

## cpd briefing

**36****REACH – the EU Chemical Safety Regime****INTRODUCTION**

**REACH is a new European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances and came into force on 1 June 2007 along with the new European Chemicals Agency (ECHA), which is based in Helsinki. REACH is designed to streamline and improve the legislative framework on chemicals across the European Union (EU).**

REACH applies to any business which manufactures, imports, distributes, sells or uses chemicals throughout the supply chain. It applies the principle of professional risk assessment to the chemicals industry and transfers responsibility for the assessment of risk from the regulators to the manufacturer or importer of the chemical(s).

The overarching objective of REACH is to improve the protection of human health and the environment through a better understanding of the characteristics of substances and their impacts. A comprehensive set of toxicological data and environmental information will be developed for both existing and new chemicals, and this data will be shared freely across the EU chemicals industry. REACH will also restrict animal testing and promote alternatives, as far as possible. It is also intended to promote free movement of chemicals within the EU plus enhance competitiveness and innovation in the EU chemicals industry.

The benefits of REACH will be gradual as the registration of the existing 30,000 chemicals in use today will take place over a period of 11 years under the co-ordination of the European Chemicals Agency (ECHA) which became fully operational on 1 June 2008.

**In essence REACH requires:**

- industry to take responsibility for managing the risks from chemicals and to provide safety information on such substances

- manufacturers and importers to gather information on the properties of their chemical substances to facilitate their safe handling and use. This information will be registered on a central database run by the ECHA and become accessible (in a simplified form) to both consumers and professionals
- the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

REACH is to be supplemented by a Globally Harmonised System of Classification and Labelling of Chemicals (GHS) which will be implemented over the next few years.

**IMPORTANT SUMMARY**

Business continuity could be adversely impacted by REACH and supply chains disrupted. Effective supply chain communication and analysis is crucial in order to adequately identify the risks posed under REACH. The administrative scale of this is potentially large and time consuming. There are IT systems available to streamline the data gathering exercise.

It should be noted that the legislation has substantial impact to downstream users of chemicals. All manufacturing sectors that use chemical preparations and 'articles containing substances designed for release' are liable to face considerable impact:

- a large proportion of SMEs and downstream users of chemicals will be potentially unaware of REACH and its impact on their respective businesses
- downstream users of chemicals, that are unaware of the impact of the regulation, may find raw materials and preparations become unavailable without warning as substances are taken off the market; re-formation will therefore become a necessity
- obligations are placed on the downstream user to demonstrate compliance with the exposure scenarios provided in the extended Safety Data Sheet (SDS) created under REACH.

## LEGAL DUTY

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

REACH is a complicated piece of legislation and unusual in respect of the time period over which it will be implemented.

REACH requires the registration of substances imported (from outside the European Union) or manufactured at  $\geq 1$  tonne per year. This registration requirement also applies to substances in preparations. Companies should check with their suppliers the exact composition of the substance in order to be able to calculate if they are importing over a tonne of a substance. Note: the tonnage thresholds are per importer not per preparation.

Manufacturers and importers of substances on the European Inventory of Existing Commercial Chemical Substances (EINECS) will have to pre-register those substances if they are being manufactured or imported in volumes of 1 tonne or more in accordance with the REACH implementation timescale.

## REACH IN ESSENCE

The philosophy behind REACH is that any company who manufactures chemicals in the EU or imports chemicals into the EU must:

- know what those chemicals are used for
- be aware of their effects on man and the environment
- share what they know (upstream and downstream to users)
- supply a risk assessment to the competent authority to demonstrate that the risks associated with the chemical (to include its disposal) are known, understood and manageable.

## Chemicals to which REACH applies

REACH applies to 'substances' and this term is defined as:

*'a chemical element and its compounds in the natural state or obtained by any*

*manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'.*

In practice, REACH covers most chemical substances that are manufactured in or imported into the EU. These can be:

- substances on their own
- substances in a 'preparation' (eg a mixture such as ink or paint)
- substances that make up an 'article' (ie an object that is produced with a special shape, surface or design).

For ease of understanding, the term 'substance' is frequently interchanged with the term 'chemical' when describing the implications of REACH.

## REACH requirements

Although REACH will have an impact on almost all businesses in the UK, there are three main groups of duty holder and these are:

### 1. Manufacturers/Importers

Any business that manufactures or imports (from outside the EU)  $\geq 1$  tonne per year of a substance to which REACH applies will need to register a dossier of information with the ECHA about that substance, in accordance with the requirement placed on registrants.

The option of pre-registration of existing substances/chemicals is possible (at no charge) between 1 June 2008 and 30 November 2008. This pre-registration process allows full registration to be deferred. Full registration must subsequently be made in accordance with the REACH implementation timetable. Any existing substance that is not pre-registered will, in effect, be banned from 1 December 2008 until it undergoes full registration.

Companies outside the EU cannot register chemicals themselves but can appoint an EU-based agent – an 'only representative' to act on their behalf.

### 2. Downstream users

The term 'downstream user' refers to any business using chemicals and REACH

places an onus on such businesses to use chemicals in accordance with the safety information supplied to them via the supply chain. Downstream users have a responsibility to inform registrants how they are using chemicals and for what purpose, so that this information can be taken into account when manufacturers/importers are assessing the risks from their chemicals.

Downstream users may need to supply risk assessment and risk management measures to the ECHA if they don't want their supplier to know how they actually use their chemicals. Some users may also be importers and have a duty to register.

Downstream users are specifically advised to ascertain the REACH timescales as they relate to their businesses and to ensure that compliance will be achieved by the relevant deadlines. If you are unsure, expert advice should be sought as a matter of urgency.

### 3. Others in the supply chain (ie; distributors and suppliers)

Businesses that sell chemicals have specific duties to pass information down to their customers, and also to pass information back to their own suppliers when customers ask them to do so.

There is a requirement common to all duty holders to share information.

In addition to the aforementioned duty holders, an onus is placed on the ECHA to orchestrate REACH: provide central guidance; host the Registration process and operate the relevant committee and authorisation processes.

A Member State's Competent Authority (the HSE in the UK) must provide:

- a national helpdesk
- enforce compliance with registration (at least reactively)
- evaluate selected priority substances
- participate in EU committee process.

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## Substances of Very High Concern (SVHC)

REACH also aims to control the use of Substances of Very High Concern (SVHC). These are those substances which can cause cancer, persist in the environment and/or show bioaccumulative tendencies. Around 1,500 substances may fall into this category. Substances of very high concern include CMRs (carcinogenic mutagenic or substances toxic to reproduction), PBTs (substances of very high concern that are persistent in the environment, bio accumulative and toxic), and vPvBs (very persistent and very bio-accumulative substances). SVHC's may need authorisation for specific uses before they may be placed on the market. The ECHA aims to control the use of such substances via the authorisation process and encourage industry to substitute these substances for safer ones. It will publish a list containing substances to be considered for the authorisation process by 1 June 2009.

Applicants for authorisation will have to demonstrate that the risks associated with the use of these substances are adequately controlled, or alternatively, that the socio-economic benefits of their use outweigh the risks.

## Exemptions from REACH

Substances do not need to be registered under REACH if they are manufactured or imported at less than 1 tonne per year per manufacturer/importer.

Some substances are exempt from REACH altogether. These include:

- the transit of dangerous substances
- waste as defined in Directive 2006/12/EC
- polymers due to their generally inert nature
- radioactive substances
- intermediates (that only exist during an enclosed reaction)
- substances under customs supervision
- substances necessary for the interests of defence.

Some substances are exempt from certain aspects of REACH in that they are given 'partial exemptions'. These substances include cosmetics which are regulated under the Cosmetics Directive; this makes them exempt from REACH as far as human health risk assessments are concerned. The environmental effects of cosmetic products are not subject to

professional assessment under the Cosmetics Directive so these aspects are subject to REACH.

Some chemicals covered by more specific legislation, such as human and veterinary medicines, food and food additives are subject to tailored provisions under REACH.

## REACH Timetable

It will take 11 years before the new REACH system is fully operational so both its benefits and impact on the chemicals industry will be gradual. It is imperative that duty holders effect compliance with REACH in accordance with the following timetable:

- |                         |   |
|-------------------------|---|
| <b>1 June 2007</b>      | REACH came into force and European Chemicals Agency (ECHA) formed   |
| <b>1 June 2008</b>      | ECHA became fully operational plus: <ul style="list-style-type: none"><li>• registration of new (non-phase in) substances starts</li><li>• pre-registration of existing EINECS<sup>1</sup> registered chemicals starts. Note: the pre-registration window is for 6 months only. If this deadline is missed then a chemical cannot be marketed or brought into the EU until the FULL registration requirement has been satisfied</li></ul> |
| <b>30 November 2008</b> | pre-registration of existing/non-phase in substances ends   |
| <b>1 December 2008</b>  | full registration for existing substances that have not been pre-registered starts, also new substances (non phase in)  |
| <b>1 January 2009</b>   | publication of information about all of the chemicals that have been pre-registered on the EU Database plus the contact details of the companies associated with each substance   |
| <b>1 February 2009</b>  | formation of the Substance Information Exchange Fora (SIEF)   |
| <b>1 June 2009</b>      | first recommendation of priority substances to be considered for authorisation published by ECHA  |
| <b>1 December 2010</b>  | <b>PHASE 1:</b> registration deadline for substances which are: <ul style="list-style-type: none"><li>• high volume <math>\geq 1,000</math> tonnes per annum (tpa) or</li><li>• persistent, bio-accumulative, highly toxic to the aquatic environment <math>\geq 100</math> tpa or</li><li>• carcinogens, mutagens, reproductive toxicants <math>\geq 1</math> tpa</li></ul>  |
| <b>1 June 2013</b>      | <b>PHASE 2:</b> registration deadline for medium volume substances $\geq 100$ tpa   |
| <b>1 June 2018</b>      | <b>PHASE 3:</b> registration deadline for low volume substances $\geq 1$ tpa  |
| <b>2 June 2018</b>      | REACH now fully operational   |

<sup>1</sup>The European Inventory of Existing Commercial Chemical Substances (EINECS) is a list of all the so called 'existing substances'

## Pre-registration of 'existing' substances

The pre-registration process does not involve any charges payable to the ECHA. To pre-register any chemical the following information needs to be supplied to the ECHA:

- name of the chemical including an identifying number (eg CAS Registry or EINECS number)
- the potential registrants company name and contact details
- deadline envisaged for registration and tonnage band
- identifier information of any structurally similar substance to be relied upon to provide useful evidence on hazards as part of the registration package.

## Registering a 'new' substance

Any substance controlled under REACH that is not already registered on the EINECS database and which has not been pre-registered as an existing substance with the ECHA by 30 November 2008, will be classified as a new substance. As such it will be subject to the full REACH registration process. Any substance that has not been manufactured previously has now to be registered with immediate effect.

## The registration process

Potential registrants have to submit a technical dossier to the ECHA if a

substance is produced in quantities of  $\geq 1$  tonne per year. The technical dossier contains information on the properties, uses and on the classification of a substance as well as guidance on safe use.

A chemical safety report (CSR) is required if the quantity is  $\geq 10$  tonnes per year per registrant. In effect, the CSR is a documentation of the chemical safety assessment (CSA). The requirements of the CSA are described in Annex I of the REACH text and this involves assessment of hazards in relation to the following fields:

- human health
- physicochemical properties
- environmental fate and behaviour

## Offences and enforcement

In practice, under REACH it will be an offence to:

- manufacture, import, sell, supply or use a substance without the appropriate registration
- use a hazardous substance outside the terms of an authorisation or contrary to a restriction
- fail to provide required information up and down the supply chain
- fail to comply with other duties regarding information, eg workers' or consumers' rights of access to information
- fail to comply with the duty to apply recommendations, eg in safety assessments

- fail to comply with the duties to co-operate and to supply information in a timely manner.

The HSE and Health and Safety Executive Northern Ireland (HSENI) will enforce the information and supply chain-related obligations of REACH. The use-related requirements of REACH will be enforced by the HSE, HSENI, Environment Agency (EA), the Scottish Environment Protection Agency (SEPA), Environment and Heritage Service Northern Ireland (EHSNI) and local authorities.

The exact details of enforcement, penalties, and administrative arrangements have yet to be finalised as the necessary enforcement Statutory Instrument is the subject of consultation as of spring 2008. The enforcement regime must be in place by 1 December 2008.

## WHAT MUST I DO?

It is envisaged that compliance with REACH will necessitate extensive intra-industry cooperation and communication until the system is fully operational in 2015 and beyond.

## Responsibilities under REACH

The impact of REACH will depend on the activities a company undertakes and the relevant duties must be discharged in accordance with the REACH implementation timetable. These duties can be categorised as follows:

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Task	Duty Holder
<p><b>Data gathering</b> to determine the applicability of REACH to an organisation's commercial activities.</p> <p>Importers should check their substance/product inventory and ask whether they import anything from outside the EU. If the answer is no then there are no responsibilities under REACH other than those of a downstream user. If the answer is <b>yes</b> then the application of REACH to the business needs to be carefully considered.</p>	<p><b>Manufacturers, importers, retailers and users</b></p> <p><b>Importers</b></p>
<p><b>Pre-registration</b> of existing chemicals with the European Chemicals Agency (ECHA) by 30 November 2008 so that these chemicals can continue to be produced and sold. This will also enable manufacturers and importers to take advantage of an extended time span in which to complete the full REACH registration process.</p> <p>Pre-registration is free and fairly simple. For each chemical the following information must be supplied to the ECHA:</p> <ul style="list-style-type: none"> <li>• name of the chemical including an identifying number (eg CAS or EINECS number)</li> <li>• the potential registrants company name and contact details</li> <li>• deadline envisaged for registration and tonnage band</li> <li>• identifier information of any structurally similar chemical to be relied upon to provide useful evidence on hazards as part of a registration package.</li> </ul>	<p><b>Manufacturers or importers</b></p>
<p><b>Submission of information to the ECHA's chemicals database.</b></p>	<p><b>Manufacturers or importers</b></p>
<p><b>Publication of data on pre-registered chemicals.</b></p>	<p><b>ECHA</b></p>
<p><b>Mandatory sharing of information in the Substance Information Exchange Fora (SIEF).</b> Pre-registering a chemical will entitle registrants to become part of a group of companies who have also pre-registered that same chemical. This group, called a Substance Information Exchange Forum (SIEF), will share information on hazards so that only one set of technical information has to be submitted to the ECHA thus reducing costs. The SIEF will also work collectively on other aspects of the full registration package. Membership of a SIEF will also help to share expertise and spread costs with members paying reduced registration fees.</p>	<p><b>Manufacturers or importers</b></p>
<p><b>Registration of existing chemicals</b> in accordance with REACH timetable. This involves providing a package of technical information on the chemical and its hazards (a 'dossier') to the ECHA. The amount of information to be supplied will depend on the tonnage but will include:</p> <ul style="list-style-type: none"> <li>• toxicological and environmental testing (if appropriate) and data assessment</li> <li>• risk assessment data</li> <li>• preparation of a materials Safety Data Sheet (SDS) where relevant.</li> </ul>	<p><b>Manufacturers or importers</b></p>
<p><b>Risk assessment of new chemicals</b> to market: a full dossier of information will be required.</p>	<p><b>Manufacturers or importers</b></p>
<p><b>Provision of adequate information to downstream users</b> so that they can use chemicals safely.</p>	<p><b>Manufacturers and importers</b></p>
<p><b>Supply of information on product use to the manufacturer/importer</b> (upstream user) so that how chemicals are being used is taken into account when assessing risk.</p>	<p><b>Retailers and users</b></p>
<p><b>Request continued availability of relevant chemicals</b> from manufacturer/importer in consideration of the fact supply may be interrupted if the decision is taken to de-list a chemical(s) to avoid the need to comply with REACH. It will be left to industry (including importers) to decide if they want to continue the production or marketing of all EINECS substances.</p>	<p><b>Retailers and users</b></p>

## KEY TERMS

**Article** – the REACH Regulation applies in certain cases to articles. There is a specific REACH definition for articles that should be considered before deciding whether to produce or import articles. However, generally speaking an article is a finished product such as clothing, furniture, motor vehicle parts etc. Substances contained in articles are to be registered if they are intended to be released and they are in those articles in quantities totalling over 1 tonne per year. For most articles it is unlikely a registration will be required as very few intentionally release substances

**Bioaccumulative substances** – substances that gradually build up in animals via the food chain

**CAS Registry Number** (often referred to as a CAS Number) - a unique numeric identifier which has no chemical significance but represents a link to a wealth of information about that chemical substance. CAS is a division of the American Chemicals society

**CSA** – chemical safety assessment. This should address all the identified uses of a substance on its own (including any major impurities and additives), in a preparation and in an article. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions

**CSR** – a chemical safety report. A CSR should be completed for all substances subject to registration in quantities of 10 tonnes or more per year per registrant, this is a documentation of the chemical safety assessment (see above)

**Downstream users:** downstream users include any business using chemicals, which probably includes most businesses in some way. Companies that use chemicals have a duty to use them safely, and according to the information on risk management measures that should be passed down the supply chain. There is also an opportunity to pass information about use back to registrants so that this can be taken account of when assessing the risks of chemical used. Downstream users may need to supply risk assessment and risk management measures to the European Chemicals Agency if they don't want their supplier to know about how they use the chemicals. Some users may also be importers and have a duty to register

**ECHA** – European Chemicals Agency. The Agency established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of the REACH Regulation and to ensure consistency at Community level in relation to these aspects

**ECB** – European Chemicals Bureau

**EHSNI** – Environment and Heritage Service Northern Ireland

**EINECS** – the European Inventory of Existing Commercial Chemical Substances

**GHS** – Globally Harmonised System of Classification and Labelling of Chemicals

**HSENI** – Health and Safety Executive Northern Ireland

**PBT** – persistent, bioaccumulative and toxic. Annex XIII defines criteria for the identification of substances that are Persistent, Bio-accumulative and Toxic and Annex I lays down general provisions for PBT assessment. PBTs are substances of very high concern (SVHC) and may be included in Annex XIV and by that be made subject to authorisation  
**RIPs** – REACH Implementation Projects

**SDS** – Safety Data Sheets. The Safety Data Sheet provides a mechanism for transmitting appropriate safety information on classified substances and preparations, including information from the relevant Chemical Safety Report down the supply chain to the immediate downstream users. The information provided in the Safety Data Sheet shall be consistent with the information in the Chemical Safety Report, where one is required

**Substance** – a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

**SVHC** – Substances of Very High Concern

**vPvB** – very persistent and very bioaccumulative. Substances of very high concern, which are very persistent (very difficult to break down) and very bio-accumulative in living organisms. Annex XIII defines criteria for the identification of vPvBs and Annex I lays down general provisions for their assessment. vPvBs may be included in Annex XIV and by that be made subject to authorisation.

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