, with proposals for testing of the chemical to fill knowledge gaps. Dossier evaluation consists of a mandatory review of testing proposals submitted (primarily for substances supplied or manufactured in quantities greater than 100 tonnes per year) and a mandatory compliance check of at least 5% of registration dossiers. Dossier evaluation will be carried out by the ECHA.

- **substance evaluation** – this consists of further evaluation of substances where these may pose a risk to human health or the environment. Substance evaluation will be co-ordinated by the Agency. Member States' competent authorities will carry out the evaluation
- **authorisation** – for substances of high concern, where alternatives cannot be substituted, businesses must apply for authorisation for specific uses where the risks can be adequately controlled or where there is a socio-economic case for continuing use of the substance. *Note that all other non-authorised uses of these chemicals will be prohibited.*
- **restrictions on marketing and use** of substances where the risks to human health and the environment are deemed to be unacceptable. REACH will carry forward the existing EU restrictions regime, with the Agency to play a co-ordinating role in the examination of proposals for new restrictions.

What information do I need?

Downstream users

As a downstream user of chemical substances you need data sheets setting out the hazards and management controls for each substance. Manufacturers and importers will supply this data, and you must implement the guidance given (this is very similar to the current UK regime operated under the CHIP regulations).

Manufacturers and importers are not obliged to supply data sheets for substances that are not dangerous, or are supplied in overall quantities of less than 10 tonnes per year.

If they choose to operate outside manufacturers' or importers' guidance (for instance, for a commercially confidential purpose), downstream users must carry out their own chemical safety assessment and develop their own control procedures. In that case, there are reporting obligations to the ECHA.

Manufacturers and importers

The chemical data obligations on manufacturers and importers are too complex to be usefully summarised here.

Accessible information is available in the European Commission's 'Question & Answers on REACH' document which is available as a reference to this Guide.

Help and technical guidance

The onus is on industry to identify the measures needed to manage the risks posed by chemicals, products and preparations.

ECHA has launched a multilingual website. The website will serve as a single access point for general information on chemicals, guidance documents and other tools on how to comply with the REACH legislation. From 1 June 2008, it will also provide an interface for on-line registration of substances. At present little information is available on the ECHA website and readers may prefer to look at this website for guidance: EU joint research centre .

UK Helpdesk

Companies will also have access to a helpdesk through the ECHA website. The UK's helpdesk may be contacted on 0845 408 9575, or via email at UK REACH helpdesk .

Legislation

The EC REACH regulations have legal effect in their own right and accordingly will *not* be transposed through UK statutory instruments.

The UK will amend domestic law to remove requirements in its legislation which will have legal effect under REACH itself. In some cases, restrictions under the old classification, packaging and labelling Directives were subject to discretionary exceptions which the UK decided to apply. Some of those exceptions are still permitted under REACH.

DEFRA has begun a review to identify which existing UK statutory instruments should be revoked or amended, and whether there are any specific provisions which need to continue.

Enforcement

Examples of activities where UK law enforcement is involved are:

- manufacture, import, sale, supply or use of substances without the appropriate registration

SES GS Region Information



- using a hazardous substance outside the terms of an authorisation or contrary to a restriction
- failure to provide required information up and down the supply chain
- failure to comply with other duties regarding information, eg, workers' or consumers' rights of access to information
- failure to comply with the duty to apply recommendations, eg, in safety assessments
- failure to comply with the duties to co-operate and to supply information in a timely manner.

Existing enforcing authorities will use the powers already provided to inspectors alongside current regulatory activities to enforce REACH. It is proposed that:

- HSE (and HSENI) will enforce the information and supply chain-related obligations of REACH, and
- HSE, HSENI, EA, SEPA, EHSNI and local authorities will enforce the use-related requirements of REACH.

The exact details of enforcement, penalties, and administrative arrangements have yet to be finalised.

REACH and REHAU Ltd

REHAU is a member of the British Plastics Federation and is working closely with the REACH Liaison Committee on this subject.

We have set up an internal project team including our Technical, Purchasing, Safety and Production departments in order to co-ordinate all activities to ensure a smooth implementation for both REHAU and our Customers. As our Customer we will ensure that all products we supply to you are REACH compliant.

If you have any questions on REACH, please contact our Safety, Environmental and Security Manager Richard Bladon on 01407833226 or by E Mail : richard.bladon@rehau.com

USEFUL LINKS

ECHA website

http://reach.jrc.it/index_en.htm

ECHA Guidance for Downstream Users

Http://reach.jrc.it/docs/guidance_documents/du_en.pdf

HSE REACH website

<http://www.hse.gov.uk/reach/index.htm>