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On the Strength and Validity of Hazard Banding

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ABSTRACT

Hazard Banding (HB) is a process of allocating chemical substances in bands of increasing health hazard based on their hazard classifications. Recent Control Banding (CB) tools use the classifications of the United Nations Global Harmonized System (UN GHS) or the European Union Classifications, Labelling and Packaging (EU CLP) which are grouped over 5 HBs. The use of CB is growing worldwide for the risk control of substances without an Occupational Exposure Limit Value (OELV). Well-known CB-tools like HSE-COSHH Essentials, BAuA-Einfaches Maßnahmenkonzept Gefahrstoffe (EMKG), and DGUV-IFA-Spaltenmodell (IFA) use however different GHS/CLP groupings which may lead to dissimilar HBs and control regimes for individual substances. And as the choice for a CB tool seems to be determined by geography and/or local status these differences may hamper a global, aligned HSE approach. Therefore, the HB-engines of the three public CBs and an in-company (Solvay) CB called 'Occupational Exposure Banding' (S-OEB) were compared mutually and ranked in their relation with the OELV as the 'de facto' standard. This was investigated graphically and using a 5 strength indicator, statistical method. A data set of 229 substances with high-quality GHS/CLP classifications and OELVs was used. HB concentration ranges, as linked to S-OEB and COSHH, were validated against the corresponding OELV distributions. The four HB-engines allocate between 23 and 64% of the 229 substances in the same bands. The remaining substances differ at least one band, with IFA placing more substances in a higher hazard band, EMKG doing the opposite and COSHH and S-OEB in between. The overall strength scores of S-OEB, IFA, and EMGK HB-engines are higher than COSHH, with S-OEB having the highest overall strength score. The lower ends of the concentration ranges defined for the 3 'highest' hazard bands of S-OEB were in good agreement with the 10th percentiles of the corresponding OELV distributions obtained from the substance data set. The lower ends of the COSHH concentration ranges comply with the 10th percentiles of the COSHH OELV distributions for dust/aerosol but not for vapour/gas substances. Both the S-OEB and COSHH concentration ranges underestimate the overall width of the OELV distributions that can span 2–3 orders of magnitude. As the performance of the S-OEB HB-engine meets our criteria of being at least as good as the public engines, it will be used as a standard within Solvay's global operations. In addition, the method described here to evaluate the strength of HB-engines and the validity of their corresponding concentration ranges is a useful tool enabling further developments and worldwide alignment of HB.

INTRODUCTION

In workers' exposure control, compliance with an occupational exposure limit value (OELV) is the preferred approach. If no OELV is available, the application of a hazard banding (HB) is an alternative. HB is a key component of occupational assessment tools identified as Control Banding (CB) (Zalk and Nelson, 2008), Risk Prioritisation (RP) (Marquart *et al.*, 2008), or Occupational Exposure Banding (OEB) (Guest, 1998), which are further called 'CB-tools' in this text. A list of the meaning of the acronyms used throughout the text, can be found in Supplementary Material, available at *Annals of Occupational Hygiene* online. In these CB-tools, a substance is allocated to one of usually five hazard bands according to a scheme, which is called here 'HB-engine' (Hazard Banding engine).

In the last decades, many generic (HSE, 1999; ILO, 2006; Smola, 2011; INRS, 2015; Kahl *et al.*, 2012) and branch specific (ECETOC, 2006; EBRC, 2015) CB-tools were introduced in many countries. It is known that many chemical manufacturers developed at the same time in-house CB-tools for their no-OELV or data poor substances. Solvay SA, a worldwide operating chemical manufacturer, also developed a HB-engine, which is for clarity reasons called in this manuscript 'S-OEB' (Solvay OEB). It has been noticed that HB-engines do not allocate substances in the same hazard bands (Ruppich, 2005; Smola, 2011; Scheffers, Wieling, and Coucke, 2014; Scheffers, 2015; Scheffers and Wieling, 2015). Hazard bands are often used in combination with determinants of exposure potential such as vapour pressure, dustiness, and handled volumes for semi-quantitative risk assessment and implemented in public and private tier 0/1 RP tools like ECETOC TRA (ECETOC, 2004) and Stoffenmanager (Marquart *et al.*, 2008). As only five hazard bands exist, shifting one or several bands up or down may lead to substantially different risk controls.

The United Nations Global Harmonized System (UN GHS (UNECE, 2013) is becoming the world standard for hazard classification as it is implemented in a growing number of countries and regions, e.g. in the European Classification, Labelling and Packaging (EU CLP) (EC, 2008), US Hazard Communication (OSHA Hazard Communication, 2012), and the Chinese Safe Management of Hazardous Chemicals Regulation (State Council of China, 2011). The GHS system consists of several 'building blocks' and not all have been implemented equally in every country. In addition, some region-specific hazard phrases have been defined, e.g. the European Union Hazard (EUH) phrases. The application of CB is boosted as GHS classifications have become publically available for tens of thousands substances in recent years through company Safety Data Sheets and public databases, such as the EU ECHA website (ECHA, 2016) or the Australian GHS Hazardous Chemical Information List (Safe Work Australia, 2016).

For global operating organisations and occupational health professionals, like most authors of this manuscript, the dissimilarities in HB-engines over countries and branches may hamper a coherent and aligned risk management approach. The aim of this study was therefore to establish the impact of the HB allocation differences. As, to our knowledge, this is not done earlier, methods to compare the allocation differences of HB-engines, their strength related to the OELV and the validity of HB concentrations ranges, are described and applied using a data set of high-quality, data-rich substances.

METHODS

HB-engines

The HB-engines studied here allocate substances to five ordinal bands based on the grouping of GHS-specific health hazard codes (H-codes) and EU-specific hazard codes (EUH-codes). For a list of the hazard codes and their corresponding hazard statements, see Supplementary Table S1, available at *Annals of Occupational Hygiene* online. In case a substance has several H- or EUH-codes, the hazard band is determined by the hazard code linked to the highest hazard band. Substances of established low health hazard and therefore without a hazard code are allocated in the lowest hazard band. As some CB-tools call the five increasing hazard bands A to E and other use the rank numbers 1 to 5, A/1 is used here for the lowest and E/5 for the highest hazard band.

In this publication, the focus is on the four HB-engines which is part of:

- the German DGUV-IFA-Spaltenmodell (IFA) (Smola, 2011)
- the UK HSE-Control of Substances Hazardous to Health (COSHH) (HSE, 2009)
- the inhalation module of the German BAUA-Einfaches Maßnahmenkonzept Gefahrstoffe (EMKG) (BAUA, 2009)
- the in-house-developed Solvay OEB system (S-OEB), designed in the mid-90s, and revised in 2013, taking in account new CLP classification criteria

The way these HB-engines group the hazard codes is shown in Table 1.

Substance data set

The performance of the four HB-engines was investigated using a set of 229 substances. Solvay has access to the extensive data set on these substances because it is manufacturer/importer [>100 tonnes/year REACH dossier (EC, 2007)] or because the chemicals are purchased and used in manufacturing processes. Substances were grouped in two major categories, i.e. substances leading to possible inhalation exposure of gases or vapours, and substances leading to possible inhalation exposure of dusts or aerosols.

For each of these substances the following information was collected:

- The EU Harmonised Classification and Labelling
- The GHS UN classification based on in-house expert assessment
- EU-specific hazard phrases (EUH phrases)
- Specific EU REACH (EC, 2007) status: exempted from Chemical Safety Assessment due to low toxicity or substances considered to cause minimum risk (Annex IV)
- Available 'Health based only' OELV: 8-hour Time Weighted Average values from SCOEL (SCOEL, 2013), ACGIH (ACGIH, 2013), the company-specific Solvay Acceptable Exposure Levels, or the long-term REACH Derived No Effect Level (DNEL for workers, inhalation route, systemic, or local effect) (ECHA, 2012). Health based only means that OELVs that may integrate technical and socio-economic factors in the limit setting (e.g. UK WEL, German MAK, US PEL), were not taken into consideration.

The substance information on the hazard codes and OELVs was extensively reviewed using the CLH-Tables (EC, 2008) and DOHSBase, an industrial hygiene library with worldwide public substance hazard information (DOHSBASE v.o.f., 2015). If the OELV sources provided different values for a given substance, the lowest value was taken. In total, 7% of the selected OELVs are established by SCOEL, 30% originate from ACGIH and 60% are DNEL values defined in the REACH dossier. The remaining 4% are in-house OELV values (SAEL). If the OELV referred to a component of a substance (e.g. silver in silver nitrate with an OELV for silver-soluble compounds), the OELV was converted to the substance itself using the molecular weight in order to assure comparability between the different OELVs. For example, the OELV for silver nitrate (MW170) converts from 0.01 (as Ag, MW107) to 0.016 mg $AgNO_3/m^3$. See Supplementary Table S2, available at *Annals of Occupational Hygiene* online, for the substance data set, the physical state and the OELVs.

Performance analysis of S-OEB HB-engine

To investigate the performance of the 4 HB-engines, a step-wise approach was used as presented most recently at the IOHA conference (Scheffers, 2015; Scheffers and Wieling, 2015). Three HB-engine performance aspects were addressed:

(i) The substance allocation based on hazard codes
(ii) The differences in strength relative to OELV
(iii) The validity of the S-OEB and the COSHH concentration ranges

Assessments were performed separately for substances leading to possible inhalation of gases or vapours, and substances leading to possible inhalation of dusts or aerosols.

HB-engine allocation differences

The 229 substances in the data set were processed by the four different HB-engines. The chi-square test was applied to the HB-engine by hazard band contingency

Table 1. The hazard codes grouping over the hazard bands of four HB engines

Hazard band #	IFA	COSHH	EMKG (inhalation)	S-OEB
E/5	*300, 310, 330* (Tox)	EU070 (Tox)	340, 350(i) (Car,M)	372 (Tox)
	340, 350(i) (Car, M)	340, 341, 350(i) (Car, M)	360F (R)	340, 350(i) (Car,M)
	EU032 (Tox gas release)	334 (S)		334 (S)
D/4	301, 311, 331, 370, 372 (Tox)	*300, 310, 330,* 372 (Tox)	*300, 330,* 372 (Tox)	*300, 310, 330*; 370, 373 (Tox)
	341, 351, 360_{xy} (Car,M,R)	351, 360_{xy}, 361, 362 (Car,R)	360D (R)	341, 351, 360 (Car,M,R)
	EUH029, EUH031 (Toxic gas release)	EUH070 (I,C)	EUH032 (Toxic gas release)	314 cat A, EUH071 (I,C,S),
	317, 334, 318, EUH070 (I,C,S)			
C/3	302, 312, 332, 371, 373 (Tox)	301, 311, 331, 314, 370, 373 (Tox)	301, 331, 314, 370, 371, 341, 351, 361f/d (Car,M,R)	301, 311, 331; 371,304, EUH070 |(lung, eye damage) (Tox)
	$361_{f/d}$, 362 (R)	317, 318, **335**, EUH071 (I,C)	373 (Tox)	361, 362 (R & Lact)
	314 (pH ≥ 11,5, pH ≤ 2), EUH071 (I,C)		334 (S)	314 cat B and C, 317, 318, **335** (I,C,S)
	non-toxic gases which may cause asphyxiation		EUH031 (Toxic gas release)	
B/2	315, 319, **335** (I)	302, 312, 332, 371 (Tox)	302, 332 (Tox)	302, 312, 332 (Tox)
	304, EUH066, 336 (solvents)		318 (C)	315, 319 (Irr)
				336, EUH066 (solvents)
A/1	substances for which experience showed them to be harmless (e.g. water, sugar, paraffin etc.)	303, 313, 333(Tox) 315, 319,316,320(I)	319, **335** (I)	303, 313, 333 (Tox)
		304, 305 (Aspiration hazard)	336 (Tox)	305 (Aspiration hazard)
		336 (Tox), EUH066 (solvent effect) and all H-numbers not otherwise listed	304 (Aspiration hazard)	316, 320 (I)
			Non-health hazard H-codes	REACH Annex IV or ES exempted

C, corrosive; Carc, carcinogen; I, irritant; Lact, effect on lactation; M, mutagen; R, reprotoxic; S, sensitizer; Tox, toxicity. Some H-codes are bold or italicized to illustrate grouping differences between the HB-engines, see also section 3.1. See Supplementary Table S2, available at *Annals of Occupational Hygiene* online, for the meaning of the hazard codes.

table to test whether the HB-engines differ in the allocation of the 229 substances to the five bands. Bar charts picture the number of substances in each hazard band (Fig. 2a) and the percentage distribution of the following 3 differences: S-OEB minus EMKG, S-OEB minus COSHH, and S-OEB minus IFA (Fig. 2b).

Strength differences

In all CB-tools, the five health hazard bands A/1 to E/5 represent increasing health hazard. A universal objective quantifier for increasing health hazard does however not exist, meaning that the different grouping of hazard codes in HB-engines cannot be compared against a gold standard. COSHH (Guest, 1998) and others (ECETOC, 2006; Ruppich 2005) used the OELV as a 'de facto' standard to validate the HB-engine and showed that the hazard bands and OELV are interrelated to some extent. Whereas a classification is based on the presence of specific hazards, OELVs are based on a detailed evaluation of qualitative and quantitative toxicological information of all available health parameters, leading to a concentration below which exposure is considered to be safe. OELVs can be any numerical level in a range of 10 orders of magnitude (Scheffers and Wieling, 2014). Strength is defined here as the ability of a HB-engine to construct five independent OELV distributions relating a high-hazard band to a low OELVs and *vice versa*. An HB-engine with high strength is linked to five OELV distributions covering the whole OELV range and with the following properties:

- equal and unimodal (single peak) shape
- minimal overlap/small variances
- equidistant midpoints
- fitting a mathematical function with a location and dispersion descriptor

OELV frequency distributions fit the lognormal distribution characterized by the geometric mean (GM) and the geometric standard deviation (GSD). Fig. 1 illustrates the lognormal OELV distributions (left side) of a strong (top) and a weak (bottom) HB-engine. The corresponding cumulative log-normalized probability plots (right side) show straight lines as the log(OELV) (*x*-axis) are plotted against the standard normal deviates (vertical axis). The upper two panels show the regular pattern of OELV distributions from a high-strength HB-engine with straight, parallel, steep, equidistant, and spacious lines in the cumulative plot. The

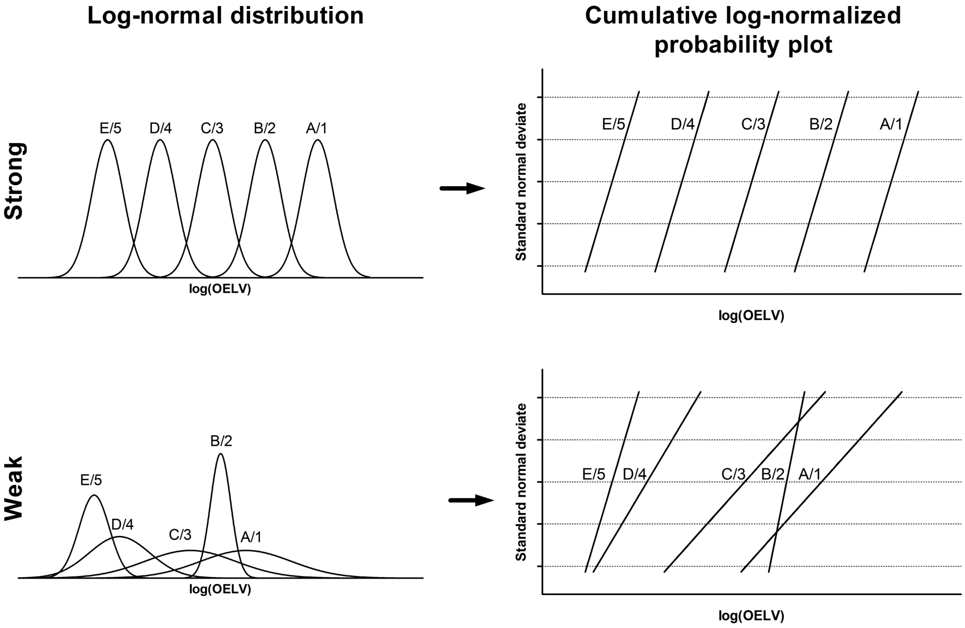

Figure 1 Illustrative example of OELV distributions obtained with a strong and weak HB-engine. The left panel shows the lognormal distributions, the right panel the corresponding cumulative lognormal probability plots. The latter type of plot is used for the strength assessment.

two lower panels illustrate a weak HB-engine although all distributions are lognormal.

The five OELV frequency distributions per HB-engine produced from the data set were assessed, using the following five strength indicators:

(i) Shape: the lognormal distributional fit of the OELV distributions was visually assessed using the graphics and statistically tested with the Shapiro–Wilks test [p(S-W)] on the residual log(OELV) resulting from the regression analysis mentioned under indicator 2 (Shapiro and Wilk, 1965)

(ii) Minimal overlap between bands and minimal dispersion within bands: the amount of total log(OELV) variance between bands explained by the HB-engine in ANOVA or regression (using polynomial contrast analysis and including all contrasts). The higher this explained (between-band) variance, the lower the unexplained or residual (within-band) variance, which is visible as lines with steep slopes in the cumulative probability plots

(iii) Equal variance: the Levene test for homogeneity of the variances of the log(OELV) between the bands of a given HB-engine. Distributions with approximately equal variances are visible in the cumulative probability plot as parallel lines (=equal slopes)

(iv) Equidistant midpoints: the distances between the means of the adjacent pairs of log(OELV) distributions, using visual inspection, and statistical testing of absence of non-linear trend by using polynomial contrast analysis. That is testing whether the successive log(OELV) midpoints A/1 to E/5 can be fitted with a linear function or need a quadratic or even more complicated mathematical function

(v) Minimal overlap: the number of log(OELV) means that differ pairwise ($P < 0.05$), using the *post-hoc* Student *t*-test for each adjacent pair of bands of a given HB engine

The ISO 5479 (ISO/TC 69, 1997) graphical approach was used to picture all strength indicators in one plot. For the statistical assessment, the outcome of each indicator was ranked from 1 (low) to 4 (high) over the engines and the sum of the ranks per engine was identified as the overall strength score of that engine.

Given that the A/1 band of S-OEB and IFA contain only 3 substances for vapour/gas, and only one for dust/aerosol, the analyses of all indicators were repeated for S-OEB and IFA without the A/1 band and the few substances in that band to ensure the robustness of analysis.

Validity

The COSHH CB-tool (HSE, 2009) links target airborne exposure ranges (Brooke, 1998; Gardner and Oldershaw, 1991; Guest, 1998) to the hazard bands A/1, B/2, and C/3. The exposure ranges span one order of magnitude and increase one order of magnitude per hazard band. For D/4 an upper concentration is defined. Concentrations ranges are used within Solvay as *ad-hoc* guidance for Tier 0/1 exposure assessment.

For vapour/gas, the S-OEB A/1, B/2, and C/3 concentration ranges are equal COSHH. Concentration ranges have also been defined for D/4 and E/5. Based on in-company experience, the S-OEB concentration ranges for dust/aerosol were set one order of magnitude higher than COSHH. For the lowest dust/aerosol hazard band (A/1), the S-OEB concentration band is set at the ACGIH TLV of 10 mg/m^3 (inhalable) which is the guidance for (insoluble or poorly soluble) dusts not otherwise specified (ACGIH, 2016). IFA

Table 2. The concentration ranges of S-OEB and COSHH for vapour/gas and dust/aerosol

Hazard band	**S-OEB concentration range**		**COSHH concentration range**	
	Vapour/gas (ppm)	**Dust/aerosol (mg/m^3)**	**Vapour/gas (ppm)**	**Dust/aerosol (mg/m^3)**
E/5	0.005–0.05	0.001–0.01	Not established, consult a specialist	
D/4	0.05–0.5	0.01–0.1	<0.5	<0.01
C/3	0.5–5	0.1–1	0.5–5	0.01–0.1
B/2	5–50	1–10	5–50	0.1–1
A/1	50–500	10	50–500	1–10

and EMKG do not have concentration ranges linked to their HB-engine.

The concentration ranges of COSHH and S-OEB are displayed in Table 2. The validity of the concentration ranges of S-OEB and COSHH was tested by comparing them with the 10th and 90th percentile of the corresponding OELV distributions. The OELV numbers per hazard band varied between 1 and 59. No percentiles were calculated for hazard bands with less than three OELVs. The extremes were used as percentiles for bands with 3 to 10 OELVs. With more than 10 OELVs, the percentiles were estimated unbiased (Proschan, 1953), using the lognormal GM and GSD. The deviations from the lognormal distribution were confirmed not to influence the outcome significantly (see chapter 4.2 in Supplementary Material, available at *Annals of Occupational Hygiene* online).

If the lognormal fit was acceptable after censoring outliers in the tails of the distribution (per band per engine, see probability plots per band per engine in Supplementary Table S13, available at *Annals of Occupational Hygiene* online) and more than 10 date were non-censored, then GM and GSD were estimated from log(OELV) and normal order statistics (Royston, 1982), and the percentiles were estimated as above.

RESULTS

The results are summarized in the text below, in Figs. 2–4, and in Tables 1 and 3. Additional figures and the details of the statistical analyses on allocation (Allocation differences), strength (Strength), and validity (Validity of the concentration ranges) are provided in the chapters 3, 4, and 5, respectively, of the Supplementary Material, available at *Annals of Occupational Hygiene* online.

Allocation differences

The hazard code grouping and grouping differences between the four HB-engines are displayed in Table 1. **H335** ('May cause respiratory irritation') is grouped in three different bands: A/1 (EMKG), B/2 (IFA), and C/3 (COSHH and S-OEB). *H300, 310, 330* (Acute Fatal), and several others are grouped in two bands (H-codes in bold and with italics, see Table 1).

The allocation distribution of the set of 229 substances is displayed in Fig. 2a. The chi-square test on the engine by allocation contingency table was significant [$p(X^2) < 0.01$], indicating that the four engines allocate substances differently. Fig. 2a shows that the IFA hazard engine is more conservative, putting 61% [=(99 + 41)/229] of the data set in the highest two hazard bands (D/4, E/5). For EMKG, this is only 24%. COSHH (39%) and S-OEB (47%) are in between. Relative to the two other engines, S-OEB and IFA only yielded a small number of substances allocated to hazard band A/1, i.e. 4 substances for each.

The four HB-engines allocate between 24% (IFA and EMGK) and 65% (COSHH and EMKG) of the substances in the same bands (see Supplementary Table S7, available at *Annals of Occupational Hygiene* online). Fig. 2b visualizes that S-OEB allocates 64% of the data set to equal hazard bands as COSHH, 27% to a higher band and the remaining 9% to a lower band. With EMKG, 40% of the allocations is equal, 59%

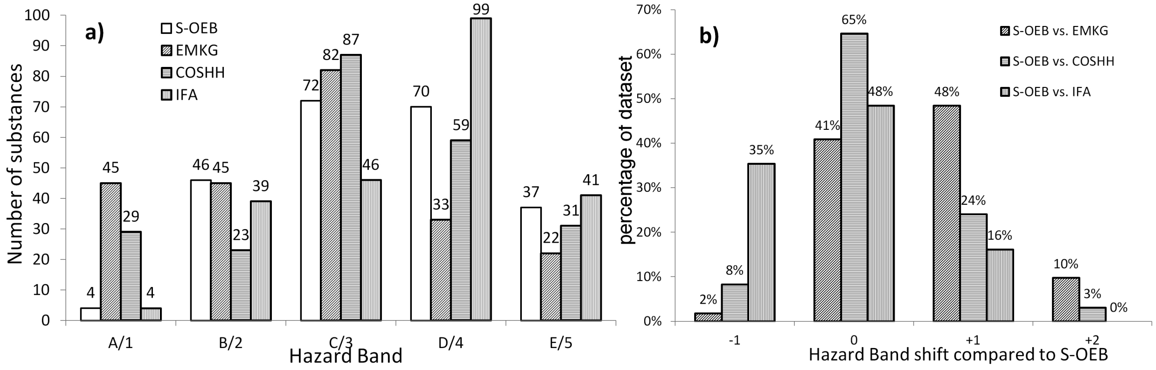

Figure 2 The allocation of 229 substances processed by the four HB-engines (a) numbers per hazard band (b) hazard band shifts of the three public hazard bands compared to the S-OEB hazard band.

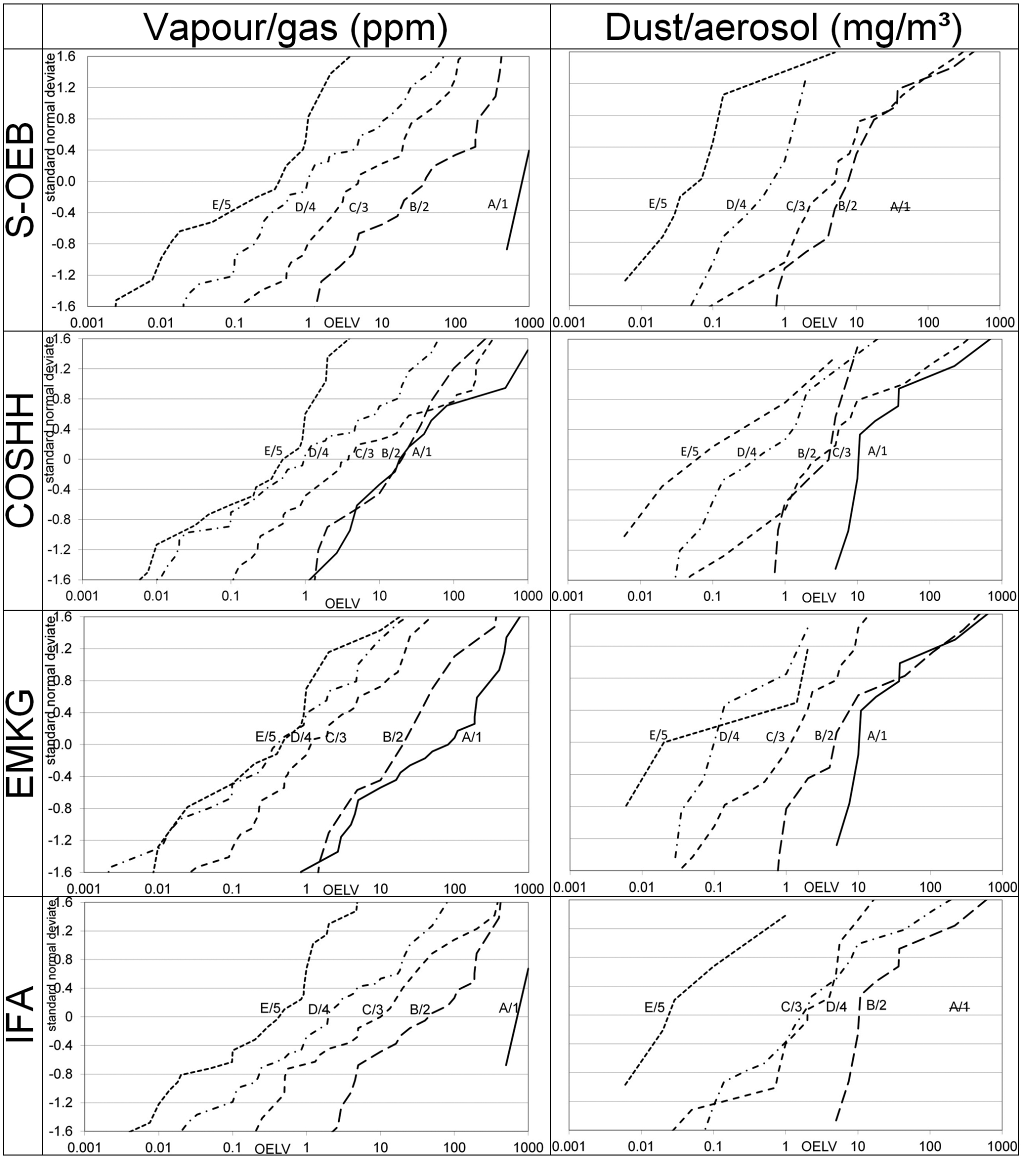

Figure 3 The 4 HB-engines' OELV distributions per hazard band (E/5 to A/1) for vapour/gas (ppm) and dust/aerosol (mg/m^3) substances, as cumulative lognormal probability plots.

is higher, and only 1% is less hazardous. With IFA, 48% is equal, 17% is higher, and 35% is allocated in a lower band.

Comparable allocation differences were found for the 3 public engines using a data set of 4140 CLH substances as presented at the IOHA 2015 conference (Scheffers, 2015). In Supplementary Table S8, available at *Annals of Occupational Hygiene* online, the CLH distributions are presented including the S-OEB engine, confirming that the different allocation by the four HB-engines is independent from the type or size of the reference data set.

Strength

Fig. 3 shows the hazard band specific, cumulative log(OELV) distributions of the four HB-engines. The results are presented separately for substances generating vapour/gas and dust/aerosol. When comparing

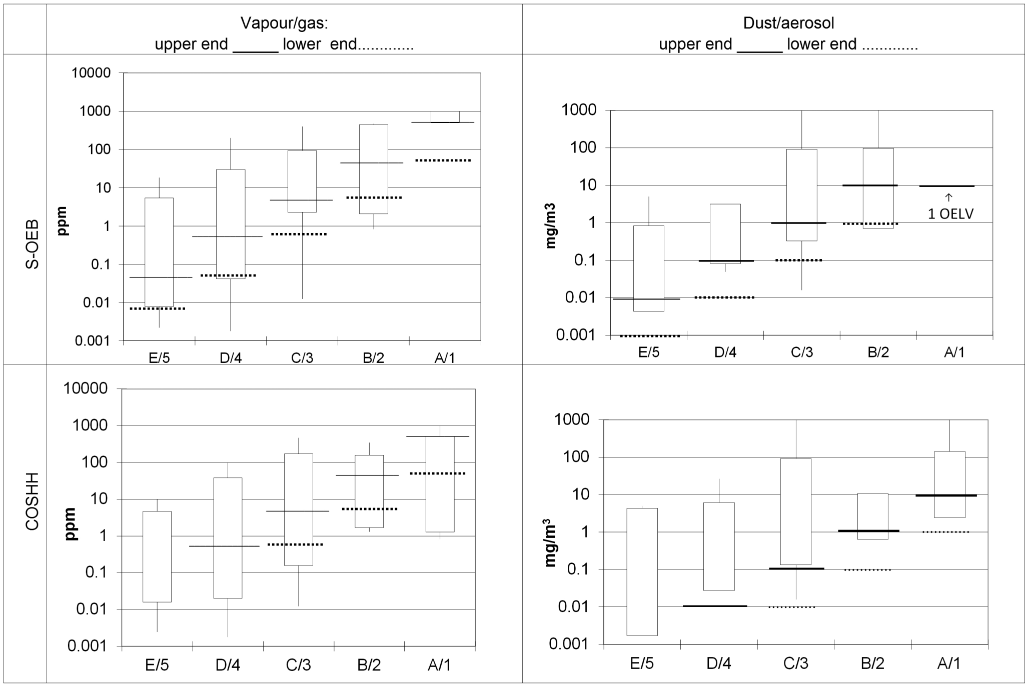

Figure 4 The concentration range per hazard band (horizontal lines) and the OELVs distribution box-plots (vertical lines represent the range, the rectangles representing the 10th and 90th percentiles).

the figures for vapour/gas, S-OEB, and IFA show a similar pattern consisting of non-crossing, parallel, and equidistant lines, although line A/1 is incomplete as it is based on only three OELVs. For COSHH vapour/gas, the OELV lines A/1, B/2, and C/3 are overlapping while the lines E/5 and D/4 are close in the left part of the plot. For EMKG vapour/gas, the OELV lines of the two hazard bands A/1-B/2 are overlapping, as are the lines of bands D/4-E/5. For dusts and aerosols, only one substance was allocated to hazard band A/1 by S-OEB and IFA, so only four lines are displayed. The log(OELV) lines B/2-C/3 of S-OEB and C/3-D/4 of IFA overlap while the B/2-C/3-D/4 lines of COSHH and D/4-E/5 of EMKG seem non-linear and crossing.

Table 3 shows the results of the statistical strength indicators. For vapour/gas, S-OEB and EMKG performed better in the lognormal goodness-of-fit than IFA and COSHH [indicator 1, p(S-W)] whereas all engines failed the test of lognormality for dust/aerosol (i.e. all p(S-W) were below 5%). However, the graphs of the residuals (see Supplementary Table S10, available at *Annals of Occupational Hygiene* online) did not show severe violations of the lognormal fit. Therefore, parametric statistics are used for the other indicators. The overall OELV variability for vapour/gas explained by the COSHH HB-engine (indicator 2) is lower than for the other HB-engines, which were close to each other. For the dust/aerosol, S-OEB and EMKG perform better on this than COSHH and IFA. Homogeneity of the log(OELV) variance between bands (indicator 3) appears to be satisfied for all engines except COSHH vapour/gas [p(Levene) = 0.043]. With respect to equidistant log(OELV) means over the hazard bands (indicator 4), S-OEB, and IFA perform better than COSHH and especially EMGK for vapour/gas. For dust/aerosol, however, EMGK performs best with respect to the equidistance of log(OELV) means. For vapour/gas, a similar pattern is observed for the number of significantly differing adjacent pairs of HB bands (indicator 5): S-OEB and IFA have the smallest overlap between bands. For dust/aerosol, COSHH performs less than the other HB-engines. Note that for dust/aerosol only three pairs (B2 versus C3, C3 versus D4, and D4 versus B5) were tested as the A/1 hazard band of S-OEB and IFA contained only one OELV.

Table 3. Ranks (and values) per strength indicator over the HB-engines and the rank sum as Overall Strength Score

HB-engines	1) p (S-W)[a] of the residuals	2) Percentage of overall log (OELV) variability explained by hazard banding	3) Homogeneity of log (OELV) variance within the hazard bands (p(Levene))	4) Equidistant log(OELV) means. P(non-linear contrast)	5) Number of pairwise independent log(OELV) means ($p < 0.05$)[b]	Overall Strength Score
Vapour/gas ($n = 158$)						
S-OEB	3 (0.526)	3 (38%)	2 (0.187)	4 (0.722)	4 (4 out of 4)	16
COSHH	1 (0.040)	1 (25%)	1 (0.043)	2 (0.535)	1 (1 out of 4)	6
EMKG	4 (0.909)	4 (41%)	3 (0.281)	1 (0.055)	2 (2 out of 4)	14
IFA	2 (0.129)	2 (36%)	4 (0.338)	3 (0.701)	3 (3 out of 4)	14
Dust/aerosol ($n = 71$)						
S-OEB	1 (0.003)	4 (50%)	4 (0.793)	2 (0.078)	3 (2 out of 3)	14
COSHH	2 (0.025)	2 (41%)	2 (0.160)	3 (0.174)	1 (1 out of 3)	10
EMKG	3 (0.029)	3 (49%)	1 (0.127)	4 (0.640)	3 (2 out of 3)	14
IFA	4 (0.042)	1 (38%)	3 (0.427)	1 (0.007)	3 (2 out of 3)	12

[a] P(S-W): the probability of lognormal goodness-of-fit, using the Shapiro–Wilks test.

[b] To compare the HB-engines for dust/aerosol, the B/2-A/1 pair was excluded as the A/1 band of S-OEB and IFA contained only 1 OELV.

The graphs in Fig. 3 and Table 3 show that the overall strength scores of S-OEB, IFA, and EMGK HB-engines are higher than COSHH, with S-OEB having the highest overall strength score for vapour/gas and equal to EMKG for dust/aerosol.

The re-analysis of all indicators for S-OEB and IFA without the A/1 band and the few substances in that band showed that this omission hardly affected the results shown in Table 3. For vapour/gas, the overall strength score decreased by one for EMKG and increased by one for IFA and did not change at all for S-OEB and COSHH. For dust/aerosol, the overall score did not change for any HB-engine (see chapter 4.4 in Supplementary Material, available at *Annals of Occupational Hygiene* online).

Validity of the concentration ranges

The validity analysis of the concentration ranges of S-OEB and COSHH is shown in Fig. 4. The lower limits of the S-OEB concentration ranges for vapour/gas substances are at or below the 10th percentile of the corresponding OELV distribution produced by the S-OEB engine, with the exception of B/2. Nineteen percent of the OELV distribution of the vapour/gas substances in hazard band B/2 is below the lower limit of 5 ppm and for the dust/aerosol substances 13% of the OELV distribution is below the lower limit of 1 mg/m^3. The same analysis for the COSHH engine on the vapour/gas substances showed that 62%, 25%, and 19% of the OELV distributions were below the lower limit of the COSHH concentrations ranges for the A/1, B/2, and C/3 hazard bands, respectively. For dust/aerosol substances, the 10th percentiles of the COSHH OELV distribution ranges are well above the lower limit of the corresponding COSHH concentration ranges.

Note that, whereas the concentration ranges span only one order of magnitude, the corresponding OELV distributions are much wider, comprising typically two orders of magnitude for the dust/aerosol OELVs and three for vapour/gas.

DISCUSSION

The number of data-rich, public OELVs useful to establish workers safe exposure is limited, i.e. about 3% of the 123 000 substances notified by enterprises as being used in the EU (ECHA, 2016). New approaches are developed to fill this gap, e.g. EU REACH (EC, 2007), ECETOC data poor substance Occupational Exposure Limits (ECETOC, 2006), CB (Zalk and Nelson, 2008), and kick-off levels (DOHSBASE v.o.f., 2015). This study investigated the hazard part of CB. Whereas the validation of the exposure modelling of some of the CB-tools has been studied extensively (Lamb and van Tongeren, 2015; Tielemans *et al.*, 2008; Tischer, Bredendiek-Kämper, and Poppek, 2003), the current study focused the hazard part of CB-tools, i.e. the HB-engines. A method to establish the strength of the relation between HB-engines and the 'de facto' OELV standard both graphically and statistically using five indicators is described and applied in this manuscript.

The allocation of the HB-engines was investigated. The differences between the 4 HB-engines in grouping of the hazard codes, lead to significant allocation differences for the data-rich data set confirming what was found for a data set of CLH substances (Scheffers, 2015) (see also chapter 3.2 Supplementary Material, available at *Annals of Occupational Hygiene* online). The presence of these differences is not surprising and should be considered as a mere consequence of the expert-judgement-driven (subjective) grouping of the (up to) 48 hazard codes into five hazard bands.

The selection of substances with high-quality, health hazard classification and OELV information may have caused that low hazardous substances (A/1) are under-represented. The authors are aware that some substances have less extensive toxicological dossiers. Users are therefore encouraged to evaluate the quality and relevance of the substance classification before using them in an HB-engine. In addition, HB should be always considered a lower tier tool and avoided if a reliable OELV is available. In the latter case, higher tier exposure and risk CB-tools should be preferred.

The statistical strength test was developed in such a way that it includes independent indicators of the desired strength, which was defined as equal shaped, homogeneous OELV distributions with high, linear contrast between the bands. Steep lines in Fig. 1 indicating small log(OELV) variances (minimal unexplained variance within bands) is the same property as maximum explained variance between bands (indicator 2) using analysis of variance (ANOVA)/regression and was therefore not included as an independent indicator. The pairwise differences between the mean log(OELV) i.e. indicator 5 overlaps partly with indicator 2 and indicator 4 but results in a different ranking than indicators 2 and 4. Indicator 5 was therefore maintained in the overall strength score.

The comparative strength analysis showed that HB-engines perform differently for the vapour/gas and the dust/aerosol substances. Therefore, the use of a single HB-engine for both (Table 1) may be reconsidered. The validity assessment showed that the use of the lower limits of the S-OEB concentration ranges as 'indicative exposure limits' for tier 0/1 risk assessment is appropriate. Since the concentration ranges are compared relative to the 10th percentile of the OELV distribution rather than the lowest value, a degree of uncertainty remains for every HB-engine. Therefore, the overall process should be supported by toxicological/occupational hygiene expertise.

All studied HB-engines have five hazard bands. However, some hazard bands (see Fig. 3) showed overlapping or crossing log(OELV) distributions, e.g. EMKG and COSHH vapour/gas. Reducing the HB-engines to four bands may improve the discriminating power of HB (Scheffers and Wieling, 2015). Also, optimizing the allocation of the H-codes over the hazard band may decrease the current OELV ranges towards the 1 order of magnitude of Table 2. The authors are aware that more HB-engines exist, but the three public HB-engines were used in this study because of their availability, level of documentation, and widespread use. Recently, IFA, one of the studied HB-engines, proposed an update (Arnone *et al.*, 2015) which shows an increasing number of similarities with S-OEB and EMGK. What the impact of these modifications is on allocation and strength was not investigated in the current study, but it may be part of a broadened assessment in which aspects such as a larger data set containing more low-hazard and dust/aerosol substances, refined grouping, and other HB-engines could be considered.

The applicability of the S-OEB HB-engine as a standard within Solvay's global operations was confirmed because its performance was at least as good in terms of allocation, strength, and validity as that of the three public and widely used HB-engines. Evidently, the S-OEB HB-engine is a part of a larger in-company exposure control approach including exposure assessment and resulting RMMs, which will be published elsewhere.

CONCLUSIONS

Our investigations confirmed the applicability of the S-OEB HB-engine as a standard within Solvay's global operations.

The method described here to evaluate the strength of HB-engines and validity of the corresponding concentration ranges was able to discriminate and rank HB-engines, even with a relatively small but high-quality data set, and is therefore a useful tool enabling further developments and alignment of HB.

SUPPLEMENTARY DATA

Supplementary data can be found at http://annhyg.oxfordjournals.org/.

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REFERENCES

ACGIH. (2016). *ACGIH TLVs® and BEIs®. Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices*. Cincinnati, OH. Available at http://www.acgih.org. Accessed 15 February 2016.

Arnone M, Koppisch D, Smola T *et al.* (2015) Hazard banding in compliance with the new Globally Harmonised System (GHS) for use in control banding tools. *Regul Toxicol Pharmacol*; 73: 287–95.

BAUA. (2009). *EMKG—Einfaches Ma{ß}nahmenkonzept Gefahrstoffe: inhalativ*. Dortmund Berlin Dresden: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin.

Brooke IM. (1998). A UK scheme to help small firms control health risks from chemicals: toxicological considerations. *Ann Occup Hyg*; 42: 377–90.

DOHSBASE v.o.f. (2015). DOHSBase. A database with Occupational Hygiene Exposure Limits and Sampling Methods. Dohsbase. Available at www.dohsbase.com. Accessed 1 January 2015.

EBRC. (2015). The Metals Occupational Exposure Assessment Tool (MEASE). Available at http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/mease.php. Accessed 1 January 2015.

EC. Regulation (EC) No 1907/2006 (REACH). 7211/1/07 REV 1. Corrigendum 29 October 2007 (2007). European Council.

EC. Regulation (EC) No 1272/2008. On classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Amended by: Commission Regulation (EC) No 790/2009 (2008). European Commission.

ECETOC. (2004). *Targeted Risk Assessment. Technical Report No. 093*. Brussels, Belgium: European Centre for Ecotoxicology and Toxicology of Chemicals. Available at www.ecetoc.org.

ECETOC. (2006). *Guidance for Setting Occupational Exposure Limits: Emphasis on Data-Poor Substances Technical Report No. 101*. Brussels, Belgium: European Centre for Ecotoxicology and Toxicology of Chemicals. Available at http://www.ecetoc.org.

ECHA. (2012). *Guidance on Information Requirements and Chemical Safety Assessment. Part E: Risk Characterisation*. Helsinki, Finland. Available at http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment. Accessed 15 February 2016.

ECHA. (2016). European Chemicals Agency. Available at www.ECHA.eu. Accessed 10 January 2016.

Gardner RJ, Oldershaw PJ. (1991). Development of pragmatic exposure-control concentrations based on packaging regulation risk phrases. *Ann Occup Hyg*; 35: 51–9.

Guest I. (1998). The chemical industries association guidance on allocating occupational exposure bands. *Ann Occup Hyg*; 42: 407–11.

HSE. (1999). *COSHH Essentials: Easy Steps to Control Chemicals, HSG 193*. UK: Health and Safety Executive. Available at https://books.google.com/books?id=VYhIAAAACAAJ. Accessed 30 August 2016. ISBN: 0717624218, 9780717624218.

HSE. (2009). *The technical basis for COSHH essentials: easy steps to control chemicals. Table 3 Allocation of R-phrase or GHS phrase to Hazard Group; concentration range*. Available at www.coshh-essentials.org.uk. Accessed 15 February 2016.

ILO. (2006). *Programme on Safety and Health at Work and the Environment (SafeWork). International Chemical Control Toolkit. Identification of the Inhalation Hazard Group*. Available at http://www.ilo.org/legacy/english/protection/safework/ctrl_banding/toolkit/icct/hgroup.htm. Accessed 15 February 2016.

INRS. (2015). SEIRICH Evaluer le risque Chimique. Available at http://www.seirich.fr/. Accessed 15 February 2016.

ISO/TC 69. (1997). *ISO 5479:1997 Statistical interpretation of data—Tests for departure from the normal distribution*. Geneva, Switzerland: International Organization for Standardization ISO.

Kahl A, Wilmes A, Guhe C *et al.* (2012). *Einfaches Maßnahmenkonzept Gefahrstoffe (EMKG) Version 2.2. Eine Handlungsanleitung zur Gefährdungsbeurteilung für Sicherheitsfachkräfte und andere fachkundige Personen*. Dortmund Berlin Dresden.

Lamb J, van Tongeren M. (2015). Presentation Session 9c–IOHA 7th International Control Banding Workshop. Available at http://www.ioha2015.org/ioha-2015-presentations/.

Marquart H, Heussen H, Le Feber M *et al.* (2008) 'Stoffenmanager', a web-based control banding tool using an exposure process model. *Ann Occup Hyg*; 52: 429–41.

OSHA Hazard Communication (2012). Occupational Safety & Health Administration, United States Department of Labor. Available at www.osha.gov/.

Proschan F. (1953). Confidence and tolerance intervals for the normal distribution. *JASA*; 48: 550–64.

Royston JP. (1982). Algorithm AS 177: expected normal order statistics (exact and approximate). *J R Stat Soc Ser C Appl Stat*; 31: 161–5.

Ruppich N. (2005). *Einfaches Massnahmenkonzept Gefahrstoffe – fachliche Hintergründe: Empirische Zusammenhänge von Einstufung und Arbeitsplatzgrenzwert*. Dortmund Berlin Dresden.

Safe Work Australia. (2016). Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Available at http://www.safeworkaustralia.gov.au/sites/swa/whs-information/hazardous-chemicals/ghs/pages/ghs. Accessed 10 January 2016.

Scheffers T. (2015). The best performing GHS/CLP health hazard categorizations. In *IOHA*. London. Available at http://www.ioha2015.org/wp-content/uploads/2015/05/9c_Alignment.Theo_Scheffers.IOHA2015.7ICBW.150428.pdf. Accessed 19 August 2016.

Scheffers T, Wieling G. (2014). Careful with that DNEL, Occupational Hygienist! *BOHS Magazine*, 3, 39–40. Accessed 19 August 2016.

Scheffers T, Wieling G. (2015). Differences in control banding health hazard categorization. In *IOHA*. London. Available at http://www.ioha2015.org/wp-content/uploads/2015/05/8c-Validation.Theo_Scheffers.IOHA2015.7ICBW.1504281.pdf. Accessed 19 August 2016.

Scheffers T, Wieling G, Coucke C. (2014). Validation of the Hazard Grouping in Control Banding. In *AIHCe*.

SCOEL. (2013). *SCOEL Recommendations*. Brussels, Belgium: European Commission Employment, Social Affairs & Inclusion Health and Safety at work—The Scientific Committee on Occupational Exposure Limits.

Shapiro SS, Wilk MB. (1965). An analysis of variance test for normality (complete samples). *Biometrika*; 52: 591–611.

Smola,T. (2011). *Das GHS-Spaltenmodell. Eine Hilfestellung zur Substitutionsprüfung nach Gefahrstoffverordnung*. Sankt Augustin: Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (DGUV-IFA).

State Council of China (2011) Decree 591. Regulations on the Safe Management of Hazardous Chemicals in China—Full English Translation (non-official). Available at http://www.cirs-reach.com/China_Chemical_Regulation/Regulations_on_safe_management_on_hazardous_chemicals_China_2011.pdf. Accessed 19 August 2016.

Tielemans E, Noy D, Schinkel J, Heussen H, *et al.* (2008). Stoffenmanager exposure model: development of a quantitative algorithm. *Ann Occup Hyg*; 52:443–54.

Tischer M, Bredendieck-Kämper S, Poppek U. (2003). Evaluation of the HSE COSHH Essentials Exposure Predictive Model on the Basis of BAuA Field Studies and Existing Substances Exposure Data. *Ann Occup Hyg*; 47:557–69.

UNECE. (2013). Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Rev 5. Annex 1 Classification and labelling. Available at http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev05/English/05e_annex1.pdf. Accessed 15 February 2016.

Zalk DM, Nelson DI. (2008) History and evolution of control banding: a review. *J Occup Environ Hyg*; 5: 330–46.