Ann. Occup. Hyg., Vol. 50, No. 2, pp. 149–156, 2006

Published by Oxford University Press
doi:10.1093/annhyg/mei054

Margins of Safety Provided by COSHH Essentials and the ILO Chemical Control Toolkit

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Received 10 May 2005; accepted 22 August 2005; published online 19 September 2005

COSHH Essentials, developed by the UK Health and Safety Executive, and the Chemical Control Toolkit (Toolkit) proposed by the International Labor Organization, are 'control banding' approaches to workplace risk management intended for use by proprietors of small and medium-sized businesses. Both systems group chemical substances into hazard bands based on toxicological endpoint and potency. COSSH Essentials uses the European Union's Risk-phrases (R-phrases), whereas the Toolkit uses R-phrases and the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals. Each hazard band is associated with a range of airborne concentrations, termed exposure bands, which are to be attained by the implementation of recommended control technologies. Here we analyze the margin of safety afforded by the systems and, for each hazard band, define the minimal margin as the ratio of the minimum airborne concentration that produced the toxicological endpoint of interest in experimental animals to the maximum concentration in workplace air permitted by the exposure band. We found that the minimal margins were always <100, with some ranging to <1, and inversely related to molecular weight. The Toolkit–GHS system generally produced margins equal to or larger than COSHH Essentials, suggesting that the Toolkit–GHS system is more protective of worker health. Although, these systems predict exposures comparable with current occupational exposure limits, we argue that the minimal margins are better indicators of health protection. Further, given the small margins observed, we feel it is important that revisions of these systems provide the exposure bands to users, so as to permit evaluation of control technology capture efficiency.

Keywords: Chemical Control Toolkit, control banding; COSHH Essentials; safety margins

INTRODUCTION

Small and medium-sized enterprises employ large numbers of workers around the world. For example, as of 2001, ~36% of paid employees in the US worked in firms with 1–99 employees, and in this category, 50% worked in firms with <20 employees (US Census Bureau, 2001). These smaller enterprises have traditionally had difficulty accessing and utilizing information on occupational safety and health. Among a sample of 1000 facilities in the UK (64% of which had 10 or fewer employees) in which there was regular or heavy chemical use, only 50% of employer representatives understood the term 'occupational exposure limit' (Topping, 1998). Given the overall magnitude of employment in small enterprises and the limited managerial awareness of health and safety hazards, the UK Health and Safety Executive (HSE) has developed an approach to workplace risk management called COSHH Essentials (Russell *et al.*, 1998). COSHH Essentials, which is available online (http://www.coshh-essentials.org.uk) and as a booklet (HSE, 2003), requires users, that is, proprietors of small and medium-sized enterprises, to complete five steps that culminate in the identification of task-specific controls (Table 1). Working with the HSE, the International Occupational Hygiene Association and the International Labor Organization (ILO) have drafted a Chemical Control Toolkit (the Toolkit), which is based on COSHH Essentials and intended for use internationally (Jackson, 2002).

The model of workplace risk management used in COSHH Essentials and the Toolkit has been described as 'control banding' (Jackson, 2002). Originating from the performance-based exposure control limits in the pharmaceutical industry (Naumann *et al.*, 1996), a control banding approach groups

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Table 1. The five steps of the COSHH Essentials and the Chemical Control Toolkit

Step	Description
1. Hazard classification	R-phrases or GHS classifications are used to assign the substance to hazard band A (low hazard), B, C, D (high hazard) and/or S (skin hazard)
2. Scale of use	Volume of substance used: small, medium or large
3. Ability to become airborne	This is defined as the volatility of liquids (based on the boiling point and process temperature) and the dustiness of solids, and may be: low, medium or high
4. Control approach	Answers from Steps 1–3 are used with a matrix to identify the appropriate control approach: (i), dilution ventilation; (ii), engineering control; (iii), containment; or (iv), specialist advice
5. Task-specific guidance	The control approach level from Step 4 is used to identify a guidance sheet for the specific task in which the substance is used

Table 2. The toxicological dose criteria for vapors and aerosols in COSHH Essentials and the Chemical Control Toolkit

Hazard bands	COSHH Essentials			Chemical Control Toolkit				
	R-phrases	Toxicological criteria		GHS class	Toxicological criteria		Exposure bands	
		Vapor (mg/l)	Aerosol (mg/l)		Vapor (mg/l)	Aerosol (mg/l)	Vapor (p.p.m.)	Aerosol (mg/m^3)
A				Acute lethal 5	2000–5000 mg/kg[a]	2000–5000 mg/kg[a]	>50–500	>1–10
B	22	>2–20[b]	>1–5[b]	Acute lethal 4	>10–20[b]	>1–5[b]	>5–50	>0.1–1
				Systemic single 2	>10–20[b]	>1–5[b]		
C	25	>0.5–2[b]	>0.25–1[b]	Acute lethal 3	>2–10[b]	>0.5–1[b]	>0.5–5	>0.01–0.1
				Systemic single 1	<10[c]	<1[c]		
	48/22	<0.25[d]	<0.25[d]	Systemic repeated 2	>0.2–1[d]	>0.02–0.2[d]		
D	28	<0.5[b]	<0.25[b]	Acute lethal 1,2	<2[b]	<0.5[b]	<0.5	<0.01
	48/25	<0.025[d]	<0.025[d]	Systemic repeated 1	<0.2[d]	<0.02[d]		
E							Seek expert advice	
S							Skin and eye precautions	

The toxicological dose criteria for vapors and aerosols differ, but the target 8 h TWA airborne concentrations (exposure bands) are the same.
[a]LD50: Dose that is lethal to 50% of animals exposed.
[b]LC50: Dose that is lethal to 50% of animals exposed for 4 h.
[c]Exposure duration of 4 h.
[d]Lowest observed effect level (LOEL) in a 90 day study where animals were exposed for 6 h per day.

chemical substances into 'bands' based on the similarity of potential health hazards, and in some manifestations considers exposure potential in identifying a control approach (analogous to biosafety levels 1-4 for infectious agents) or prioritizing risk. COSHH Essentials and the Toolkit group chemical substances by hazard, defining hazard bands based on toxic endpoint and potency. The indicators of toxic endpoint and potency used by COSHH Essentials are the European Union's Risk-phrases (R-phrases) (European Union, 2001), whereas the Toolkit uses R-phrases or the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals (United Nations, 2003). Although, the toxicological criteria for hazard bands differ between COSHH Essentials and the Toolkit, the assignment of exposure bands to the hazard bands is identical (Table 2). An exposure band is a range of target 8 h time-weighted average (TWA) airborne concentrations applicable to all chemical substances assigned to the given hazard band. The range of target airborne concentrations in the exposure bands were chosen based on toxicological considerations and pragmatic hygiene considerations (Brooke, 1998).

COSHH Essentials, and consequently the Toolkit, was designed to be health-conservative (Russell *et al.*, 1998). One metric of health protection is the similarity between the exposure bands and occupational exposure limits. In COSHH Essentials, the health protection provided by the exposure bands is equivalent to or better than that provided by health-based exposure limits in the UK (Brooke, 1998). Of course, to protect health, a workplace must comply with the occupational exposure limit or exposure band. Exposure data available to Germany's Bundesanstalt fur Arbeitsschutz und Arbeitsmedizin (BAuA) through peer-reviewed literature, data provided by industry, and BAuA field studies were generally within or below the COSHH Essentials target exposure bands (Tischer *et al.*, 2003). In the presence of the recommended control systems, solvent exposures were found to exceed the target exposure band primarily for milliliter quantities of solvent use under Control Approach 1, and particulate exposures under Control Approach 2 (Tischer *et al.*, 2003). In contrast, our analysis suggests that the ability of controls recommended by COSHH Essentials to adequately limit workplace air concentrations is substantially poorer, with inadequate control seen in 55% (34/62) of air samples collected by the National Institute for Occupational Safety and Health for vapor degreasing operations in the presence of COSHH Essentials recommended control technology (Jones and Nicas, in press). A second metric of health protection is the ratio (margin) of the dose producing the toxicological endpoint used for classifying the substance into the hazard band to the dose permitted in the target exposure band. COSHH Essentials is not as successful under this metric, as the authors report that this ratio can be <1 (Brooke, 1998). A ratio <1 means that the target exposure level for workers is greater than the exposure level that produced adverse effects in experimental animals, adjusted to reflect 8 h of exposure per day.

In a poster presented at the 2nd International Control Banding Workshop (Jones and Nicas, 2004), we commented on the level of protection offered by the Toolkit framework when R-phrases are used in hazard classification. We observed that for inhalation exposures to vapors, the margins between toxicological endpoints that define the R-phrase and the target exposure bands were inconsistent from chemical to chemical, inversely related to molecular weight, and in most cases substantially less than the margins employed in environmental health risk assessment. Given the impending adoption of the GHS, which uses the same toxicology tests as the R-phrase system, but different dose criteria, it is informative to similarly evaluate the GHS classification assignments provided by the Toolkit. In addition, we extend the analysis to the inhalation of dusts/mists, henceforth termed aerosols, and explicitly address the R-phrase assignments in COSHH Essentials, which differ slightly from those in the Toolkit.

METHODS

Most R-phrases and GHS classifications do not have toxicological dose criteria, but are based on a critical toxic effect, such as reproductive toxicity or cancer; the R-phrases and GHS classifications that have dose criteria, and indicate inhalation hazards are included in Table 2. The target exposure bands for vapors and aerosols are also included. The assignment of the R-phrases to the hazard bands were taken from the second edition of COSHH Essentials (HSE, 2003), because this document was felt to reflect current practice. Note that the assignments of R-phrases to hazard bands has changed since the scheme was originally described (Brooke, 1998). The GHS classifications were taken from the Chemical Control Toolkit (Draft) Guidelines (ILO, 2005).

The toxicological basis of the R-phrases R22 (Harmful), R25 (Toxic), R28 (Very Toxic) and the GHS classification Acute Toxicity (Lethal) Classes 1–5 is the concentration of airborne contaminant that was lethal to 50% of rats exposed for 4 h (the LC50). The GHS classification Acute Toxicity (Systemic) Classes 1–2 is based on the concentration of airborne contaminant that produced specific target organ systemic toxicity in one exposure of unspecified duration, but presumably <24 h. The R-phrase, R48 (Danger of serious damage by prolonged exposure), and the GHS classifications Repeated Exposure Toxicity (specific target organ systemic toxicity) Classes 1–2 are based on the lowest dose that produced significant adverse effects (LOAEL) in rats exposed for 6 h, repeatedly over 90 days. Unlike the R-phrase system, the GHS criteria, particularly for single and repeated exposure target organ systemic toxicity, are described as *guidance values* and are not intended to be strict demarcation values (United Nations, 2003). Both systems, however, allow the assignment of a more, or less, rigorous classification given appropriate human exposure-effect data. The toxicological criteria for R-phrases and GHS classes pertaining to inhalation toxicity are presented in Table 2, note that the dose criteria differ between the systems.

For those R-phrases and GHS labels that are based on dose criteria, doses were converted to 8 h TWA concentrations using the method employed by Brooke (1998). Sample calculations are included in Appendix I.

We define the margin as the ratio of the 8 h TWA of the experimental dose producing the critical toxic effect (the LOAEL or the LC50) to the upper limit target exposure band concentration. This definition is similar to the US Environmental Protection Agency's margin of exposure (MOE), which is the factor by which the no observed adverse effect level (NOAEL) of the critical toxic effect exceeds the estimated exposure dose received by humans (EPA, 1993). We define the 'minimal margin' as the ratio of the 8 h TWA of the minimum experimental dose in the R-phrase or GHS classification for a given hazard band, and the upper limit of the associated target exposure band. Our minimal margin is equivalent to the 'worst-case' margin identified by Brooke (1998). Here, however, we have compared the experimental dose of vapors and aerosols with the exposure band using a molar concentration basis rather than the mass concentration basis used by Brooke (1998).

In the toxicology literature, potency is conventionally reported on the basis of mass concentration (i.e. chemical mass per unit volume), because it is difficult, if not impossible, to determine the molar concentration of certain particulate substances such as asbestos fibers. However, the potency of substances that exist as individual molecules is best compared on the basis of molar concentration (molarity), defined as the number of moles of solute chemical per liter of solution. For this reason, we calculated the margins for vapors based on the molar concentration, with one liter of air representing one liter of 'solution'. Of course, converting a chemical's vapor mass concentration to molarity involves using the chemical's molecular weight. We considered molecular weights in the range of 50–250 g per mole because chemical substances with these molecular weights may be liquids that can readily evaporate.

In the COSHH Essentials scheme, hazard band A includes all substances for which no other classification is appropriate, the implication being that the criterion is an LC50 >20 mg/l. This value was used to determine the minimal margin. With regard to hazard band D, there is no minimal margin because the toxicological criteria are maximum experimental doses, rather than minimal experimental doses. For the sake of comparison, the ratio of the maximum 8 h TWA of the toxicological dose to the maximum target airborne concentration in the exposure band, 0.5 p.p.m., was determined.

The Acute Toxicity (Systemic) Classes 1 and 2 of the GHS classifications have toxicological criteria and hazard band assignments in the Toolkit equivalent to Acute Toxicity (Lethal) Classes 3 and 4, respectively. Therefore, Acute Toxicity (Systemic) has not been treated separately in this evaluation.

RESULTS

The minimal margins provided by the use of R-phrases for the inhalation of vapors are less than or equal to those provided by the GHS classifications for all hazard bands (Figs 1–3). This result was anticipated owing to the different toxicological criteria (Table 2). In all hazard bands, the minimal margins are inversely related to molecular weight, with the sharpest decreases occurring when the molecular weight increases from 50 to 100 g per mole. This effect remains when the toxicological criteria are compared with the exposure bands on the basis of mass concentration (Jones and Nicas, 2004). In addition, minimal margins calculated using molar concentration varied only slightly from minimal margins calculated using mass concentration (data not shown).

With some exceptions (such as R-phrase-based hazard band C for repeated exposures), it appears that the minimal margins increase with hazard.

In the COSHH Essentials scheme, in which R-phrases are used, minimal margins of ≤10 were observed consistently for hazard bands A, B and C (repeat exposures). In the latter band, minimal margins <1 were observed for substances with molecular weights ≥100 g per mole; again, a minimal margin <1 means that the minimum 8 h TWA exposure level corresponding to the toxicological endpoint is less than the upper limit of the target exposure band. For hazard band C (acute exposures), the minimal margin ranged from 5 to 25.

In the Toolkit, when the GHS classification is used, minimal margins of ≤10 were observed consistently

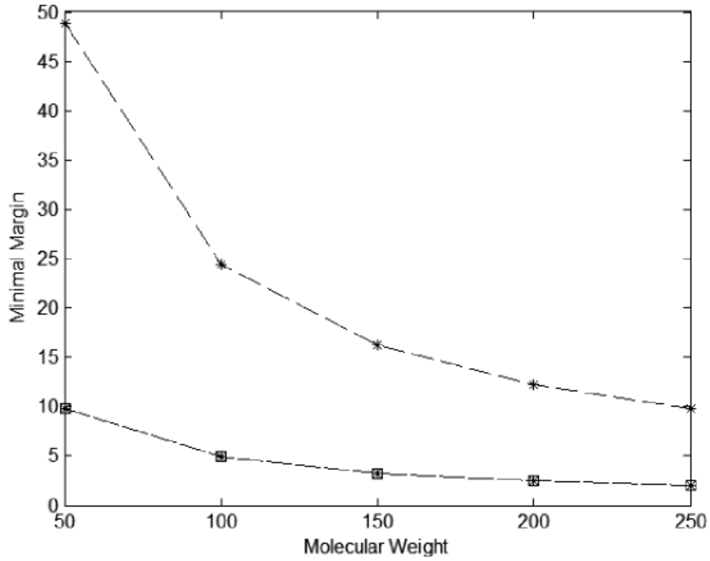

Fig. 1. The minimal margins for acute lethal toxicity from vapors in hazard bands A (squares) and B (asterisk). The minimal margins for the COSHH Essentials R-phrase system for bands A and B coincide with the Toolkit GHS classification (dashed line) for hazard band A. The minimal margin for hazard band B is smaller for COSHH Essentials R-phrase system than for the Toolkit GHS classification.

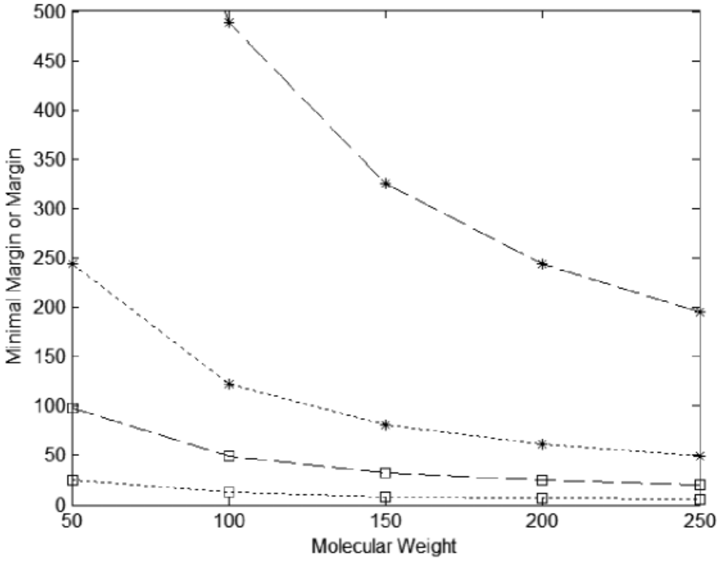

Fig. 2. Minimal margins for acute lethal toxicity from vapors in hazard band C (squares) and the margins for hazard band D (asterisks). The minimal margins and margins are smaller for the COSHH-E R-phrase system (dotted lines) than for the Toolkit GHS classifications (dashed lines).

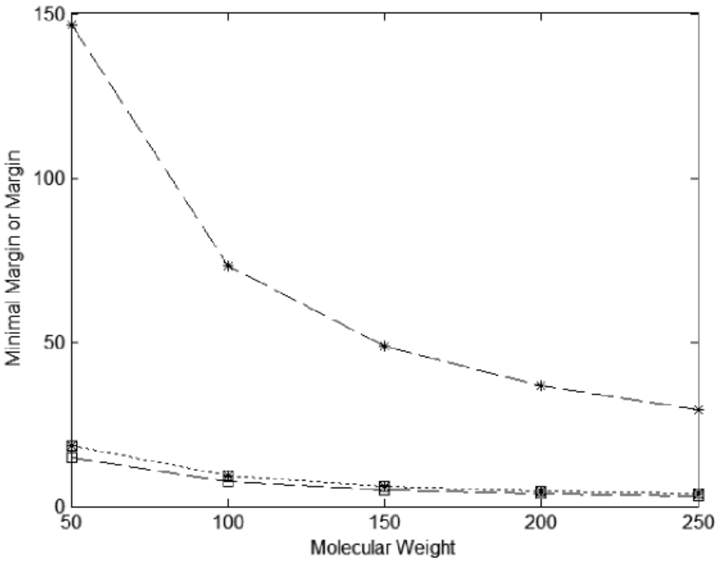

Fig. 3. Minimal margins for repeated systemic toxicity from vapors in exposure band C (squares) and margins for exposure band D (asterisks). The margin from the Toolkit GHS classification (dashed lines) is greater than the margin from COSHH Essentials R-phrase system (dotted lines) for band D, but not for band C.

for hazard band A, and for substances in hazard band C (repeat exposures) with molecular weights >70 g per mole. For hazard bands B and C (acute exposures) the minimal margins ranged from 10 to 50, and from 20 to 100, respectively.

For hazard band D, no minimal margins could be defined. The margin for repeated exposures for both COSHH Essentials and the Toolkit had the same range of 4–19. The Toolkit, however, provided a much larger margin (200–1000) than COSHH Essentials (50–250) for acute exposures.

Similar to the case with vapors, the minimal margins provided by the use of R-phrases for the inhalation of aerosols are less than or equal to those provided by the GHS classifications for all hazard bands (Table 3). The minimal margins afforded for aerosols are much greater than those afforded for inhalation exposures to vapors; the aerosol minimal margins all exceed 100, some by an order of magnitude. As with inhalation of vapors, owing to the toxicological criteria of hazard band D, no minimal margin can be provided.

Table 3. Margins for inhalation of aerosols

Hazard band	R-phrase		GHS classification	
	Acute lethal	Repeated systemic	Acute lethal	Repeated systemic
A	250	—	1400	—
B	500	—	500	—
C	1250	190	2500	150
D	12 500	1900	25 000	1500

The margins presented for hazard bands A–C represent minimal margins, while for hazard band D, the margin is the ratio of the maximum toxicological criteria to the maximum exposure band.

DISCUSSION

We have demonstrated that the minimal margins afforded by the COSHH Essentials R-phase and the Toolkit GHS hazard classification schemes for those vapors and aerosols that produce acute and repeated exposure toxicity via inhalation range from <1 to 100, with the Toolkit GHS classifications generally being more health-conservative than the COSHH Essentials R-phase classifications. Margins presented for hazard band D in both schemes vary greatly, but only for the GHS-based Toolkit scheme, are the margins consistently >100. These margins, however, are not minimal margins, because the toxicological criteria are defined as maximum experimental doses such that for a given worker exposure level the margin will decrease with increasing potency.

In the context of occupational standards, such as those recommended by the UK WATCH committee between 1990 and 1993 for non-cancer and non-reproductive outcomes, these margins are typical (Fairhurst, 1995). Compared, however, with the margins incorporated in the determination of environmental exposure limits the margins afforded by COSHH Essentials and the Toolkit are small. Given a non-cancer LOAEL, identified in a 90 day study, such as is used in COSHH Essentials and the Toolkit, methodology of the US EPA would suggest that an uncertainty factor of 10 000 be applied to determine the reference concentration, where the reference concentration is the concentration below which exposures pose no appreciable risk of adverse effects (EPA, 1993). The US EPA has no methodology for deriving reference doses from acute lethal toxicity (the LC50 or LD50). However, estimates for a provisional ‘reference dose’ have been found to require a factor between 100 000 and 1 000 000 (reviewed by Calabrese and Kenyon, 1991). Although, the US EPA reference dose methods have been widely critiqued, and alternative methods that reduce or replace the 10-fold uncertainty factors with factors based on conditions specific to the chemical substance and the animal model have been suggested (Zielhuis and van der Kreek, 1979; EPA, 2002; Gaylor and Kodell, 2002), comparing the margins afforded by COSHH Essentials and the Toolkit with the US EPA reference dose methodology highlights the disparity in acceptable risk between the workplace and the community. The impact of this disparity will increase in significance as the workforce expands to reflect the general population’s variability and susceptibilities (Institute for Environment and Health, 2002).

COSHH Essentials was designed to be a health-conservative approach to the control of occupational exposures, but with a pragmatic attitude toward hygiene considerations (Russell *et al*., 1998). In a validation of the scheme, Brooke (1998) reports that health-based occupational exposure limits in the UK were lower than the target airborne concentration range of the hazard band for only 2 of 111 (2%) of the substances evaluated. This achievement is analogous to the similarity in margins afforded by COSHH Essentials and those applied by the UK WATCH committee in the setting of occupational exposure limits (Fairhurst, 1995). However, this successful comparison with occupational exposure limits may be more indicative of the schemes’ ability to replicate current industrial hygiene practice than to protect employee health. One might expect that in the years since Roach and Rappaport (1990) found that 1976 Threshold Limit Values (TLV) correlated better with measured exposure levels than with exposure levels not causing adverse health effects, occupational exposure limits would have become more reflective of health outcomes. However, even contemporary standards that purport to be explicitly health-based, such as the German MAKs, are influenced by socioeconomic and technical factors (Hansson, 1993; Seeley *et al*., 2001). Comparison of the exposure bands with occupational exposure limits may, therefore, be a poor indicator of health protection. A better indicator of the health protection of an exposure band, or exposure limit, is the margin between the dose of the chemical substance, which produced the critical toxic effect (in humans or animals) that served as the basis for the exposure limit, and the limit itself.

A limitation of the evaluation presented here is the exclusive focus on the experimental animal toxicity criteria without consideration of human health experience in the R-phrase and GHS classification systems. Accounting for human experience might lead to a more, or less, stringent classification in the systems because of reduced uncertainty. Further, variability in the true efficacy of control technologies makes it uncertain that a recommended control technology will limit exposures to within the target exposure band; under-control errors are likely to be observed in practice. For example, when air monitoring was conducted at vapor degreasing operations in the presence of controls recommended by COSHH Essentials, 55% (34/62) of the measurements were greater than the maximum of the exposure band (Jones and Nicas, in press). When recommended and other, non-recommended, control technology were present, the relative frequency of air samples that exceeded the maximum of the exposure bands was 78% (140/179) and 52% (83/158) in vapor degreasing and bag filling operations, respectively.

With regard to the assessment of under-control error, we note that the exposure bands (Table 2) are not explicitly provided to the users of COSHH Essentials (HSE, 2003) or the Toolkit (ILO, 2005). In the absence of these target airborne concentrations, users are unable to evaluate whether the airborne concentration has been limited to a value consistent with the minimal margin. Presumably this information has not been included to simplify the schemes, owing to awareness of the poor understanding that proprietors of small and medium-sized enterprises have for occupational exposure limits (Topping, 1998). However, this means that to evaluate control efficacy, the end user must look elsewhere for occupational exposure limits that may or may not exist for the chemical substance in use. Given the small margins between doses that produce significant toxic effects in experimental animals and the exposure bands in COSHH Essentials and the Toolkit, we recommend that the target airborne concentrations be made readily accessible to users.

CONCLUSIONS

We believe that by shifting the focus away from meeting health-based exposure levels in favor of installing specified control technologies, without making target exposure levels explicit, COSHH Essentials and the Toolkit may not adequately protect worker health. By not including the target exposure bands in COSHH Essentials and the Toolkit, users are forced to look elsewhere to identify appropriate exposure limits with which to demonstrate adequate exposure control, effectively undermining the goals of the systems: to make occupational safety and health more accessible to small businesses, and to provide exposure limit guidance when formal occupational exposure limits are lacking. In our view, introducing such systems without providing end users sufficient information to gauge the level of control permits a false sense of health protection in the workplace.

APPENDIX I

Sample margin calculation

Conversion of the airborne exposure level of an experimental animal to an 8 hr TWA requires an adjustment for the duration of exposure. For example, 20 mg/l for 4 h is the inhalation exposure level that is lethal to 50% of exposed rats, and forms the upper bound for hazard band B, and lower bound for hazard band A (Table 2). This concentration–time product is converted to 10 mg/l as an 8 h TWA as follows:

$$\frac{20\text{ mg}}{\text{l}} \times \frac{4\text{ h}}{\text{day}} \times \frac{\text{day}}{8\text{ h}} = \frac{10\text{ mg}}{\text{l}} \times 8\text{ h TWA}$$

For sub-chronic or chronic toxicity, experimental animals were exposed for 6 h per day, so a similar correction was made to report the dose as an 8 h TWA.

The molar concentration (molarity, M) is the number of moles of solute per liter of solution. Given a chemical substance, say isopropanol, which has molecular weight 60.10 g per mole, and considering the above experimental dose as an 8 h TWA, the mass concentration is converted to a molar concentration:

$$\frac{10\text{ mg}}{\text{l}} \times \frac{1\text{ g}}{1000\text{ mg}} \times \frac{1\text{ mole}}{60.10\text{ g}} = 1.7 \times 10^{-4}$$

The minimal margin is the ratio of the minimum 8 h TWA as molar concentration (or as mass concentration for dusts/mists) in a hazard band to the maximum concentration in the associated exposure band. Continuing with the boundary between hazard bands A and B, to obtain the minimal margin for hazard band A, the molar concentration derived above, should be compared with the molar concentration of the maximum exposure level, 500 p.p.m:

$$500\text{ p.p.m.} = \frac{500\text{ ml}}{1\text{ m}^3\text{ air}} \times \frac{1\text{ m}^3\text{ air}}{1000\text{ l air}} \times \frac{1\text{ l}}{1000\text{ ml}} \times \frac{1\text{ mole}}{24.45\text{ l}} = 2 \times 10^{-5}\text{ M}$$

It follows that the minimal margin is:

$$\frac{1.7 \times 10^{-4}\text{ M}}{2 \times 10^{-5}\text{ M}} = 8.5$$

To generate Figs 1–3, these calculations were repeated for each of the maximum doses in Table 2 with molecular weights ranging from 50 to 250 g per mole.

Acknowledgements—The authors would like to acknowledge Dr Martyn Smith for comments regarding the units of potency and Dr Tom McKone for comments regarding the role of acute lethal toxicity testing in risk assessment.

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