SQUIRE SANDERS

A GUIDE TO REACH: EU CHEMICALS LAW

Q WHAT IS REACH?

A REACH is the acronym for the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals. It is an EU Regulation that came into force on 1 June 2007 and creates the new regime for the regulation of chemicals in the EU.

The aim of REACH is to ensure chemicals are utilised in a way that minimises risks to human health and the wider environment. It is envisaged that this aim will be achieved by evaluating substances before they are approved for use, and shifting the burden of responsibility for evaluation onto the supply chain and away from public authorities.

Q WHO ENFORCES REACH?

A There are a number of enforcing authorities for REACH including:

- Health and Safety Executive ("HSE"), who in most cases will be the primary enforcing authority and will in particular, enforce against breaches relating to the registration of substances and the supply chain;
- The Environment Agency for England and Wales, the Scottish Protection Agency and the Department of the Environment in Northern Ireland;
- Local authorities; and
- The Secretary of State for the Department for Business, Innovation and Skills.

Q WHAT TYPE OF ORGANISATIONS DOES REACH APPLY TO?

A REACH imposes obligations on three main types of organisations, referred to in REACH as "actors". These are manufacturers, importers and downstream users.

Generally, REACH will apply to companies who operate in, or import products into, the EU. For example, this will include chemical and raw material manufacturers, and will affect many different sectors such as clothing, automotive and detergents.

Q WHAT CHEMICALS FALL UNDER REACH?

A REACH applies to all chemicals manufactured or marketed in the EU, and any new chemicals manufactured for the first time.

It is important to note that REACH applies to substances and not products. Substances can exist on their own, within preparations (i.e. as a mixture of substances) and in articles (i.e. items that have a particular shape or design that determines function).

Some substances are excluded from REACH including radioactive substances and waste. Further substances are excluded from Registration and/or Authorisation including cosmetics, pesticides, medicinal products and some food additives.

Q HOW WILL REACH COME INTO EFFECT?

A As stated above, REACH came into force through EU Regulation 1907/2006/EC (Registration, Evaluation, Authorisation and Restriction of Chemicals) on 1 June 2007.

The European Chemicals Agency ("ECHA"), created by REACH, has a central co-ordination and implementation role and became operational on 1 June 2008.

On 1 June to 1 December 2008, pre-registration of phase-in substances took place.

The next critical registration deadlines for REACH are:

- 30 November 2010 - Deadline for registration of substances of 1,000 tonnes or more per year; substances that are carcinogenic, mutagenic or toxic to reproduction of 1 tonne or more per year; and substances of 100 tonnes or more per year that are classified as very toxic to aquatic environments.
- 31 May 2013 - Deadline for registration of substances of 100 tonnes or more per year.
- 31 May 2018 - Deadline for registration of substances of 1 tonne or more per year.

Q HOW DOES REACH WORK?

A REACH consists of four main limbs: Registration, Evaluation, Authorisation, and Restrictions.

Q WHAT SUBSTANCES NEED TO UNDERGO REGISTRATION?

A Registration only applies to substances that are manufactured or imported in quantities of 1 tonne or more. If a substance is manufactured or imported in quantities of 1 tonne or less, other obligations mentioned below may still apply. There are an estimated 30,000 substances in the EU that will need to be registered.

Q WHAT DOES REGISTRATION INVOLVE?

A Manufacturers and importers of substances must register those substances with the ECHA, assuming no exemptions apply and the tonnage requirements are met. There are numerous exemptions, including those substances used in research and development.

Registration involves the submission of detailed technical dossiers containing all relevant information about each individual use of a substance. The amount of information needed will increase depending on tonnage and/or the hazardous nature of any particular substance. For example, where a substance is manufactured or imported in excess of 10 tonnes per year, a chemical safety report must accompany the technical dossier.

Failure to register those substances will mean the substance in question cannot be manufactured, imported or put out to the EU market. There are therefore potentially significant and costly implications for non-compliance.

Q WHAT IS EVALUATION?

A After the submission of the technical dossier, the ECHA and the HSE will decide whether further testing and information about a substance is needed. This process is known as Evaluation. They will also decide whether the substance in question requires an authorisation or whether restrictions should be imposed.

Q WHAT IS AUTHORISATION?

A Substances categorised as substances of very high concern ("SVHCs") are required to undergo authorisation. It is estimated that around 1,500 substances will need to go through the authorisation process.

SVHCs are separated into four categories, those that are:

1) Carcinogenic, mutagenic or toxic to reproduction;
2) Persistent, bio-accumulative and toxic;
3) Very persistent and very bio-accumulative; and
4) Give rise to similar concerns as the three above categories.

There are then four steps in the authorisation process:

1) Identification of SVHCs. The ECHA or HSE will advise that a substance should be included in the Candidate List. Any interested party is invited to submit comments and if no comments are received, the substance will automatically be included on the Candidate List.

   If any comments are received, these will be reviewed and the ECHA will decide whether the substance should be included on the Candidate List. If the ECHA cannot make a unanimous decision, then the European Commission ("EC") will decide if it should be included.

2) Recommendation process. The substances that make the Candidate List are then prioritised to make an Authorisation List (otherwise known as Annex XIV). The ECHA will then prepare a draft recommendation which will include:

- An application date, which will be at least 18 months before the sunset date. If a SHVC is to be continued to be used or placed on the market post-sunset date, applications must be received by this application date.
- A sunset date. This is the date from which use and market placement of the SVHC is prohibited unless authorisation is granted.
- Any uses or categories exempted from authorisation.

  In light of the final recommendation and the consultation that accompanies the recommendation process, the EC will decide whether the SHVC should be included in the Authorisation List.

3) Applications for authorisation. Once a SHVC is included on the Authorisation List, the substance cannot be placed on the EU market or is to be continued to be used in the EU after the sunset date. An organisation can make an application for authorisation of a SHVC which must include:

- A chemical safety report; and
- An analysis of possible alternative substances or technologies. If there is a suitable alternative, a substitution plan must be submitted explaining how the organisation intends to replace the substance by the alternative.

4) Grant of authorisation. An authorisation will be granted by the EC if the organisation can demonstrate that the risk from their use of the substance is adequately controlled. If this cannot be demonstrated, an authorisation may still be granted if it can be shown that the socio-economic benefits outweigh the risks and there are no suitable alternatives.

Q WHICH SUBSTANCES ARE SUBJECT TO RESTRICTIONS?

A The manufacture, importation or use of certain substances such as asbestos, may be restricted or banned. All restricted substances are named in Annex XVII of REACH.

There have been some additions to this list recently (1 April 2010) including dichloromethane, grill lighter fluids, organostannic and lamp oils.

Q WHAT ARE THE PENALTIES FOR NON-COMPLIANCE?

A The most common offences under REACH include contravening a REACH provision or causing or permitting another person to contravene a REACH provision.

Criminal sanctions can range from substantial fines to imprisonment. It is also possible that civil proceedings could be taken if the relevant enforcing authority (in most circumstances, the HSE) considers that a criminal sanction would be ineffective.

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