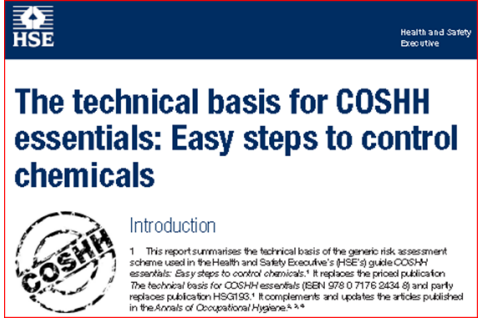
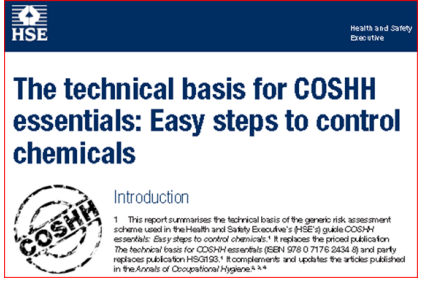


Validation of the Hazard Grouping in Control Banding

Finding the best hazard grouping to establish "Kick-off" levels (next presentation)

Theo Scheffers,
Geert Wieling,
Caroline Coucke.

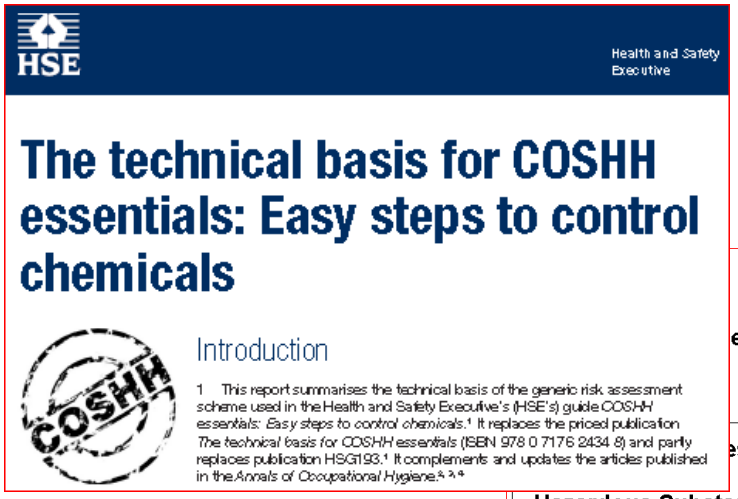


Control Banding (CB)

a generic technique for assessing and managing workplace exposure risks:

- without the use of an Occupational Exposure Limit Value (OELV)
- with the use of grouped Health Hazard Identifiers like the EU R-phrases or EU/GHS H3##-statements

Identified Control Banding schemes (1)



ew version of TRGS 600 supersedes

Hazardous Substances	Substitution	

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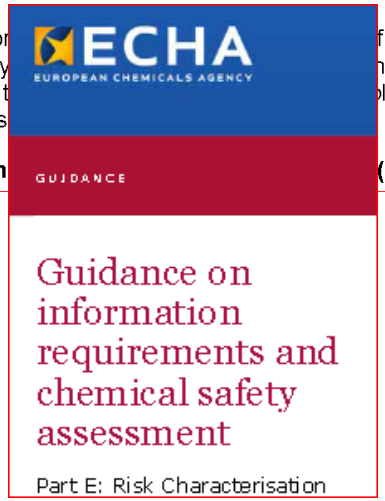
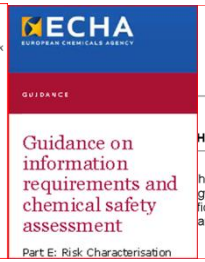
Com
(AGS)



Identified CB Schemes (2)

- 7 R-Phrases based CB schemes,
  - R-phrases will be phased out in 2015
- REACH CSA Part E, limited # H-statements
- ILO Toolbox with GHS classifications
- NIOSH Exposure banding process
- 3 CLP H-Statements based CB schemes are enrolled
  - See next slide



H-statement based schemes selected

- COSHH Essentials (HSE: Health and Safety Executive)
- einfaches Maßnahmenkonzept Gefahrstoffe (EMKG) (BAuA: Federal Institute for Occupational Safety and Health). Separated hazard grouping for skin route
- GHS Spaltenmodell; based on TRGS600 (DGUV IFA: Institute for Occupational Safety and Health of the German Social Accident Insurance)

Validation (1) theoretical base

- H-statements are a qualitative and quantitative mix
  - 2 to 6 dose levels: toxicity, different routes (H300->32 acute; H370->373 repeated)
  - 1 or 2 Severity levels: irritation, corrosive, sensitization
  - 3 to 5 levels weight of evidence as human health hazard: Carcinogenic, Mutagenic, Reprotoxic
  - Special single warnings: lactation
  - Examples : next slide

Grouping of H-statements, resulting in an ranked measure.

What kind of ranking?

Health hazard grouping (simplified)

Hazard category	Health Hazard Identifiers (HHI) like R-phrases, H- & EUH statements and REACH & CMR classifications (IARC, etc.)
5/E	Human Carcinogen R45, 49, H350(i), IARC 1, 2a
4/D	Very toxic, R26, H330, Possible Carc. R40, H351 , IARC 2b.
3/C	Toxic R23,H331, Corrosive 34, 35, H314, EUH071
2/B	Harmful R20, H332; Irritation R37, H335
1/A	Harmless. R36, 38; REACH non ES obligation, Annex IV

Increasing hazard group # lead in a CB scheme to a more structural & stringent control regime

R-phrases and H-statements don´t match !

Acute toxicity: LD50 – oral mg/kg

Dose mg/kg	R-phrase	hazard group	CLP hazard class & -category	H-Statement	Hazard group
<5	28	D	Acute Tox 1	300	D
5-25	28	D	Acute Tox 2	300	D
25-50	25	C	Acute Tox 2	300	D
50-200	25	C	Acute Tox 3	301	C
200-300	22	B	Acute Tox 3	301	C
300-2000	22	B	Acute Tox 4	302	B

Conclusions theoretical base

- There is no theoretical base for an allocation in 3 to 5 ordered hazard groups
  - Endpoint of health hazard statements are mutually independent
  - Endpoint with >1 H-statement : discrete (tox), ordinal or categorical (CRM) related
- R-phrase and H-statement based hazard grouping differ
- 50 EU health R-phrases and 38 H3##/EUH## health statements based on 84 classification criteria
  - Most CB schemes do not take the classification differences between R-phrases to H-statement into account.
  - Substances may end up in a different hazard group when switching from an R-phrase to H-statement based Control Band Scheme

Validation (2) reproducibility

If H-statements cannot be grouped theoretically what is the reproducibility of different hazard groupings?

In an experimental setting: repeated, independent trails must result in the same outcome

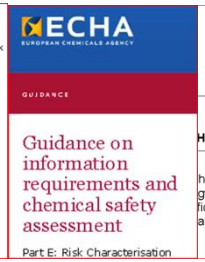
- multiple institutions throughout the world have performed hazard grouping (more or less independent)

Reproducibility: differences in allocating H-statements

Hazard category	DGUV IFA Spaltenmodell	HSE COSHH Essentials	BAUA EMKG (Einfaches Maßnahmenkonzept) (inhalation)
5/E	H300, H310, H330, EU032 H340 (AGS Mut 1AB) H350, H350i (AGS K1/2 & TRGS 906)	H334, H340, H341, H350, H350i	H340, H350, H350i, H360F (TRGS 905 & 906)
4/D	H301, H311, H331 EUH070, EUH029, EUH031 H370, H317 (Sh), H334 (Sa), H318 $H360_{xy}$ (AGS R_{EF}1/2) H351 (AGS K3), H341 (AGS M3), H372	H300, H310, H330 H351, $H360_{xy}$, H361, H362, H372	H300, H330, H360D, H372, EUH032
3/C	H302, H312, H332 H314 (pH ≥ 11,5, pH ≤ 2), H371, EUH071 $H361_{f/d}$, H373, H362 non-toxic gases which may cause asphyxiation	H301, H311, H331, H314, H317, H318, H335, H370, H373, EUH071	H301, H331, H314, H334, H341, H351, H361f/d, H370, H371, H373, EUH031 (TRGS 907)
2/B	H315, H319 damage to the skin during wet work H304, EUH066, H335, H336 Substances chronically harmful in other ways (no H-statement, but still hazardous)	H302, H312, H332 H371	H302, H332, H318
1/A	substances which experience shows to be harmless (e.g. water, sugar, paraffin etc.)	H303, H304, H305, H313, H315, H316, H319, H320, H333, H336, EUH066 and all H-numbers not otherwise listed	H319, H335, H336, H304 No health hazard H-statements

Reproducibility of CB hazard grouping

- CB hazard grouping is a combination of:
  - Basic toxicological knowledge
  - Professional judgement
  - Risk perception
  - National sentiment
  - ….
- The reproducibility of CB hazard grouping is limited



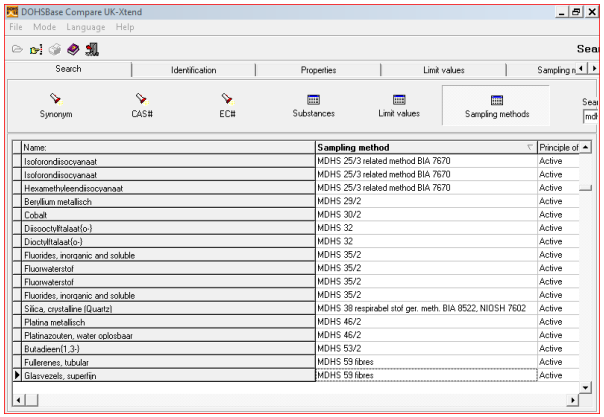
Validation (3): compare with standard

- A “golden” standard does not exist
- OELVs are used to validate hazard grouping
  - OELV is a quantitative measure
  - Substances with both OELV and HHI exists
- Is anybody in the audience aware of a better standard ? (afterwards)

The most comprehensive database of OEL's and measurement methods

DOHSBase Compare
www.dohsbase.com

172000 substances
225000 synonyms
40000 PhysChem properties
8000 harmonized CLPs
3800 OELV
2000 Kickoff levels
2000 REACH DN/MELs
2500 analytical methods



The most comprehensive database of OEL's and measurement methods

Database with hazard groups & OELV

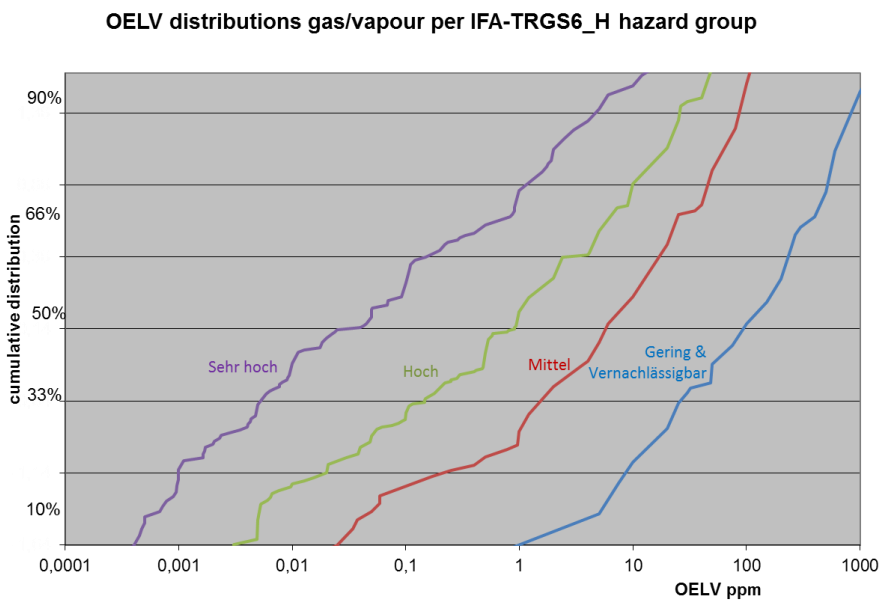
NAME	MG_M3	PPM	Reference	SOR	STATE	EMKG_HO	IFA_SPLT_H	COSHH_H	H_PHRASES
Aluminium	4		DFG 2013, Mitteilung 49	301	Solid	1	1	1	H261 H228
Aluminum chloride	0,05		Gr 2009/02OSH	201	Solid	4	3	4	H314
Tetraethylorthosilicaat		1,2	Gr 2000/15OSH131	201	Liquid	2	2	3	H226 H332 H319 H335
Tetraethylsilicaat		5	SCOEL-SUM 064	211	Liquid	2	2	3	H226 H332 H319 H335
Fosfor, wit en geel	0,01		DFG 2013, Mitteilung 49	301	Solid	4	4	4	H250 H330 H300 H314 H400
Fosfortrichloride		0,3	2013 TLVs and BEIs with 7th	311	Liquid	4	4	4	H330 H300 H373** H314
Fosforyltrichloride		0,1	2013 TLVs and BEIs with 7th	311	Liquid	4	4	4	H330 H372** H302 H314
Fosforpentoxide	1		SEG-SUM 014 EUR-15091: 39-4	111	Solid	3	2	3	H314
Tributylfosfaat		0,18	2013 TLVs and BEIs with 7th	201	Solid/Liquid	4	3	4	H351 H302 H315
Tributyl phosphate	5		2013 TLVs and BEIs with 7th	311	Solid/Liquid	4	3	4	H351 H302 H315
Triorthocresylfosfaat	0,1		2013 TLVs and BEIs with 7th	311	Liquid	3	3	3	H370** H411
Dichloorvos		0,11	DFG 2013, Mitteilung 49	301	Solid/Liquid	4	4	4	H330 H311 H301 H317 H400
Mevinfos	0,01		2013 TLVs and BEIs with 7th	311	Solid/Liquid	4	4	4	H310 H300 H400 H410
Mevinfos		0,01	DFG 2013, Mitteilung 49	301	Solid/Liquid	4	4	4	H310 H300 H400 H410
Trichloorfon	1		2013 TLVs and BEIs with 7th	311	Solid	2	3	3	H302 H317 H400 H410
Tetraethylpyrofosfaat		0,005	DFG 2013, Mitteilung 49	301	Solid	4	4	4	H310 H300 H400
Tetraethyldithiopyrofosfaat	0,1		SEG-SUM 069	111	Solid/Liquid	4	4	4	H310 H300 H400 H410
Demeton-O		0,01	Gr 2000/15OSH068	201	Liquid	4	4	4	H310 H300 H400
Demeton-S		0,01	Gr 2000/15OSH068	201	Liquid	4	4	4	H310 H300
Demeton-S-methyl	0,01		Gr 2000/15OSH072	201	Solid/Liquid	3	3	3	H311 H301 H411
Demeton-S-methyl	0,05		2013 TLVs and BEIs with 7th	311	Solid/Liquid	3	3	3	H311 H301 H411
Foraat	0,02		Gr 2000/15OSH075	201	Liquid	4	4	4	H310 H300 H400 H410
Foraat	0,05		2013 TLVs and BEIs with 7th	311	Liquid	4	4	4	H310 H300 H400 H410
Parathion	0,1		DFG 2013, Mitteilung 49	301	Liquid	4	4	4	H330 H300 H311 H372** H400 H410
Parathionmethyl	0,02		2013 TLVs and BEIs with 7th	311	Solid	4	4	4	H226 H330 H300 H311 H373** H400 H410
Ethyl-p-nitrofenylthiobenzee	0,5		DFG 2013, Mitteilung 49	301	Solid	4	4	4	H310 H300 H400 H410
Coumaphos	0,05		2013 TLVs and BEIs with 7th	311	Solid	4	4	4	H300 H312 H400 H410
Azinfos-methyl	0,2		DFG 2013, Mitteilung 49	301	Solid	4	4	4	H330 H300 H311 H317 H400 H410
Diazinon	0,1		DFG 2013, Mitteilung 49	301	Solid/Liquid	2	2	2	H302 H400 H410
Malathion	15		DFG 2013, Mitteilung 49	301	Liquid	2	3	3	H302 H317 H400 H410
Ethion	0,05		2013 TLVs and BEIs with 7th	311	Liquid	3	3	3	H301 H312 H400 H410

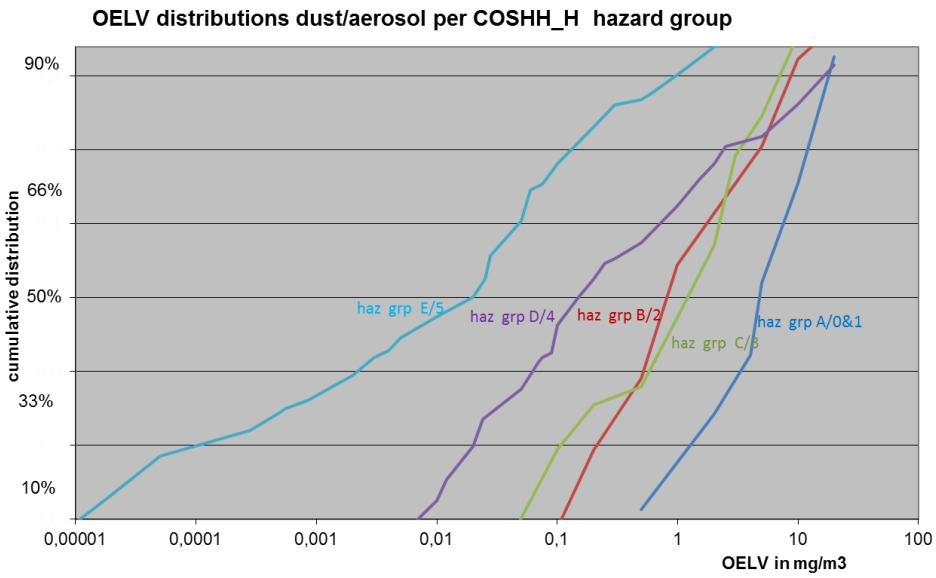
Results hazard grouping OELV distributions

Per hazard group and physical state the OELV distribution is constructed

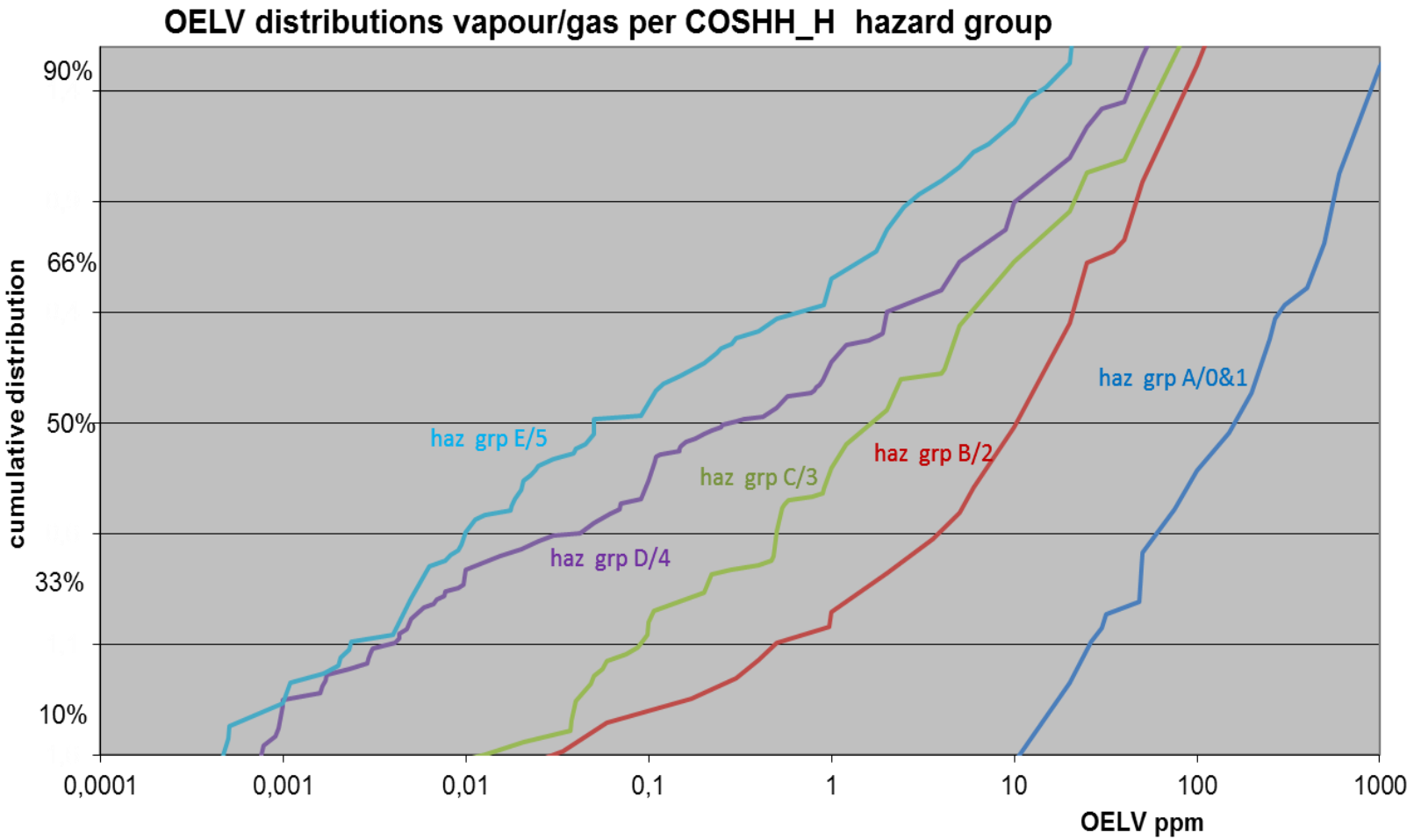
Next slides:

- COSHH Essentials HSE
- EMKG einfaches Maßnahmenkonzept Gefahrstoffe BAuA
- IFA-spaltenmodell/TRG600 DGU

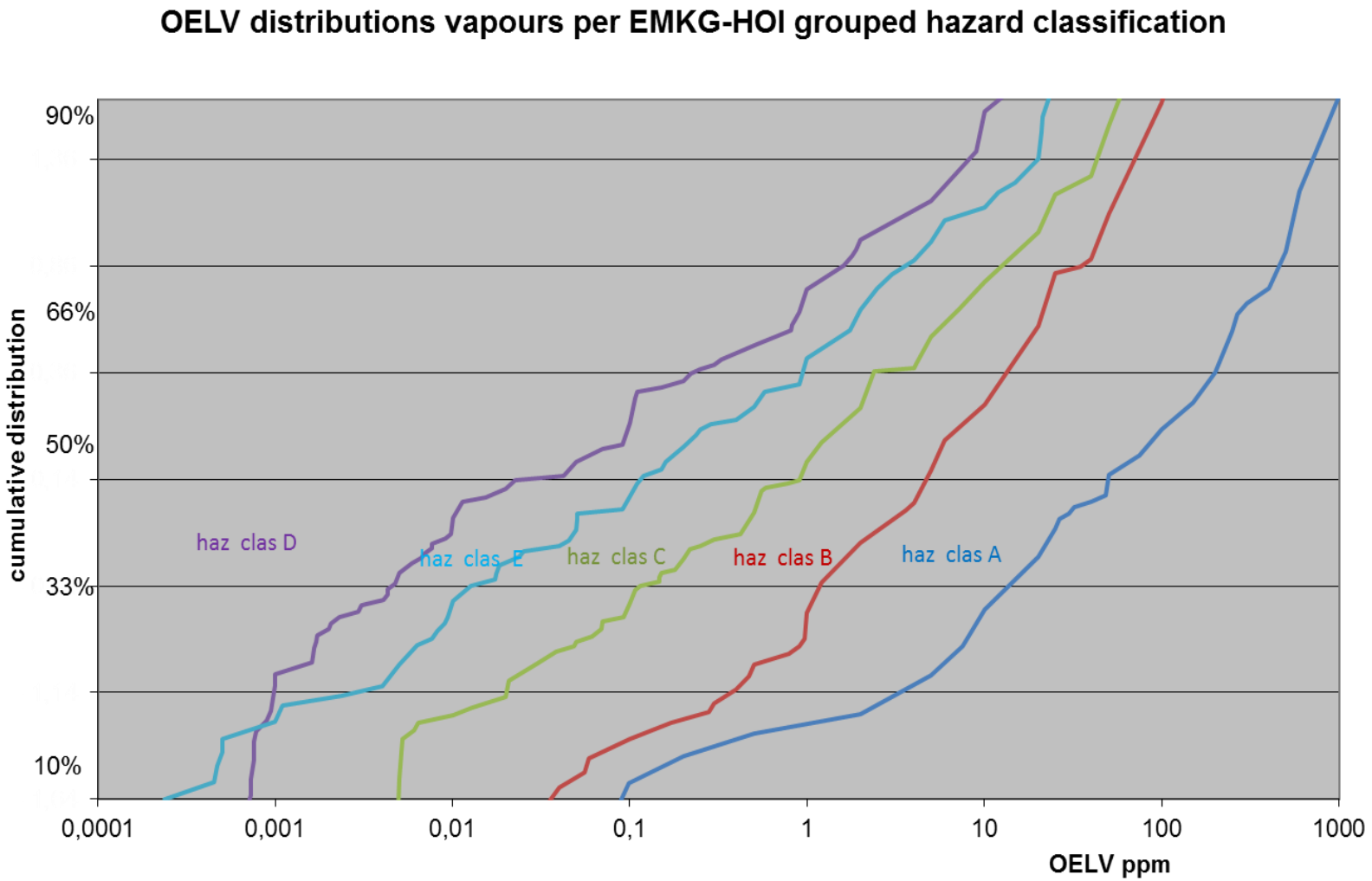




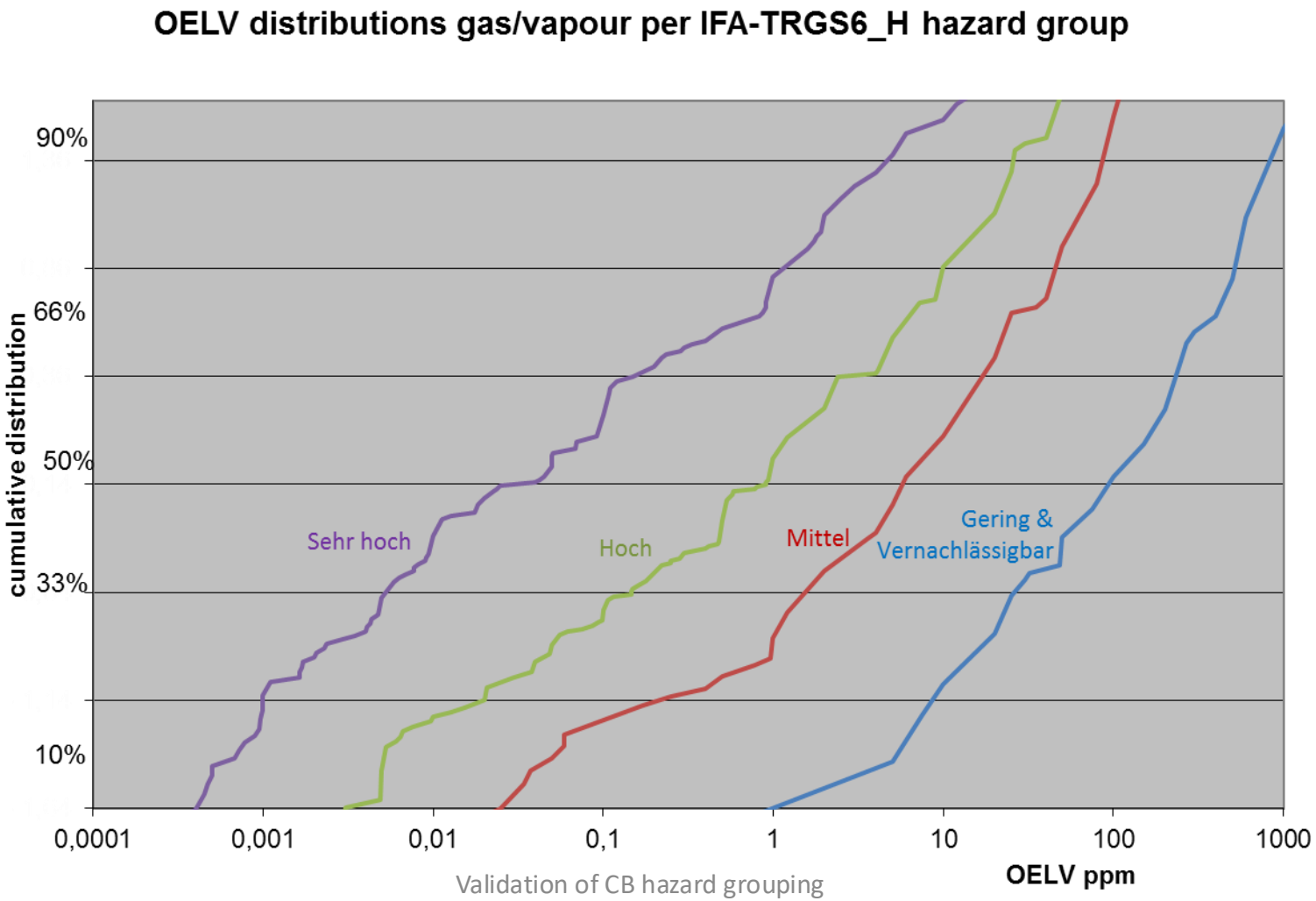
Results – COSHH vapour/gas



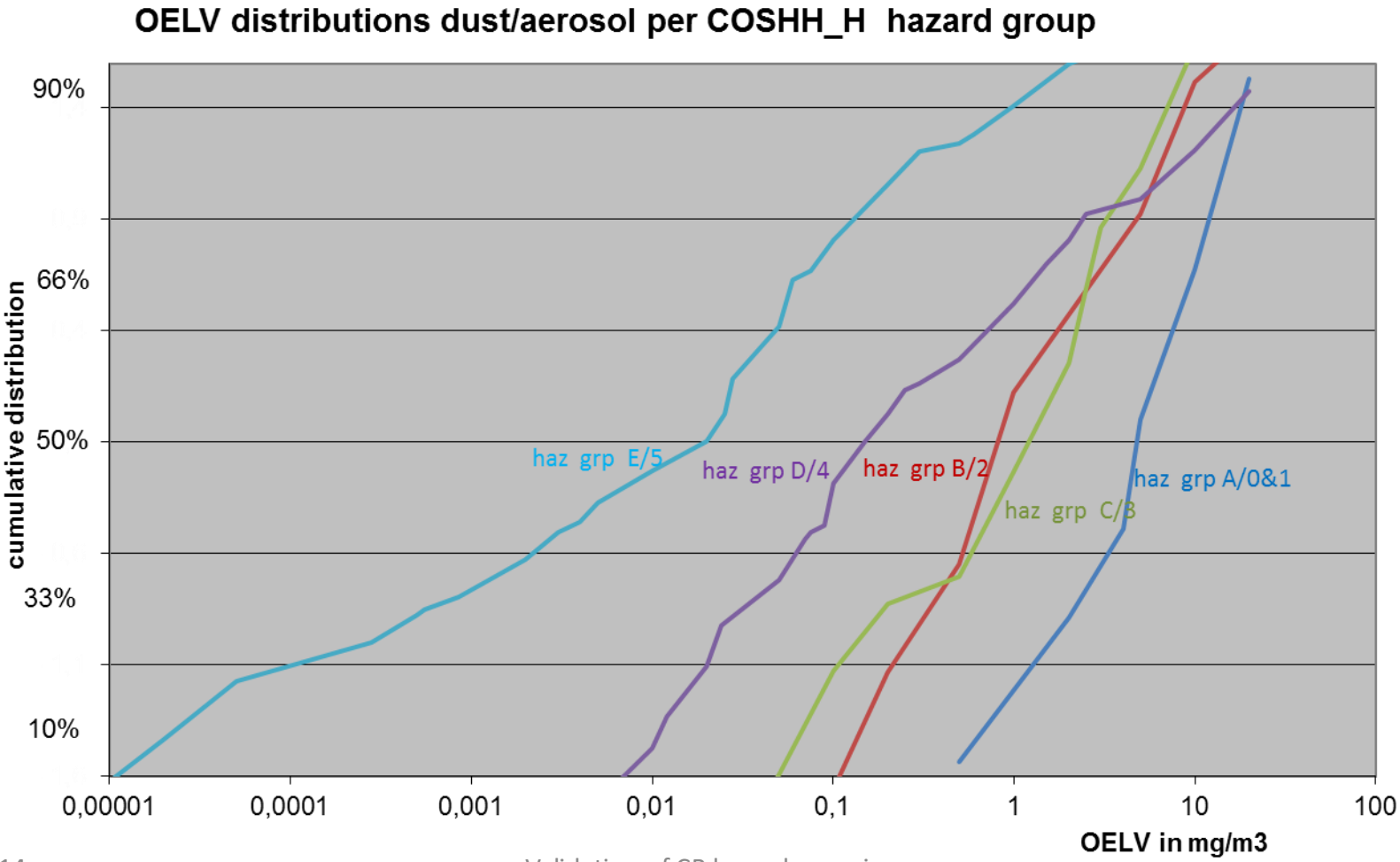
Results – EMKG (inhalation) vapour/gas



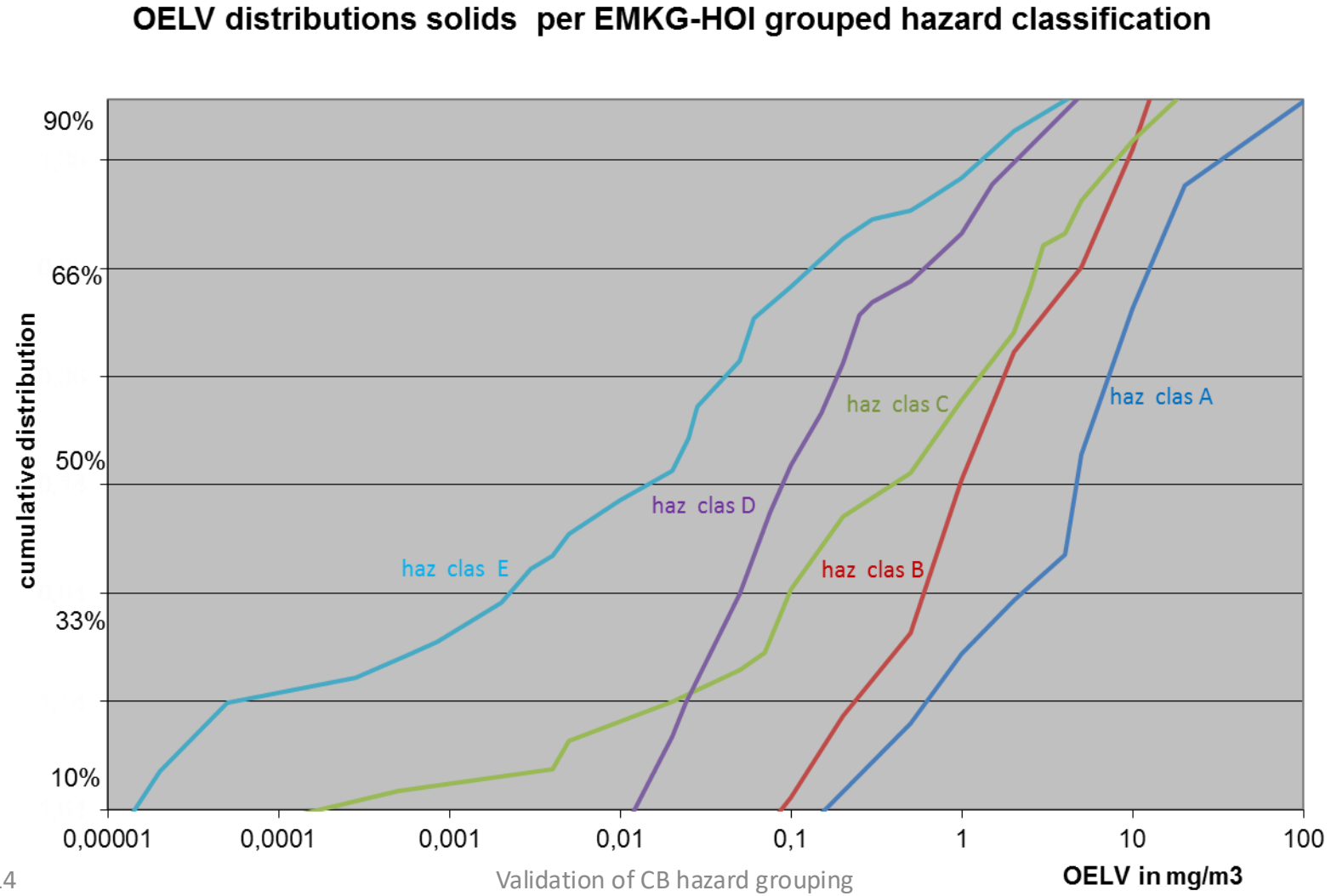
Results – IFA/TRGS600 vapour/gas



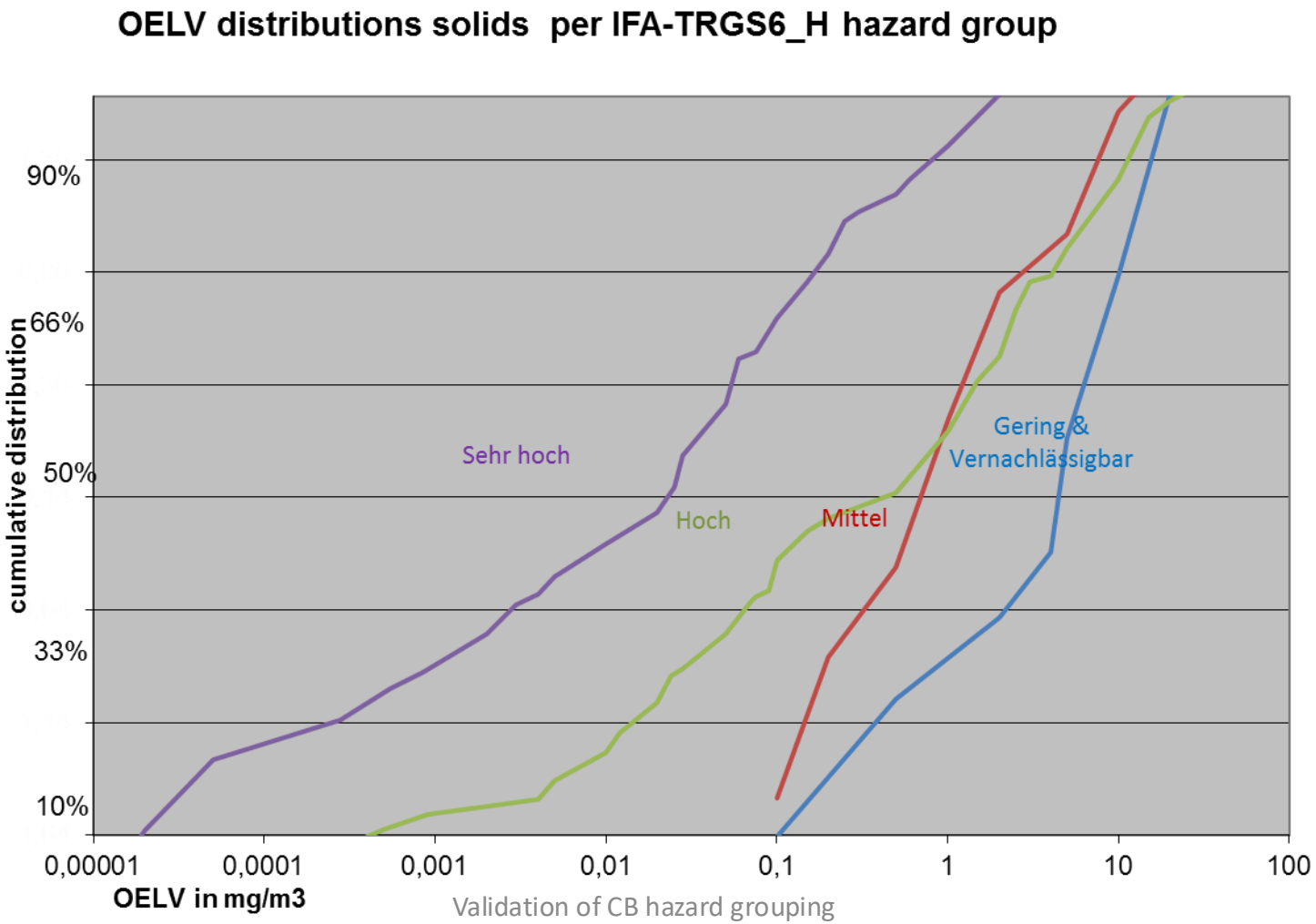
Results – COSHH dust/aerosol



Results – EMKG (inhalation) dust/aerosol

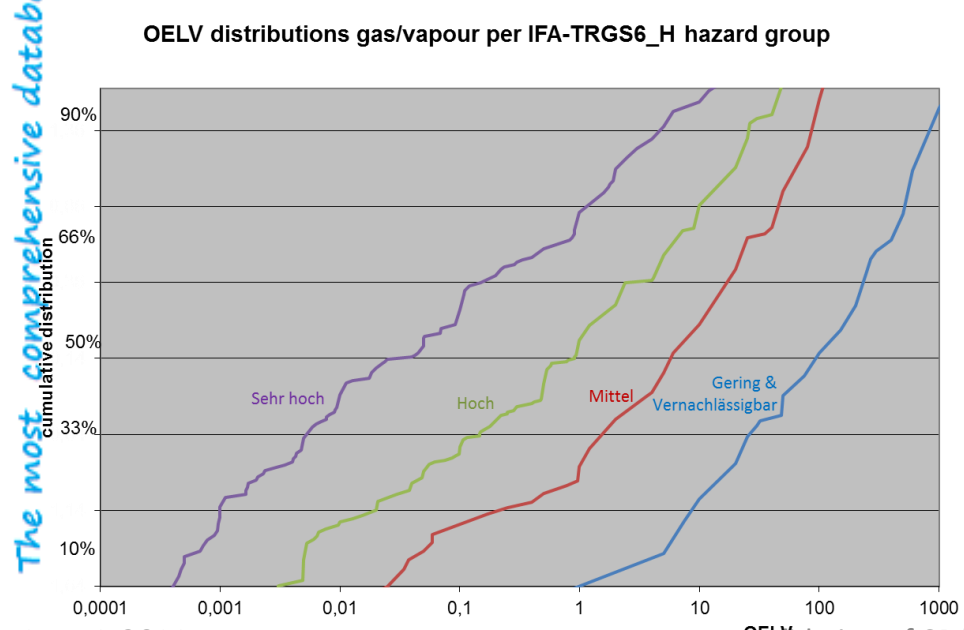


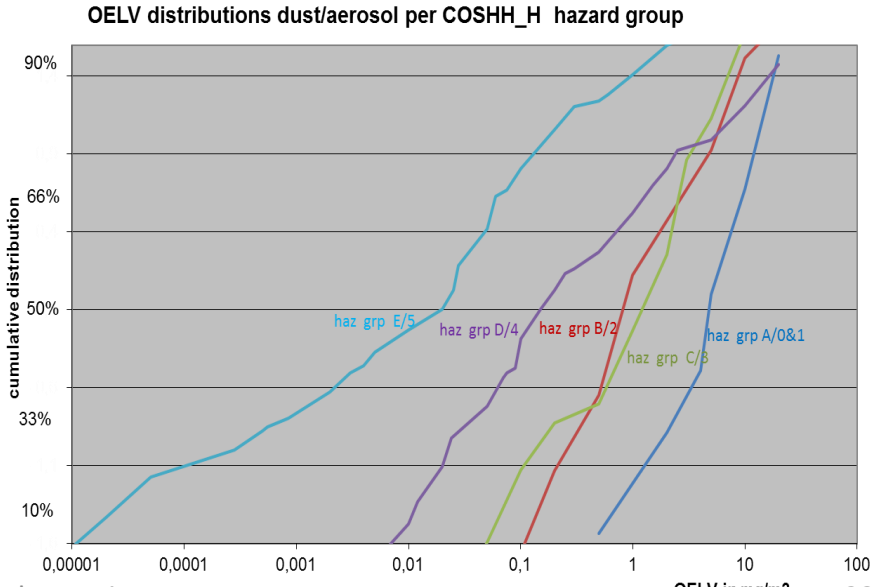
Results – IFA/TRGS600 dust/aerosol



Results hazard group OELV distributions

Observationally the OELV distribution strongly indicates that hazard grouping is an ordered measure but that the CB Schemes differ in power





OELV, statistical inference

Physical state ->	VAPOUR/GAS			DUST/AEROSOL		
Institution/ parameter	COSHH	EMKG	IFA	COSHH	EMKG	IFA
P(Kruskal-Wallis)	8E-47	8E-45	4E-56	3E-27	6E-19	2,1E-22
Fraction variance explained by grouping	0,33	0,29	0,40	0,35	0,27	0,25
P(log, regression coefficient <> 0)	3E-54	1E-47	1E-70	2E-27	4E-24	2,1E-20

The best OELV-hazard group performances:

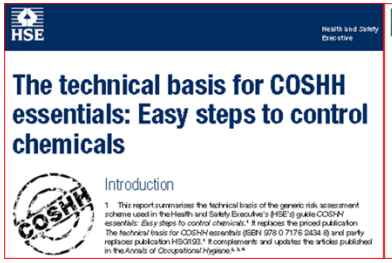
- IFA-spaltenmodell/TRG600 for vapour/gas
- COSHH Essentials for dust/aerosol

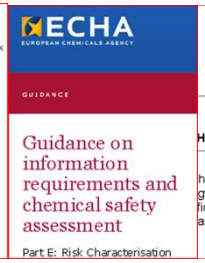
Conclusions on hazard grouping

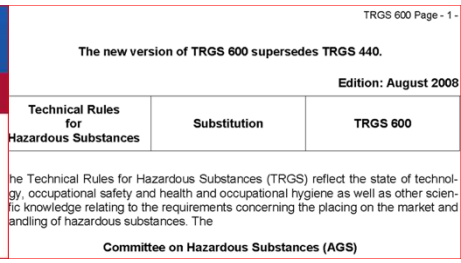
Hazard grouping in CB schemes is an ordered measure:

- observationally it explains part of OELV dispersion
- it lacks uniformity between institutions (the whole CB system depends on it !)
- Working condition control depends on it !

Despite the short comings, hazard grouping and OELV are strongly related, making it suitable to establish kick-off levels (earlier presentation)



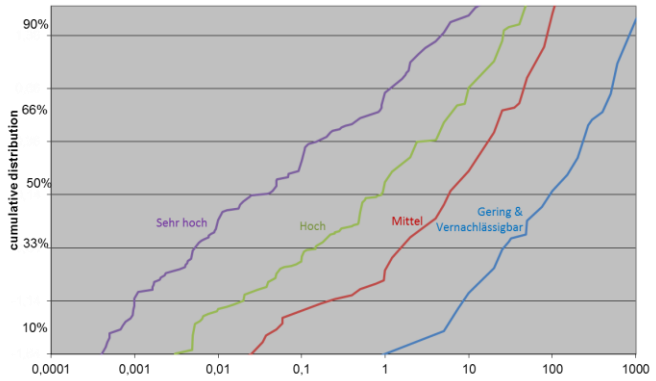


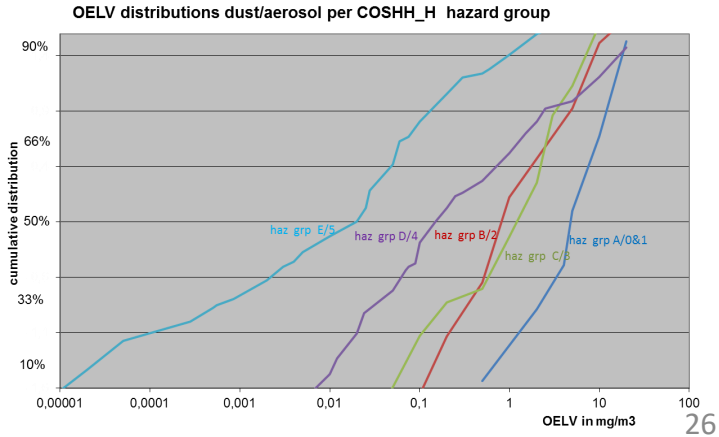


Recommendations

To really fulfil the claim of helping SME's with a simple tool:

- Develop and use **one** universal Control Banding scheme
- Optimize hazard grouping of H-statement by minimizing OELV dispersion (GSD), maximizing OELV location (GM) differences and optimizing Lognormal goodness-of-fit





The most comprehensive database of OEL's and measurement methods

Vapor/gas

Dust/aerosol

Thank you!

Theo.Scheffers@dohsbase.nl