

Testing strength and validity of Hazard Band engines

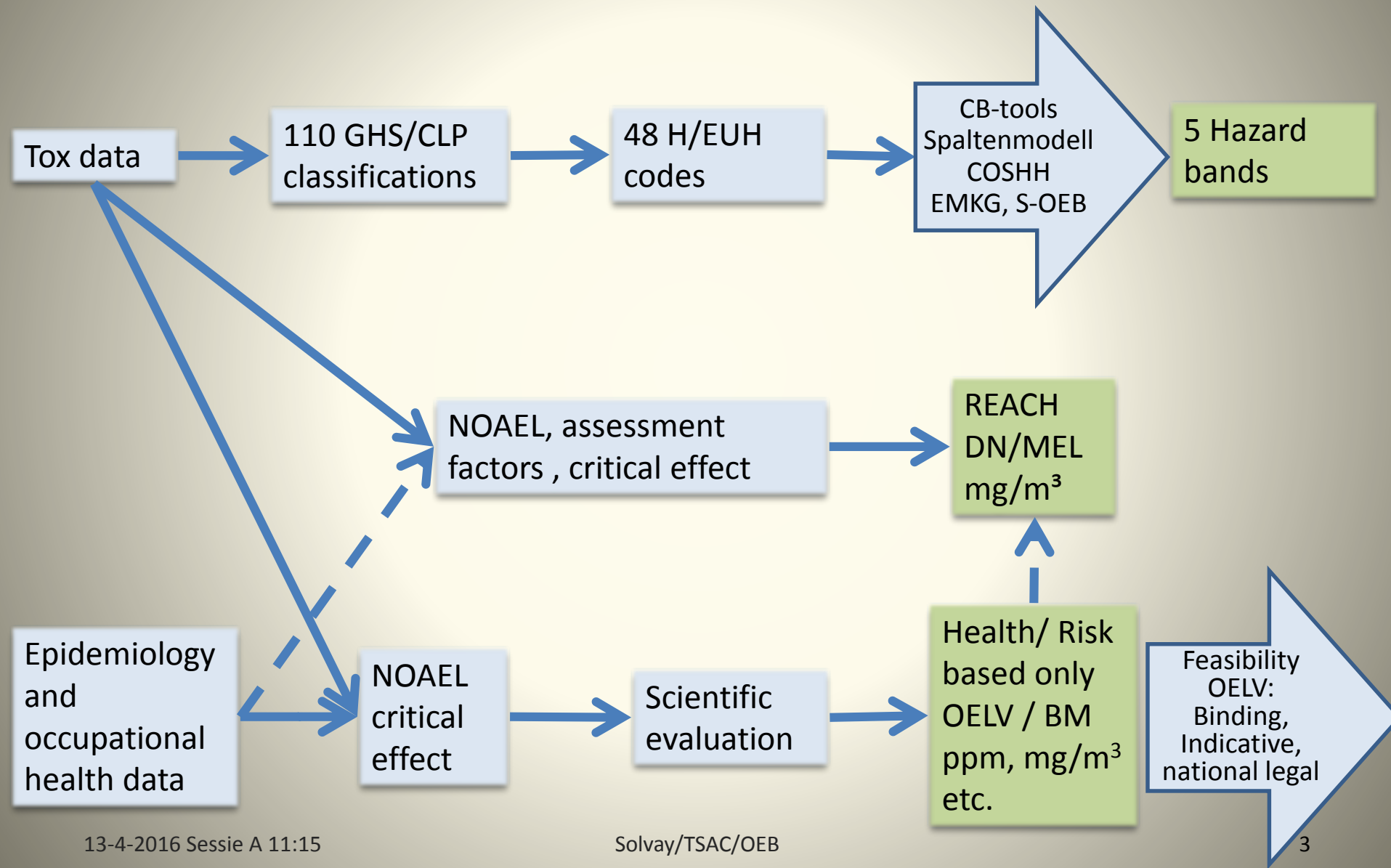
NVvA 13 april 2016, 11:15
co-project/co-presentation
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Hazard band: if no OELV exists

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

DOHSBase Compare NL Xtend

Bestand Modus Taal Help

Zoeken Identiteit Eigenschappen Grenswaarden 1/21 Meetmethoden 1/16

Grenswaarden & schadelijkheidsinformatie, hiërarchisch georderd

Wettelijk:	Onderbouwing	Verbijzondering (als)	Medium grenswaar...	Gren...	Dimensie	Ref...	Dimensie
DFG 2014, Mitteilug 50	DFG MAK- und BAT-werte Liste	Se, Inhaleerbare fractie	Werkplek-atmosfeer	0,02 mg/m ³	8	Uur	
DFG 2014, Mitteilug 50	DFG MAK- und BAT-werte Liste	Se, Inhaleerbare fractie	Werkplek-atmosfeer	0,16 mg/m ³	15	Minuten	
2014 TLVs and BEIs with 7th Edition D	ACGIH	Se, "total" particulate m	Werkplek-atmosfeer	0,2 mg/m ³	8	Uur	
Deutsche Forschungsgemeinschaft	DFG 2013, Mitteilug 49	Seleen	Serum	150 ug/l	0	Not critic	
EH 40/2005 Edition 2011, WEL	WGD 1989 RA 07	Se, inhalable fraction	Werkplek-atmosfeer	0,1 mg/m ³	8	Uur	
Regulation Standard - 29 CFR 1910.1	DHSA-PEL 1910.1000 (Table Z1)		Werkplek-atmosfeer	0,2 mg/m ³	8	Uur	
REACH Art 10 full dossier registration	GESTIS DNEL Database		Werkplek-atmosfeer	0,05 mg/m ³	0		
see https://www.dohsbase.nl/en/cont	DOHSBase 2014 kick-off	Inhalable particles	Werkplek-atmosfeer	0,1 mg/m ³	8	Uur	

Identificatie

Belastende factor naam: Seleen metallisch

ECHA
EUROPEAN CHEMICALS AGENCY

About Us Regulations Addressing Chemicals of Concern Information on Chemicals

ECHA > Information on Chemicals > C&L Inventory


C&L Inventory

This database contains classification and labelling information on notified and registered substances received from manufacturers and importers. It also includes the list of harmonised classifications. The database is refreshed regularly with new and updated notifications. However, updated notifications cannot be specifically flagged because the notifications that are classified in the same way are aggregated for display purposes.

Classifications derived from joint submissions to the REACH registration process are flagged accordingly. For more information on these substances, please consult the [Registered substances database](#).

Please note that some of the information on C&L Inventory may belong to third parties. The use of such information may therefore require the prior permission of the third party owners. Please consult the [Legal Notice](#) for further information.

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

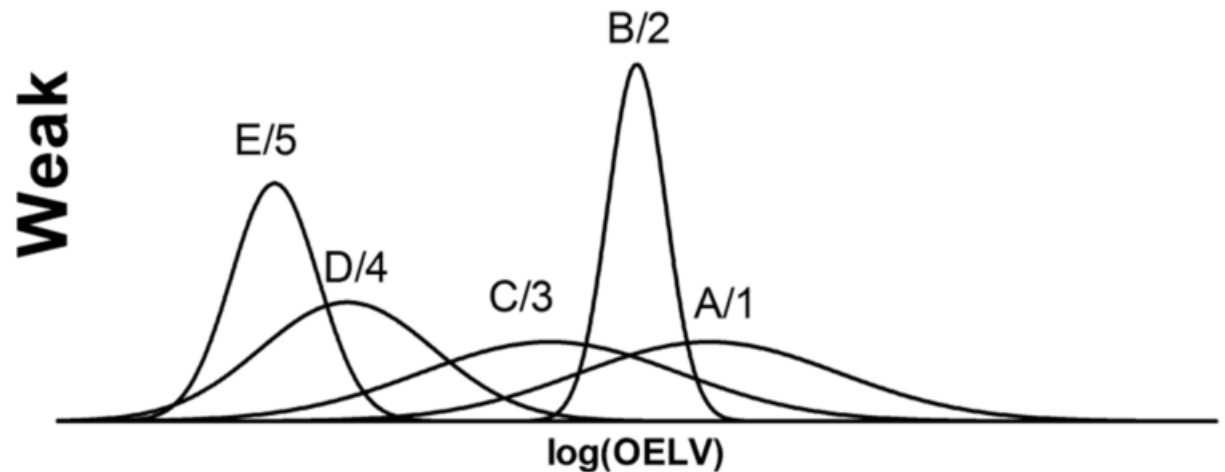
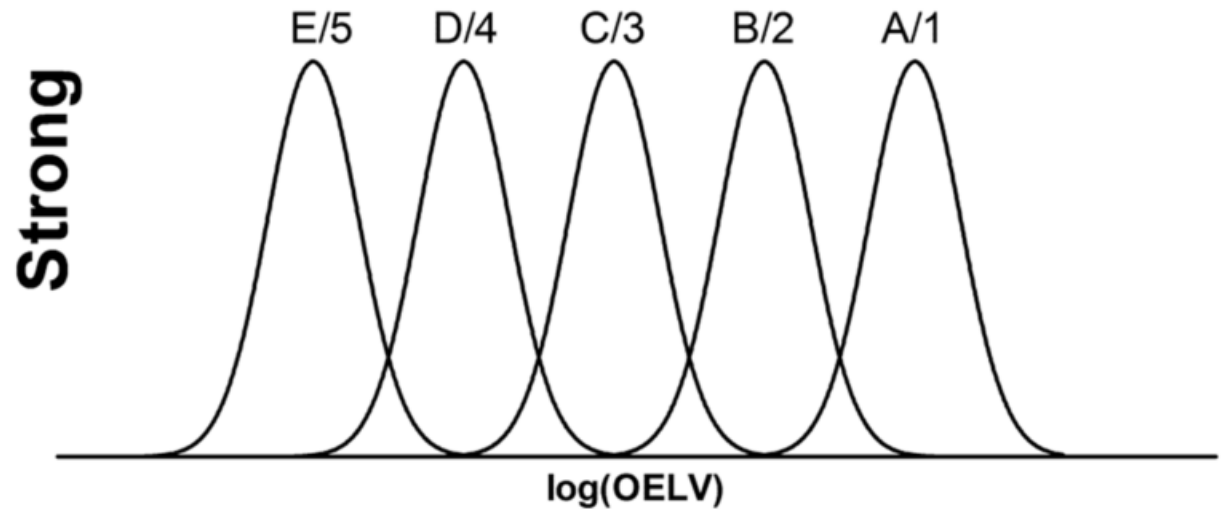
ILO

SEIRICHH

IFA (2015)

.....

.....



Context



*SAEL: Solvay Acceptable 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

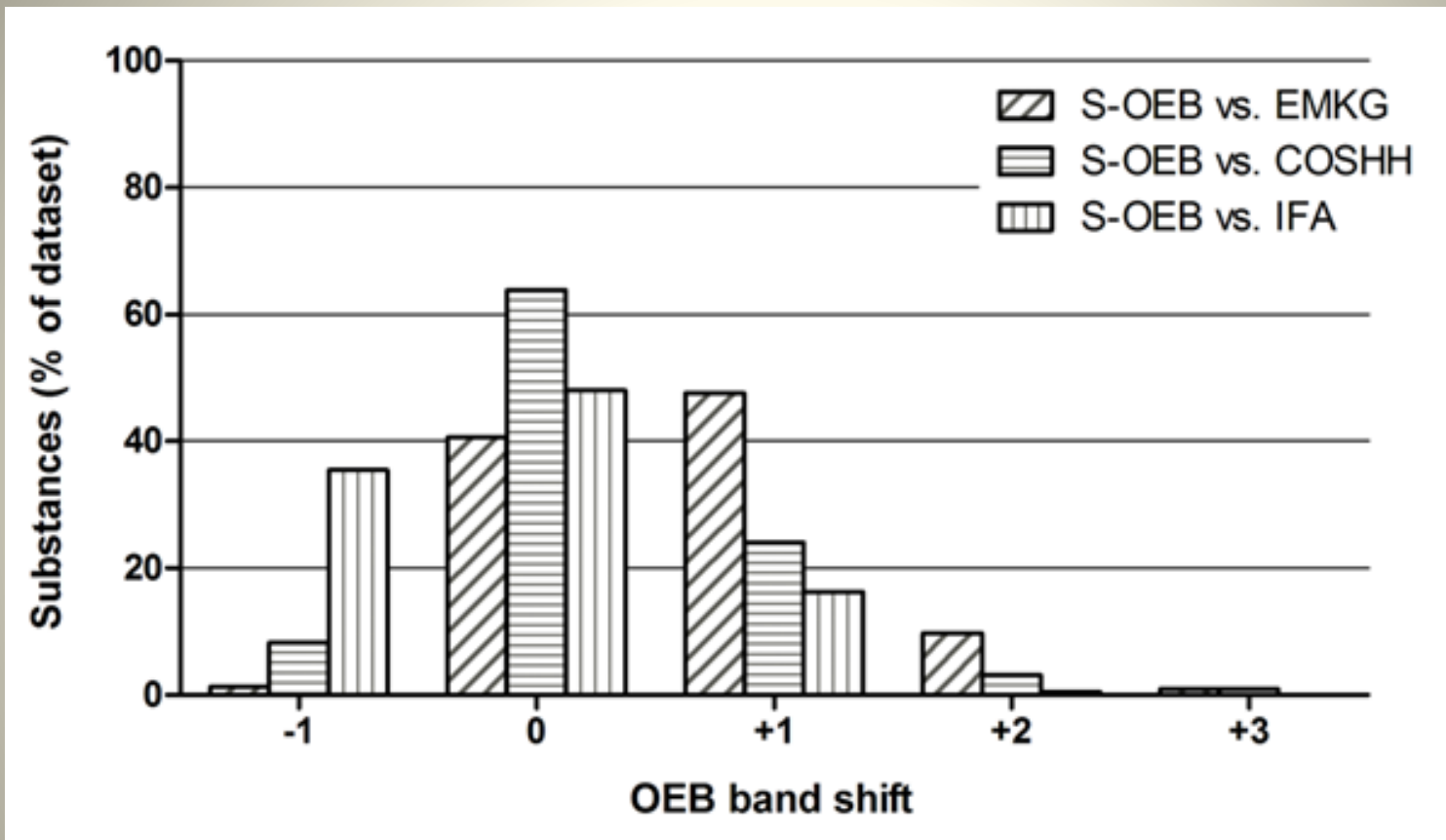
Solvay's questions:

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

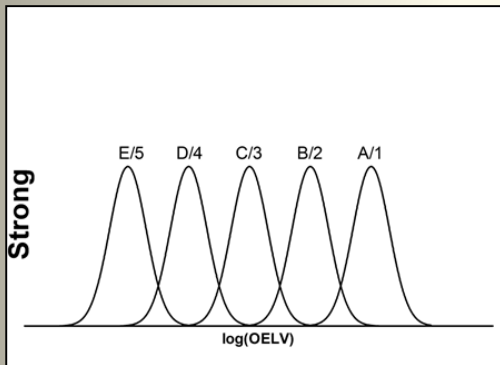


Results:

Strength of differentiation rel. to actual OELV

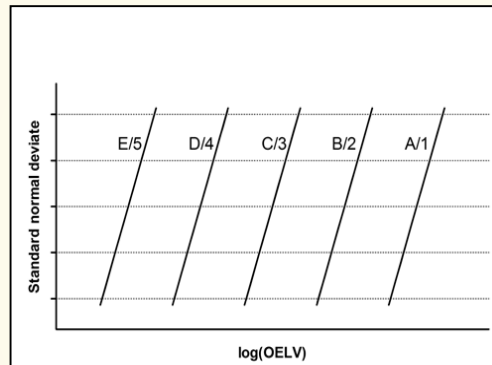
Log-normal distribution

Theory



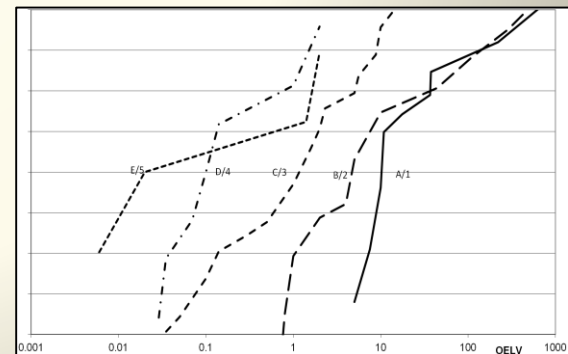
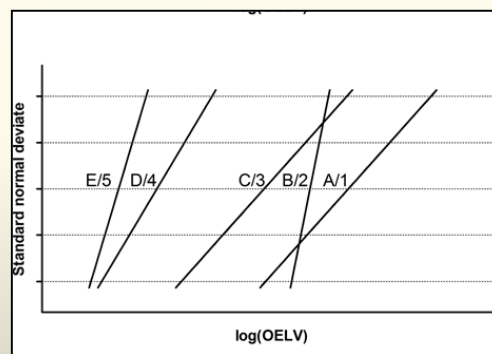
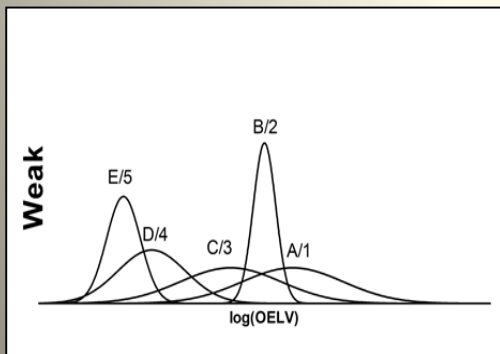
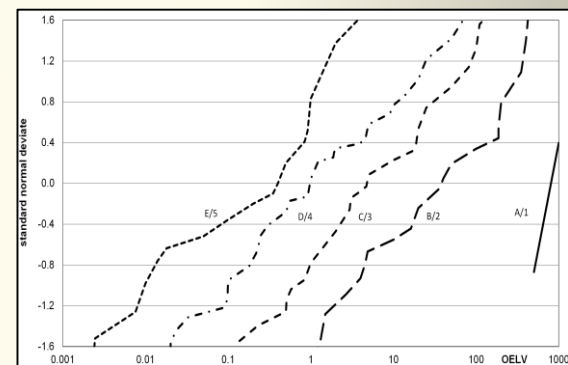
Cumulative log-normalized probability plot

Theory



Cumulative log-normalized probability plot

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:

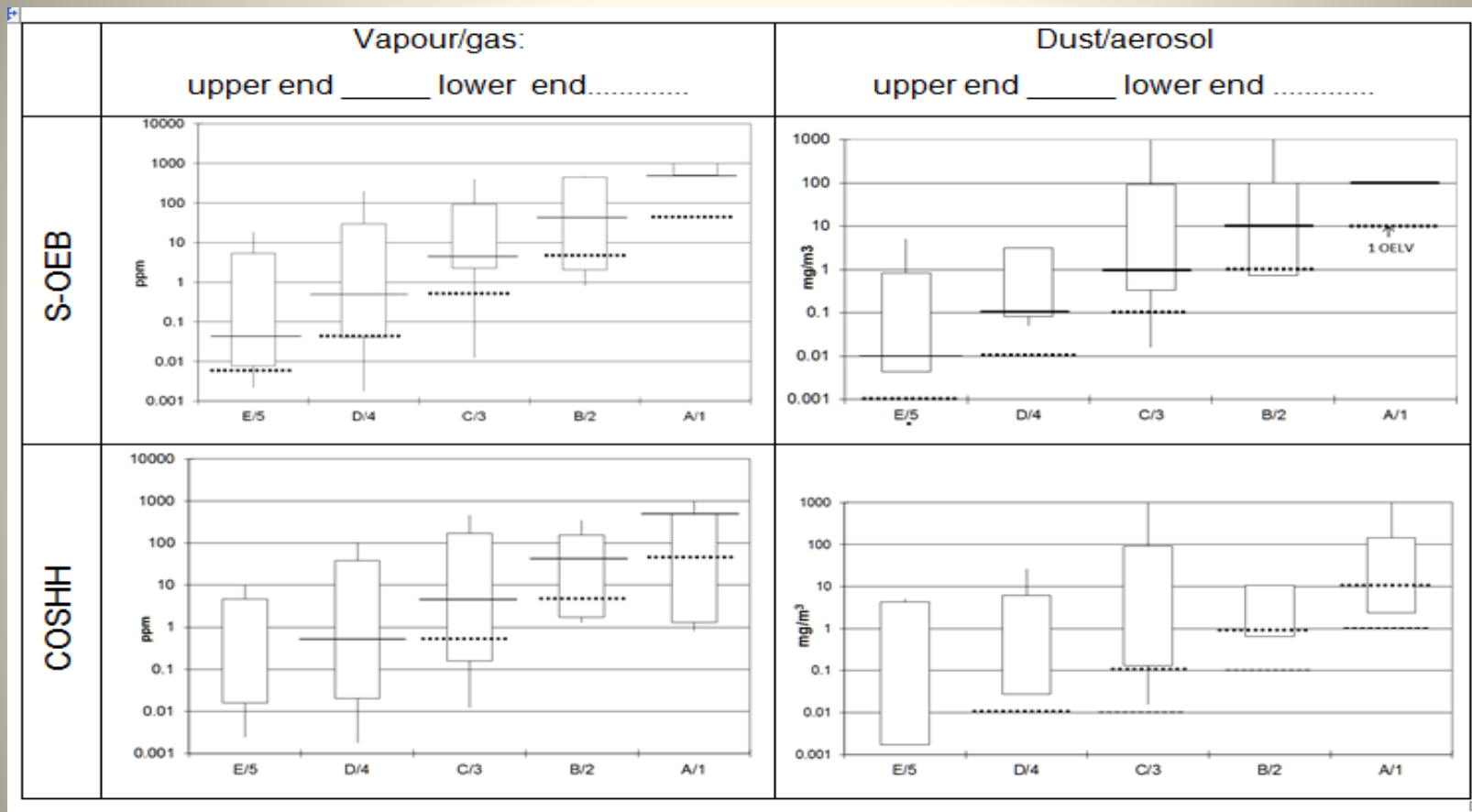
Validity of the airborne concentration ranges

(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

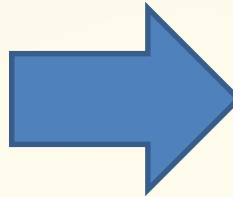
- The strength of the relation between a HB-engine and OELV can be determined using 1 picture and 5 statistical indicators with high discriminating power despite a limited dataset
- IFA, EMKG and S-OEB perform better than COSHH with S-OEB having the highest rank

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/m ³)	0,0001	0,01	0,1	1

*: COSHH Essential Groups B+C combined

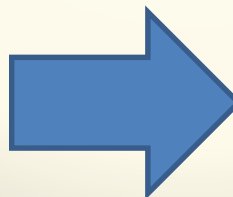
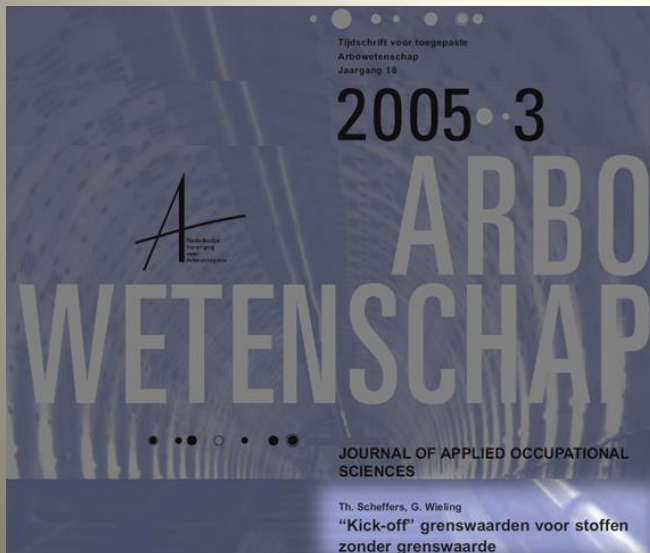
Proposed based kick-off values for gases/vapors
(basis: DGUV IFA Spaltenmodell)

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

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Eye Irrit. 2 H319	2	1	1	2
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Final Hazard-Band	4	3	1	3

