REACH: Part 2 of a 2-Part Feature

Do you know your RIPs from your SIEFs?

The new European law on chemicals, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force on 1 June 2007.

**Availability of Guidance Documents**
The European Chemicals Agency (ECHA) website lists all the Guidance Documents, which are currently available, or will be become available. These documents have been developed with the participation of many stakeholders (Industry, Member States and NGOs) within projects managed by the Commission. The objective of these documents is to facilitate the implementation of REACH by describing good practice on how to fulfill the obligations.

Some parts of these documents have been or will be translated in all the European Community languages. Guidance is (or will be) available under the following headings.

- Guidance on the different processes under REACH
- Guidance mainly for Industry use
- Guidance mainly for Authorities use
- Guidance on the different methods under REACH

**Manufacturers and Importers**

**Pre-registration** (to gain the correct phase-in registration periods)
- Collect available information
- Locate other relevant information holders and consider consortium
- Share data

**Registration** (normally together with the other substance suppliers)
- Carry out the Chemical Safety Assessment and write the Chemical Safety Report (≥10 tonne)
- Compile and submit Registration Dossier
- Communicate up and down the supply chain

**Don’t forget to pre-register in time!**
The vast majority of obligations under REACH apply to manufacturers and importers of substances in the EU. The REACH processes relevant for manufacturers and importers are: -

**Substance registration**
Manufacturers and importers of substances must submit a registration to the Agency for each substance manufactured or imported in quantities of 1 tonne or above per year. Failure to register means that the substance cannot be manufactured or imported. Producers and importers of articles need to pre-register and register substances which are present in their articles in quantities over one tonne a year and if those substances are intended to be released (e.g. printing cartridges). For these cases, the same registration obligations as for manufacturers and importers of substances apply in analogy.

Registrants wishing to use the phase-in provisions will be required to pre-register to the Agency to permit sharing of available information (data sharing). Registrants will be required to share data gained by vertebrate animal testing.

Registrants are required to update their registrations on their own initiative as soon as the quantity of a substance reaches the next tonnage threshold and/or when relevant new information becomes available.

**Notification obligations for articles**
If an article contains a substance of very high concern (≥ 0.1% w/w) which has been placed on the candidate list for authorisation there is an obligation to notify the Agency. This requirement applies if the substance is present in the article produced or placed on the EU market in quantities of 1 tonne or more a year and exposure to humans or the environment cannot be excluded. The obligation will apply from 1 June 2011 at the earliest (or six months from the date the substance has been placed on the candidate list, in case the substance has not been on the list before 1 December 2010).

**Classification and labelling inventory**
Manufacturers and importers must notify to the Agency the classification and labelling of all substances subject to registration or classified as dangerous (Art. 1 of Directive 67/548/EEC) and placed on the EU market. The Agency will include the notified substances in the Classification and Labelling Inventory.

**Information in the supply chain**
REACH will replace the current Safety Data Sheets Directive. The SDS requirements and responsibilities for manufacturers and importers will remain and be extended by the requirement to convey information from any relevant chemical safety assessment.

When a chemical safety assessment is performed (substances placed on the market in quantities ≥ 10 tonnes per year by a manufacturer or importer), exposure scenarios must be developed for dangerous substances and PBT/vPvB substances. These exposure scenarios shall be placed in an annex to the Safety Data Sheet. The exposure scenarios contain a description of the risk management measures which the manufacturer or importer has implemented and recommends downstream users to implement. For this purpose, manufacturers or importers must assess all uses that are identified to them by their downstream users. If they decide not to support a particular use, they must justify this and notify the Agency and their downstream user. Producers or importers of articles containing a substance of very high concern (≥ 0.1% w/w) which has been placed on the candidate list for authorisation must supply sufficient information to allow safe use of those articles to industrial and professional users. To consumers this information must be provided on request. In addition, the same information obligations as for manufacturers and importers of substances apply in analogy for substances in articles intended to be released.

**Substances subject to authorisation**
An authorisation is required for uses and placement on the market of substances included in Annex XIV of the REACH Regulation. An authorisation can be requested by manufacturers, importers or downstream users on their own or in collaboration with other actors in the supply chain. Importers of articles are not required to apply for authorisation even if the article contains a substance included in Annex XIV.
Applicants for authorisation have to demonstrate that the risks from their uses are adequately controlled or that the socio-economic benefits outweigh the risks, in cases where there are no suitable alternative substances or processes.

**Substances subject to restriction**

Manufacturers and importers and their customers must comply with the restrictions listed in Annex XVII of the REACH Regulation.

**Downstream Users**

- Make an inventory of your substances and uses
- Communicate up and down the supply chain and outside.
- Approach suppliers about their uses and their possible exposure scenarios
- Ask your customers about their uses
- Develop partnerships in your chain and / or with similar uses
- Ensure uses are covered in the exposure scenario of the Safety Data Sheet (SDS) that you communicated to the supplier.
- Implement the risk management measures (RMMs) assigned for the chemicals used.
- If you wish to keep a particular use confidential, prepare own Chemical Safety Assessment (check the exceptions to this rule)

Downstream users may be formulators of preparations (e.g. paints, glues, lubricants, detergents, plastics or rubbers), users of chemicals (e.g. oils, lubricants, anti-foams) in industrial processes, professional users (e.g. car repair shops and cleaners) or producers of articles (e.g. electronic components, computers, toys or cars). Distributors and consumers are not regarded as downstream users under REACH.

However, distributors must ensure safety information (e.g. a Safety Data Sheet -SDS) is provided with the substances they sell and pass on to the consumers.

**Information in the supply chain**

Downstream users may use a substance for an authorised use provided they obtain the substance from a company that has received an authorisation for this use and they use it within the conditions laid out in that authorisation.

It is possible that many phase-in substances will not be pre-registered by their registrant. The implication of this failure to register is that the substance may be withdrawn from the market either because EU manufacture has stopped or the substance is no longer being imported. It will be critical for each business to ensure that they are aware of what actions their suppliers are considering. Just like the Scouts: ‘Be Prepared’. If there is the potential for a substance to be withdrawn from your supply chain — your supply chain relationships are a key essential together with the process of identifying and assessing alternative substances.

**Potential Difficulties**

Points of Relevance for non-EU companies

Pre-registration is required for extended registration:

Your EU-importer or your ‘only representative’ must participate in the SIEF

Avoid unco-ordinated testing:

Testing can only be carried out once agreed in the SIEF

For higher volumes: Before testing can start, Agency must approve testing proposal

Substances intended to be released from articles:

These substances may also need to be registered

agency helpdesk addresses questions from outside the EU

Rod Parker
Great Health and Safety myths

Courtesy of the UK Health and Safety Executive, readers may wish to download copies for use in their own companies. They refer to UK regulations and the common myths that seem to make the rounds, but are untrue!

These posters are free to download and can be found at the following link.

**LINK**
www.hse.gov.uk/myth/index.htm

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**Great health and safety myths**

**The myth**  HSE has banned stepladders

**The reality**  We have not banned stepladders - nor have we banned ladders! Despite this, the allegation is regularly repeated and some firms have fallen for the myth and acted upon it.

For straightforward, short-duration work stepladders and ladders can be a good option, but you wouldn’t want to be wobbling about on them doing complex tasks for long periods.

A large number of workers are seriously injured or killed using ladders and stepladders each year. So:

Yes - we want people to use the right equipment for the job. Yes - there are some common-sense rules for using them safely. But no - we have not banned them!

Go to www.hse.gov.uk/myth/index.htm to find out more

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Great health and safety myths

The myth: Risk assessment must always be long and complex.

The reality: On the one hand, paperwork never bored anyone. It is a means to an end, not an end in itself. Action is what protects people. So risk assessments should be fit for purpose and acted upon.

OK, if you’re running an oil refinery, you’re going to need a fair amount of paperwork, but for most people these points were very well understood. See what we mean - check out our example risk assessments.

Go to www.hse.gov.uk/myth/index.htm to find out more

Great health and safety myths

The myth: Egg boxes are banned in craft lessons as they might cause salmonella.

The reality: This story started after a school briefly banned children from using cardboard egg boxes to make things. The following years of Blue Peter tradition. They were concerned that children might catch salmonella.

Within a few days the story reached national coverage from the local council and an organisation for teachers called CRAGS. Making clear that as long as egg boxes and toilet roll covers look clean, there is no reason why they should not be used. Just another story in an egg box...

Go to www.hse.gov.uk/myth/index.htm to find out more

Great health and safety myths

The myth: New regulations would require trapeze artists to wear hard hats.

The reality: Despite being widely reported at the time and regularly repeated since, this story is utter nonsense. There were never any such regulations. Hard hats do an excellent job of protecting building workers from falling debris - but they have no place on a trapeze.

Go to www.hse.gov.uk/myth/index.htm to find out more