

Getting ready for REACH

Implications for occupational hygiene

With new European regulation of chemicals due to come into force in April 2007, BOHS president Andy Gillies explores the implementation of the new REACH regime and examines where occupational hygienists will play a key role.

THE European Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH) is due to enter into force in April 2007. A common position was agreed by the Council of the European Union on 12 June 2006¹. Final adoption of the proposal is expected by the end of 2006.

REACH will affect all manufacturers, importers and users of chemicals in the European Union, and streamlines the existing legislation on 'new' and 'existing' substances. It is concerned with ensuring adequate control of risks to humans and the environment from the manufacture, use and disposal of chemicals.

A BRIEF INTRODUCTION TO REACH

The objectives of the proposed REACH Regulation are to provide a high level of protection of human health and the environment, to facilitate the free movement of chemicals within the market, and to enhance competitiveness and innovation within the chemicals sector. The Regulation has been drawn up to ensure full compliance with the principles of sustainable development, and its provisions are underpinned by the precautionary principle.

REACH is made up of four parts:

- ▶ Registration of chemicals, documenting that risks are adequately controlled
- ▶ Evaluation of the registration dossiers, in particular any proposals for additional animal testing
- ▶ Authorisation of substances of very high concern
- ▶ Restriction of substances at EU level.

The Regulation requires industry to register all existing and new substances used in quantities greater than 1 tonne/annum (tpa) with the new European Chemicals Agency (ECA) to be located in Helsinki, Finland. Registration applies to chemicals whether in pure form or supplied as part of preparations or articles (such as printer cartridges). A phase-in period of three to 11 years is planned for registration of existing substances (estimated to be around 30,000), with higher tonnage substances and those of high concern

being done first. All new substances will have to be registered before they are allowed to be manufactured or marketed.

This represents a major shift in the approach to risk assessment of chemicals. The responsibility for ensuring the safe manufacture, use and disposal of chemicals throughout their life cycle is placed with the supplier (either the manufacturer or the importer). The supplier has to give guidance to downstream users on the risk management measures needed to achieve adequate control. Good communication both ways in the supply chain is essential for this to work effectively.

A technical dossier containing basic information is required for registration of low volume (1–10 tpa) existing substances. For high volume substances (greater than 10 tpa) registration dossiers will also require a detailed Chemical Safety Report (CSR – not to be confused with the acronym for Corporate Social Responsibility!). The CSR will include a chemical safety assessment covering human health and environmental risk, classification and labelling information, and risk characterisation for each identified use of the substance. Suppliers must demonstrate that risks are adequately controlled throughout the chemical life cycle through recommended risk management measures and appropriate operational conditions. Exposure scenarios describing processes, tasks, exposure estimates and risk management measures will provide the basis for the chemical safety assessment.

Evaluation of registration dossiers is done by the ECA or Member State Competent Authorities. There are two types of evaluation: a review of the documents, including animal testing proposals (for all dossiers), and a full dossier evaluation including a compliance check (covering at least 5% of dossiers registered in each tonnage band and those substances where authorities may have identified properties or uses of a substance that give rise to concern).

An authorisation procedure will be used for substances of very high concern, in other words, those classified as carcinogenic, mutagenic or toxic to

The value of occupational hygiene in REACH Implementation – the BOHS guiding statement

BOHS is a multidisciplinary learned and professional society acting as the voice for occupational hygiene in the UK and is a founding member of the International Occupational Hygiene Association.

The Society strongly supports the aims of REACH to reduce any adverse health impact associated with the use of chemicals. The skills and competencies embodied in the role of professional occupational hygienists are uniquely placed to assist in the successful practical implementation of the REACH legislation. Those areas where occupational hygienists make a key contribution to the multidisciplinary team are:

- Providing advice to manufacturers and importers (M/I) on recognising, evaluating and controlling health risks from handling chemicals, all of which are key elements in the chemical safety assessment.
- Helping M/I develop guidance for downstream users (DU) on practical and effective risk management measures (RMM), thereby providing concise and comprehensible input for the exposure scenario within an extended safety data sheet.
- Impartially advising the Commission (ECB/Chemicals Agency) and industry – particularly small and medium-sized enterprises – on key areas where its membership has

practical expertise, including exposure assessment approaches, the effectiveness of RMM and practical implementation of control strategies.

- Organising events to ensure that occupational hygienists are aware of the opportunities and training/competency needs, and that industry are aware of the skills and services that occupational hygienists can provide to help them comply with their legal duties.
- Assisting DU with site-specific advice on RMM to ensure compliance with REACH.
- Providing OH-specific guidance to supplement the technical guidance document.
- Working with EU bodies and competent authorities to develop guidance relevant to the above.
- Developing training modules for occupational hygienists and others to encompass the more specialist aspects of REACH.

BOHS views REACH as a real opportunity to further reduce exposure to chemicals in the workplace. The Society can help to achieve this by working in partnership with all involved to ensure that the skills and competencies of occupational hygienists are utilised in the most effective way.

Source: British Occupational Hygiene Society, www.bohs.org

reproduction in categories 1 and 2 (CMR), substances which are persistent, bioaccumulative and (eco)toxic (PBT), and substances which are very persistent and very bioaccumulative (vPvB). Other substances with a similar level of concern (for example, endocrine disrupters) may also be subject to authorisation. The authorisation will cover one or more specific uses of a substance where safe use can be demonstrated or where a socio-economic analysis shows that societal benefits outweigh the risks.

Restrictions – the ‘missing R’ in REACH – on the marketing and use of substances will be proposed by the European Commission or a Member State where it is deemed that risks to human health and the environment are unacceptable.

IMPLEMENTATION

A Competent Authority (CA) will be established in the UK to administer the Regulation. At the time of writing the identity of the CA has not been revealed but it is likely to involve the Health and Safety Executive (HSE) and the Environment Agency in some form. As an EU Regulation, REACH will have ‘direct effect’ in Member State jurisdictions and does not require transposing legislation to take effect. However, a number of pieces

of existing legislation, for example those dealing with ‘new’ and ‘existing’ substances, will have to be modified or repealed. It is important to note that UK health and safety legislation, such as the Control of Substances Hazardous to Health Regulations 2002 (COSHH), is not affected in this way and will continue alongside REACH.

REACH AND OCCUPATIONAL HEALTH

REACH has been driven by the European Directorate-Generals for the Environment and for Enterprise at European Commission level, and the most intensive lobbying has come from groups interested in the environmental rather than health issues. Nevertheless, this is changing as industry and regulators start grappling with the detail of how it will work in practice. Many aspects of REACH touch on fundamental occupational hygiene practice and occupational health professionals must be engaged to deliver effective implementation. The key issues affecting occupational health are outlined below.

EXPOSURE SCENARIOS

An exposure scenario sets out how a substance can be applied in a given use, or uses, in a way that risks are adequately controlled. It covers:

- ▶ descriptions of the processes and tasks involved in the manufacture and identified uses of the substance
- ▶ the operational conditions employed – including frequency and duration of specified operations
- ▶ risk management measures needed to prevent or adequately control exposure – including controls on emissions at source, design of process equipment, work environment, personal protective equipment (PPE)
- ▶ other relevant information.

The exposure scenario must be included as an appendix to the Safety Data Sheet. Downstream users of the substance must ensure that their operational controls conform to the exposure scenario provided by the supplier. Exposure scenarios are needed to cover the manufacture and all identified uses throughout the life cycle of the substance. Substance life cycles can be very complex with the substance used in pure form or as part of different preparations or articles. Activities of consumers and the duration and frequency of their exposure may be relevant, and waste management measures to minimise exposure during waste disposal or recycling should be considered.

For the manufacturer this can be a daunting prospect. How can a company really know how its substance or product is used in all situations down the supply chain? This is where good communication is essential and it is envisaged that exposure scenarios and risk assessments will be developed in an iterative way, with initial scenarios being refined and improved over time. There is a balance to be struck between generic and site-specific exposure scenarios. From the manufacturer's viewpoint a generic scenario covering a number of uses is probably favoured. This gets over the problem of producing a risk assessment for a workplace you have not seen and where other substances presenting different health risks are in use. However, it would probably result in over-cautious recommendations for risk management measures, since the prescribed measures will have to give adequate control in all situations. On the other hand, site-specific scenarios will tailor risk management measures to the defined use but the effort needed to develop these throughout the substance life cycle would be considerable. In practice, the level of detail in the exposure scenario is likely to reflect the severity of the hazard or the expected degree of exposure.

A model already exists for how exposure scenarios might be constructed in the form of Control Guidance Sheets used in the HSE's COSHH Essentials protocol. These guidance notes describe equipment design, work procedures, maintenance, housekeeping, PPE, training and other measures. They have been developed for a number of standard operations (such

as, bag filling and spray painting) and industry sectors (for example, foundry, service and retail). Much work is going on behind the scenes in a series of REACH Implementation Projects to develop guidance on implementation of the Regulation, and advice on constructing exposure scenarios will be a key outcome.

RISK MANAGEMENT MEASURES

The basic principles for preventing or controlling health risks during the handling of hazardous materials are laid out in the chemical agents directive (98/24/EC), which is implemented in the UK by the COSHH Regulations. The hierarchy of control and principles of good occupational hygiene practice (Schedule 2A of the COSHH Regulations, as amended) provide the starting point for deciding on appropriate risk management measures for occupational health. (REACH, of course covers environmental and safety risks as well, but they are outside the scope of this article.)

REACH distinguishes between 'operational conditions' and 'risk management measures'. Operational conditions in the workplace context include process details, physical form of the substance, worker activities and duration and frequency of exposure. Risk management measures cover techniques to reduce or avoid exposure in manufacture, use and disposal/recycling activities. All routes of exposure (inhalation, skin contact and accidental ingestion) must be considered.

A range of measures exists to reduce exposure, from modifying product design details (for example, limiting the amount of substance in a preparation to below a threshold concentration) to labelling with instructions for safe use. In the workplace context, options may include process and equipment design, engineering controls such as automated handling, containment and ventilation systems (general and local), restrictions on entry or duration of exposure and the use of PPE. The best combination of control options differs for each situation but generic advice can be very helpful to direct users to proven solutions.

One of the most important questions, of course, will be: 'How effective is the control measure?' The question might concern, for example, the effectiveness of a local exhaust ventilation (LEV) system. The answer is that it depends on the circumstances. In the case of the LEV system, control will depend, amongst other factors, on the design of the hood, how close the inlet is to the source and the energy of release of the contaminant. A rough guide is given in control banding schemes such as COSHH Essentials, which suggests three levels of control: general ventilation; engineering control; and containment. Exposure predictor bands can then be derived for each approach depending on the quantity and dustiness (or volatility)

of the substance. In this way, a manufacturer or downstream user can get a feel for the likely level of control that may be required. More validation of control banding predictions by direct exposure monitoring is needed to increase confidence in this application.

DNELs AND WELs

The Regulation requires that manufacturers and users achieve adequate control of exposure to a substance throughout its life cycle. Conditions are specified in exposure scenarios, and adequate control is defined as an exposure scenario where the estimated exposure levels do not exceed the 'derived no effect level' (DNEL). DNELs for a substance will be set for each relevant human population (for example, workers, consumers, pregnant women, the general population via indirect exposure) and for different routes of exposure (such as inhalation, dermal and oral). For a given exposure scenario a single DNEL may be sufficient but it needs to take into account data uncertainty, the sensitivity of sub-populations, and the nature and severity of the health effect.

The basis of DNEL values will be a substance hazard assessment carried out by the supplier, which evaluates relevant non-human and human toxicological information. The results of animal tests, quantitative structure-activity relationships (QSARs), epidemiology studies, and other information sources will be reviewed and summarised as part of the registration phase. The information giving rise to the highest concern shall be used to establish the DNEL. The DNEL values will be included in the safety data sheet.

Under the COSHH Regulations, UK employers must comply with workplace exposure limits (WELs). But how will the DNELs compare with these existing workplace limits? This question cannot be answered until the DNELs have been set, but it is probable that, at least for some substances, DNELs will be set at lower numerical values than WELs. And this, of course has legal ramifications for the operator. If it complies with the WEL then it is meeting the requirement to achieve 'adequate control' under the COSHH Regulations, but may not be meeting its duties under REACH. The interface of the REACH Regulation with existing health and safety legislation is a puzzling area and more clarity is needed from the European Commission.

THE RESPONSE OF THE PROFESSION

The British Occupational Hygiene Society (BOHS) has been actively engaged in REACH developments for a long time. We realise that the Regulation will have a major impact on the work of occupational hygienists and other OH professionals and could make a real

CONCLUSIONS

- The European Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH) is expected to come into force in April 2007
- It is designed to protect both human health and the environment and will require the registration of all new substances before being manufactured or marketed
- Life-cycle responsibility will be placed on the supplier (manufacturer or importer) of chemicals
- In the UK, the COSHH Regulations will continue alongside the duties imposed by REACH
- OH professionals need to engage with other stakeholders in the development of guidance and in compliance issues

difference in reducing exposures and ill health caused by work if it is implemented properly.

In December 2005, BOHS co-hosted a two-day workshop in Brussels with the Belgian Society for Occupational Hygiene². This looked at some of the implications for occupational hygiene and opened up debate on key issues with European Commission officials, trade association representatives and others. We have drawn up a one-page statement of the value of occupational hygiene in the effective implementation of REACH, which summarises the areas where hygienists can make a useful contribution (see box). The BOHS Steering Group on REACH is actively engaged in producing straightforward guidance for manufacturers and downstream user groups, raising awareness amongst our members and others about the new Regulation, and providing technical input to developing guidance.

Will REACH achieve its aims of providing a high level of protection of human health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation? It is a tall order, but it will happen if all the actors pull together. ■

Andy Gillies is president of the British Occupational Hygiene Society and chair of its REACH steering group.

Notes

¹ Council of the European Union. Common position: the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Brussels: Council of the European Union, 12 June 2006, <http://register.consilium.europa.eu/pdf/en/06/st07/st07524.en06.pdf>

² Northage, C, Urbanus J, van Hemmen, JJ. REACH: Implications and Opportunities for the practice and profession of Occupational Hygiene – an International Workshop 14–15 December 2005, Brussels. Report of workshop sessions and summary of conclusions. Derby: British Occupational Hygiene Society and the Belgian Society for Occupational Hygiene 2006.