

Presentation on Registration, Evaluation, Authorisation and Restriction of
CHEMICALS Regulation 2006
by Richard Bishop, HM Inspector of Health and Safety
REACH UK Competent Authority

Richard belongs to the special HSE Unit set up to enforce- the operation in UK, the REACH UK Competent Authority.

Before that he had been an Inspector in the Field Operations Directorate for many years.

Richard told us that the REACH Regulation came into force on 1st June 2007 and that, unlike other EU-derived legislation, it was not a Directive, and did not need a distinct UK set of Regulations, so the new requirements are a straight translation of the original. However, special UK Enforcement Regulations are needed and these are being drafted with technical specifications, which will cover all substances in the workplace, either on their own, or in a preparation or article. The REACH Regulations are not just for the Chemical Sector!

Richard added that REACH was 10 years in the making and was introduced because of a widespread lack of knowledge on chemicals. It was estimated that, of the approximately 100,000 known chemicals, less than 1% were adequately controlled. There was also a high incidence of conception and birth defects across Europe that caused serious concern. It, therefore, aims to ensure a high level of protection for human health and the environment and it replaces a patchwork of other legislation with a single system. It does not replace COSHH and in fact works alongside it so that the two sets of regulations are mutually supportive.

The key players are: -

- **European Chemicals Agency (ECHA)**, based in Helsinki
- **Department for Environment Food and Rural Affairs (DEFRA)** – has the policy lead on REACH and acts on behalf of the devolved administrations.
- **UK Competent Authority (CA)** – located within the HSE, responsible for the day-to-day running of REACH in UK

One of the benefits of Registration has been an increase in research and a corresponding increase in the flow of relevant information into the supply chain. One of the drawbacks with COSHH has been that there is a burden on the user, aggravated by poor Product Safety Data Sheets. Under REACH, the burden of assessment would be transferred more to the Importers and Manufacturers who were required to register relevant chemicals. Richard went on to say that Manufacturers/Producers outside the EU could appoint **‘only representatives’** to act for them in dealing with registration and downstream users.

Other REACH roles were the Suppliers/Distributors in the Supply Chain to the Downstream Users, such as an End User, Industrial User, Article Producer, Craftsman, micro enterprise. A Single person may have several roles in REACH.



George Allcock of GKN commented that if you imported grease from outside the EU for use in an article that you manufactured, then you became an “Importer”.

Examples of articles containing chemicals

Richard explained that “Registration” was required where producers/importers supplied more than 1 tonne of chemical per year. This threshold was based on the amount of chemical in any preparation, not on the Gross Weight. Chris Fantom asked about motor tyres and brake pads that released chemicals in use. Richard said that this was not covered as a use, but might be covered as a ‘preparation’. He went on to describe examples of certain chemicals and preparations, to demonstrate REACH Terminology.

Substance	Preparation
Copper	Brass (alloy of copper + zinc)
Zinc	
Titanium dioxide	White Paint (Titanium dioxide +)
Ethylene Glycol	Antifreez (Ethylene Glycol +)
Ylang-ylang Extract	Fragrance Concentrate (Ylang-ylang Extract +)

Substances NOT covered are: -

- Radioactive materials
- Dangerous goods in transit
- Substances in Customs
- *Non-isolated* intermediates
- Waste

There are special tailored provisions for the following: -

- Human and Veterinary Medicines
- Food and foodstuff additives
- Plant protection products and biocides
- Isolated intermediates
- Substances used for Research and Development
- Polymers

Registration involves the submission of a Technical Dossier containing safety related information similar to that in existing Product Safety Data Sheets. In addition, there will be guidance on anticipated 'Exposure Scenarios', including a method of use and a forecast of quantities released, rather like COSHH Essentials. There will be different Exposure Levels for Workers and Members of the Public. If the substance imported is more than 10 tonnes per year, then a Chemical Safety Report is also required. On 1st June 2008, until 30th November 2008, substances may be "Pre-Registered" to take advantage of the phased introduction between 2008 and 2018. It is: -

- Free of charge
- Flags up an intention to register, although there is no commitment to final registration.
- It is simple top do – via ECHA electronically
- Allows manufacturers/importers to join with other wanting to register the same substance in a Substances Information Exchange Forum (SIEF)

Through registration, safety data sheets will contain more information about the risk management measures needed, because of the 'risk scenarios'. On the other hand there is also a commitment to pass information up the supply chain if 'users' find hazardous chemicals or different method of use. Substances not pre-registered must be Registered in December 2008, or cannot be manufactured, imported, or placed on the market legally. Any new substances must be registered from 1st June 2008.

George Allcock asked if there were any standards in REACH on the clarity of of information provided. Richard replied that there was not and that it would not affect packages covered in CHIP3. Users could always ask for more information if they needed any clarification. He added that 'consumers' were not defined in the regulations because they cannot be held responsible for the correct use under Health and Safety Law. 'Users', however, were identified for acceptable uses, whereas non-acceptable uses were addressed in a Chemical Safety Report.

The Evaluation stage included: -

- A completeness check
- A compliance check
- A Dossier evaluation
- A substance evaluation.

The Authorisation phase will proceed as follows: -

- Applied "Substances of very high concern"
- By June 2009 ECHA will produce a list of substances for Authorisation
- Industry will then need to submit an application for authorisation to either market or use.
- It is designed to encourage substitution as applicants will be expected to prove that they cannot use a viable alternative! If they have done this – users will not have to duplicate the process.

- There will be a cost to apply for authorisation

Restriction enters into force on 1st June 2009 and Annex XVII contains a list of restricted substances. The restrictions take many forms and are not always outright bans. From that time, it will be illegal to manufacture, market or use a substance outside the conditions of the restriction. This provision replaces the 'Marketing and Use Directive' but is not a new concept, as shown by the banning of Chromium VI in cement some years ago.

Linda Simpson of SHE Impact asked if Nano-Technology products were covered by REACH and Richard replied that he did not know what the ECHA viewpoint was.

(Secretary's Note: On this link www.hse.gov.uk/reach/faq.htm, the answer is "The EU is still considering whether or not nanosubstances require special treatment under REACH but in principle if the substance is supplied or imported at greater than 1 tonne per annum then, yes, it would be in the scope of REACH").

DEFRA Consultation on Enforcement will be carried out in 2008 and will adopt a 'Best fit' approach, based on current: -

- legislation
- enforcing bodies and
- their responsibilities

Enforcement proposals will result in a Statutory Instrument as follows: -

- **Registration Related Duties** – HSE in its role as Competent Authority
- **Supply Chain Related Duties** – HSE until Retail Sale (Trading Standards, thereafter)
- **Use Related duties** – existing UK enforcement regime and enforcing authorities for health, safety and environmental legislation

On the question of REACH and COSHH, Richard went on to say that: -

- They would apply 'without prejudice' to each other
- There were differences in scope and application
- There were differences in philosophies
- Nevertheless, they should be complementary

In addition, he said: -

- REACH should generate much better information about the hazardous properties of chemicals and the risks associated with their uses.
- These will be communicated to users via safety data sheets
- It will inform the COSHH Assessment
- Will include Occupational Exposure Limits

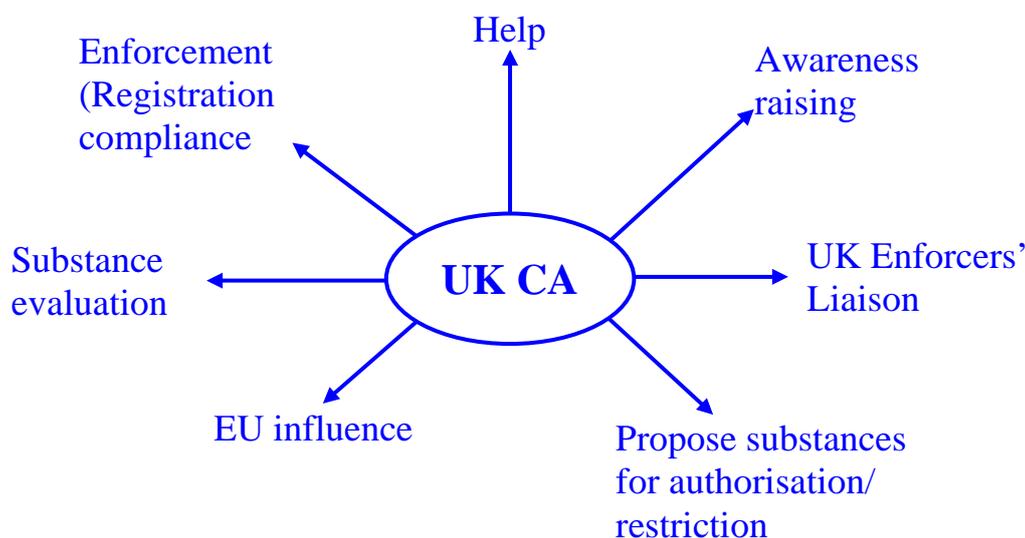
The next step for a manufacturer/importer should be: -

- Compile an inventory of substances
- Prioritise them – which are business critical?
- What will you do if your supplier stops selling the product?
- Build relationships with others
- Pre-register as soon as possible

In particular for downstream users, Richard said: -

- Consider the way you use chemicals
 - ♣ Standard chemicals in standard ways – nothing to worry about
 - ♣ Niche chemicals in a novel way – think about talking to suppliers about registration intentions, are your uses covered?
- Downstream Users **do not** have to register or pre-register

Richard then explained role the Competent Authority in the process, as follows: -



Members' Questions

Mike Wilkinson of Marsh UK asked if welding rods came under REACH and Richard said they would and definitely under COSHH.

John Merchant of DSM Demolition asked if dust from sites came under REACH. Richard said that as the dust was not supplied it did not come under REACH but definitely came under COSHH.

George Allcock asked if there was a REACH Database and if it was available on the website. Richard replied that there was a EU Database and added that only the

enquirer's own details would be available. Registration and Authorisation numbers stored on this database were printed on the safety data sheets.

Mick Thurman of Coltman Precast Concrete asked if concrete components had to be registered and Richard said it depended on a number of factors because they contained multiple substances in different proportions.

Mark Hoare of Birmingham University asked if there would be an improvement in the standard of information on Product Safety Data Sheets. Richard said there was unlikely to be an immediate improvement because of the delaying effect of the pre-registration which gave suppliers time to implement the Regulations.

As there were no more questions, Mark closed the meeting and asked members to show their appreciation of Ricard's very informative presentation.

Useful contacts for the UK CA Helpdesk

- **Telephone:**
0845 408 9575
0845 408 9574 (to book in for HSE led educational events)
- **Email:**
UKREACHCA@hse.gsi.gov.uk
reachmeetings@hse.gsi.gov.uk (to book in for HSE led educational events)
- **Post:**
UK REACH CA Helpdesk, 2.3 Redgrave Court, Bootle, Merseyside, L20 7HS
- **Website:**

www.hse.gov.uk/reach

The following guidance has just been published for "downstream users": -
http://reach.jrc.it/docs/guidance_document/du_en.htm