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No.54 page 1

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 fulfil 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 manufactures 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 your 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 relevant information within the supply chain.

The REACH processes relevant for downstream users are: -

Substance registration and chemical safety reports

Downstream users of substances do not have registration obligations. However, to get the relevant information, downstream users have the right to make their uses known to their suppliers, so that the suppliers can include these uses in their chemical safety assessments as "identified" uses or pass the request up the supply chain. In doing so, they provide sufficient information to allow their supplier to prepare an exposure scenario. Downstream users can give brief general descriptions of uses that can be used as a minimum to identify such uses to the supplier. They can also provide an exposure scenario describing their use to the supplier. The manufacturer is not obliged to supply a substance for a use that he considers he cannot support.

Downstream users must prepare their own chemical safety reports (including the development of exposure scenarios) for uses outside the conditions described in an exposure scenario included in the Safety Data Sheets supplied to them as soon as they use at least 1 tonne per year. This provision enables downstream users to keep their use(s) confidential from their supplier, if they wish to do so.

"Notification" obligations

A downstream user must report to the Agency:

- if he uses a substance outside the conditions described in the supplier's exposure scenario;
- if he concludes (e.g. as an outcome of a chemical safety assessment) that the classification and labelling of his substance is different from that received by their supplier;
- within 3 months of the first supply of authorised substances.

Information in the supply chain

Downstream users must communicate information on dangerous substances and preparations down the supply chain through SDSs. They must communicate information up the supply chain when they gain new information on hazardous properties of the substance or the appropriateness of risk management measures in the SDS supplied to them.

REACH will replace the current Safety Data Sheets Directive. The SDS requirements and responsibilities for downstream users who formulate preparations and supply them further down the supply chain will remain and be extended by the requirement to convey information from any relevant chemical safety assessment (in particular exposure scenarios). In addition, downstream users may be supplied with additional safety information on the substances and/or preparations they purchase. They must follow this information and will also need to make sure that their customers have all the information necessary to use their products safely.

Substances subject to authorisation

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. The information on the uses covered by the authorisation and any applicable conditions must be provided by the supplier. Alternatively, downstream users can apply for an authorisation for their own or customers' uses.

Substances subject to restriction

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

Potential Difficulties

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.

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

Lube-Tech
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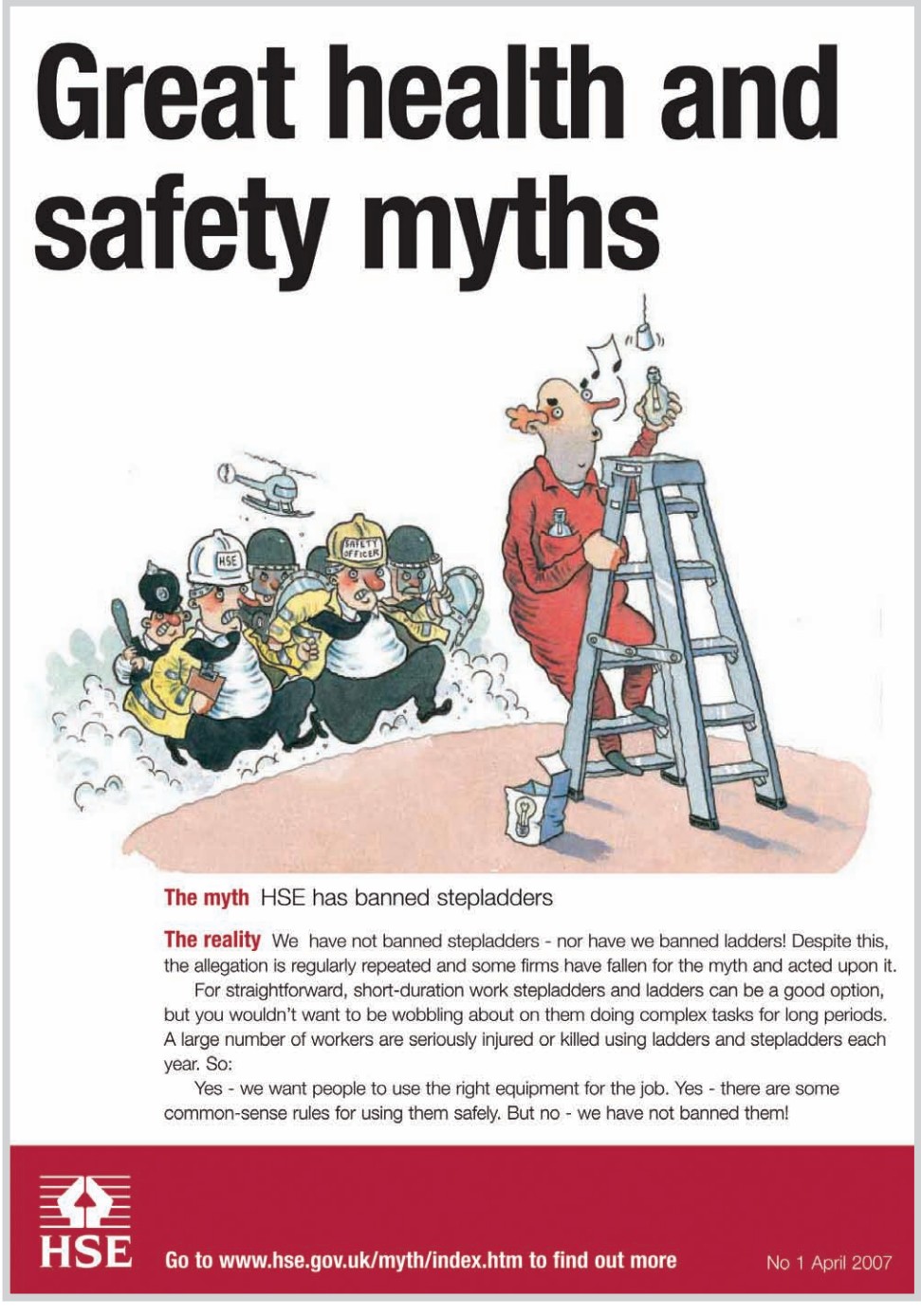
No.54 page 3

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



Lube-Tech

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No.54 page 4

Great health and safety myths

The myth Risk assessment must always be long and complex

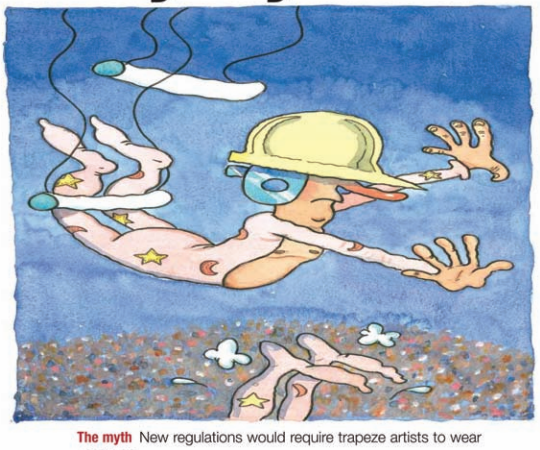
The reality On its own, paperwork never saved anyone. It is a means to an end, not an end in itself - action is what protects people. So risk assessments should be fit for purpose and acted upon.

OK, if you're running an oil refinery, you're going to need a fair amount of paperwork. But for most people bullet points work very well indeed.

See what we mean - check out our example risk assessments.

HSE Go to www.hse.gov.uk/myth/index.htm to find out more No 2 May 2007

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 never were any such regulations.

Hard hats do an excellent job of protecting building workers from falling debris - but they have no place on a trapeze.

HSE Go to www.hse.gov.uk/myth/index.htm to find out more No 3 June 2007

Great health and safety myths

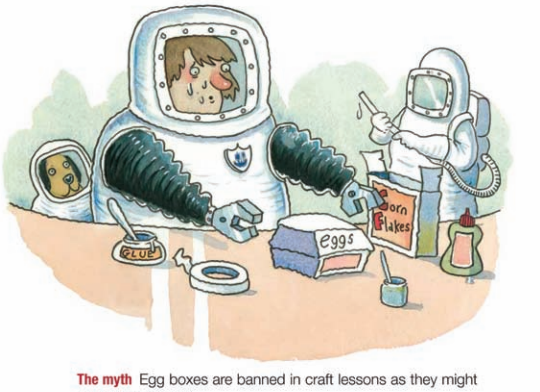
The myth All office equipment must be tested by a qualified electrician every year

The reality No. The law requires employers to assess risks and take appropriate action.

HSE's advice is that for most office electrical equipment, visual checks for obvious signs of damage or simple tests by a competent member of staff are sufficient.

HSE Go to www.hse.gov.uk/myth/index.htm to find out more No 4 July 2007

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, threatening years of Blue Peter tradition. They were concerned that children might catch salmonella.

Within a few days the school realised there was guidance from the county council and an organisation for teachers called CLEAPSS, making clear that as long as egg boxes and toilet roll centres look clean, there is no reason why they should not be used.

Just another storm in an egg cup…

HSE Go to www.hse.gov.uk/myth/index.htm to find out more No 5 August 2007