# **REACH** - The Basics

If you have responsibilities under REACH then you need to know what impact this might have on your business. This leaflet summarises the different elements of REACH which may affect your business.

#### What is REACH?

REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) is the system for controlling chemicals in the EU. It became law in the UK on 1<sup>st</sup> June 2007.

Because any company could be affected by REACH, it is important that they understand what REACH requires and their duties under the legislation. Identifying where your company fits into the supply chain is important as this will determine what you have to do and when you have to do it – not all requirements of REACH apply immediately. Below are summarised the key stages in the process.

### Registration

Any company manufacturing or importing into the EU a substance on its own, in a preparation (mixture of substances), or intentionally released from articles (finished manufactured goods) at or above 1 tonne per year may have to register it. This is done by submitting a dossier to the European Chemicals Agency (the Agency; ECHA), based in Helsinki. The dossier contains details of the substance's properties, other relevant information about risks and how these risks can be managed. You will not be able to manufacture or import a substance within the EU, or import an article that intentionally releases a substance, unless the substance has been registered.

To ease the move to the REACH provisions, registration will be 'phased-in' over 11 years, generally for those substances that have been around since 1981. More information on the various registration deadlines is given in 'UK REACH Information Leaflet Number 6 - REACH Timeline', but the key registration deadlines are given below. Chemicals manufactured or imported in large volumes and certain 'substances of very high concern' (i.e., with particular hazardous properties) will need to be registered first, those manufactured or imported in smaller volumes may be registered later.

1 Dec 2010	Registration of: substances supplied at ≥1000 tonnes per annum; substances classified under CHIP¹ as Very Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment (R50/53) at ≥ 100 tonnes per annum; substances classified under CHIP as Category 1 or 2 CMR² at ≥1 tonnes per annum
1 June 2013	Registration of substances supplied at ≥100 tonnes per annum
1June 2018	Registration of substances supplied at ≥1 tonne per annum

1 CHIP - Chemical (Hazard Information and Packaging for Supply) Regulations 2002  $\,$ 

2 CMR - Substances that are, Carcinogenic, Mutagenic or Toxic to Reproduction

# **Pre-registration**

To take advantage of the phased registration provisions substances need to be pre-registered.

Companies who manufactured/imported chemical substances between 1<sup>st</sup> June 2007 and 1<sup>st</sup> December 2008 (inclusive) were required to pre-register them with the Agency between 1 June 2008 and 1 December 2008 in order to continue to market and use them legally.

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Companies who have started to manufacture/import their substance for the first time after 1<sup>st</sup> December 2008 can, in some cases, complete a 'late pre-registration'.

There is more information in <u>UK REACH CA Information Leaflet Number 7 - Pre-registration</u> including guidance on what to do if you should have pre-registered by 1<sup>st</sup> December 2008, but missed the deadline.

There are some exemptions from registration, as well as other parts of REACH, and you should check whether any apply to your business. There is more information in <a href="UK REACH CA Information Leaflet Number 8">UK REACH CA Information Leaflet Number 8</a> - Exemptions.

Companies that only use chemicals purchased from within the EU do not need to pre-register and do not have a duty to register.

More information on registration is available on the European Chemicals Agency's website.

#### **Evaluation**

Evaluation covers several processes under REACH. The first is simply that the Agency will assess a proportion of the substance registration dossiers it receives to ensure they contain the correct information, known as 'compliance checking'. For substances registered at 100 tonnes/annum or more, any proposals for further animal toxicity tests to obtain missing information to complete registration dossiers will be carefully considered by the Agency, before deciding whether to approve the proposed tests. This is known as 'Dossier Evaluation'.

Finally, there is 'Substance Evaluation' in which a Member State authority will look at all dossiers for a particular substance for which there may be a need for regulatory action. In order to ensure a harmonised approach, the Agency shall in cooperation with the Member States develop risk-based criteria for prioritising substances for these further evaluations.

#### **Authorisation**

Substances of very high concern (SVHC) will need to be authorised for specific uses if they appear in Annex XIV. The substances chosen for Authorisation will be drawn from a 'Candidate List'. There will not be any sort of "blanket" authorisation for a substance to be used generally. Instead, applications for authorisation for a specific use may be made by companies that register the substances, or by those that use them. When a substance is placed on Annex XIV, a 'sunset date' will be set after which its use will be prohibited, unless an authorisation has been granted.

Authorisation decisions will be made by the European Commission advised by the Agency in agreement with the national Competent Authorities, and can be granted in two ways:

- 1. The use is considered safe as long as the risks are adequately controlled, and the conditions of the authorisation are met, or
- 2. The use is considered safe as above AND the substance can be demonstrated to be so important on socio-economic grounds that its continued use outweighs the risks to human health and the environment.

Either way, those applying for authorisations must provide information on the availability of alternatives, and if there is a suitable alternative, a plan for phasing out the SVHC in question (known as the 'substitution plan').

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More information on authorisation can be found in <u>UK REACH CA Information Leaflet Number 19 – Authorisation</u>. More on SVHC and in particular other potential requirements relating to them can be found in <u>UK REACH CA Information Leaflet Number 12 – Substances of Very High Concern (SVHC)</u>.

#### **Restrictions**

This is a direct and unambiguous means of controlling the risks associated with any given hazardous substance. A substance on its own, in a preparation or in an article, which has been restricted shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. Restriction will be used when it is felt that action at the European level is needed. Restriction decisions will also be made by the European Commission based on advice from the Agency, consulting with EU Member States and others. Restrictions in place already from previous legislation are carried over into REACH in Annex XVII; further restrictions will be added to this Annex.

### **Classification and Labelling**

An important part of chemical management is clear provision of information about any dangerous properties a chemical may have. The information gathered through registration can be used to classify chemicals according to the criteria in the CLP Regulation' (Regulation (EC) No 1272/2008)

# Information provisions

The passage of information up and down the supply chain is one of the key features of REACH – users should be able to understand what manufacturers and importers know about the dangers involved in using chemicals, and they can also pass information back up the supply chain.

REACH adopts and builds on an existing system for passing information in a structured way down to chemicals users – the Safety Data Sheet (SDS). This should accompany materials down through the supply chain, providing the information that users need to ensure chemicals are safely managed. REACH will also allow for information on uses of chemicals to be passed back up the supply chain, so that these can be reflected in the SDS. More information on the compilation of safety data sheets is in <a href="UK REACH CA Information Leaflet Number 13 - Safety Data Sheets">UK REACH CA Information Leaflet Number 13 - Safety Data Sheets</a>.

Downstream users of chemicals (i.e. those who use them at work) will need to comply with any conditions described in the SDS. Where SDS have attached exposure scenarios that detail how chemicals may be used, then users should implement the required risk management measures (or use equivalent measures). For more information see <a href="UK REACH CA Information Leaflet Number 4 - What REACH Means for Users of Chemicals">UK REACH CA Information Leaflet Number 4 - What REACH Means for Users of Chemicals</a> and the European Chemicals Agency's 'Guidance for Downstream Users'.

#### **Further information**

For advice on the application of REACH obligations, you can contact the UK REACH Competent Authority's national helpdesk:

Email: UKREACHCA@hse.gsi.gov.uk

Website: www.hse.gov.uk/reach

