Invited Editorial

European Chemical Regulation and Occupational Hygiene

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Occupational hygienists and other health scientists should have little problem in accepting that approaches to the management of risk should be based on soundly constructed principles of risk assessment. Such thinking permeates many aspects of occupational health practice and is reflected in supporting legal frameworks, for example the Chemical Agents Directive (EC, 1998) and UK Control of Substances Hazardous to Health (COSHH) Regulations (Department of Health, 1999). Yet within Europe, such approaches are now under discussion concerning their relevance to other aspects of chemicals management. Three areas in the current debate are most pertinent.

1. Despite the fact that Europe has in place an extensive regulatory system covering the marketing of chemicals, there remains a lack of information about their properties and uses. This, coupled with concerns over the effectiveness and efficiency of the system itself, has led the European Commission to reassess how the risks from chemicals ought best to be regulated in the marketplace. The Commission Strategy for a Future Chemicals Policy (European Commission, 2001b) outlines a basis for a new approach. The key feature of the proposal is a single system (termed ‘REACH’) where key information for most chemicals will be registered in a central database. The information requirements will vary, with higher levels being demanded when higher risks are likely. For some chemicals of very high concern (most probably established carcinogens, mutagens and reprotoxins), manufacturers of these substances will additionally be required to seek authorization for their continued use and to demonstrate that safer alternatives are not realistically usable.

Some groups have viewed certain aspects of the proposals as tantamount to ‘reversing the burden of proof’, by assuming that a chemical is dangerous until evidence exists to demonstrate that it can be used safely. But an analysis of the proposals suggests that the ‘increased burdens’ are defined largely by concepts of risk. In theory, therefore, the changes ought to provide a better basis for future regulation. What are missing, however, are details of how any risk-based scheme will operate and, in particular, the role of exposure data in the process. The challenge for REACH, therefore, will be to deliver a workable scheme which is built upon sound concepts of risk, while accounting for the concerns that have arisen as a consequence of the previous regulatory regimes (EEA, 2001). The use of exposure data in the regulatory process is discussed in two papers in this issue (Money and Margary, 2002; Tielemans et al., 2002).

2. One criticism of this approach to regulation is that whilst it may be good at addressing what is known, it is unable to deal adequately with what is unknown. Thus, for major human and environmental concerns this deficiency is regarded by some as unacceptable, pointing to the need for an alternative approach to existing mechanisms of regulation. Alternative approaches are now being promoted (Raffensperger and Tickner, 1999), some of which use extreme interpretations of the precautionary principle as their basis.

The precautionary principle (European Commission, 2000) is not a new concept for occupational hygiene. Simply stated, the precautionary principle mandates that action should be taken, even without clear evidence, when the potential adverse effects for man or the environment are serious. It could be argued that some aspects are already embodied in the hierarchy of exposure controls (elimination > substitution > isolation, etc.) that forms a cornerstone of professional practice. But there is a difference between some
of the interpretations of the precautionary principle now advocated and those enshrined within occupational hygiene control hierarchies. The latter operate in conjunction with a risk-based decision framework (the workplace risk assessment), whereas the structure under which the former function remains somewhat unclear and, in some cases, relegates considerations of risk to a subsidiary level. This may appear disconcerting, but in the case of the Carcinogens Directive (EEC, 1990; EC, 1999), the precautionary principle already determines how carcinogens can be used within European workplaces. Thus its real impact is likely to result from how it is used, rather than from theoretical extrapolations of what it states (Patrie, 2000).

3. Existing legal instruments cause much regulatory action to be undertaken selectively and in isolation. Such approaches do not address wider considerations, such as the benefit that any technology or chemical may have for society, compared with the harm that may arise from their use. The Integrated Product Policy (IPP) is intended to fill this need (European Commission, 2001a). This provides for a more holistic approach to the regulation of product (including workplace chemicals) impacts throughout their life cycle. It seeks to minimize such impacts through measures that would enable financial incentives to help ‘reward’ products with desirable characteristics. In combination with better product information, IPP would provide a basis by which consumer choice and pricing would use market forces to deliver improved environmental quality.

The effect that these developments will have on occupational hygiene and health practice is still unclear, but they are certain to have impacts and, dependent on one’s viewpoint, these may be positive or negative. For example, if stricter criteria are applied in judging whether a chemical can be used without undue risk to health, better quality exposure and human effects data may be needed. And as such data will need to extend across the life cycle of the chemical, new fields may open to apply many traditional occupational hygiene skills to consumers and the public generally, for example.

In contrast, the increased use of extreme interpretations of the precautionary principle could be viewed as devaluing the role of scientific investigation and debate in managing chemical risks. Rather, it suggests that effective risk management can be driven simply by considerations of hazard rather than the more complex and less obvious considerations of risk (Morris, 2000). The discussions that are currently underway within Europe on these contrasting approaches will continue during 2002 and 2003. This must be welcomed, as scientific assumptions and values should always be challenged and debated, so they can be calibrated to society’s needs.

In response to the foregoing, the European chemical industry (CEFIC) is now in part beginning to restructure the content and objectives of its scientific research programmes. CEFIC, together with partner trade associations in the US, Japan, Canada and Latin America, has begun to develop a programme that identifies key research issues that the chemical industry needs to address if sufficient science-based information is to be available for regulators and the public to reach risk-based judgements (CEFIC, 2001). This has started with the Long-range Research Initiative (LRI), which recognizes that research foci will differ by region. But several themes are common, notably the key role that a thorough understanding of exposure has in describing human and environmental risks.

One aspect of the LRI of interest for occupational hygienists is the need for better quality exposure information; a top priority across all the areas of research, especially where current knowledge is limited, e.g. dermal exposure to solids and uncertainty in exposure models. It also extends to the development of tools and mechanisms by which exposure information might be obtained in situations where data are limited, e.g. in small and medium sized organizations (Money, 2001).

During 2002–2005 in Europe alone LRI will make available over 6000000 euros for human exposure-related research. Many research priorities will result from ongoing research activities, but others will be determined by the feedback that CEFIC receives from interested stakeholders. To this end, the LRI has funded two Web sites, one on occupational hygiene (http://www.herox.org) and the other on indoor air (http://wads.cfs.le.ac.uk/ieh/erie/welcome.htm), specifically designed to share and publicize recent scientific developments in these fields. Both sites also have the objective of soliciting comments on new research needs and stimulating discussion on new findings.

Occupational hygiene is a discipline based upon sound and relevant scientific principles whereby workplace risks are reduced and much industrial injury and disease prevented. Occupational hygienists might wish to consider how best to participate in the wider dialogue now taking place in Europe on the role of science in policy making, so that these principles continue to be effectively used in the wider protection of public health.

REFERENCES


