

Editorial

REACH—how is it going?

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REACH, the Registration, Evaluation, Authorisation and Restriction of Chemicals regulation (European Union (EU), 2006), is the greatest upheaval ever in European regulation of chemicals. Its implementation is now well under way. The European Chemical Agency (ECHA) in Helsinki administered much of the scheme and tried to restrict the number of chemicals in the first pre-registration stage to 10 000, but by the end of 2008, 165 000 substances had been pre-registered by 65 000 companies (ECHA 2008a, 2009). Registration must be complete by 30 November 2010 for chemicals supplied at >1000 tons year⁻¹, with lower thresholds for chemicals that show certain serious effects. Registration will involve completion of a Chemical Safety Assessment, culminating in risk management measures (RMMs) for each application of each chemical, if it is classified for health or environmental effects (ECHA, undated). Eventually, all classified chemicals supplied at >10 tons year⁻¹ will need such an assessment. The process is dominating the activity of many occupational hygienists in the European chemical industry and is affecting many others.

The British and Dutch Occupational Hygiene Societies (BOHS and NVvA) convened a 2-day second European Conference and Workshop on REACH in Brussels at the beginning of October 2009, at which 180 delegates from 15 countries reviewed occupational hygiene aspects of the work in progress, especially exposure scenarios and safe handling advice. The presentations are available on the BOHS and NVvA websites <http://www.bohs.org/eventDetails.aspx?event=164> and www.arbeidshygiene.nl.

The central feature of REACH is that key responsibilities for specifying controls at the point of use are now placed on manufacturers, if in the EU, or importers of the chemicals. Manufacturers or importers (MoI) must estimate human exposure by all routes for each potential use and specify RMMs which will reduce exposure below an exposure limit. The user is obliged to implement these control measures. In the past, there have been EU supply regulations requiring central risk assessment of chemicals, but this has been very slow. EU legislation has generally made control in the workplace the responsibility of the employer, not the manufacturer, with control subject to risk assessment at the point of exposure. Now MoIs are the key people, although the earlier workplace legislation also remains in force.

Most past EU regulation of the workplace has been by directives imposing minimum standards, which each member state is then responsible for implementing through its own legislation. REACH is a direct-acting regulation, not requiring national implementation of its main measures. The regulation covers not only the workplace but also consumers and the environment as well. It comes under enterprise and environment components of the Treaty of Rome, not the social provisions of the Treaty that are the usual basis for EU workplace legislation. To the outside observer, it looks as if concern for the consumer and the environment has overwhelmed lessons from good practice in the workplace.

Present occupational health regulations, based on the Chemical Agents and Carcinogens Directives and others, remain in place (EU, 1998, 2004), and REACH will apply alongside them. They will obviously remain important for hazardous substances which are not supplied, such as welding fume,

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respirable silica generated by processes, and asbestos, but in addition measures like health surveillance, not covered by REACH, are unchanged.

Much of the conference focused on the problems of the exposure limits used by REACH and the estimation of exposure that might be achieved with particular control measures. Traditionally, occupational exposure limits (OELs) have been derived by regulators or professional bodies by careful consideration of the evidence, usually with greatest weight being given to human epidemiology. This has only succeeded in producing a few hundred OELs, and the process has taken many years. OELs may cover the great majority of hazardous workplace exposures, but the number of chemicals covered is clearly inadequate. This is said to be part of the motivation for REACH, which requires MoI to derive exposure limits as a condition of being allowed to market their products.

MoIs are given a mechanistic system for calculating the exposure limits (ECHA, 2008b), which are called derived no effect levels (DNELs). In contrast to OELs, they are largely based on animal toxicology tests, with little reference to human health studies. Several successive safety factors must be applied in predicting the threshold of human health effect from the animal toxicology, and when this is applied to chemicals for which an OEL exists, the resulting DNEL can be an order of magnitude or more below the OEL. MoIs must make DNELs available by November for all chemicals supplied >1000 tons year⁻¹ and eventually for all >10 tons year⁻¹, probably tens of thousands of them. Each chemical may need several different DNELs, covering different routes, for example, dermal exposure.

Not surprisingly, occupational hygienists are very interested in how DNELs for inhalation exposure will relate to OELs (Bailey, 2007), and the Brussels conference discussed this at length. In principle, they are different. Under current workplace legislation, 'adequate control' has been partly determined by compliance with OELs, which are defined as 8-h or 15-min time-weighted averages, and must not be exceeded (EU, 1998, 2004). To achieve this consistently, controls have to be in place so that average exposure is usually a fraction of the OEL (Ogden, 2009). DNELs are used differently—together with estimates of exposure they are used to specify RMMs, so that DNELs impact the workplace through RMMs. However, REACH also requires new extended safety data sheets for all the chemicals, and these will state the DNELs; so for the people in the workplace—employers or workers—these will surely become the numbers that count. Current

workplace OELs may be used as DNELs under very restricted conditions. Where there is an EU indicative OEL derived under the Chemical Agents Directive (EU, 1998), this may be used with some restrictions unless there is more recent scientific information. National health-based OELs may be used as DNELs if they are in line with DNEL standards (ECHA, 2008b, Appendix R, 8–13).

Many of us brought up under the old system are sceptical about the new one because it is well known that the effectiveness of most RMMs, for example engineering controls, depends crucially on how they are installed, maintained, and used, and specifying them on a data sheet in the belief that this on its own will achieve a particular exposure in the workplace is very optimistic. However, REACH may provide an incentive to productive research in this field. Fransman *et al.* (2008) have developed an Exposure Control Efficacy Library, which brings together 433 efficacy measurements of various RMMs from 90 peer-reviewed publications. Also, the system ought to result in routine tighter control of a far wider range of chemicals, which should positively impact human health. The user is supposed to report inadequate RMMs to the MoI, but it is unclear how this will deal with inadequate installation or maintenance.

The other topic which gave rise to a lot of discussion at the conference was the system for deciding what exposures would occur for the many uses of chemicals. Put against the DNELs, these provide the specification for the RMMs. Of course available measurements are very inadequate for the purpose because of low quality, lack of contextual information, or because they are usually shift-average rather than task-based. One delegate said they had thousands of measurements in internal company files but only 1 or 2% were useful for this purpose. And of course, if the chemicals are new products or applications, measurements do not exist.

For this reason, REACH has generated much work on modelling exposure, so that levels can be predicted from information about the chemical and the workplace, and these models also produced a lot of discussion at the conference. Three 'Tier 1' models were presented. The European Centre for Ecotoxicity and Toxicology of Chemicals has produced its Targeted Risk Assessment tool, ECETOC-TRA (<http://www.ecetoc.org/tra>). The second Tier 1 model is Stoffenmanager (<https://www.stoffenmanager.nl/Public/Explanation.aspx>), developed by TNO, and the Netherlands consultancy Arbo-Unie (Marquart *et al.*, 2008; Tielemans *et al.*, 2008a). Stoffenmanager now has ~10 000 users worldwide. The

third model is the EMKG-EXPO-Tool (Tischer *et al.*, 2009; EMKG is Einfaches Massnahmenkonzept Gefahrstoffe), which was developed by the German federal health and safety agency Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BauA) in Dortmund. Details are available (in German) at http://www.baua.de/nn_5846/sid_2255F2549BF8B1D46C7FE3CB73E7D2B0/de/Themen-von-A-Z/Gefahrstoffe/EMKG/EMKG__content.html?__nnn=true. This tool is similar in structure to the British control banding approach used by Control of Substances Hazardous to Health (COSHH) Essentials, but takes account of German Hazardous Substances Ordinances.

The Tier 1 models are intended to be conservative for inhalation exposure, that is, they usually predict higher exposures than occur in practice. However, little attention has been given so far to validation of the available Tier 1 models. ECETOC-TRA and Stoffenmanager also predict dermal exposures, which is important because dermal DNELs are required for chemicals under REACH. Stoffenmanager uses the RISKOFDERM toolkit in its dermal assessment (Goede *et al.*, 2003).

The Tier 1 models are being improved in various ways, but there was a lot of attention given to a Tier 2 model, the Advanced REACH Tool (ART) <http://www.advancedreachttool.com/>. This is being developed by a consortium of TNO, the Institute of Occupational Medicine in Edinburgh, the Health and Safety Laboratory, BauA, the University of Utrecht, and the National Research Centre for the Working Environment in Denmark (Tielemans *et al.*, 2007, 2008b). ART integrates a mechanistic model with any measurements available to the user, using a Bayesian algorithm. The output gives expected percentiles of the exposure distribution. An example (Cherrie and van Tongeren, 2009) showed how the input of a relatively few measurements from an analogous scenario much reduced the uncertainty of the estimates and how different possible RMMs affected the predicted exposure. The model is still under development, but a beta version should be released shortly. BOHS (2009) is supporting the ART consortium to gather data to calibrate the model for various scenarios. One of the planned developments of ART will cover dermal exposure.

One person who is a chemical user gave his idea of how models might be used with inhalation exposures. (i) Select RMMs that would be chosen according to present legislation, in Britain the COSHH Regulations. (ii) Use a Tier 1 model to see if this predicts compliance with the DNEL. If so, this is a satisfactory outcome because Tier 1 models overestimate exposure. If not (iii) use a Tier 2 model, and if

this still predicts exposure over the DNEL, (iv) select RMMs which give exposure estimates below the DNEL.

Viewing all this as an observer, and considering the huge task and the time pressure, the atmosphere at the conference was very calm. The timetable to the first registration deadline may have looked relaxed to those who drew up the regulation, but industry has been given very little time to work this huge revolution. Also, occupational hygiene skills are necessary to produce adequate Chemical Safety Assessments, but the size of the task surely dwarfs the total availability of this expertise in Europe. Even for the models, several presenters mentioned the importance of training. What percentage of the 65 000 companies that pre-registered chemicals have any access to occupational hygiene expertise or have even heard of the discipline? Not many of the 65 000 were represented at the conference!

A very experienced hygienist working for a major MoI was similarly calm: 'Perhaps in five years time this will look to be quite a good scheme. For the moment, we just have to get everything registered by November.' BOHS and its collaborators plan future meetings, and it will be interesting to see how things look then.

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