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Registration, Evaluation; Authorisation
& restriction Of **C**hemicals

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SUMMARY

REACH

Registration, Evaluation, Authorisation & restriction of **C**hemicals.

Introduction

REACH is European Union regulation concerning the Registration, Evaluation, Authorisation and restriction of **C**hemicals. It came into force on 1st June 2007 to replace a number of European Directives and Regulations with a single system. With Brexit, the regulation may change but still in force until further notice.

Key Points

- The main aim of REACH is to provide a high level of protection of human health and the environment from the use of chemicals via improved labelling and safety data sheets and making the manufacturers and importers responsible for managing the risks associated with the chemicals. All chemicals now need to be registered with the European Chemicals Agency (ECHA) in Helsinki.
- According to the regulations we are described as a 'downstream user'.
- REACH affects all businesses as it covers most chemicals including cleaning products, paints, metals, glues and chemicals used in the laboratories. Therefore, we need to ensure that we are REACH compliant.
- Manufacturers or suppliers needed to pre-register their substances by **1st June to 1st December 2008**. Pre-registration is not a legal requirement of REACH but is strongly advised by the UK Competent Authority.
- Registration is a requirement on industry (manufacturers/importers) to collect and collate specified sets of information on the properties of those substances they manufacture or supply at or above 1 tonne per year. This information is used to perform an assessment of the hazards and risks that a substance may pose and how those risks can be controlled. This information and its assessment are submitted to the European Chemicals Agency (ECHA) in Helsinki.
- If we are using widely available chemicals (such as cleaning products) in ways that are quite safe, REACH probably won't mean significant changes but you still need to check with your suppliers that they are registered (or currently pre-registered) somewhere along the supply chain.
- If you rely on receiving specialist chemicals (such as in the laboratories) or ones that are not very common (certain solvents), you may need to be sure that these will still be available in the future. You should therefore, contact your supplier to find out if the chemical(s) in question will be registered by whoever makes or imports it. It is possible that some companies, for example for business reasons, may decide not to register chemicals. If so, then you may need to find an alternative source or even re-think your processes. You really need to be thinking about this now to avoid any problems next year.
- If you use a chemical in a novel way that is perhaps not expected then you will need to consider letting your supplier know. This use will need to be considered for registration by the supplier. If you don't want to let your supplier know about this use (for example because of commercial concerns) then you don't have to **but** it will mean that you will have to let the ECHA know about this use and possibly have to submit your own risk assessment.

For further information see attached document.

REACH

Registration, Evaluation, Authorisation & restriction of CHemicals.

What is REACH?

REACH is a new European Union regulation concerning the Registration, Evaluation, Authorisation and restriction of CHemicals. It came into force on 1st June 2007 and replaces a number of European Directives and Regulations with a single system.

Aims

REACH has several aims:

- To provide a high level of protection of human health and the environment from the use of chemicals.
- To make the people who place chemicals on the market (manufacturers and importers) responsible for understanding and managing the risks associated with their use.
- To allow the free movement of substances on the EU market.
- To enhance innovation in and the competitiveness of the EU chemicals industry.
- To promote the use of alternative methods for the assessment of the hazardous properties of substances i.e. QSAR and read across.

A major part of REACH is the requirement for manufacturers or importers of substances to register them with a central European Chemicals Agency (ECHA). A registration package will be supported by a standard set of data on that substance. The amount of data required is proportionate to the amount of substance manufactured or supplied.

Scope and exemptions

REACH applies to substances manufactured or imported into the EU in quantities of 1 tonne per year or more. Generally, it applies to all individual chemical substances on their own, in preparations or in articles (if the substance is intended to be released during normal and reasonably foreseeable conditions of use from an article).

Some substances are specifically excluded:

- Radioactive substances
- Substances under customs supervision
- The transport of substances
- Non-isolated intermediates
- Waste
- Some naturally occurring low-hazard substances

Some substances, covered by more specific legislation, have tailored provisions, including:

- Human and veterinary medicines
- Food and foodstuff additives
- Plant protection products and biocides

Other substances have tailored provisions within the REACH legislation, as long they are used in specified conditions:

- Isolated intermediates
 - Substances used for research and development
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Pre-registration

Manufacturers or suppliers needed to pre-register their substances since **1st June to 1st December 2008**. Pre- registration is not a legal requirement of REACH but is strongly advised by the UK Competent Authority.

Registration

Registration is a requirement on industry (manufacturers/importers) to collect and collate specified sets of information on the properties of those substances they manufacture or supply at or above 1 tonne per year. This information is used to perform an assessment of the hazards and risks that a substance may pose and how those risks can be controlled. This information and its assessment are submitted to the European Chemicals Agency in Helsinki.

Authorisation

In order to place on the market or use substances with properties that are deemed to be of "very high concern" industry must apply for an authorisation. The European Chemicals Agency (ECHA) in Helsinki published list of substances considered for the authorisation process by 1 June 2009. A company wishing to market or use such a substance must submit an application to the ECHA for an authorisation. Decisions on authorisation are made by the European Commission. Applicants have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio- economic benefits of their use outweigh the risks. Applicants must also analyse whether there are safer suitable alternatives or technologies. If there are then they must prepare substitution plans and if not then they should provide information on research and development activities if appropriate.

Restrictions

Any substance that poses a particular threat is restricted. Restrictions take many forms, for example, from a total ban to not being allowed to supply it to the general public. Restrictions can be applied to any substance, including those that do not require registration. This part of REACH takes over the provisions of the Marketing & Use Directive.

Classification and labelling

An important part of chemical safety is clear information about any hazardous properties of a substance. The classification of different chemicals according to their characteristics (for example, those that are corrosive, or toxic to fish, etc.) currently follows an established system, which is reflected in REACH. Over the next few years, work is underway to establish in the EU a classification and labelling system based on the United Nations Globally Harmonised System, or GHS. REACH has been written with GHS in mind.

Information in the supply chain

The passage of information up and down the supply chain is a key feature of REACH. Users should be able to understand what manufacturers and importers know about the dangers involved in using chemicals and how to control risks. However, in order for suppliers to be able to assess these risks they need information from the users about how they are used. REACH provides a framework in which information can be passed both up and down supply chains.

REACH adopts and builds on the previous system for passing information - the Safety Data Sheet. This should accompany materials down through the supply chain, providing the information users need to ensure chemicals are safely managed. In time these safety data sheets will include information on safe handling and use.

What do we need to do to for REACH?

According to REACH, we are described as a 'downstream user'.

A downstream user is defined by REACH as someone, other than a manufacturer or importer "who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities" (article 3(13) of REACH)

The question is do we use chemicals at the University? The answer is YES, and not only in the laboratories. All cleaning products, paints, metals or glues are subject to REACH. If we are using widely available chemicals (such as cleaning products) in ways that are quite safe, REACH probably won't mean significant changes but you still need to check with your suppliers that they are registered (or currently pre-registered) somewhere along the supply chain.

If you rely on receiving specialist chemicals (such as in the laboratories) or ones that are not very common (certain solvents), you may need to be sure that these will still be available in the future. You should therefore, contact your supplier to find out if the chemical(s) in question will be registered by whoever makes or imports it. It is possible that some companies, for example for business reasons, may decide not to register chemicals. If so, then you may need to find an alternative source or even re-think your processes.

If you use a chemical in a novel way that is perhaps not expected then you will need to consider letting your supplier know. This use will need to be considered for registration by the supplier. If you don't want to let your supplier know about this use (for example because of commercial concerns) then you don't have to **but** it will mean that you will have to let the ECHA know about this use and possibly have to submit your own risk assessment.

Compile an inventory

Build an inventory of every chemical that comes into, is part of, or goes out of the business - what feedstocks, intermediates (isolated or otherwise), and products are used or created?

You need to know **all** the substances you use; for preparations you need to find out what the ingredients are. Keep a record of each one, and include essential information for example the name of the chemical and the percentage in any preparations. You can use this information to determine the tonnage per year.

Additionally you need to know whether you produce or import articles. If you do, establish if any substance (which is intended to be released under normal or reasonably foreseeable conditions of use) is present in these articles in quantities totalling over 1 tonne.

Once this inventory has been established, you can begin to understand what substances you rely on, and consider the impact on your business should REACH influence the supply (or for registrants, the production or import) of a substance. Consider contingencies, for example alternative supply, routes, chemicals or processes, or supporting suppliers in their REACH obligations, etc.

Prioritise

Every business making use of chemicals that aren't exempt from REACH needs to understand how valuable these substances are to them, and plan to make effective business decisions based on this knowledge. Consider the importance of each substance to your business. Ask yourself the following sorts of question:

- What do you use it for?
- Are the uses to which you put chemicals going to be supported by their registrants?
- How much of it do you use?
- Are there any alternative substances or processes that could replace this?
- Will your supplier/s maintain supply of important substances if REACH impacts the commercial viability of doing so?
- What will be the impact for you if the price increases or the supply drops, and what can you do about it?
- Do you want to share information back to registrants about what you use chemicals for, or is this information so sensitive that you would prefer to compile risk assessments yourself, and submit these directly to the European Chemicals Agency? What will this involve?
- Identify any chemicals that may be '**substances of very high concern**'.
- Determine your role in relation to each substance on the inventory.

Build relationships

Establish a relationship with your suppliers. You need to know how REACH is going to impact on your supply chain before you can decide what to do about it. Identify an appropriate person as the main REACH contact in your organisation and make them the focus for communications with suppliers and customers.

Placing orders for any Chemicals

When ordering any chemicals as described earlier it is important that you fill out the "Chemical Supplier Declaration Form" and attach it to the order. Your supplier will fill in the remaining details and return it to the University. This ensures that we are compliant.