Testing strength and validity of Hazard Band engines

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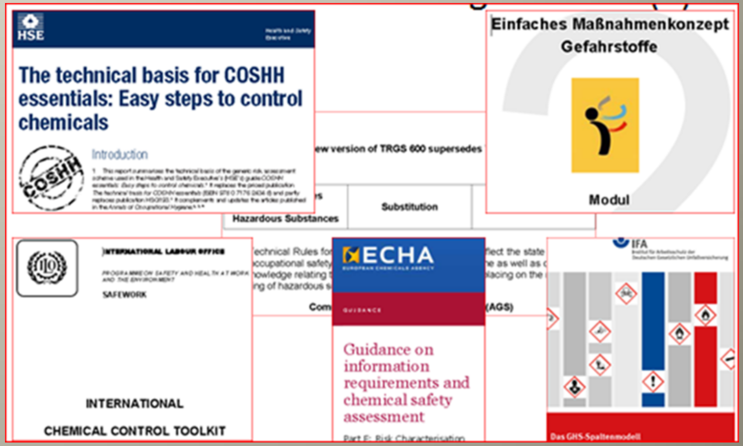
co-project/co-presentation

Erik.Vanmiert@Solvay.com

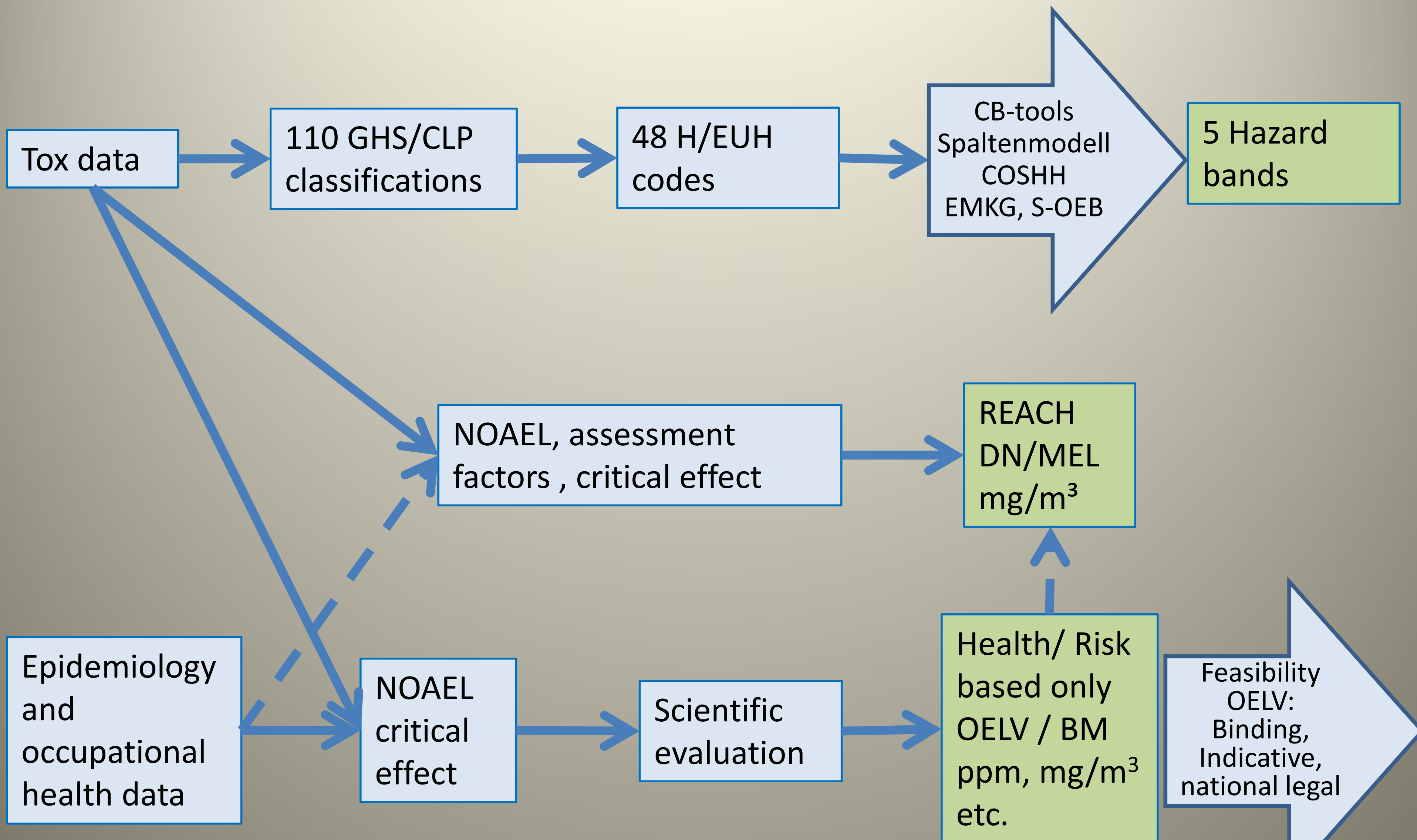
Theo Scheffers@TSAC.nl

Hazard band: if no OELV exists

- Hazard part of Control Banding
- First done in pharmacy (Naumann, 1996)
- COSHH (1999, R-phrases based)
- Spaltenmodell, EMKG
- In-company SOLVAY OEB,……
- SEIRICH (France INRS)
- ILO-toolbox (WHO)
- (semi) commercial Stoffenmanager RP(NL) /CHEMHYSS (Fr)/ ChemRADE (NL) ??

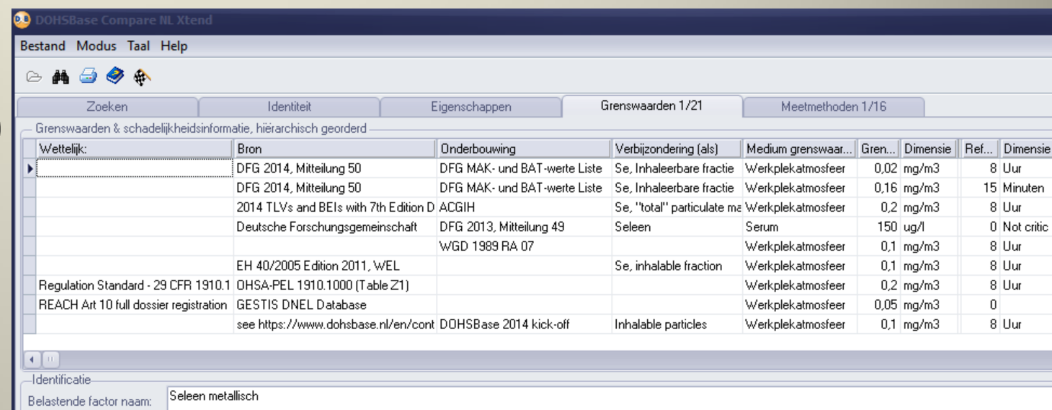


Limit Value & Hazard Band



Realm of hazard bands

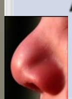
- >172.000 substances identified (DOHSBase 16-01)
- 110.000 notified in the EU as being used
- Substances with OELV:
  - grow 800 (1990)→6000
    - 4000 LV/BM
    - 3662 DNELs
    - 2609 Kick-off's (CLH)



Wettelijk:	Bron	Onderbouwing	Verbijzondering (als)	Medium grenswaar...	Gren...	Dimensie	Ref...	Dimensie
	DFG 2014, Mitteilung 50	DFG MAK- und BAT-werte Liste	Se, Inhaleerbare fractie	Werkplekatmosfeer	0,02	mg/m3	8	Uur
	DFG 2014, Mitteilung 50	DFG MAK- und BAT-werte Liste	Se, Inhaleerbare fractie	Werkplekatmosfeer	0,16	mg/m3	15	Minuten
	2014 TLVs and BEIs with 7th Edition D	ACGIH	Se, "total" particulate ma	Werkplekatmosfeer	0,2	mg/m3	8	Uur
	Deutsche Forschungsgemeinschaft	DFG 2013, Mitteilung 49	Seleen	Serum	150	ug/l	0	Not critic
		WGD 1989 RA 07		Werkplekatmosfeer	0,1	mg/m3	8	Uur
	EH 40/2005 Edition 2011, WEL		Se, inhalable fraction	Werkplekatmosfeer	0,1	mg/m3	8	Uur
Regulation Standard - 29 CFR 1910.1	OHSA-PEL 1910.1000 (Table Z1)			Werkplekatmosfeer	0,2	mg/m3	8	Uur
REACH Art 10 full dossier registration	GESTIS DNEL Database			Werkplekatmosfeer	0,05	mg/m3	0	
	see https://www.dohsbase.nl/en/cont	DOHSBase 2014 kick-off	Inhalable particles	Werkplekatmosfeer	0,1	mg/m3	8	Uur

- ~104.000 substances used in EU without limit value, but GHS/CLP classified: ECHA's C&L inventory→
  - HB-engine in Control Banding

different HB-engines allocate H/EUH-codes in different bands

Hazard band	DGUV IFA Spaltenmodell	HSE COSHH	BAUA EMKG (inhalation)*	Solvay OEB
 E/5	300, 310, 330 (Tox) 340, 350, 350i (CM) EU032 (Tox gas release)	340, 341, 350(i) (CM) 334 (S) EU070 (Tox)	340, 350, 350i (CM) 360_F (R)	372 (Tox) 340, 350 (CM) 334 (ICS)
D/4	301, 311, 331, 370, 372 (Tox) 341, 351, 360_{xy} (CMR) EUH029, EUH031 (Tox gas release) 317, 334, 318, EUH070 (ICS)	300, 310, 330, 372 (Tox) 351, 360_{xy}, 361, 362 (CR)	300, 330, 372 (Tox) 360_D (R) EUH032 (Tox gas release)	300, 310, 330; 370, 373 (Tox) 314 (+ cat A), EUH071 (ICS), 341, 351, 360_{xy} (CMR)
C/3	302, 312, 332(Tox) 314 (pH ≥ 11,5, pH ≤ 2), 371, EUH071 $361_{f/d}$, 373, 362 non-toxic gases which may cause asphyxiation	301, 311, 331, 314, 370, 373 (Tox) 317, 318 , 335, EUH071 (IC)	301, 331, 314, 370, 371, 373 (Tox) 334 (S) 341, 351, 361f/d (CMR) EUH031 (Tox gas release)	301, 311, 331; 371 (Tox) 304, EUH070 (lung, eye damage) 314 cat B and C, 317, 318, 335 (ICS) 361, 362 (R & Lact)
B/2	315, 319, 335, ** (I) 304, EUH066, 336 (solvents) ***	302, 312, 332, 371 (Tox)	302, 332 (Tox) 318 (C)	302, 312, 332, 336 (Tox) 315, 319, EUH066 (I)
A/1 	substances which experience shows to be harmless (e.g. water, sugar, paraffin etc.)	303, 313, 333(GHS Tox4) 315, 316, (GHS) 319, 320 (I) 304, 305 (Aspiration) 336 , EUH066 (solvents) and all H-numbers not otherwise listed	319, 335 (I) 336 (solvent) 304 (Aspiration) Non health hazard H-statement codes	303, 313, 333 (GHS Tox 4) 305 (ICS) 316 (GHS-> noCLP), 320 (GHS eye irr 2b->CLP 319)

Hazard band allocation differences

Dibenzylperoxide (CAS# 94-36-0; ID# 617-008-00-0)

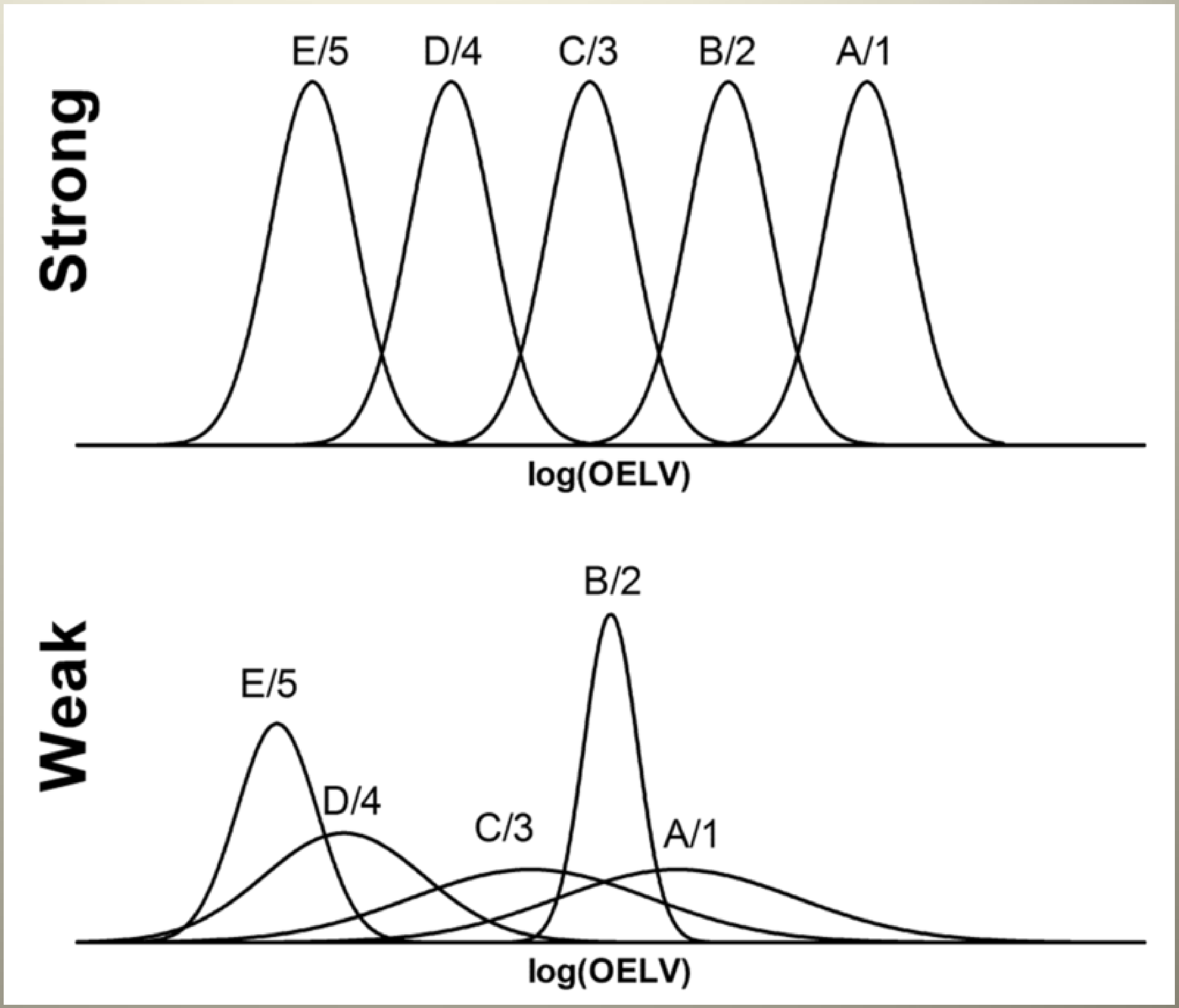
EU harmonized classification: H241, H317, H319

Hazard band allocation	IFA Spaltenmodell (2011)	COSHH (2009)	EMKG-HOI (2009)	S-OEB
Eye Irrit. 2 H319	2	1	1	2
Skin Sens. 1 H317	4	3	-	3
Final Hazard-Band	**4**	**3**	**1**	**3**

Theo Scheffers question:
how to maximize the HB-engine/OELV relation?

HB-engines:
COSHH
Spaltenmodell
EMKG
S-OEB

ILO
SEIRICHH
IFA (2015)
…..
…..



Context

SAEL: Solvay Accceptable Exposure Limits: voluntary, world-wide occupational exposure limit

70 SAEL

800 OELs
(National and TLV)

Around 7000 chemicals without national OELS or SAELs

⇨ **S-OEB**

Identification & application of adequate RMMs

S-OEB:
Semi-automated tool managed by corporate HSE, yet applied across Solvay by local HSE staff

If nanomaterial: nanobanding tool

Possible refinement

1. Expert OEB

Adjustment of hazard band allocation based on toxicological data and expert judgement

2. SAEL

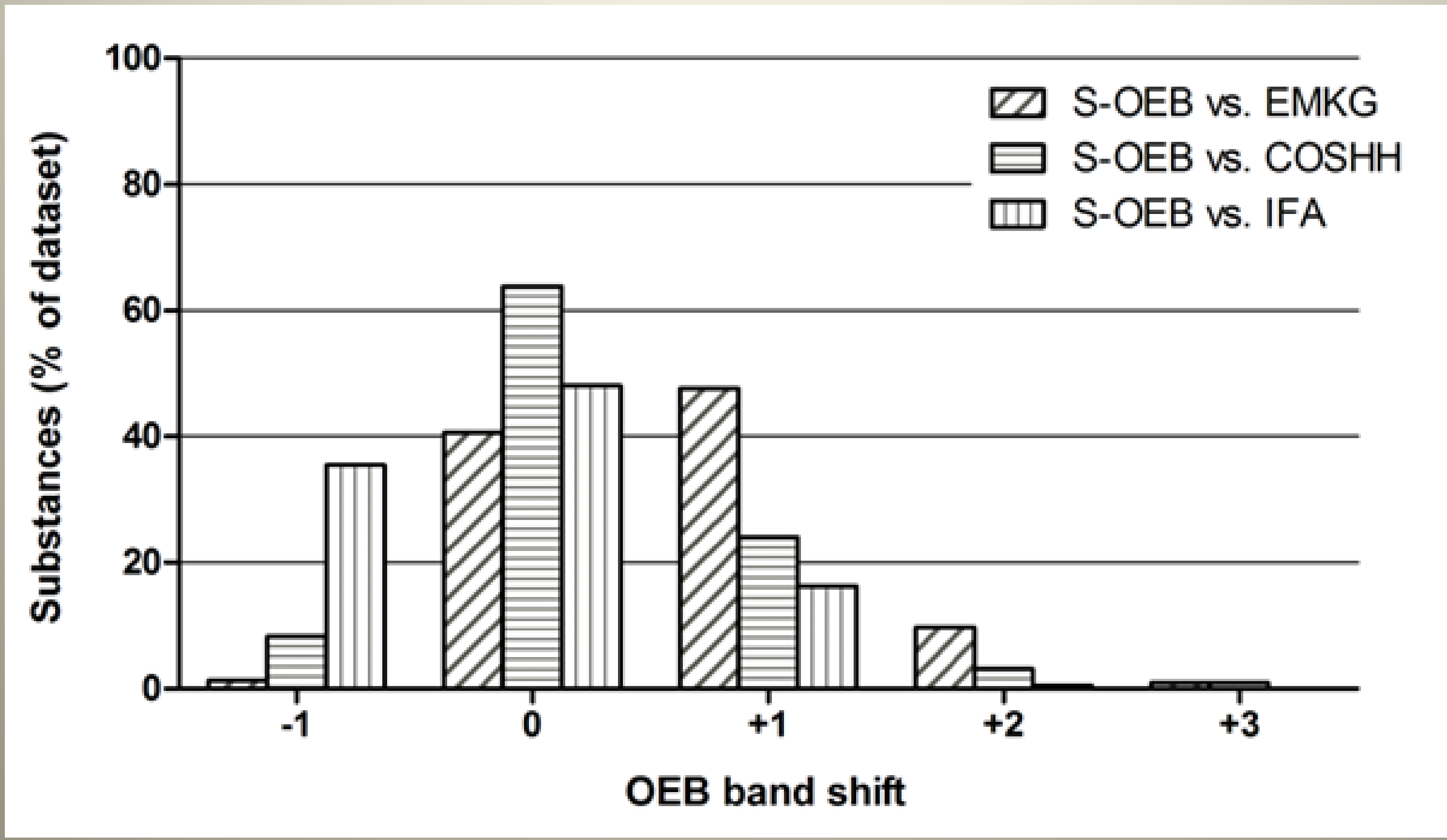
Definition of an internal OELV based on a extensive toxicological data set and expert judgement

Solvay’s questions:

How to get an accepted global HSE CB approach that aligns or includes the national CB-tools.

1. How does S-OEB perform relative to COSHH, IFA and EMGK?
2. Are the S-OEB concentration ranges valid?

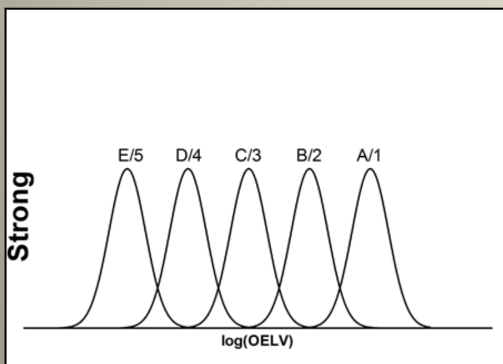
Results:
Difference in Hazard Band allocations

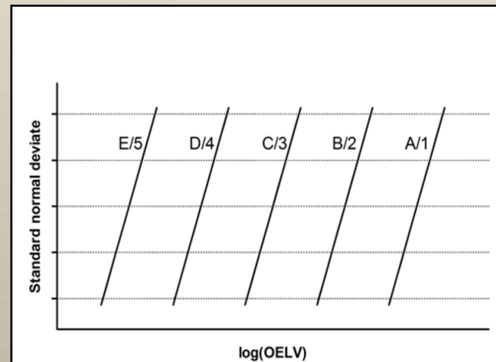


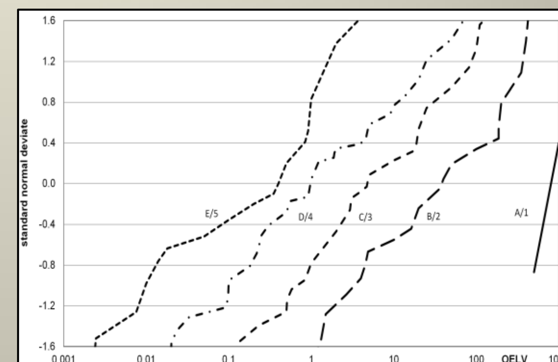
Relative to S-OEB, the 3 HB systems assign equal bands for at least 40% of the substances.
The remaining substances differ at least one band, with IFA placing more substances in a higher and EMKG doing the opposite

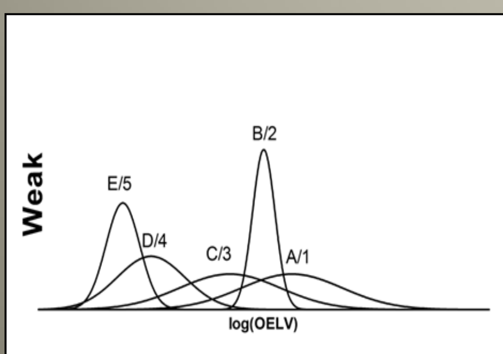
Results:
Strength of differentiation rel. to actual OELV

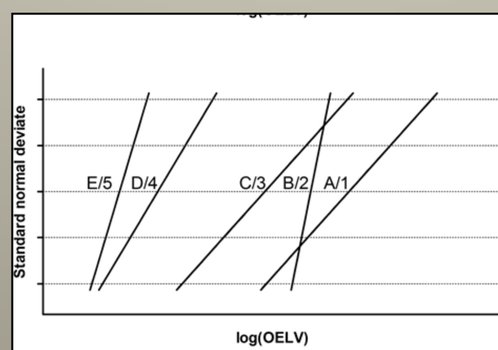
Log-normal distribution	Cumulative log-normalized probability plot	Cumulative log-normalized probability plot
Theory	*Theory*	*Actual*

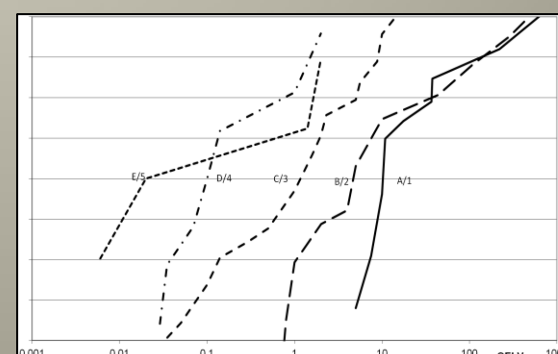


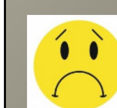












Results:
Strength of differentiation rel. to actual OELV

HB-System	p(S-W) of the residuals	Percentage of overall log(OELV) variability explained by hazard banding	Homogeneity of log(OELV) variance within the hazard bands (p(Levene))	Equidistant log(OELV) means. P(Non-Linear contrast.)	Number of pairwise independent log(OELV) means ($p < 0.05$)	Overall Strength Score
Vapour/gas (n=158)						
S-OEB	3 (52.6%)	3 (38%)	2 (18.7%)	4 (72.2 %)	4 (4 out of 4)	**16**
COSHH	1 (4.02%)	1 (25%)	1 (4.3%)	2 (53.5 %)	1 (1 out of 4)	**6**
EMKG	4 (90.9%)	4 (41%)	3 (28.1%)	1 (5.5 %)	2 (2 out of 4)	**14**
IFA	2 (12.9%)	2 (36%)	4 (33.8%)	3 (70.1 %)	3 (3 out of 4)	**14**
Dust/aerosol (n=71)						
S-OEB	1 (0.3%)	4 (50%)	4 (79.3%)	2 (7.8 %)	3 (2 out of 3)	**14**
COSHH	2 (2.5%)	2 (41%)	2 (16%)	3 (17.4 %)	1 (1 out of 3)	**10**
EMKG	3 (2.9%)	3 (49%)	1 (12.7%)	4 (64.0 %)	3 (2 out of 3)	**14**
IFA	4 (4.2%)	1 (38%)	3 (42.7%)	1 (0.7 %)	3 (2 out of 3)	**12**

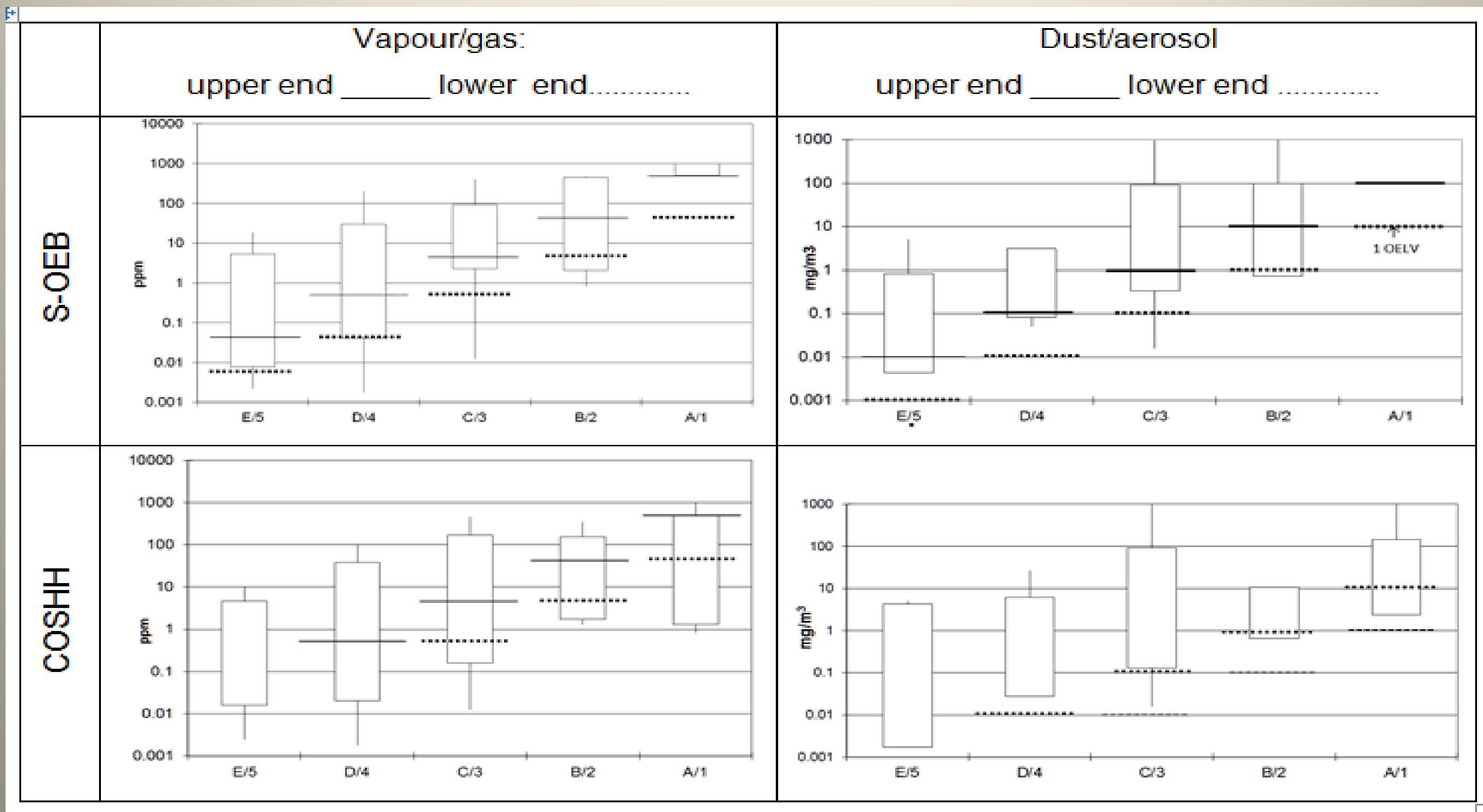
S- OEB relates at least as strongly to OELV
as the other HB systems

Results:
Validity of the airborne concentration ranges

(2 HB systems only)

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
C3	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

Results:
Validity of the airborne concentration ranges



The use of the lower limits of the S-OEB concentration ranges as "indicative exposure limits" for tier 0/1 risk assessment is appropriate.

Conclusions

- The strength of the relation between a HB-engine and OELV can be determined using 1 picture and 5 statistical indicators with high discriminating power despite a limited dataset
- IFA, EMKG and S-OEB perform better that COSHH with S-OEB having the highest rank

Making it public

R-phrases based

Tabel: Kick-off grenswaardeniveaus (TGG 8 uur) gebaseerd op het TRGS440 gevaarklassenschema

	Gevaarklasse			
	1	2	3	4
R-zinnen	36, 37, 38, 65, 66, 67*	20, 21, 22 34, 41, 62, 63, 64	23, 24, 25, 29, 31, 33, 35, 40, 42, 43, 48/21,21,22, 60, 61, 68	26, 27, 28, 32, 45, 46, 48/23,24,25, 49
Kick-off grenswaarde per gevaarklasse en fysische staat:				
Gasen en dampen (ppm)	4	0,2	0,01	0,001
Aërosolen (mg/m^3)	0,24	0,06	0,02	0,01

GHS/CLP H/EUH-code based

Proposed kick-off values for dust/aerosols
(basis: COSHH Essentials)

Hazard Group	4	3	2 *	1
H-statements	H334, H340, H341, H350, H350i	H300, H310, H330, H351, H360F/D/FD/Fd /Df, H361f/d/fd, H362, H372	H301, H302, H311, H312, H314, H317, H318, H331, H332, H335, H370, H371, H373, EUH071	H303, H304, H305, H313, H315, H316, H319, H320, H333, H336, EUH066, other H-statements n.o.s., REACH Annex IV
Dusts (mg/m³)	0,0001	0,01	0,1	1

*: COSHH Essential Groups B+C combined

Proposed based kick-off values for gases/vapors
(basis: DGUV IFA Spaltenmodell)

Hazard Group	4	3	2	1
H-statements	H300, H310, H330, H340, H350, H350i, EUH032	H301, H311, H317, H318, H331, H334, H341, H351, H360F/D/FD/Fd/Df, H370, H372, EUH029, EUH031, EUH070	H302, H312, H314, H332, H361f/d/fd, H362, H371, H373, EUH071	H304, H315, H319, H335, H336, EUH066, other H-statements n.o.s., REACH Annex IV
Gases/vapors (ppm)	0,001	0,01	0,1	5

- https://www.dohsbase.nl/en/content-2-2-2/kick-off-levels-2014/
- NVvA (≤2016)/CGC (2014)
- AIHCe2014/ IOHA2015
- BOHS 2016

Publication submitted:

The Annals of Occupational Hygiene

Future steps

- International cooperation to align HB-engines
- Larger dataset
- Optimize allocation H/EUH codes statistically and/or expert judgement
- New concepts:
  - Less bands (4 bands = kick-off)
  - 110 GHS/CLP classifications HB-engine
  - Separate acute and repeated dose

Thanks !

- Blandine Doornaert
  Solvay, Toxicological and Environmental Risk Assessment (TERA), Lyon, France
- Prof. Gerard van Breukelen
  Department of Methodology and Statistics, CAPHRI Research School of Public Health and Primary Care, University of Maastricht, The Netherlands
- Nathalie Berne, Antoine Leplay
  Solvay, Industrial Hygiene, Lyon, France

Question:

What to do in practice with large difference between HB-engines?

Dibenzylperoxide

Hazard band allocation	IFA Spaltenmodell (2011)	COSHH (2009)	EMKG-HOI (2009)	S-OEB
Eye Irrit. 2 H319	2	1	1	2
Skin Sens. 1 H317	4	3	-	3
Final Hazard-Band	**4**	**3**	**1**	**3**