REACH

OVERVIEW

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).

REACH is the European Community Regulation on chemicals and their safe use. 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.

In Jan 2019 ECHA published "How to report changes to identity under REACH and CLP". Click here to download the document.

Also published in Jan 2019 - the ECHA's "How to act in dossier evaluation"

GUIDANCE

The 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. REACH will also restrict animal testing and promote alternatives, as far as possible.

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 coordination 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; and
- The progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

Legal Requirements

REACH requires the registration of substances imported (from outside the European Union) or manufactured at > 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) had to pre-register those substances if they were being manufactured or imported in volumes of 1 tonne or more in accordance with the REACH implementation timescale.

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); and
- 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

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

- Substances on their own;
- Substances in a 'preparation' (e.g. a mixture such as ink or paint); and
- Substances that make up an 'article' (i.e. 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 as follows:

Manufacturers/Importers

Any business that manufactures or imports (from outside the EU) > 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.

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.

Others in the supply chain (i.e. 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.

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; 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 bioaccumulative 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. 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.

Substance Information Exchange Forums (SIEF)

In pre-registering a chemical the registrant will 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. Different forums will be set up for different substances.

The SIEF will also work collectively on other aspects of the registration package. Membership of a SIEF will also help to share expertise and spread costs with members paying reduced registration fees.

You can obtain full details on the REACH Regulations by visiting the main <u>European</u> REACH website.