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The Chemical Industries Association Guidance on Allocating Occupational Exposure Bands

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Many hazardous substances which may require control of inhalation exposures do not have occupational exposure limits. The necessary data and other resources required for setting such limits is restricted and unlikely to match the potential demand. A hazard categorization scheme has therefore been developed for application within the chemical industry. The scheme uses readily available information on toxicological endpoints (CHIP R-phases) to place hazardous substances into a limited range of hazard categories, expressed as Occupational Exposure Bands. The Occupational Exposure Bands can be used as a basis for risk assessment and the selection of appropriate control regimes. © 1998 British Occupational Hygiene Society. Published by Elsevier Science Ltd.

INTRODUCTION

This paper outlines the development of a scheme for allocating hazardous substances to Occupational Exposure Bands (OEBs) using readily available indicators of toxicological hazard. The development of this scheme preceded and was an influence on the development of a structured approach to the selection of control strategies described elsewhere in this journal (Russell *et al*., 1998; Brooke, 1998; Maidment, 1998). The UK Chemical Industries Association scheme described here (CIA, 1997) sets out a concept of hazard categorization leading to the placement of substances into Occupational Exposure Bands. The more recent work has taken the concept forward to link hazard categorization and exposure banding with structured guidelines for control of occupational exposure.

In the United Kingdom, the Control of Substances Hazardous to Health Regulations, 1994 (COSHH) and the associated general Approved Code of Practice (HSE, 1997) provide the legal framework and primary guidance for the control of exposure to substances which may present risks to employees' health. For those substances which have been assigned official Occupational Exposure Limits (OELs), either as Maximum Exposure Limits (MELs) or as Occupational Exposure Standards (OESs), effort is required to ensure that exposures, by the inhalation route, are in compliance with the OELs as defined in the Regulations. For those substances which have not been assigned official OELs under COSHH, the general Approved Code of Practice advises that, in some cases, there may be sufficient information to set a self imposed working standard. When sufficient data are available, an in-house OEL may be set. Guidance on how such limits may be set has been published by UK trade associations, (CIA, 1990; ABPI, 1995) as well as in the wider scientific literature.

The procedures used to generate in-house OELs are intended to support the development of scientifically robust 'health-based' OELs. A pre-requisite for the development of an in-house OEL is, therefore, the availability of a toxicological database of sufficient size and quality to enable the appropriate end point to be determined with a reasonable level of certainty. In addition to the availability of sufficient data, a company would also need sufficient expertise to be available to interpret the data and devise an appropriate value for the OEL. In the absence of either an official OEL or in-house OEL, it is still necessary to establish an appropriate control regime, although the basis for selecting the regime and the standards to be achieved may be much less clear. The scale of this potential problem is very large when one considers that the European Inventory of Existing Substances (EINECS) covers more than 100,000 substances, of which the vast majority have neither official nor in-house OELs. Given the large number of substances for which an OEL could be beneficial and the existing methods for setting OELs, it is unlikely that either the regulatory authorities or individual companies could make a significant impact on reducing the number of substances that could benefit from the availability of

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an OEL. Sharing of data and internationalization of the processes for setting OELs could provide some improvement but would still leave the majority of substances without any indication of what may be an adequate standard of control for inhalation exposure.

To address the issue of such a large number of substances which would not have OELs set in the foreseeable future, the UK Chemical Industries Association (CIA) has developed a set of guidelines for member companies which would enable them to categorize substances for control purposes. The CIA guidelines set out a pragmatic case-by-case approach to the review of any available information for the purpose of placing substances in broad hazard bands as a precursor to the selection of appropriate controls.

DESCRIPTION OF THE APPROACH

A structured approach to the design of fine chemical plant has been described by Money (1992). The approach was focused on a limited range of chemicals, particularly aromatic amines and equivalent chemicals used in the colourants industry. The concept outlined involved matching the standards of occupational hygiene control to available evidence for carcinogenicity and the TD_{50} for a substance. Specific exposure limits were not proposed. In a subsequent publication (CIA, 1993), the concept was broadened to include other potential toxic endpoints. Toxicological endpoints of relevance to human health are considered during classification of substances under the Chemicals (Hazard Information and Packaging for Supply) Regulations 1994 (CHIP). The R-phrases assigned for classification purposes were selected as readily accessible indicators of hazard and guideline control levels were also incorporated into the scheme. A list of relevant R-phrases is given in the Appendix. In another paper (Gardner and Oldershaw, 1991), an analysis of national OELs for volatile organic substances enabled a relationship to be established with CHIP risk phrases, and pragmatic exposure control concentrations were identified for two groups of substances, those classified as harmful by inhalation and those classified as toxic/very toxic by inhalation.

The purpose of the CIA guidelines is to provide an integrated, general scheme, for hazard classification, which would cover the wide range of hazardous substances handled by CIA member companies. Substances would be allocated to hazard categories, or Occupational Exposure Bands (OEBs) where the OEB defined the upper limit of acceptable exposure and exposure should normally be kept as low as reasonably practicable below that limit (established as an eight hour time weighted average exposure). An OEB would only need to be considered where:

- No MEL, OES or other internationally recognized or acceptable OEL was available.
- No OEL (in-house or national) was provided by a supplier.
- Insufficient data or expertise were available to set an in-house health based OEL.

The OEB would provide a guide level for the engineering control considered appropriate to a substance's hazards. Focused on inhalation exposure and relying on the use of limited data, the scheme would be supportive of broader strategies designed to prevent occupational ill-health.

To be acceptable and workable the scheme needed to be kept relatively simple. It needed to be usable by small to medium sized companies who may not have specialist occupational health and hygiene resources readily available and who may also have limited access to hazard data. Also, in many situations, from laboratory scale to large-scale manufacturing, there are a limited number of control options with only three or perhaps four levels of control available. Therefore, a limited number of bands which give a broad indication of an acceptable range of exposure is all that is needed to drive a decision making process for the selection of control measures.

Analysis of the range of values for official OELs showed that they cover a range of more than six orders of magnitude. The OEB scheme therefore needed to span the same range using a maximum of four categories, implying that a logarithmic scale would need to be adopted. The OEB ranges finally adopted are set out in Table 1.

The upper limits of OEB D (for gases and vapours) and OEB C (for dusts) are intended to reflect good occupational hygiene practice and the requirements under the COSHH regulations for 'substantial' concentrations of any dust to be effectively controlled. For the total inhalable dust fraction 'substantial' concentration is defined in the Approved Code of Practice as $10\,mg/m^3$ 8-hour time-weighted average. In addition to the numerical bands, a separate Category X was established to accommodate those substances which, because of the nature or severity of their hazardous properties, cannot be assigned to one of the four numerical bands. Such substances would require special consideration, on a case by case basis, which may involve a company seeking external advice or support.

To assign substances to an appropriate band, CHIP risk phrases were used as the main set of selection criteria. This was consistent with the proposals and findings of earlier publications (CIA, 1993; Gardner and Oldershaw, 1991) and used information that

Table 1. Occupational Exposure Bands

	Gases and vapours	Dusts
Category X	Special considerations	
OEB A	<0.5 ppm	$<0.1\,mg/m^3$
OEB B	0.5–5 ppm	$0.1–1\,mg/m^3$
OEB C	5–50 ppm	$1–10\,mg/m^3$
OEB D	50–500 ppm	Not applicable

should be readily available for a hazardous substance which is supplied for use at work. In addition to the CHIP risk phrases, criteria based on adverse effects in humans were also included.

Table 2 shows a typical cross section of the criteria suggested for the allocation of dusts to appropriate OEBs. In the guidelines, a separate set of analogous criteria are used to suggest how gases and vapours may be allocated to appropriate OEBs. OEB A is essentially reserved for substances which, although not qualifying for Category X, are nevertheless of very high toxicity, warranting low exposure levels and stringent control regimes. OEB B has been established as a default category, used for any substance for which no information is available. In the absence of any data it is considered that a precautionary approach should be adopted and that a relatively stringent control regime is justified.

When using the scheme it is important to recognize that the European Union classification scheme for a number of end points, e.g., carcinogenesis or sensitisation, is based on a weight of evidence approach and substances exhibiting such effects may show activity over a wide range of exposures and not all substances in Category X will require stringent control measures. Similarly, substances which have been classified as toxic to reproduction (R60, 61, 62, 63) are also classified on weight of evidence and the potency of such substances may vary over a wide range. Advice may be required on the application of the banding criteria to substances classified as toxic to reproduction when data are available which may indicate that a more or less stringent OEB should or could be chosen.

When assigning a substance to a particular OEB, the most sensitive endpoint for which information is available is chosen, giving rise to the most stringent standard of control for the substance. For example, a substance classified as R20/R62 would be placed in OEB B in preference to OEB C. It is intended that substances with very limited databases would initially be allocated to an OEB and when more data become available, these substances would be reviewed and may be moved to other OEBs. If sufficient data become available, substances could eventually be assigned OELs. If data for a substance are limited, consideration will need to be given to the provision of

Table 2. Cross Sectional Sample of Criteria for the Allocation of Dusts to OEBs

OEB	Criteria	Comments
Category X (Special Considerations)	(i) Substances assigned R45, R46, or R49 risk phrases should be handled in accordance with the principles of the COSHH Carcinogens ACoP (iv) Respiratory and skin sensitisers (R42 and R43). (v) Substances showing adverse effects in humans at exposure levels $<0.05\,mg/m^3$ by inhalation or $<0.01\,mg/kg.bw/day$.**	In some situations, it may be necessary to seek advice from an occupational health professional on whether a substance should be in Category X and, if so, what control measures would be appropriate*. Advice may be needed on whether a substance meets Criteria (ii) or (v), particularly when the database is limited or a decision is based on analogy with another substance.
OEB A ($<0.1\,mg/m^3$)	(i) Substances which are Toxic to Reproduction (R60 or R61 risk phrases). (iii) Substances classified as Very Toxic (R26, R27 or R28).	Advice may be required from an occupational health professional on whether a substance fits Criteria (ii), particularly where the decision is based on a limited database or by analogy with another substance.
OEB B ($0.1–1.0\,mg/m^3$)	(i) Substances which are Toxic to Reproduction (R62 or R63 risk phrases), unless their potency suggests a more or less stringent OEB. (iii) Substances classified as Toxic (R23, R24, R25, or R48). (v) Substances of unknown toxicity not allocated to a more stringent OEB.	Advice may be required, as noted above, on application of Criteria (ii) and (v) to some substances, as well as on the potency of substances with the R62 or R63 risk phrases (Criterion (i)).
OEB C ($1.0–10\,mg/m^3$)	(ii) Substances classified as Harmful (R20, R21, R22, or R48) (iv) All dusts not allocated to a more stringent OEB.	

* The EU classification scheme is based solely on a weight-of-evidence approach. Carcinogens and sensitisers, for example, may show activity over a wide range of exposures and not all substances in Category X will require stringent control measures.

** = Milligrams, per kilogram bodyweight, per day.

health surveillance as part of the risk management strategy for the substance.

DISCUSSION

The development of these guidelines on an Occupational Exposure Banding scheme should provide a useful tool to assist companies to develop a rational basis for their risk assessments and control regimes. The guidelines only provide hazard categories for inhalation exposure and are targeted at those substances for which there are insufficient data to set an OEL. For those substances and processes where other routes of exposure may be important, these factors will also need to be considered as part of the risk assessment process in addition to the control of airborne contaminant concentrations. As only limited toxicological data will be available for such substances, consideration will also need to be given to requirements for health surveillance and occupational hygiene measurements as part of the overall risk management strategy.

Before such a scheme can be recommended, it is essential that it should be tested to provide a high degree of confidence in the OEBs predicted. Control of exposure below the upper boundary of an OEB should offer an acceptable degree of health protection for a majority of substances. If attempts are made to compare OEBs with OELs, inevitably some OEB values will be either above or below the actual OEL. OELs are derived using a thorough scientific appraisal of an extensive dataset covering many toxicological endpoints whilst an OEB, often intended to prevent chronic health risks, may be based on short term or single dose toxicity tests. If the predicted OEBs are too high this could result in employees health being compromised whilst OEBs which are too low will result in the use of unnecessary resources to establish controls which are more stringent than are actually required. However, as a test exercise, the performance of the scheme was evaluated for a number of substances for which OESs had been established. It was found that for the majority of substances the OEBs were correct to an order of magnitude and that, for approximately five percent of the substances reviewed, the OEB was less stringent than the OEL. This was considered to be acceptable for two reasons. Firstly, exposure above an OEL does not necessarily result in an adverse effect on health as most OELs have had safety margins built in. Also, the absence of any guideline values for the control of exposure could result in highly variable and possibly inadequate standards of control. The CIA guidelines should therefore provide companies with a tool to assist in the development of improved risk assessments and standards of control for the handling of chemicals. Whilst it can be used with a reasonable degree of confidence, it cannot be used as the sole measure of hazard and does not offer a simple alternative to doing a suitable and adequate risk assessment.

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APPENDIX

R-phrases: indication of particular hazards

R20	Harmful by inhalation
R21	Harmful in contact with skin
R22	Harmful if swallowed
R23	Toxic by inhalation
R24	Toxic in contact with skin
R25	Toxic if swallowed
R26	Very toxic by inhalation
R27	Very toxic in contact with skin
R28	Very toxic if swallowed
R34	Causes burns
R35	Causes severe burns
R37	Irritating to the respiratory system
R38	Irritating to the skin
R40	Possible risk of irreversible effects
R41	Risk of serious damage to eyes
R42	May cause sensitisations by inhalation
R43	May cause sensitisation by skin contact
R45	May cause cancer

R46	May cause heritable genetic damage	R60	May impair fertility
R48	Danger of serious damage to health by prolonged exposure	R61	May cause harm to the unborn child
		R62	Possible risk of impaired fertility
R49	May cause cancer by inhalation	R63	Possible risk of harm to the unborn child