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EU Regulation EC 1907/2006 Registration, Evaluation, Authorisation of Chemicals (REACH)

1. Introduction

The European Union's (EU) Registration, Authorisation of Chemicals (REACH) regulation (Regulation EC 1907/2006) was adopted on 30 December 2006 and places responsibility on manufacturers, importers, distributors and other downstream users of chemicals to register the uses of those chemicals in the EU and enter data into a central repository (IUCLID5)¹.

It also requires the industry to demonstrate the safety of chemicals via test data and exposure scenario modelling and to communicate any hazards and risks throughout the supply chain. The Regulation establishes a new European Chemicals Agency, based in Helsinki to enforce the Regulation.

2. The REACH System

The REACH System will be composed primarily of three elements: Registration, Evaluation, and Authorisation. There is also the possibility of a restricted authorisation – use permitted for certain applications only. Uses not giving rise to concern (such as well-controlled industrial or research laboratory use) may be exempted. The difference between REACH and the previous systems is that before only new chemicals and uses of substances above 10kg needed to be registered, now all chemicals need to be registered.

2.1. Registration requires substance manufacturers and importers to gather information on the substances they manufacture or import and use for responsible and well-informed risk management.

2.2. Evaluation of an estimated 5,000 substances will be carried out by Competent Authorities (CAs) of Member States. CAs will receive technical support and advice from the newly created EU Chemical Agency, including the development of substance-tailored testing programmes focusing on the effects of long-term exposure.

2.3. Authorisation of substances with certain hazardous properties that give rise to very high concern (CMR substances and POPs)² will be compulsory. Authorisation requires EU Commission authorities (not Member States) to give specific permission before a substance can be used for demonstrably safe, particular purposes. The number of substances subject to authorisation is estimated to be 1,400.

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¹ IUCLID5 is a web-based database managed by the EU Commission and will be used as a central repository for all substance registrations and testing data.

² *CMR Chemicals*: Chemicals classified as carcinogenic, mutagenic or toxic to reproduction : *POPs*: Persistent Organic Pollutants

3. Data Generation

Substance importers and manufacturers must provide the relevant authorities with information. Downstream users are required to provide information if the use of a given substance differs from that intended or there is a conflict with the manufacturer's recommended risk management measures.

4. Compliance

REACH covers most chemical substances that are either manufactured in, or imported into, the EU.

This can be:

- A substance on its own
- A substance in a 'preparation' (a mixture; for example ink or paint or extinguishing powder)
- A substance that makes up an 'article' (an object that is produced with a special shape, surface or design; for example a car, a battery, a smoke alarm, an extinguisher etc)

The actual responsibility for registration for manufacturers and importers is limited to the following scope:

4.1 Registration is required if:

- The substance is manufactured / imported in quantities > 1 metric tonne per year
- The substance is intended to be released from the article

4.2 Notification (a simplified registration) is required if:

- The substance appears on the candidate list for authorisation
- The substance is manufactured / imported in quantities > 1 metric tonne per year
- The substance is in the article at > 0.1% concentration

However, for manufacturers, importers and downstream users, the impact of REACH will be much greater than that implied by the limited scope of registration requirements. This is because REACH's registration requirements will cause higher costs for many substances used in articles and will even cause some substances to be removed from the market due to the increased demands and restrictions on their use. In fact, even if there is an exemption that can be applied (i.e. medical devices) all manufacturers, importers and even downstream users of articles would be advised to take the first step of contacting their suppliers to find out what substances are being used in their articles.

5. Enforcement

The enforcement regime for REACH has been implemented by the REACH Enforcement Regulations 2008. These Regulations apply to the UK and provide for the enforcement of REACH. They allocate responsibility for REACH enforcement to a number of enforcing authorities and provide them with the powers they need. The Regulations also require enforcing authorities to co-operate and share information with other bodies connected to REACH enforcement, and they set down the offences and penalties for contraventions of REACH requirements.

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5.1 Enforcement

The authorities given enforcement responsibility by the REACH Enforcement Regulations 2008 are those with existing remits to protect human health, consumer safety and the environment:

- The Health and Safety Executive (HSE)
 - The Health and Safety Executive for Northern Ireland (HSENI)
 - The Environment Agency (EA)
 - The Scottish Environment Protection Agency (SEPA)
 - The Northern Ireland Environment Agency (NIEA)
 - The Department of Energy and Climate Change (DECC)
- and
- Local Authorities (Las), as regards health and safety and consumer protection (trading standards).

Regulation 3 and Schedule 1 of the REACH Enforcement Regulations 2008 sets out which enforcing authority is responsible for enforcing the listed REACH provisions, though broadly speaking:

HSE, in its capacity as UK REACH CA, will enforce those duties in REACH concerning registration; HSE in Great Britain and HSENI in Northern Ireland will enforce supply chain related duties up to the point of retail sale, and for retail sale local authority trading standards departments are responsible.

A wide range of enforcing authorities will enforce use related duties, as per existing arrangements for enforcing health, safety and environmental legislation. HSE will enforce use-related duties relating to occupational safety and health in Great Britain.

• Offences and Penalties

The REACH Enforcement Regulations 2008 provide that it is an offence for a person to contravene a 'listed REACH provision' (this refers to the REACH requirements listed in the table Schedule 1 of the Regulations) or to cause or permit another person to do so.

The Enforcement Regulations allow for a breach of a listed REACH provision to be tried summarily (e.g. in Magistrates court) or on indictment (e.g. in Crown Courts), and provide that the same potential maximum penalty will apply for each provision, namely up to the maximum permitted under the European Communities Act 1972. These are currently:

- Up to £5,000 fine and/or up to three months imprisonment following summary conviction
- and
- An unlimited fine and/or up to two years imprisonment following conviction on indictment.

The Enforcement Regulations also provide for a number of supplementary criminal offences. These include obstruction of inspectors, providing false statements, failing to comply with enforcement notices and so on. These supplementary offences are also the subject of criminal penalties which are consistent with those above.

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6. Timeline

December 2006	Regulation adopted
1 June 2007	Regulation comes into force
1 June 2008	EU Chemical Agency begins to accept pre-registration
30 November 2008	Pre-registration of substances ends
1 December 2008	Registration for existing substances (that have not been pre-registered) starts
1 January 2009	List of pre-registered substances publishes and SIEFs are formed
1 June 2009	List of substances released
1 December 2010 Phase 1	By this date the following pre-registered 'phase-in' substances should have been registered when supplied at: <ul style="list-style-type: none"> • ≥ 1000 tonnes per annum (tpa) or • > 100 tpa and classified under CHIP as very toxic to aquatic organisms or • ≥ 1tpa and classified under CHIP as Cat 1 or 2 carcinogens, mutagens or reproductive toxicants
1 June 2013 Phase 2	Registration of Substances 100 – 1000 tonnes
1 June 2018 Phase 3	Registration of substances 1 – 100 tonnes

7. Roles

7.1 Manufacturers

A manufacturer is somebody based in the EU/EEA that produces or extracts a substance. This could be by chemical synthesis (i.e. by reacting chemicals together), by smelting (e.g. production of metals from ores) or by extracting them from another source (e.g. from crude oil or plant material).

Companies that simply blend substances together (formulators) are not generally manufacturers. However they should check this, especially when mixing acids and bases. [FIA advise that formulators of fire extinguishing agents – notably powders and foams – need to check to establish if they would be classified as manufacturers under the Directive. Further information on this is given in further FIA guidance].

Companies that want to continue to manufacture chemicals covered by REACH will need to register them with the European Chemicals Agency (ECHA) in Helsinki. Registration means providing a package of technical information on the chemical and its hazards to the ECHA. Registration is phased over a period of years based on tonnage levels and in some cases the hazards of the chemical. However, to take advantage of the phase in time chemicals needed to have been pre-registered.

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7.2 Importers

If you directly import anything from outside the EU/EEA, be it chemical substances (including metals), mixtures (e.g. paints, cosmetics), articles (finished products e.g. fire detectors, control panels, fire blankets) or articles that contain substances intended for release (e.g. fire extinguishers), then it is quite possible that you may have some responsibilities under REACH.

Companies outside EU cannot register chemicals themselves but can appoint an EU-based agent – an ‘Only Representative’ – to act on behalf of their EU-based importers.

If you want to continue to import chemicals covered by REACH you will need to register them with ECHA. Registration is phased over a period of years based on tonnage levels and in some cases the hazards of the chemical. However, to take advantage of the phase in time, chemicals needed to have been pre-registered.

7.3 Distributors

A distributor is anyone who **only** stores and places on the market a substance, on its own or in a preparation, for third parties. Placing on the market may be supply or simply making a substance available and may be in return for payment or free of charge. A retailer is a distributor. If the products that you distribute are articles, then you will also be classed as a ‘supplier of articles’.

Under REACH Distributors have the following roles:

- Pass health and safety information (including Safety Data Sheets, as appropriate) on the hazards and risks of the products you handle up and down the supply chain. For example:
 - ▶ If your supplier provides information on the hazards or safe handling of a substance/preparation, then you would have a duty to pass this on to your customers.
 - ▶ If your customers provide information about the uses to which they put the chemicals, you should pass this on to your supplier. Customers may need to make the company who will register the substances aware of their use in order for the manufacturer/importer to support it via their registration dossiers
 - ▶ Customers may want to know that the substances they are using have been pre-registered/registered under REACH so that they are meeting their legal obligations in respect of the use of these substances.

As most supply chains have many links, each distributor must pass the relevant information up and down the supply chain for REACH to operate properly.

- Not distribute products containing substances that should have been either pre-registered or registered, but haven't.

In order to ensure that you can fulfil your customer orders in the future (particularly if you distribute uncommon chemicals), you shall consider contacting your supplier to find out if the substances in question have been pre-registered (or registered already) by whoever makes or imports them. There are deadlines in 2010, 2013 and 2018 for the registration of pre-registered substances that will need to be respected by these manufacturers/importers. Substances not registered by the relevant deadline will need to be removed from the market until registered.

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- Keep all information that you require to carry out your duties under REACH for a period of at least 10 years after you last supplied a substance/preparation.

If you supply articles, containing a substance of a very high concern (SVHC) on the candidate listing a concentration above 0.1% weight/weights, you should supply your customer with sufficient information to allow safe use of the article and as a minimum the substance's name. In the future consumers may ask if SVHCs are present in articles and you (or whomever you supply) will need to provide a response within 45 days.

7.4 End Users

End users need to:

- Determine what chemicals they use
- Confirm with their supplier that the product has been pre-registered and then
- Work with the supplier to prepare the exposure scenario
- Give the exposure scenario to their end use if requested.

The best way to determine what chemicals are used is to prepare an inventory to find out what chemicals are used and in what quantities. Also you need to understand if you deal with substances on their own or in preparations. A substance on its own is any chemical element or its compounds, for example calcium, sodium nitrate or propanol. A preparation is a mixture or solution composed of substances, for example paint, ink or most extinguishing powders. Although not a legal requirement of REACH, a good way of finding out the substances/preparations you deal with is to develop an inventory of them. In its simplest form an inventory could be a basic list of the substances or preparations that come into your business.

How complex the inventory is will depend on the nature of your business and how many substances/preparations you use. This will need a dialogue with the suppliers to provide the information that they may themselves not have readily available.

Once the inventory has been prepared then the end users should contact their suppliers to ensure that they have accounted for that use in the registration information so that appropriate Exposure Scenarios can be prepared.

Note: The European Chemicals Agency website contains a search facility which you can use to find chemicals /substances that have been registered.

8. Glossary

Note: A full glossary can be found on the HSE website.

8.1 Article

An object which during production is given a special shape, surface or design, which determines its function to a greater degree than does its chemical composition. Examples of articles are a car, a battery, a telephone.

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8.2 CSA

Chemical Safety Assessment. This is carried out for all registered substances manufactured or imported at 10 tonnes per year or greater. It 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 the substance, taking into account implemented and recommended risk management measures and operational conditions.

8.3 CSR

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 and is a documentation of the chemical safety assessment (see above).

8.4 Competent Authority

The authority or authorities or bodies established by the Member States to carry out the obligations arising from REACH Regulation.

8.5 Distributor

Any natural or legal person established within the community including a retailer, who only stores and places on the market a substance, on its own or in a preparation for third parties.

8.6 Downstream User

Any natural or legal person established within the community, other than the manufacturer or the importer, who uses a substance either on its own or in preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.

8.7 Exposure Scenario

The set of conditions, including operational conditions and risk management measures, that describe how a substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

8.8 European Chemicals Agency (ECHA)

The Agency established for the purpose 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. The Agency is in Helsinki, Finland.

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8.9 Importer

Any natural or legal person established within the Community who is responsible for import.

8.10 Manufacturer

Any natural or legal person established within the community who manufactures a substance within the community.

8.11 Placing on the market

Supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.

8.12 SIEF

Substance Information Exchange Fora. SIEF participants should include all relevant actors submitting information to the Agency on the same substance.

8.13 Substance

A chemical element and its compounds in the natural state 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.

9. Further Information

- Health & Safety Executive – <http://www.hse.gov.uk/reach/index.htm>
- UK REACH Competent Authority helpdesk for information and support – email: ukreachca@hsi.gsi.gov.uk
- European Chemicals Agency (ECHA) – http://echa.europa.eu/home_en.asp