

How Safe is Control Banding? Integrated Evaluation by Comparing OELs with Measurement Data and Using Monte Carlo Simulation

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The present study aims to explore the protection level that can be achieved by the German control banding (CB) tool Einfaches Massnahmenkonzept Gefahrstoffe, 'Easy-to-use workplace control scheme for hazardous substances'. The rationale of our integrated approach is based on the Bewertungsindex (BWI), which is the quotient of the exposure level and the occupational exposure limit (OEL), with BWI <1 indicating compliance. The frequency distributions of the BWI were calculated in order to reflect statistically the variability of workplace conditions. The corresponding statistical values of the frequency distributions (percentiles etc.) are interpreted as an indicator of the level of protection that is achieved.

The occupational exposure data sets used in the calculation of the BWI frequency distribution were mainly collected from Bundesanstalt für Arbeitsschutz und Arbeitsmedizin field studies. The data sets taken into account were selected according to the criteria 'hazard band, exposure potential, control approach'. Such a combination is called the 'control banding scenario' (CBS). Measurement data are only available for two CBS: in the case of the CBS 'hazard band A, EPL3, CS1' the only data that are available ($n = 220$) relate to propane-2-ol as used in the area of offset printing. Only 0.4 % of the BWI are above 1, this indicating a high level of compliance. In the case of the CBS 'Hazard band B, EPL2, CS1', exposure data are available from screen-printing firms ($n = 50$), optician workshops ($n = 49$), and from the area of furniture production ($n = 13$). The frequency distributions of the BWI reveal almost no instances of values being exceeded in the three branches.

In a subsequent step, a Monte Carlo Simulation was employed to explore whether the BWI frequency distributions can be generalized using a probabilistic model. The frequency distributions of the exposure levels and the OELs were used as the input data for the model. The simulation results show that the model distribution, called Modellierter Bewertungsindex distribution, can reproduce the BWI distribution if the data basis is homogeneous (data from one branch) and less correlated. In case of a heterogeneous data set (pooled data from different branches), the simulation results can be interpreted as generic statements about the attainable protection level. It was found that CB does not (at least potentially) guarantee compliance in either case. On the other hand, the generic simulation showed that compliance was high for volatile liquids used in closed systems (CBS: 'hazard band C, EPL3, CS3') and for solids in the presence of local exhaust ventilation (CBS: 'hazard band B, EPS3, CS2').

Keywords: control banding; compliance; measurement data; Monte Carlo simulation

INTRODUCTION

Background

Control banding (CB) has experienced a favourable global reception in recent years. Promotion of CB by organizations such as American Industrial Hygiene Association, American Conference of Governmental Industrial Hygienists, International Occupational

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Hygiene Association, National Institute for Occupational Safety and Health, Health Service Executive (HSE), Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), International Labour Organization (ILO), Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), and World Health Organization has resulted in CB now being used worldwide by small and medium enterprises (SMEs) in developed and developing countries (CBIW, 2005, Zalk and Nelson, 2008).

A number of CB tools are currently available, such as Control of substances hazardous to health (COSHH) Essentials (Russell *et al.*, 1998; HSE, 2003), the ILO International Chemical Control Toolkit (ILO, 2006), the Stoffenmanager (Marquart *et al.*, 2007; Tielemans *et al.*, 2008), the Belgian REGETOX approach (Balsat *et al.*, 2003), and the GTZ Chemical Management Guide (Bark *et al.*, 2008). In Germany, the BAuA has developed a CB tool called Einfaches Massnahmenkonzept Gefahrstoffe (EMKG) 'Easy-to-use workplace control scheme for hazardous substances' (Packroff *et al.*, 2005) that takes into account the requirements of the German Hazardous Substances Ordinance (BUND, 2004). Many German safety and health professionals currently make use of the EMKG—in both SME and large companies (Packroff and Tischer 2008). All the tools mentioned above have been extensively tested from a practical point of view and responses have so far been very positive. (This investigation is based on the first version of EMKG which has been designed for chemical substances and preparations without a legal occupational exposure limit (OEL). The second version, offered since May 2008, covers even chemicals with an OEL and can consequently be used as a tool for deriving risk management measures for exposure scenarios under the European Chemical Regulation (ECHA, 2008) with held of derived DNEL.

Although CB has received international acclaim, thus far only a few attempts have been made to validate and verify the approach on a scientific basis. The initial work of Maidment (1998) and a subsequent study from BAuA (Tischer *et al.*, 2003) compared the COSHH Essentials exposure predictive model with measured data from field studies. In general, the level of agreement was reasonably good. Jones and Nicas (2006) evaluated the ability of COSHH Essentials to select adequate control technologies for vapour degreasing and bag-filling operations. This validation suggests that the tool does not identify operations in need of control technologies in all cases. In contrast, Hashimoto (Hashimoto *et al.*, 2007) has demonstrated that CB tends to provide safe-sided judgement.

On the hazard assessment side, Brooke's work (Brooke, 1998) in comparing the R-phrases and resulting target airborne concentrations with the relevant health-based OELs on the national lists (UK and German MAK) has given basic confidence in the hazard grouping of COSHH Essentials.

Against the background of these in part conflicting results, it is important to highlight the following: the CB tools offer neither exclusively an exposure prediction model nor a hazard grouping model but first and foremost an 'integrated' approach that includes an exposure and a hazard assessment part, followed by a risk assessment and risk management recommendations. Consideration of these elements in isolation may therefore result in the validity and the corresponding protection level of CB being judged erroneously. This insight is not new and has been previously highlighted by several authors (Money, 2006; Garrod *et al.*, 2007).

Situation

CB enables a pragmatic approach to controlling exposure in cases where only limited information on exposure and hazard is available. To take account of this uncertainty, the logic of CB is based on exposure and hazard 'bands' rather than on point values. As a result, workplace measurements and OELs are, in principle, dispensable. The protection level is already regarded as sufficient if the modelled exposure concentration range matches the target concentration range.

The general banding approach for liquids in comparison with empirical data is illustrated in Fig. 1. It is assumed that both OELs and measured exposure values (represented in Fig. 1 by frequency distributions) are available for the chemicals under consideration. In the practical application of CB this is, of course, frequently not the case because CB is geared precisely towards those chemicals for which no OELs exist (instead, only information on classification) or for which no measured values are available (instead, only the exposure conditions such as the quantity and the release). Consequently, in order to illustrate the question at issue, random frequency distributions representing a possible but hypothetical situation were selected in Fig. 1. Real frequency distributions are to be found in Figs 3–5.

For the hazard assessment, the model groups R-phrases into hazard bands and allocates them directly to target airborne concentration ranges (each spanning one order of magnitude). As CB was designed to be health conservative, it is assumed that the OELs of classified hazardous substances (if available) compare well with the target concentration range (Brooke, 1998) of the corresponding hazard band. In Fig. 1, this is exemplified by an (arbitrary) frequency distribution of OELs that fits well into the target range.

For the exposure assessment, the airborne concentration range is determined by a combination of the chemicals' ability to become airborne (volatility), the handled quantity, and the applied control strategy (CS). The corresponding (arbitrary) frequency distribution of airborne exposure measurements is assumed to fit into the target range as well.

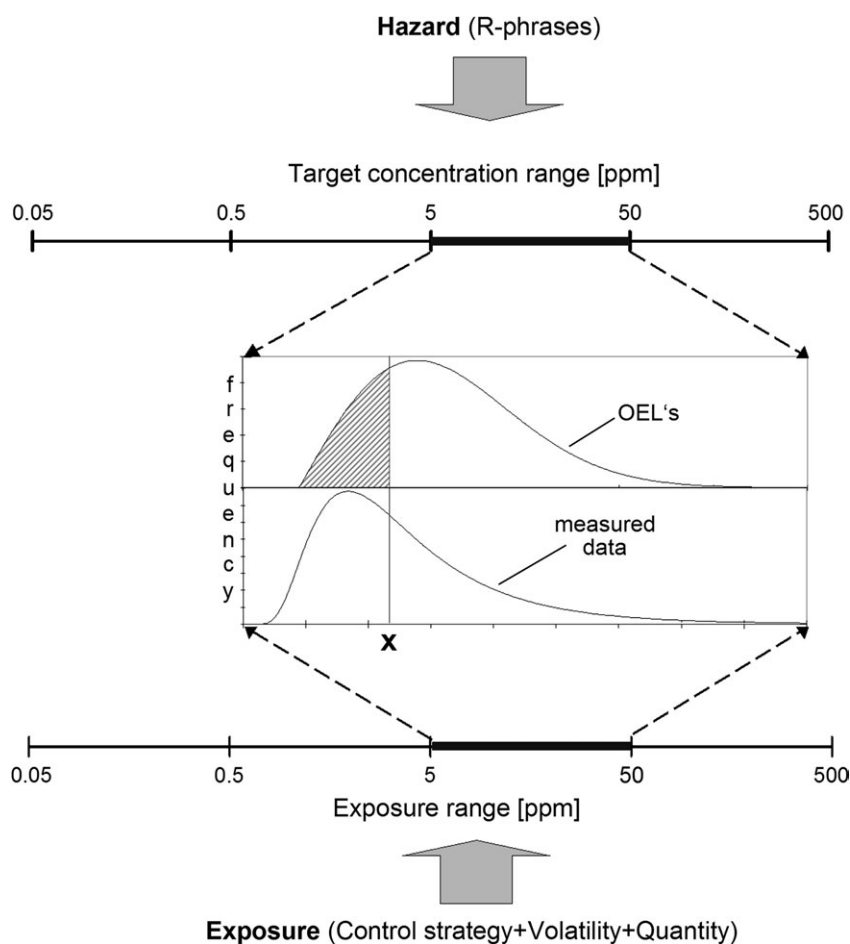


Fig. 1. General banding approach for liquids in comparison with empirical data (arbitrary example).

According to the logic of CB as applied in COSHH Essentials and the EMKG, the situation described in the above should lead to a sufficient protection level (because the target concentration range matches the exposure range). However, it is readily apparent that, for an arbitrary exposure level 'x', there is a certain probability (shaded area in Fig. 1) of exceedance (that is to say, of exposure which is higher than the OELs). Obviously, the probability for exceedance is determined by the overlap of the exposure and the OEL distribution representing the variability of exposure and hazard, respectively. Consequently, a study that aims at an integrated evaluation of the protection level of CB should take full account of the variability in exposure and hazard.

This article presents an integrated approach which considers variations in both exposure and hazard (Tischer and Poppek, 2007). The general idea is straightforward and is based upon the practice of workplace monitoring testing according to German regulations (AGS, 2008). Compliance is tested by a so-called assessment index (BWI) which is the ratio between the exposure level and the corresponding OEL, with $BWI < 1$ indicating an adequate level of

protection. The aim of our integrated assessment is to create frequency distributions of the BWI that characterize the protection level that can be achieved if workplaces adhere to CB guidelines. This is illustrated for the EMKG (Version 1) on the basis of measurement data from BAuA field studies and other (minor) sources (Tischer *et al.*, 2003). The corresponding OELs were taken from the German list of health-based OELs TRGS 900 (AGS, 2004). A comparison of the measured data with OEL was possible since OELs were available for almost all the measured substances (mainly solvents).

Measurement data are not available for most of the workplace situations that can be assessed with CB tools. Suitable models are therefore desirable in order to fill these gaps. We propose a probabilistic model that is based on probability distributions which reflect the variability of exposure and hazard. The modelled assessment index (MBI) is calculated analogous to the assessment index (BWI) which is the ratio between the exposure and the limit value. The practical calculations are performed by means of a Monte Carlo Simulation.

METHODS

The first step is to define distinct scenarios for the chemical substance or mixture that is to be assessed, with all of the necessary assumptions and contextual information needed to define the workplace situation. Within the framework of CB, at least three declarations are needed to describe a workplace situation with regard to inhalation exposure unambiguously:

- Hazard Group (A, B, C, D, E)
- Exposure Predictor band (EPL for liquids, EPS for solids)
- Control Strategy (CS)

The definitions of the hazard groups, the exposure predictor bands (EPL, EPS), and the CSs and their relationships within the EMKG are summarized in Appendix A. For example, a substance of medium volatility that belongs to hazard group A and is handled in litre quantities in the presence of local exhaust ventilation is described unequivocally by the combination: 'hazard group A, EPL3, CS2'. Such a combination is called a 'control banding scenario' (CBS).

Since the approach adopted in the EMKG is almost identical to CB according to COSHH Essentials (HSE, 1999), in the following we do not distinguish between CB and the EMKG but use the term CB synonymously. Hence, the results presented in this article can be largely transferred to the COSHH Essentials and other CB schemes based on COSHH Essentials. Our methodical approach is substantiated in a two part evaluation of CBSs whose stages build on each other:

Comparison between the measured exposure levels and OELs

The first stage is based on a comparison between the exposure data and OELs using the assessment index BWI which is the quotient of the measured exposure level and the corresponding OEL. According to the German Technical Rule TRGS 402 (AGS, 2008), the BWI is calculated using the following formula:

$$\text{BWI} = \frac{C}{\text{OEL}}, \quad (1)$$

where C denotes the airborne concentration of a single substance at the workplace.

A BWI lower than one indicates compliance with the OEL

While almost all OELs are established for single substances, in practice, many workplace exposures occur in the form of a mixed exposure to several substances. The assessment index (BWI), which uses dose additivity, represents a pragmatic way to assess mixtures. According to TRGS 402, for each component of the mixture, the exposure level (C_N) is divided by the corresponding OEL. This ratio is calculated for all components of a mixture and added up to define

the BWI for the mixture (see Appendix B). A BWI lower than one indicates compliance with the OEL. It is important to note that the approach suggested in TRGS 402 cannot be justified on a scientific basis (Bolt and Mumatz, 1996) but may be useful for ranking purposes (without being necessarily predictive of any actual individual's risk).

The most important empirical basis for our evaluation is measured data gathered in BAuA field studies (see section on measurement data). In a first step, the measured exposure data are assigned to a CBS taking into account the criteria: Hazard Group, Exposure Predictor band, and CS. In order to identify branch-specific differences, in a subsequent step, the resulting subpopulation is (if possible) further stratified according to branches. After assigning the data points to the CBS and branches, respectively, in accordance with TRGS 402, a BWI is calculated for each data point.

The evaluation of the achieved protection level is actually performed by means of frequency distributions of the BWI which are calculated for each subpopulation. A characteristic of the achieved protection level is the relative portion (%) of $\text{BWI} < 1$. However, it should be noted that the protection level is not characterized solely by a single value but by the whole course of the frequency distribution instead. Each single BWI represents a workplace situation that complies with the CB tool. Thus, the frequency distribution of the BWI represents the variability in workplaces and the corresponding protection level achieved by a certain CBS.

Probabilistic modelling and Monte Carlo Simulation

In principle, the approach outlined above admits the evaluation of arbitrary CBS. However, the time and effort required for representative workplace measurements can be substantial. Consequently, extensive evaluation of all CBS is hardly feasible. If, therefore, modelling of the empirical frequency distribution is successful and it also proves possible to transfer it to other (similar) CBS, modelling may be a feasible means of significantly reducing the time and effort required for measurement.

Whether, and, if so, under what conditions, model building is possible has been investigated in a second step on the basis of a probabilistic approach. Within a probabilistic model, point values are replaced by probability distributions representing the inherent variability and uncertainty in both the exposure and hazard parameters (OELs). The relevant distributions and their relationships are illustrated in Fig. 2 for both approaches.

The branch 'Measurement' demonstrates the procedure prescribed by TRGS 402. For a single pure substance, the BWI is reduced to the simple quotient Exposure/OEL (The more complicated mathematical procedure for mixtures is described in

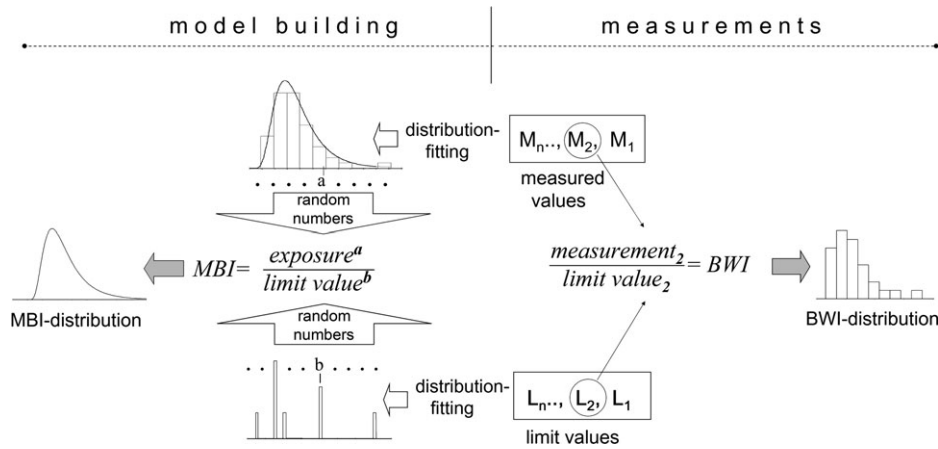


Fig. 2. Comparison of the two approaches.

Appendix B.) Each measured exposure value (symbolized by $M_1, M_2 \dots$ in Fig. 2) represents the shift average exposure level of an employee in a workplace in which only one substance is handled. Hence, each measured value corresponds to a single OEL (in Fig. 2 symbolized by $L_1, L_2 \dots$). Accordingly, the corresponding BWI is the quotient $M_1/L_1, M_2/L_2$ and so forth. If a number of BWIs are available for different workplaces and substances, it is possible to calculate frequency distributions of the BWI in order to reflect the protection level of a certain CBS.

At the same time, it is possible to construct frequency distributions for the measured exposure levels and OELs separately. Thus, three distributions are involved: the distribution of the measured data, the OEL distribution, and the BWI distribution. The distribution of the measured values represents the variability of exposure levels for a certain CBS. The OEL distribution provides information about the frequency of measurements of substances with established OELs. From the two distributions, the corresponding model distribution (MBI) is then calculated.

The branch 'model building' in Fig. 2 demonstrates how the model distribution is constructed from the empirical input data. According to equation (2) which defines the modelled assessment index (MBI) in general terms, the model distribution is called MBI distribution.

$$MBI = \frac{exposure}{limit\ value} \quad (2)$$

In a first step, probability distributions reflecting the variability and uncertainty relating to these parameters need to be determined for each input parameter (exposure level, OEL), i.e. a distribution type and a method of identifying appropriate parameters need to be selected. This task, called distribution fitting, has been performed by the BestFit module that is included in the Monte Carlo Simulation software @RISK (Palisade Corporation, 2002).

The main purpose of using Monte Carlo Simulation is to estimate the MBI distribution statistically by sampling the universe of all possible input values according to their probability distributions. Sampling from the input distributions was performed using Palisade's @RISK random number generator which employs Latin Hypercube sampling. In Fig. 2 the corresponding random numbers are symbolized by the terms exposure_a and limit value_b. According to equation (2), a possible MBI value can be calculated from a set of possible input parameters. This is usually referred to as performing a Monte Carlo trial. A random sample of the MBI distribution of size n is produced by calculating n Monte Carlo trials. If n is large enough, the resulting MBI distribution can be regarded as an image (model) of the BWI distribution.

The interpretation of the simulation results strongly depends on the meaning of the input distributions for exposure and hazard. On the exposure side, the probability distribution reflects the variability of exposure factors within a certain CBS, for example, variations in the ventilation efficiency, amount handled, volatility etc. Since most of these factors can be seen as multiplicative, a log-normal distribution of the corresponding exposure level is assumed (Limpert *et al.*, 2001). This coincides with both the results of the BestFit module and with the established conception of log-normally distributed airborne concentrations in workplaces (Rappaport *et al.*, 1995).

The situation of the hazard assessment part turns out to be somewhat different. How often substances of a certain hazard band are used and measured at workplaces and which limit value distribution results from this does not depend on exposure factors, such as ventilation efficiency, volatility etc. Instead, the limit value distribution is in fact the result of a complex substance selection process that is determined by technological aspects, economical criteria, and

safety aspects of the specific branch. Therefore, the distribution usually does not adopt a simple pattern (such as log-normally distributed), but can instead assume arbitrary shapes. Against this background, distribution fitting must be done flexibly but, at the same time, without over fitting the data. Hence, as a compromise solution, the limit value distributions are approximated by histogram distributions.

Finally, it has to be noted that the exposure level and the limit value can, in principle, be correlated. If (positive) correlations occur, low exposure levels should correlate with low limit values and vice versa. In either case, correlation of the model input must be taken into account within a Monte Carlo Simulation since this may significantly influence the model output (see section on results of the branch-specific simulation). In @RISK, this is done using Spearman's rank correlation coefficient (Sachs, 1984; Palisade Corporation, 2002).

Characterization of the empirical data

The most important source for empirical data is BAuA field studies. These studies have been performed by BAuA's own laboratory during the last 15 years in the course of research activities of BAuA. Since background information relating to this data pool has been published elsewhere (Tischer *et al.*, 2003), only the most important features are mentioned here. First, it should be noted that the data from field studies are historical. This of course means that the EMKG had not been employed for selecting control approaches. However, sufficient details were available to apply the EMKG to the reported operating conditions and to compare the installed control approach with that recommended by the EMKG subsequently. Companies and workplaces that were visited in the course of the previously described field studies were selected on a random basis in order to produce a representative exposure survey. Measured data from enforcement actions reflecting atypically poor health and safety practices were not taken into account.

Although some differences exist in terms of the amount of detail in the documentation, the data that are considered share some features. The majority (95%) of the data has been measured by personal sampling in small and medium-sized enterprises. The measurement data consist of time-weighted averages with sampling periods typically in the range of 1–4 h. The shortest sampling period was 20 min. The corresponding exposure levels are considered to be task based since the measurements were carried out exclusively during tasks as specified by a certain CBS.

All measured vapours have been determined separately by standardized analytical methods. Since almost all the substances (predominantly solvents)

have health-based OELs, it was possible to calculate BWIs in almost every case. With regard to dust exposure, the inhalable fraction was only measured gravimetrically. Since no chemical analyses were performed, it was not possible to calculate BWIs for mixtures of dusts.

The health-based OELs for substances considered in this evaluation have been taken from the German TRGS 900 (AGS, 2004). The evaluation does not include substances with R-phrases that represent toxicological end points that are allocated to hazard band E. In general, the R-phrases assigned to a substance have been used to allocate each substance to the appropriate hazard band according to the EMKG (Packroff *et al.*, 2005) (see also Appendix A). The appropriate European classification for each substance used in the evaluation was determined on the basis of Annex I of Directive 67/548/EU (EU, 2004). If a substance is assigned to more than one R-phrase, the R-phrase which leads to the most stringent hazard band was used. The number of OELs assigned to each hazard band is shown in Table 1 for vapours and dusts, respectively.

Evaluation of the protection level on the basis of BWI frequency distributions

In order to evaluate the protection level using empirical data, it is first necessary to perform a selection process in which the measured exposure data are assigned to a CBS. The choice and assignment of data points are essentially geared to the determinants of a CBS. Which combinations of hazard band, exposure potential, and control approach have to be taken into account is determined by the EMKG tool (see Appendix A). These conditions must have been fulfilled during the workplace measurements.

It must be noted that within BAuA field studies, usually mixtures of substances have been measured in the workplace atmosphere. For mixtures of chemicals, the hazard group classification has been assigned by the EMKG tool taking into account the most toxic of the mixture components. The concentration thresholds for the classification of mixtures were taken from the Directive 88/79/EU. Since the

Table 1. Distribution of OELs (listed in TRGS 900) to Hazard bands

Vapours		Dusts	
Hazard band	Number OELs	Hazard band	Number OELs
A	49	A	3
B	54	B	16
C	43	C	21
D	28	D	16
	Σ 174		Σ 56

component concentrations in the liquid mixtures were mostly not available, the airborne concentration of the most toxic substance was taken for the purpose of allocation to the hazard band. This is different from the usual application of the EMKG where the classification of a mixture (R-phrase) is used for the allocation to a hazard group.

Due to the fairly rigorous selection criteria of this study, measured data were only available for two CBS (hazard band A, EPL3, CS1 and hazard band B, EPL2, CS1). While it was only possible to evaluate measured data from offset-printing firms for the scenario B, EPL2, CS1, measured data from three branches (screen printing, optician workshops, furniture industry) were available for the scenario EPL3, CS1. Thus, it was possible to check statistically whether branch-specific differences occur within a certain CBS.

CBS 'A, EPL3, CS1'. The CBS A, EPL3, CS1 refers to propane-2-ol which is used in litre quantities as a wetting agent in the presence of general ventilation in offset-printing firms. Taking into account a boiling point of 82°C and a process temperature of 20°C (medium volatility), the exposure potential band EPL3 applies. The OEL of propane-2-ol listed in the TRGS 900 is 200 ppm. Therefore, no OEL distribution was available, only a single limit instead. On the other hand, 220 measured values, which were used to calculate the BWI and the corresponding BWI distribution, are available from BAuA studies (see Fig. 3).

Figure 3 reveals that only very few cases of exceedance occurred. Only 0.4% of the BWI are >1. Overall, the BWI distribution indicates a sufficient protection level.

CBS 'B, EPL2, CS1'. The CBS 'B, EPL2, CS1' has been observed, for example, in optical and carpentry workshops as well as in the screen-printing in-

dustry. In optical workshops, for example, spectacles are cleaned using quite small quantities of highly volatile organic solvents that are applied by means of a soaked cloth. In general, solvent quantities do not exceed a few millilitres. In carpentry workshops, larger quantities of lacquers, thinners, and adhesives are applied. Typical batch sizes are 500 or 1000 ml. By contrast, litre quantities of solvents of low volatility are used in screen-printing firms. According to Table A3 in Appendix A, this corresponds to EPL2 as well. Control approach CS1 was applied during the workplace measurements, i.e. use was made of general ventilation.

The frequency distributions of the BWI reveal (Fig. 4a–c) that almost no exceedance is observable in any of the three branches. Only in the area of furniture production is there a BWI >1. However, only a small database of 13 data points is available for this branch. Overall, the BWI distribution indicates a sufficient protection level for the evaluated CBS.

Evaluation of the protection level by Monte Carlo Simulation

The previous evaluation of the protection level was based on the statistics of discrete BWI. Additionally, it has been investigated whether a probabilistic model with adjacent Monte Carlo Simulation is able to reproduce that statistic. Two cases are considered:

I Branch-specific simulation. For a given CBS, the exposure and limit value distributions are generated from the data of a single branch. The Monte Carlo simulation aims to clarify whether and how accurately the MBI distribution can reproduce the BWI distribution.

II Generic (unspecific) simulation. For a given CBS, the exposure and limit value distributions are generated from unspecific data sources (list of limit

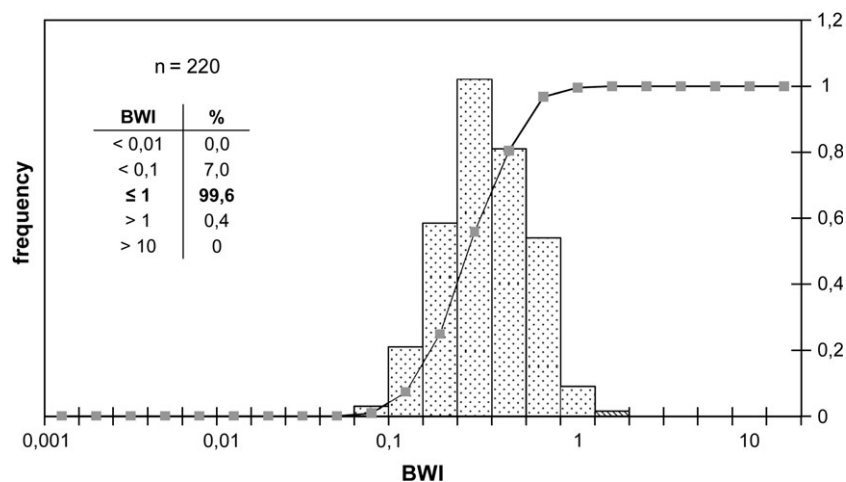


Fig. 3. BWI frequency distribution for the CBS 'A, EPL3, CS1'.

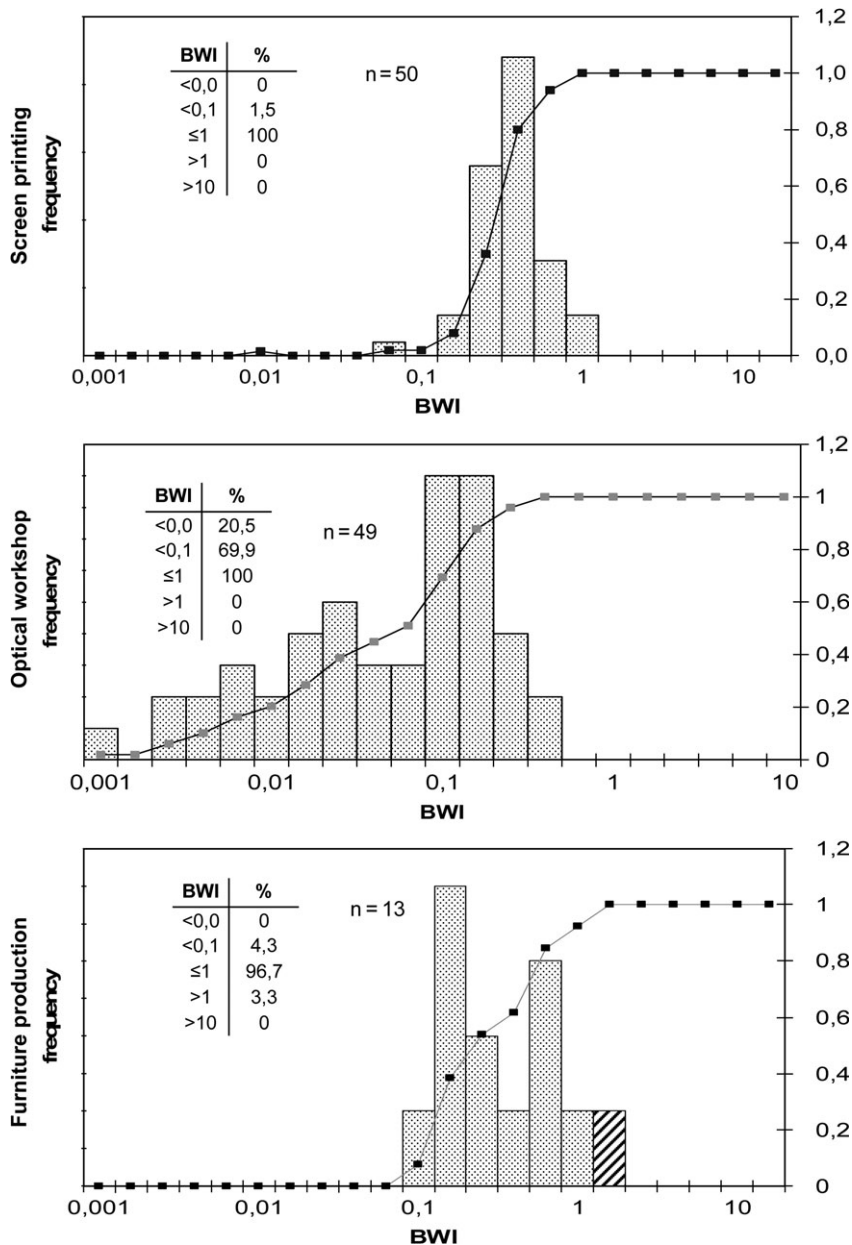


Fig. 4. (a–c) BWI frequency distribution for the CBS ‘B, EPL2, CS1’.

values TRGS 900, pooled branch data). It is thus possible to evaluate a given CBS even if no branch-specific data were available but only pooled data are taken into account. The simulation results are therefore characterized as ‘generic’.

Results of the branch-specific simulation

Only the CBS B, EPL2, CS1 has been simulated. The simulation of the CBS A, EPL3, CS1’ was considered not to make sense since only one substance (propane-2-ol) had been measured. Therefore, only a single limit value but no limit value distribution was available.

Figure 5 shows the results of the real data evaluation and the simulation, respectively. Each branch is represented by histograms and distributions of the corresponding exposure values, the concentration weighted limit (CWL) values, the assessment indices (BWI), and the modelled assessment index (MBI). Again, the BWI corresponds to the measured values and the MBI describes the outcome of the simulation. The CWL results from the approach for the assessment of the mixture presented in Appendix B. A visual comparison of the BWI distribution and the MBI distribution reveals a good level of agreement

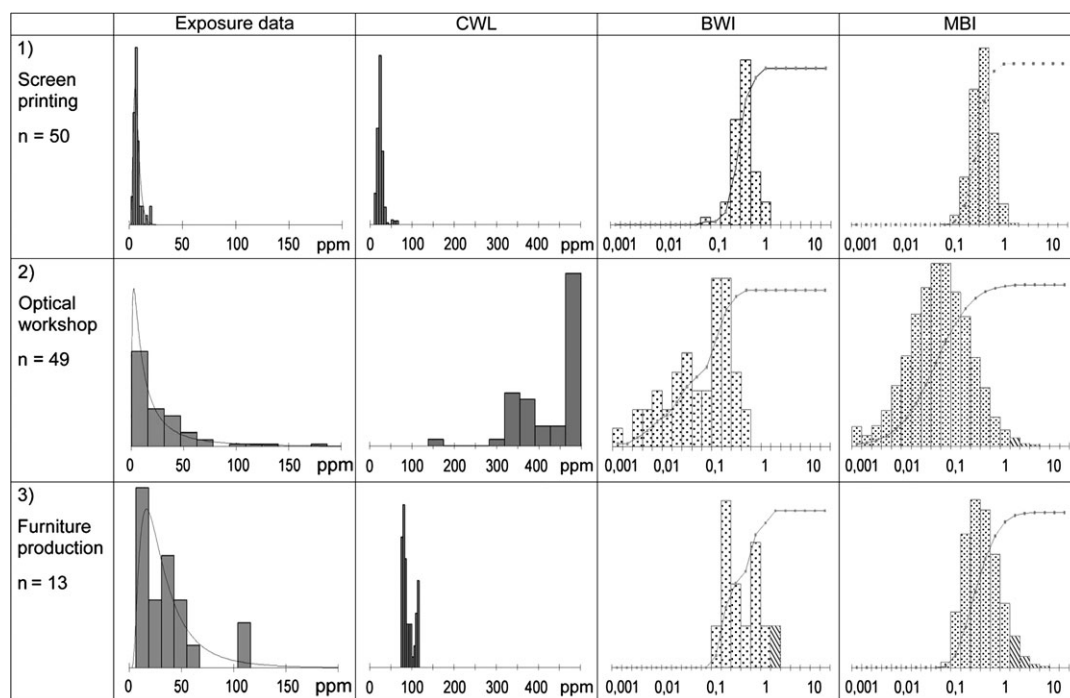


Fig. 5. Branch-specific evaluation and simulation for the CBS 'B, EPL2, CS1'.

for each branch. This is confirmed quantitatively by Table 2. The fractions for selected BWI/MBI values (>10 , >1 , <1 , <0.1 , <0.01) only differ by a few per cent at most.

To permit the evaluation of correlations between the exposure level and the limit value, the last column of Table 2 provides the corresponding Spearman correlation coefficients r_s . These correlation coefficients have been used in the branch-specific Monte Carlo simulation. All values of the r_s are in the range between $+0.3$ and -0.3 which is tantamount to weak correlations between the exposure level and the limit value (see Discussion).

Results of the generic simulation

The results presented so far are based solely on branch-specific data that could be assigned to a given CBS. Since each data point must coincide in terms of all three determinants of a CBS (hazard band, exposures potential, CS), it was only possible to evaluate two scenarios. If the condition of having coinciding hazard bands is dispensed with, a significantly higher number of data points are available. Table 3 contains the data sources that have been considered, the exposure potential in combination with the CS, and the hazard band relevant to the given combination.

Generic model building and distribution fitting for a given CBS has been done on the basis of pooled data from all data sources listed in Table 3. For instance, distribution fitting for the combination EPL3-CS1 has been carried out on the basis of

Table 2. Fraction (%) of the BWI and MBI distributions for selected BWI/MBI values (branch-specific results)

No.	BWI fraction %				MBI fraction %				r_s	
	<0.01	<0.1	<1	>10	<0.01	<0.1	<1	>10		
1	0	1.5	100	0	0	0	2.0	99.70	3.0	0.29
2	20.5	69.9	100	0	0	17.2	75.7	99.01	1.00	-0.28
3	0	4.3	96.7	3.3	0	8.1	93.66	6.4	4.0	0.13

pooled data from furniture production, textile industry, offset printing, and screen printing. The statistical weights of the specific data groups are solely determined by the number of data points. Statistical weighting based on the size of the particular branches was not applied. Finally, it must be noted that the correlations between the exposure level and the limit value were assumed to be zero in the generic simulation. This was justified by the weak (both positive and negative) correlations that were found in the branch-specific data.

While the exposure part of the simulation is based on pooled branch data, the simulation of the hazard band is based on the OELs listed in TRGS 900. The histograms corresponding to specific hazard bands are shown in Fig. 6. Within the Monte Carlo Simulation, the envelope of the histograms has been used as the input distribution.

It has to be noted, of course, that the substances listed in the TRGS 900 as well as the resulting frequency distributions of the OELs do not reflect the technological conditions encountered in specific

Table 3. Exposure data sources used for the generic simulation

No.	Exposure potential/CS	Data source	<i>n</i>	Hazard band
1	EPL3-CS1	Furniture production	16	A
		Textile industry	50	
		Offset printing	218	
		Screen printing	72	
2	EPL2-CS1	Optician workshops	13	B
		Furniture production	13	
		Screen printing	46	
		Varnishing, sticking	6	
3	EPL3-CS2	Paint production	20	B
4	EPL3-CS3	Chemical industry	158	C
5	EPS3-CS2	Chemical industry	64	B
		Textile industry	14	

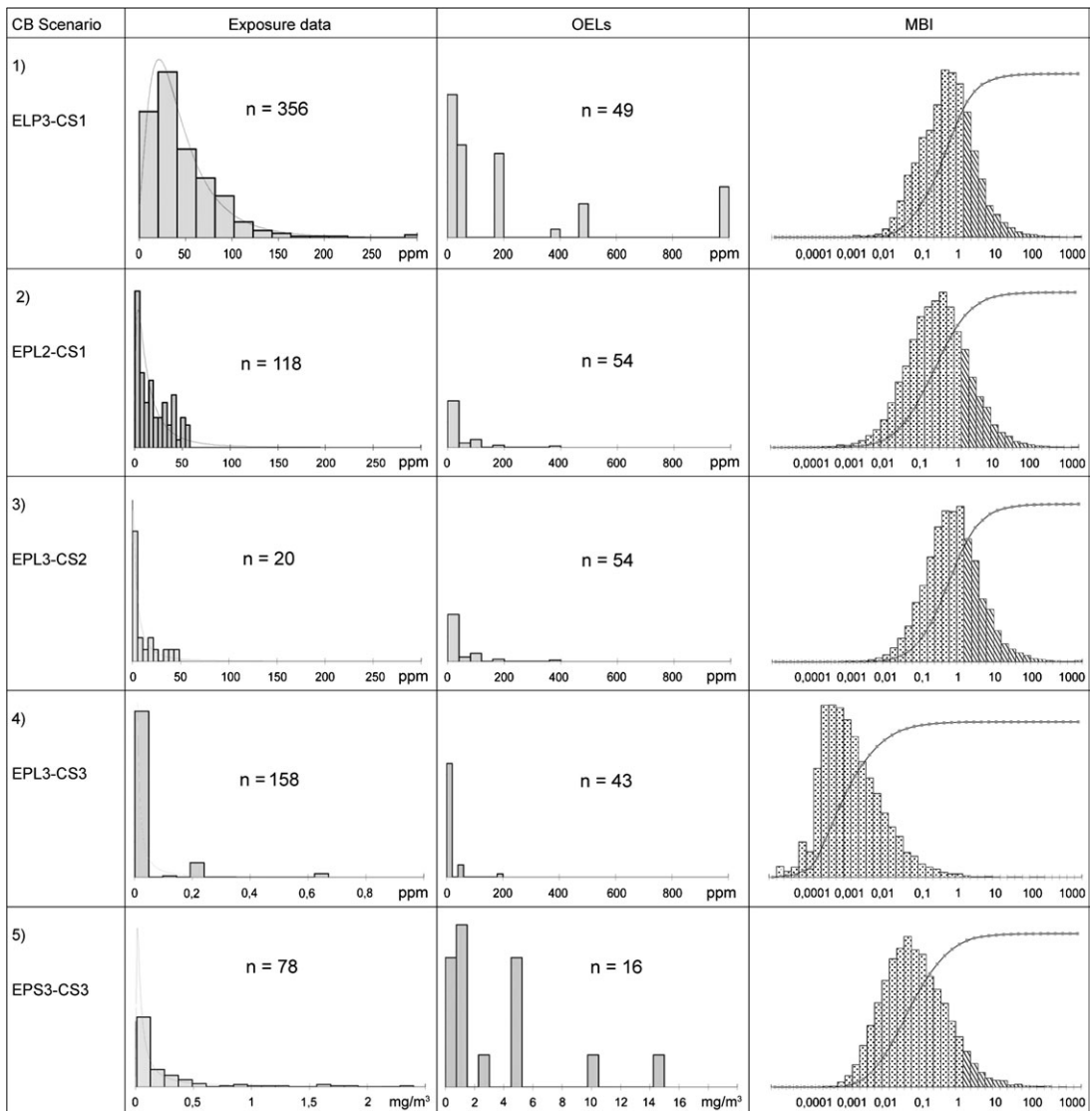


Fig. 6. Results of the generic simulation.

branches. Therefore, the relationship to specific branches is lost. In addition, substances which were not found in the branches are considered too. Overall, the spectrum of substances is extended. Simultaneously, the width and the generic character of the distributions increase.

The input distributions as well as the results of the generic simulation are shown in Fig. 6. The column MBI contains the histograms of the modelled assessment index. Visual inspection of the first three histograms reveals that a significant portion of MBI is >1 (shaded area). Obviously, situations that are not well protected may exist if liquid substances assigned to hazard bands A and B are handled in the presence of general ventilation (CS1) or local exhaust ventilation (CS2). Table 4 supports this impression quantitatively (MBI > 1 maximum 31.6%). However, due to the generic character of the input distribution, the results of the simulation only reflect potentially possible (but permissible) situations. Hence, it is difficult and uncertain to estimate how often critical situations occur in real workplaces.

A different picture emerges if liquids (EPL3 \rightarrow litre, medium volatile) which are assigned to hazard group C are used in closed systems (CS3). The fraction of the MBI distribution >1 only amounts to 0.3%. Here, the small overlap between the exposure and limit value distribution shows only a low potential for critical workplace situations.

Similar results were also obtained for solids (EPS3 \rightarrow kg, medium dusty) assigned to hazard group B which are used in the presence of local exhaust ventilation (CS2). In this case, the fraction of MBI > 1 is 6.8%.

DISCUSSION AND CONCLUSION

Although CB is generally used as a qualitative approach, as far as possible its evaluation should be performed on a quantitative basis. Taking into account the underlying banding ideas for exposure and hazard, in this study, an integrated evaluation procedure is proposed which tries to arrive at an overall statement about the level of protection. The assessment index (BWI), which is the ratio between the exposure level and the OEL, is taken as the starting point here.

Table 4. Fraction (%) of the MBI distributions for selected MBI values (generic results)

No. CBS		MBI fraction %						
		<0.001	<0.01	<0.1	<1	>1	>10	>100
1	A, EPL3, CS1	0.0	1.1	22.0	74.0	26.0	2.8	0.3
2	B, EPL2, CS1	0.0	1.1	16.6	68.4	31.6	4.1	0.5
3	B, EPL3, CS2	0.4	4.9	33.0	78.7	21.3	2.9	0.3
4	C, EPL3, CS3	55.8	88.2	97.8	99.7	0.3	0.1	0.1
5	B, EPS3, CS2	1.1	21.7	66.5	93.2	6.8	1.0	0.2

The evaluation starts with measurement data from BAuA field studies (representing the branches: offset printing, screen printing, optician workshops, and furniture production) and corresponding OELs for the chemicals involved. The frequency distributions of the BWI reveal that almost no exceedance was observed in any of the four branches.

One could argue that the existence of OELs may influence the exposure situation significantly. This could lead to a systematic shift (bias) of the exposure level towards lower exposure. At the same time, high limit values should correlate with high exposures and vice versa.

Basically, it is, of course, not possible to exclude such an influence. However, the influence is estimated to be rather low. This is confirmed by research results provided by the British HSE (Topping *et al.*, 1998). Experiences on the implementation of OELs in small firms in the UK have shown that many employers do not know how to determine whether exposure levels in their workplaces comply with the limits. The German BAuA (Voullaire and Kliemt, 1995) arrived at similar results. It was also found that air sampling for testing compliance with OELs was performed in only 1–2% of the small- and medium-sized enterprises in Germany.

An exhaustive evaluation of all possible specific CBSs is hardly feasible in practice due to the high technical and personnel-related costs involved in exposure measurements. With a probabilistic model, we therefore try to derive generic statements about the achievable levels of protection of unspecific CBS. To distinguish the model outcome from the analogous BWI, the modelled ratio is called the modelled assessment index (MBI).

The results of the Monte Carlo simulation show that the probabilistic model is able to reproduce the empirically determined level of protection with sufficient exactness. A precondition for this is a homogeneous set of measurement data. This precondition is met approximately by the evaluated branch data which reflect relatively similar workplaces. If, however, heterogeneous data groups from different branches are pooled, the MBI distribution cannot necessarily be expected to be an accurate image of the BWI distribution.

Instead, by setting the corresponding distributions off against each other, the model also describes (mixed) situations which were not encountered as such in the companies within the framework of the BAuA branch projects. The Monte Carlo simulation therefore covers a wider range of variation. As a consequence, the outcome of the simulation is more generic and unspecific in character. However, the above-mentioned workplace situations are allowed according to the CB guidelines and can emerge potentially in practice.

It has to be noted that the results of the generic simulation can offer valuable clues to the achievable

level of protection. This applies in particular when the limit value distribution is located to the right of the exposure distribution and the overlap of both distributions is small. This situation was found partly in connection with the use of liquids in closed systems and with the use of solids in the presence of local exhaust ventilation. In these cases, a sufficient protection level can be assumed.

Of course, interpretation of the results is always subject to the tension that exists between the generic and the specific. Basically, no absolute statements are to be expected but, instead, more or less reliable statements of likelihood.

If, therefore, the generic simulation reveals a relevant fraction of $MBI > 1$, attention is drawn to the need for more specific workplace evaluations based on air monitoring. The existing uncertainty that attaches to the generic simulation can, if necessary, only be removed by measurement-based evaluation. It is therefore highly desirable for further validation to be based on empirical data from a wide variety of workplaces.

APPENDIX A

Easy-to-use workplace control scheme for hazardous substances (EMKG)

The Federal Institute for Occupational Safety and Health (BAuA) has offered the 'Easy-to-use workplace control scheme for hazardous substances (EMKG)' on a special website since 2005 (<http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/EMKG/EMKG.html>). The EMKG is designed as guidance for workplace risk assessment in SMEs. Using easy available information from safety data sheets (substance related) and workplaces (task related), the user of the scheme can derive CSs to minimize exposure via inhalation or skin contact.

The EMKG is quite similar to HSE's COSHH Essentials. The main differences are some divergent allocations of R-phrases to hazard bands (see Table A1) and a more detailed tool to assess dermal exposure.

For both the EMKG and COSHH Essentials, the scale of use, volatility, and dustiness are used to build a very simple model of the exposure potential. All possible combinations of these determinants are aggregated to four combined bands which are called exposure predictor band solid (EPS) (see Table A2) and exposure predictor band liquid (EPL) (see Table A3).

For controlling substances at the workplace, there are four general CSs (see Table A4) which are underpinned by a series of Control Guidance Sheets that provide practical examples for common industrial unit operations such as weighing and filling.

The relationship between the exposure potential, the CS, and the hazard band (that corresponds to the predicted exposure ranges) is presented in the Tables A5 (dusts) and Table A6 (liquids). It has to be noted that there are some minor differences (see footnotes) between the Tables A5 and A6 and the corresponding assignment tables used in the framework of COSHH Essentials. These differences are due to requirements of the German Hazardous Substances Ordinance (BUND, 2004).

APPENDIX B

Model building for mixtures

According to TRGS 402 [see equation (B1)], mixtures are evaluated by adding together all the components with established OELs:

$$BWI = \frac{C_1}{OEL_1} + \frac{C_2}{OEL_2} + \dots + \frac{C_N}{OEL_N} = \sum_{i=1}^N \frac{C_i}{OEL_i} \quad (B1)$$

Table A1. The association between Hazard bands, R-phrases, and Target airborne concentration ranges used within the EMKG and COSHH Essentials

Hazard band	Target airborne concentration range	EMKG allocated R-phrases	COSHH Essentials allocated R-Phrases
A	1–10 mg m ⁻³ dust; 50–500 ppm vapour	All dusts and vapours not allocated to another band 36, 38, 65, 67	All dusts and vapours not allocated to another band 36, 38, 65, 66
B	0.1–1 mg m ⁻³ dust; 5–50 ppm vapour	20, 22, 41, 68/20, 68/22	20, 21, 22, 33, 67, 68/20, 68/21, 68/22
C	0.01–0.1 mg m ⁻³ dust; 0.5–5 ppm vapour	23, 25, 29, 31, 34, 35, 40, 42 48/20, 48/22, 62, 63, 68 39/23, 39/25	23, 24, 25, 34, 35, 37, 39/23, 39/24, 39/25, 41, 43, 48/20, 48/21, 48/22
D	0.001–0.01 mg m ⁻³ dust; 0.05–0.5 ppm vapour	26, 28, 32 39/26, 39/28, 48/23, 48/25, 61	26, 27, 28, 39/ 26, 39/27, 39/28, 40, 48/23, 48/24, 48/25, 60, 61, 62, 63
E	<0.001 mg m ⁻³ dust; <0.05 ppm vapour	45, 46, 49, 60	42, 42/43, 45, 46, 49, 68

Table A2. Definitions of exposure predictor solid bands (EPS)

Exposure predictor band	Description
EPS1	Gram quantities of medium/low dusty material
EPS2	Gram quantities of high dusty material and kilogram/tonne quantities of low dusty material
EPS3	Kilogram quantities of medium/high dusty material
EPS4	Tonnes quantities of medium/high dusty material

Table A3. Definitions of exposure predictor liquid bands (EPL)

Exposure predictor band	Description
EPL1	ml quantities of low volatility material
EPL2	ml quantities of medium/high volatility material and m ³ /litre quantities of low volatility material
EPL3	m ³ quantities of medium volatility material and litre quantities of medium/high volatility
EPL4	m ³ quantities of high volatility material

Table A4. Definitions of the control approaches

CS	Description
CS1	General ventilation. A good standard of general ventilation and good working practises
CS2	Emission control close to the source e.g. local exhaust ventilation
CS3	Closed systems and processes
Special	Expert advice is needed

Table A5. Dusts—prediction of CS from Hazard band and exposure potential in the EMKG

Hazard band	Exposure predictor band			
	EPS4	EPS3	EPS2	EPS1
A	CS2	CS1 (CS2) ^a	CS1	CS1
B	CS3	CS2	CS1	CS1
C	CS3 ^b	CS3 ^a	CS2	CS1
D	Special	Special	CS3	CS2
E	Special	Special	Special	Special

^aFor high dusty material handled in kilogram quantities.

^bThe EMKG requires technical advice.

Table A6. Liquids—prediction of CS from Hazard band and exposure potential in the EMKG

Hazard band	Exposure predictor band			
	EPL4	EPL3	EPL2	EPL1
A	CS2	CS1 (CS2) ^a	CS1	CS1
B	CS3	CS2	CS1	CS1
C	CS3	CS3	CS2	CS1
D	Special	Special	CS3	CS2
E	Special	Special	Special	Special

^aFor high volatile material handled in litres quantities.

For reasons of clarity, it would be desirable if the Monte Carlo Simulation could be performed using a single random number for the exposure level and the limit value, respectively. The question is how to reduce equation (B1) to a simple quotient. With regard to the exposure level, this is achieved by simple addition.

$$C_{\text{tot}} = C_1 + C_2 + \dots + C_N. \quad (\text{B2})$$

With regard to the denominator, a CWL must be defined.

$$\text{BWI} = \frac{C_{\text{tot}}}{\text{CWL}} = \frac{C_1}{\text{OEL}_1} + \frac{C_2}{\text{OEL}_2} + \dots + \frac{C_N}{\text{OEL}_N}. \quad (\text{B3})$$

Whereas

$$\text{CWL} = \frac{C_1 + C_2 + \dots + C_N}{\text{BWI}}. \quad (\text{B4})$$

Or

CWL

$$= \frac{1}{\frac{C_1}{(C_1 + C_2 + \dots + C_N) \cdot \text{OEL}_1} + \dots + \frac{C_N}{(C_1 + C_2 + \dots + C_N) \cdot \text{OEL}_N}}. \quad (\text{B5})$$

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