Sharing Toxicological Information on Industrial Chemicals

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A clear and comprehensive appreciation of the toxicological hazards of a substance is an essential prerequisite to establishing appropriate, balanced and effective risk management measures in the workplace. For many substances, there are currently numerous problems and issues surrounding: the adequacy of the toxicological information base; its interpretation; the transfer of key messages to, and their understanding by, those who need to take action; and the roles and practices of the various standard-setting bodies operating in this area and the interaction between them. This paper briefly touches on these issues, on a range of activities and initiatives directed at improving the current situation, and on the implications for all those involved, particularly the world occupational hygiene community.

INTRODUCTION

A clearly understood, well-communicated position on the toxicological properties of a substance is an essential foundation stone for the development of sound risk management positions and regulatory standards. One then has a good basis for identifying measures that should be employed to secure appropriate control of exposure in order to protect the health of those exposed to the substance at work.

Assembling a complete and robust toxicological profile for a substance can be a complex task. There are multiple potential hazards to consider (e.g. acute systemic poisoning, eye irritation, skin sensitisation, genotoxicity and its potential consequences, reproductive toxicity) and the dependency on dose level, dose pattern and exposure route for the expression of each of the hazards possessed by the substance. A substantial amount of raw data is required to enable all of these considerations to be addressed. Appreciable technical resource is necessary to process, critically analyse and interpret such information, distilling it into a succinct, accurate and readily transferable toxicological picture.

The availability of this resource is restricted. Developing countries which might not yet have strong national toxicological capability can be provided with such toxicological information by parts of the world more rich in this knowledge and expertise. There are several difficulties and barriers to overcome in pursuing this goal. Nevertheless progress is being made on a number of fronts. How things stand currently and the way in which things seem to be progressing also has implications for the world’s occupational hygiene community. This paper considers briefly the issues involved particularly in relation to occupational exposure standards and their availability and use around the world.

SOME OF THE PROBLEMS

Consideration of the current situation reveals a series of issues that create problems:

1. Shortage of Data. For many substances of occupational relevance, few toxicological studies have been conducted and/or few real-life experi-
Inadequate understanding of the science. Several analyses have concluded that there are few or no toxicological data available on many industrial chemicals (National Academy of Sciences, 1984; USEPA, 1998, Allanou et al., 2000).

2. Conflicting positions on data interpretation. For some of the better studied substances, different interpretative positions on the conclusions that should be drawn are taken by different interested parties in different parts of the world. In this respect there are as many issues of disagreement between different regulatory agencies as there are between ‘the regulatory authorities’ and other bodies, e.g. industry, academia and workers’ representatives.

3. Poor transfer of toxicological information to those exposed. The primary methods of transfer of toxicological information along with any particular substance are via a label on the substance packaging and on an accompanying Material Safety Data Sheet (MSDS). Although conceptually these enjoy universal recognition as means of communication, in practice different parts of the world employ different (or no) labelling systems, based on different principles, and the thoroughness, quality and clarity of the toxicological information carried on many MSDSs is poor. There is also probably a need for initiatives aimed at trying to improve the understanding of toxicological information by those exposed.

4. Inefficiencies in the use of the available regulatory and standard-setting toxicological resources. International co-operation and collaboration continues to develop. Nevertheless, there remains a tendency, for those (relatively few) bodies with the resources to distil, critically appraise and interpret substantial toxicological information, to duplicate activity, often working on the same substances, and revisiting them, while leaving unexamined a large number of other substances worthy of attention.

5. Inadequate understanding of the science. It has to be acknowledged that there remain many issues in toxicology for which we lack a clear understanding. This may be at the level of an individual substance, in terms of the way in which it expresses a particular experimental toxicity finding and the relevance of this finding for human health. It may also be a more general issue, for example the exposure pattern(s) that are responsible for the induction of occupational asthma, or the occurrence and, if so, means of locating a practical threshold for the production of cancer for genotoxic and carcinogenic chemicals. These uncertainties create difficulties in identifying effective, but balanced management responses for particular substances or types of substance.

PROGRESS TOWARDS IMPROVING THE SITUATION

For each of the problem areas raised above, activity is underway which is aimed at improving the situation. These are discussed in turn below:

1. More data. The International Council of Chemical Associations (ICCA) has committed itself to an initiative whereby a standard ‘baseline’ set of toxicological data will be gathered and furnished to the international community for all those substances marketed in the largest quantities around the world (the ‘High Production Volume’ [HPV] substances, marketed in quantities exceeding 1000 tonnes per annum). The dataset generated will be equivalent to the Screening Information Data Set (SIDS) of the OECD HPV SIDS programme and it is planned that the ICCA-generated assessments will feed into this OECD programme, the object being thereby to arrive at an internationally agreed, internationally available assessment of at least some of the basic toxicological characteristics of all HPV substances. Targets have been set of producing such assessments for 1000 HPV substances by 2004 and all 4100 identified HPV substances by 2015. This initiative, if delivered, should build on pre-existing programmes in the EU (e.g. Existing Substances Regulation) and USA to produce a significant improvement in appreciation of some of the toxicological properties of the most abundant chemical substances in workplaces around the world.

2. Harmonising positions on data interpretation. Almost a decade ago, the UNCED ‘Earth Summit’ held in Rio de Janeiro developed ‘Agenda 21’, Chapter 19 of which set out six Programme Areas (A–F) comprising a range of aspects of global chemicals management for which improvements were to be sought through international collaboration (UNCED, 1992). One element covered in Programme Area A is the aim of pursuing global harmonisation of approaches to risk assessment for the potential effects of chemicals on human health. Progress towards this goal has been relatively slow, but in recent years there have been a number of initiatives bringing together those involved in such risk assessment activity from industrial, academic and regulatory instructions world-wide, in pursuit of the development of greater clarity and mutual understanding of the various approaches taken and attitudes adopted. The value of one document that has emerged (‘Conceptual Framework for Evaluating a Postulated Mode-of-Action’ [for carcinogenicity]), aimed at achieving common, universal standards in the structured laying out of evidence on the mode-of-action of an experimental animal carcinogen and the interpretation of its relevance for human health, is currently being tested by various institutions around the world.
3. **Better transfer of toxicological information to those exposed.** Programme Area B of Agenda 21, Chapter 19 sets out the objective of producing a globally harmonised hazard classification system, and compatible labelling system, for all substances and preparations thereof, by the year 2000. In the last five years much of the necessary technical work to underpin such a global system has been completed. However, it must be acknowledged that substantial practical and political problems remain to be overcome before one common, global classification and labelling system becomes a reality. In relation to the other principal means of communicating toxicological information, the MSDS, the UK HSE has recently completed a report (‘The purpose, value and utility of toxicological information in Safety Data Sheets’) which is part of an ongoing project known as the ‘3Rs’ initiative (getting the right information to the right people in the right way). This project, which still has some time to run, is aimed at securing a range of improvements in the way in which people in industry receive information essential for their health and safety. Other groups have also analysed and found fault with MSDSs, and have made various suggestions for their improvement. It remains to be seen whether or not these initiatives will be converted into real advances.

4. **More efficient use of the available regulatory and standard-setting toxicological resources.** Slow but continuing progress is being made in terms of those institutions with the resources to produce high quality, critical assessments of the toxicology of industrial chemicals sharing such assessments with others and working co-operatively. UK experience is that in substance assessment for the purposes of setting occupational exposure limits, links between the technical groups involved continue to develop, with the ACGIH, UK, Dutch, German, Scandinavian and Australian groups now regularly exchanging documentation (for each other’s use), future programmes and interpretational information. The International Programme on Chemical Safety (IPCS) programme to generate CICADs (Concise International Chemical Assessment Documents) is also now quite well established, under Agenda 21, Chapter 19, Programme Area A. This programme is directed at converting extensive substance-specific toxicological assessments produced for national purposes into concise, internationally accepted and internationally available documents, which spread throughout both developed and developing countries a succinct, accurate and up-to-date toxicological picture for substances of global relevance. A steady flow of CICAD production has been sustained in the last two or three years.

5. **Improved, shared understanding of the science.** One initiative which is underway is the organis-
parent to future users of the output of such assessments.

- In the derivation of any standard, alongside the toxicological picture available at the time the extent to which practicability is taken into account must be explicit.

- The scientific terminology used in the assessment and limit-setting process needs agreement, codification, and expression in a way to meet the needs of all users.

- For the derivation of a toxicologically based standard the individual steps and deliberations of the extrapolation procedure should be clearly described. In doing so, transparency and mutual acceptance is enhanced.

REFERENCES


