

OELVs from health hazard Control banding

Shifting from R-phrases to H3##-statements.

Theo Scheffers, Geert Wieling



DOHSBASE v.o.f.





DNEL versus OELV, and other serious business!



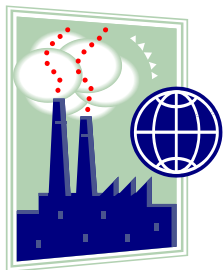
*The take off &
landing of
everything*

Theo Scheffers

www.DOHSBase.com

AIHCe 2014 San Antonio

2 types of workplace exposure limits in the EU



REACH
substance
liability:

DNEL

European Union Member States



Do they differ?

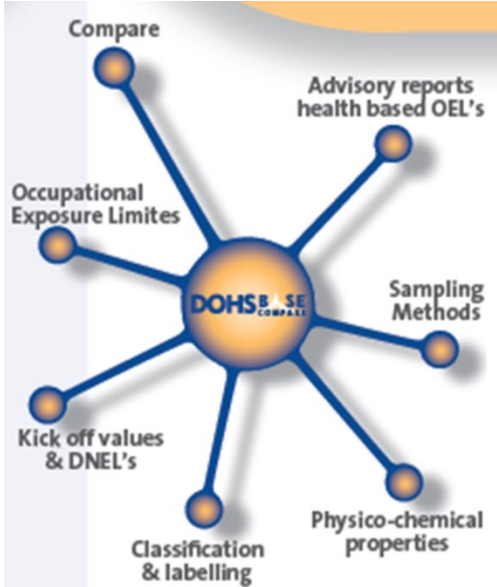
- Systematic or random?
- To what extend?



Working
condition
Control:

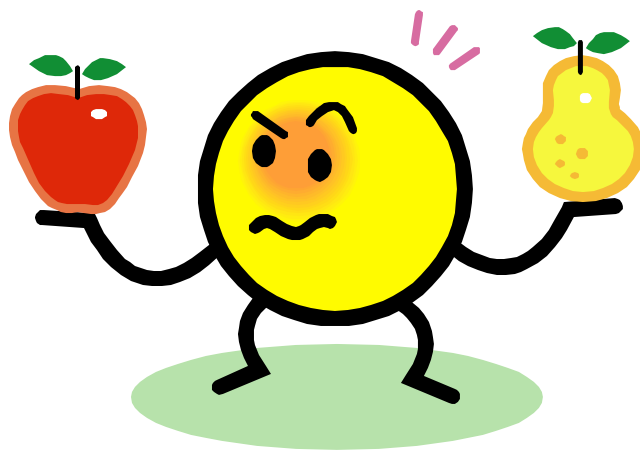
OELV





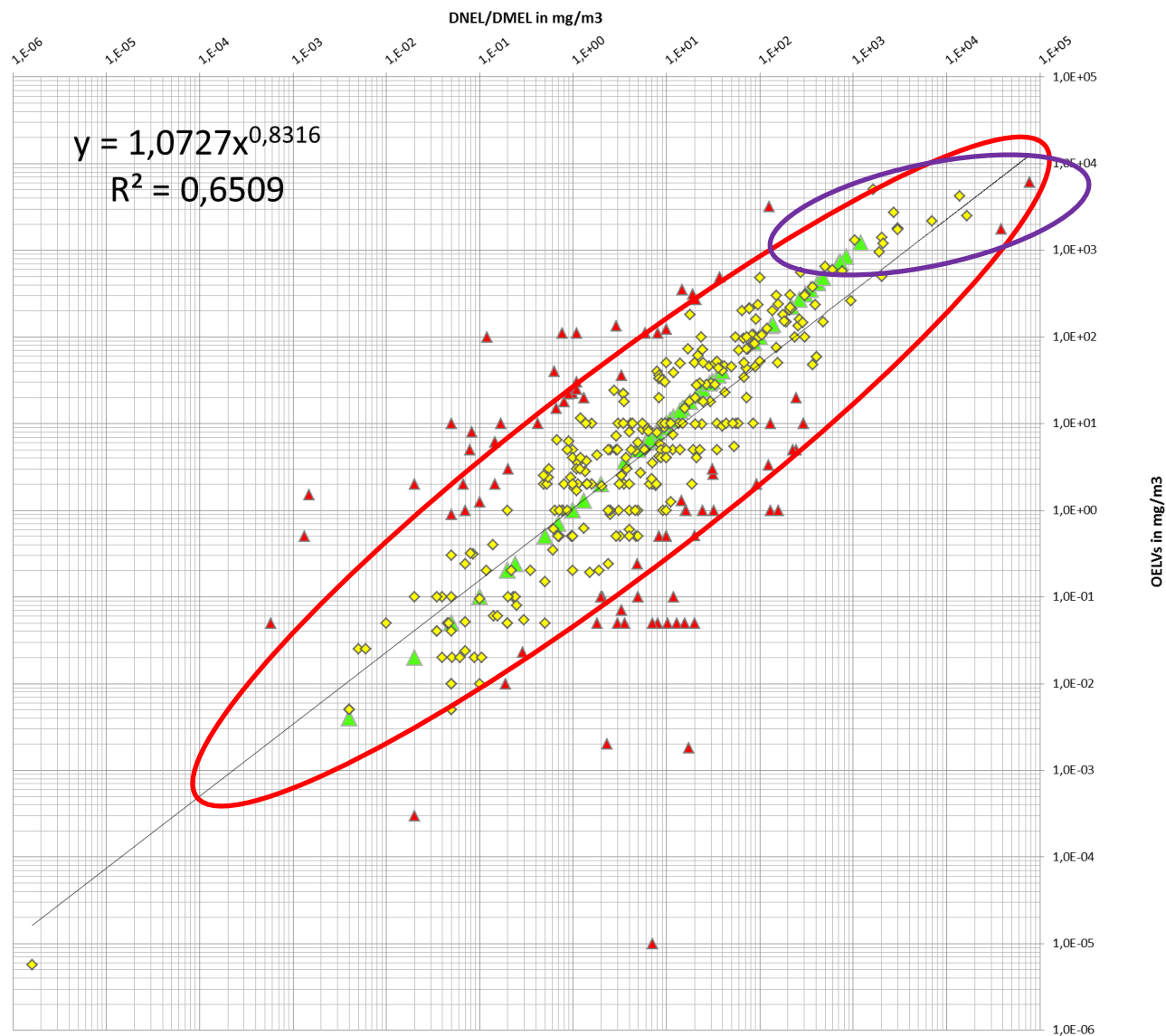
Compare!

1. OELV : approx. 3800
2. DNEL: approx. 2600
3. 475 substances with both!



REACH DNEL

DNEL (May 2014) versus OELV, 475 datapoints



OELV

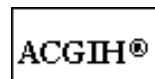


The wealth of workplace limit values

Status	US	Europe
Legal, Federal	PEL	BLV/IOLV
Legal, States/Nations	California etc.	All
Health based only	ACGIH	DFG, DECOS
Responsible Care/ Product stewardship	WEEL	AGS (Germany)
Product Liability	-	DNEL/DMEL
License to operate	-	Kick-off (NL)

The ever growing number of IH Tools

OELV



Control Banding



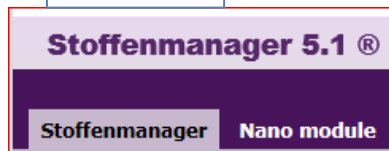
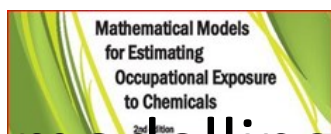
+ 8

Compliance statistics

BW
stat



Exposure modelling



Hazard classifications

CLP

GHS

International Agency for Research on Cancer



mixtures

XLUNIFAC

$$\sum_{i=1}^{i=n} \left(\frac{C_i}{OELV_i} \right) \leq 1$$

Lead substance

Harmonization of IH tools



‘Building on Occupational Hygiene Together’

OELVs from health hazard Control banding

Shifting from R-phrases to H3##-statements.

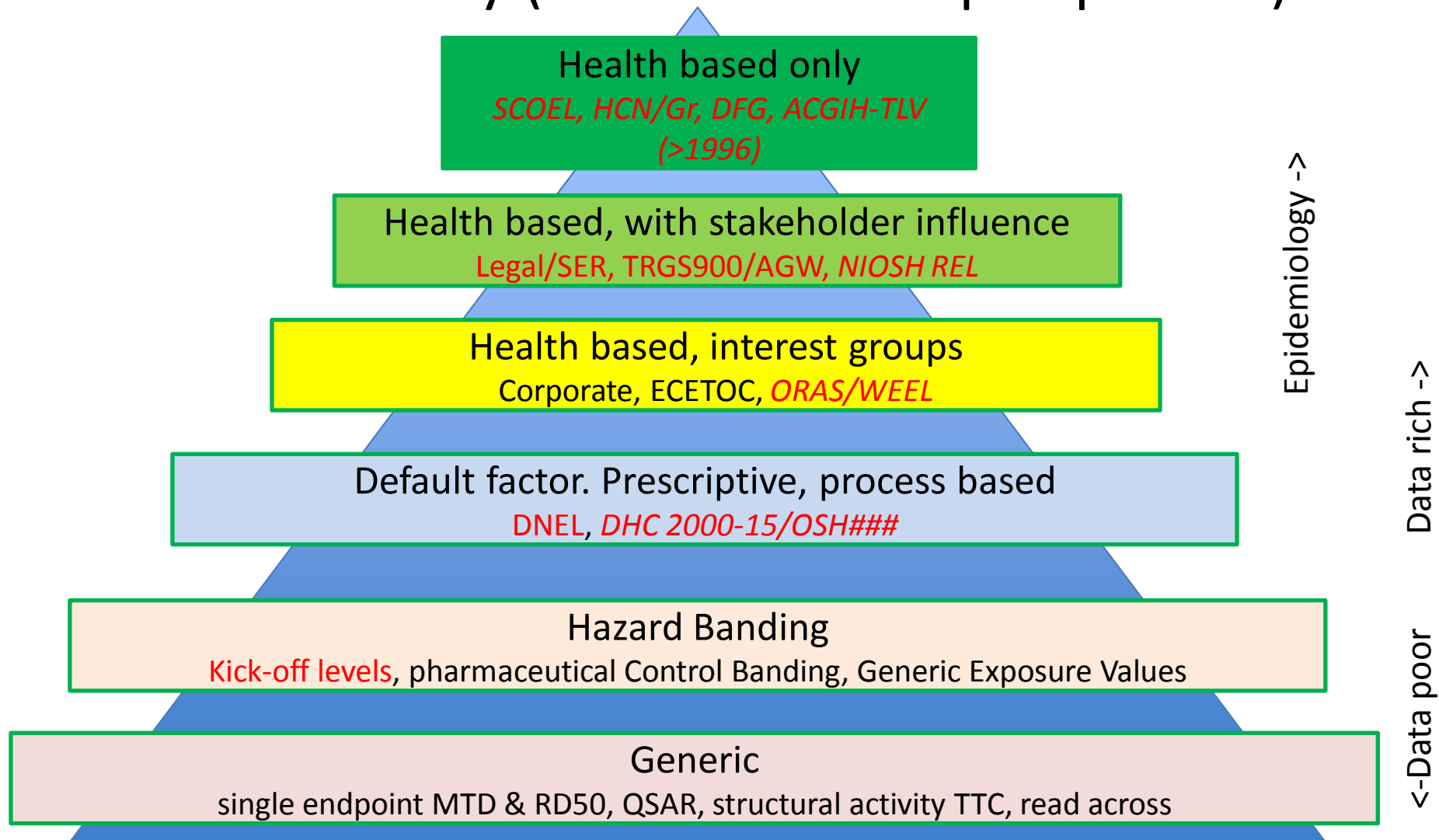
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OELV hierarchy (workers health perspective)



Health hazard control banding (simplified)

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

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

R-phphrase based kick-off levels (2005)

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

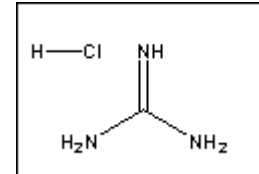
Kick-off grenswaarde per gevaarklasse en fysische staat:

Gasen en dampen (ppm)	4	0,2	0,01	0,001
Aërosolen (mg/m ³)	0,24	0,06	0,02	0,01

R-phphrase based kick-off (2005)

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

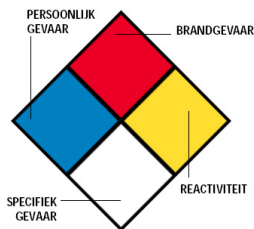
	Gevaarklasse			
	1	2	3	4
R-zinnen	36, 37, 38, 65, 66, 67*	20, 21, 22 34, 41, 62, 63, 64	23, 24, 25, 29, 31, 33, 35, 40, 42, 43, 48/21,21,22, 60, 61, 68	26, 27, 28, 32, 45, 46, 48/23,24,25, 49
Kick-off grenswaarde per gevaarklasse en fysische staat:				
Gasen en dampen (ppm)	4	0,2	0,01	0,001
Aërosolen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



- Guanidine monohydrochloride . No OELV. $C_{sat} < 0.01 \text{ mg/m}^3$
- 100-1000 t/a. Registration May 2013. no DNEL
- R36/38 => hazard group 1
- R22 => hazard group 2 => kickoff level $0,06 \text{ mg/m}^3$

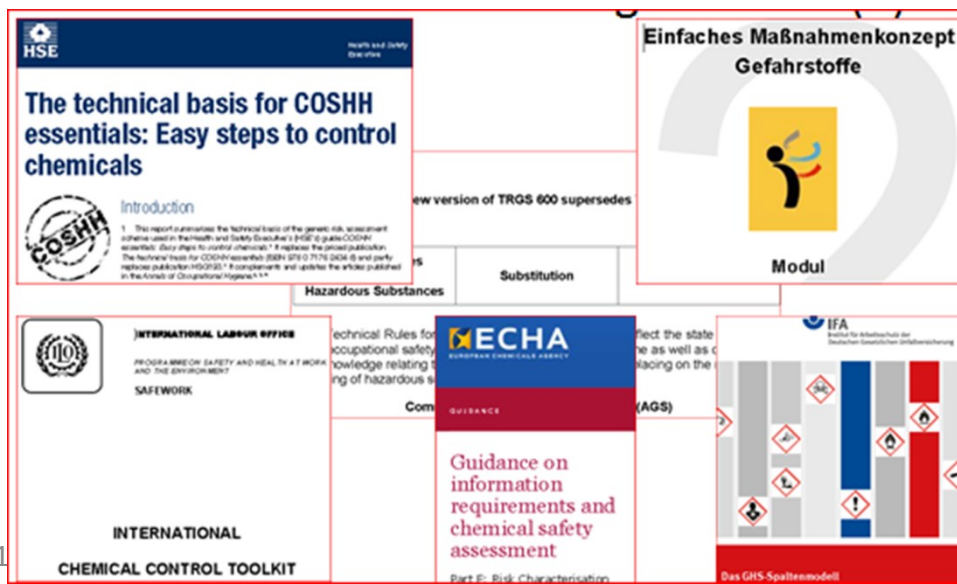
Substances with exposure & no OELV

- DOHSBase:
 - 170.000 chemicals
 - ~6000 substances with ≥ 1 OELV or DNEL (2500 and growing)
- REACH DNEL exempted:
 - Registration exempted <1 t/year
 - CSA exempted 1-10 ton/year (> 10000)
 - intermediates, polymers, exemptions (natural, non dangerous) etc.
- CLP ~110.000 substances EU notified as dangerous with no REACH registration ($\Rightarrow$ hazard banding & kickoff target)



One measuring-rod for tox ?

- Bruce Naumann (Merck 90^{ties})
- COSHH essentials (1998)
 - R-phrase 5 category health hazard grouping
- 5 R-phrases Control Bands (2005)
- 11 R-phases and H-statements CB (2014)



1. Health hazard classification criteria CLP

Between endpoints. Mutually independent:

- inhalation, dermal and oral toxicity (TOX),
- irritation, corrosion & sensitization (ICS) and
- carcinogenicity, mutagenicity & reprotoxicity (CMR)

Within endpoints. No common ranking:

- TOX (e.g. acute H300->333, repeated H370->373 per route) dose
- ICS (H314->320) : severity, duration
- CMR (H340->362) weight of evidence human risk

different measuring rules:

- Discrete (Tox)
- Ordinal or categorical (ICS, CMR)
- Single endpoints (lactation)

No universal Tox measuring rod!



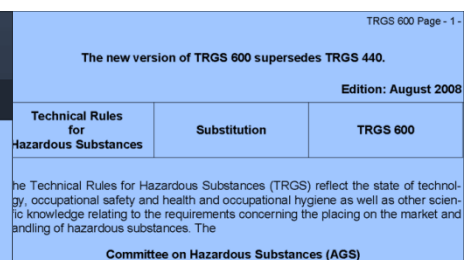
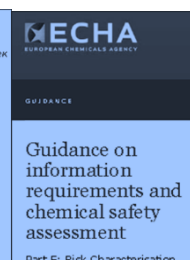
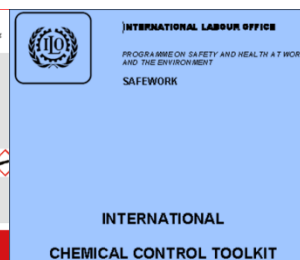
Reproducibility: differences in allocating H-statements

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

2. Reproducibility of CB hazard grouping

- CB hazard grouping is a combination of:
 - Basic toxicological knowledge
 - Professional judgment
 - Risk perception
 - National sentiment
 -

40% change H-statement in different category!



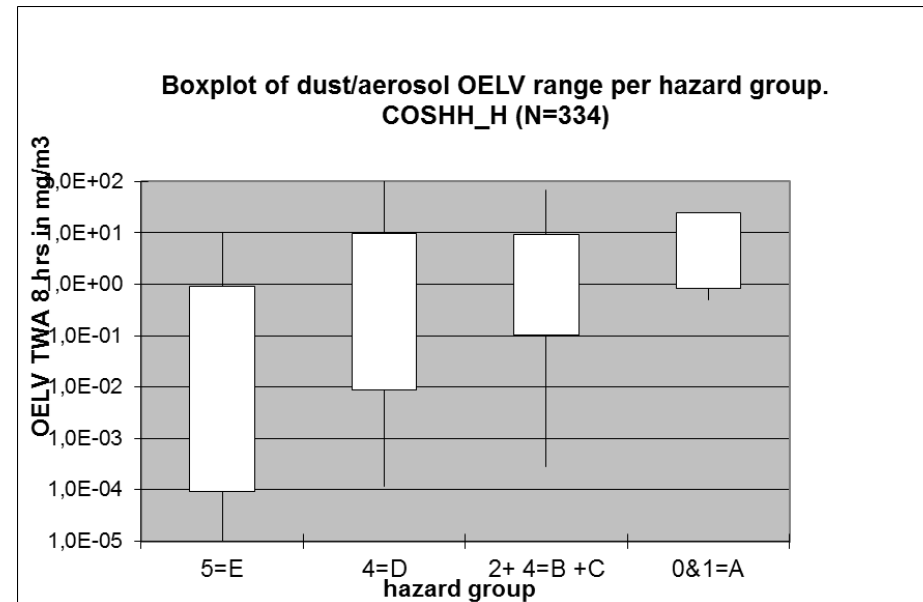
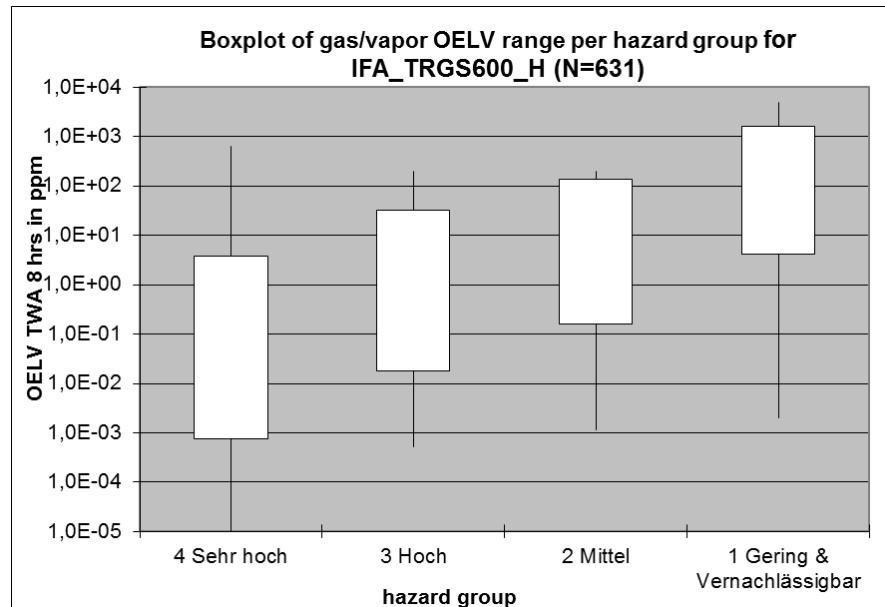
4. Different classification cut-off's for R- & H-

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

3. Compare with standard: OELV

Based on the relation between OELVs and the Hazard Grouping in Control Banding schemes

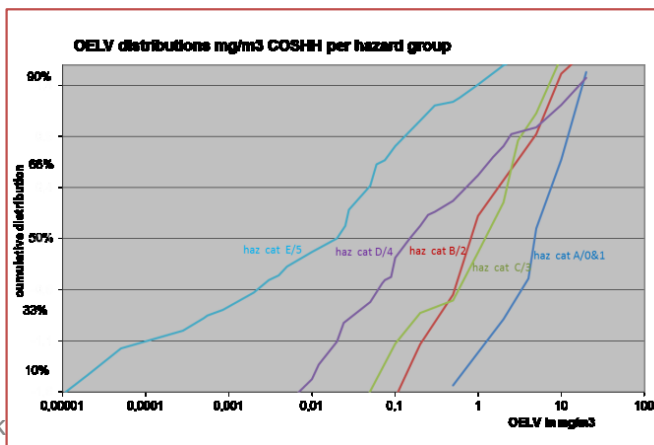
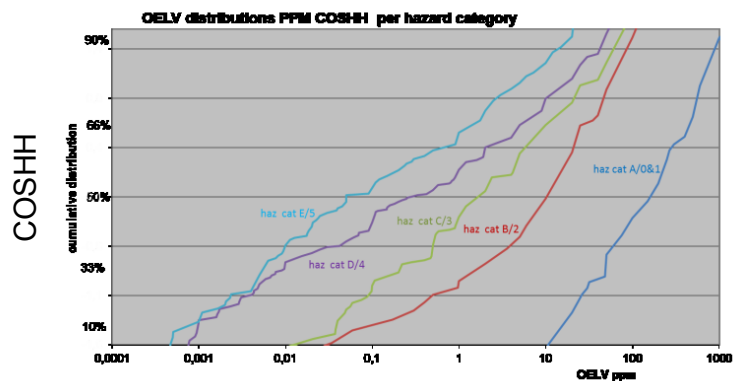
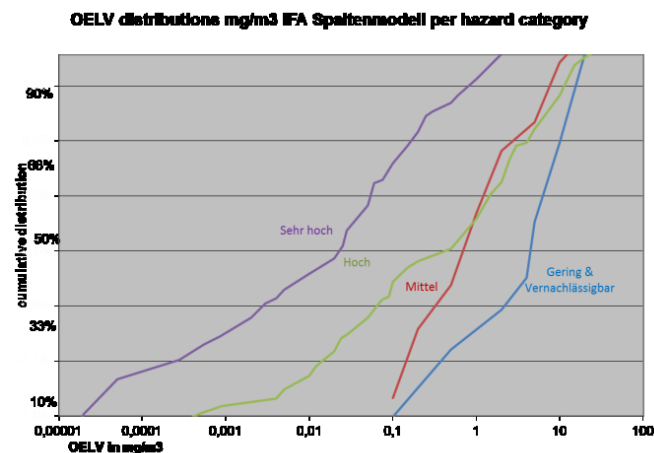
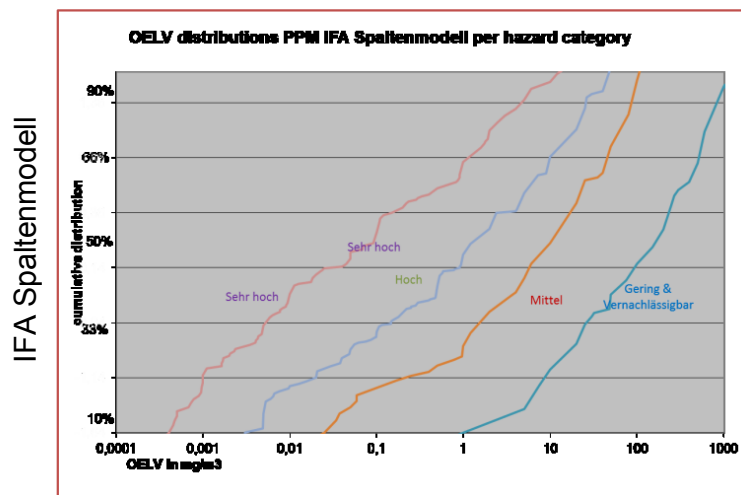
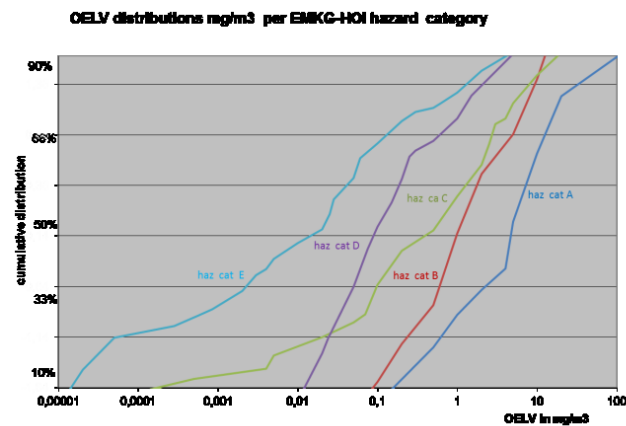
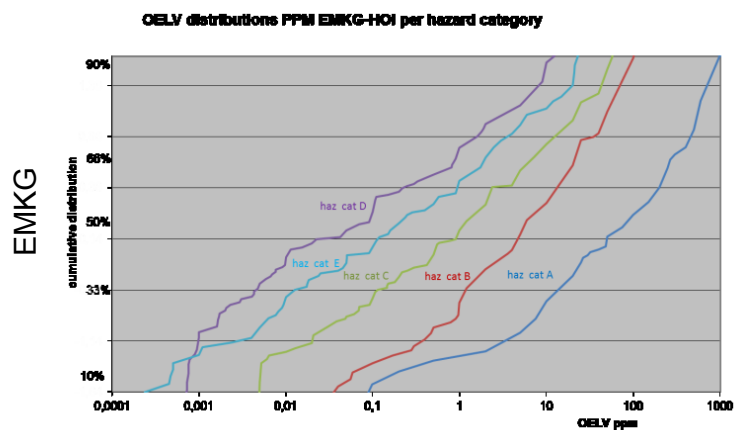


OELV distributions

- 970 unique H3##/OELV combinations
 - 635 vapors
 - 335 dusts

PPM

mg/m³



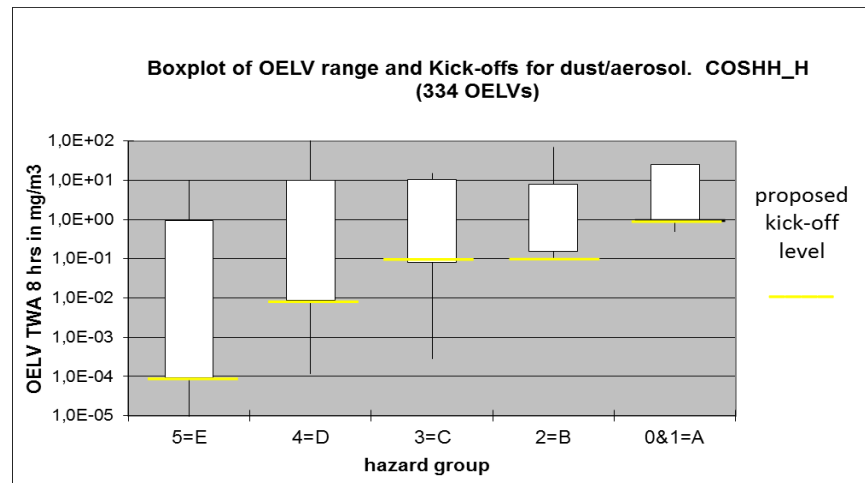
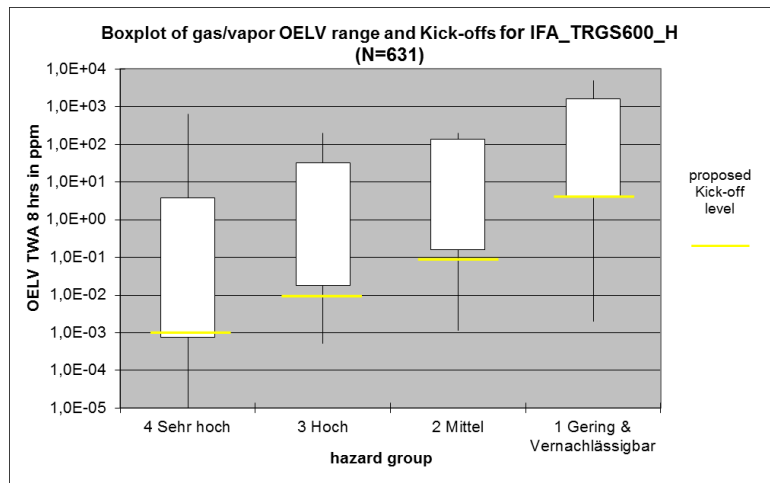
OELV distributions, statistical inference

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 $\neq 0$)	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

H-statements kick-off values



- 10%-tile of the OELV distribution
- Conservative estimate: $p > 90\%$ the “real” OELV is higher
- If non compliance, then choose between additional health research or better controls

Proposed kick-off values for dust/aerosols

(basis: COSHH Essentials)

Hazard Group	1	2	3 *	4
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)	0,00001	0,01	0,1	1

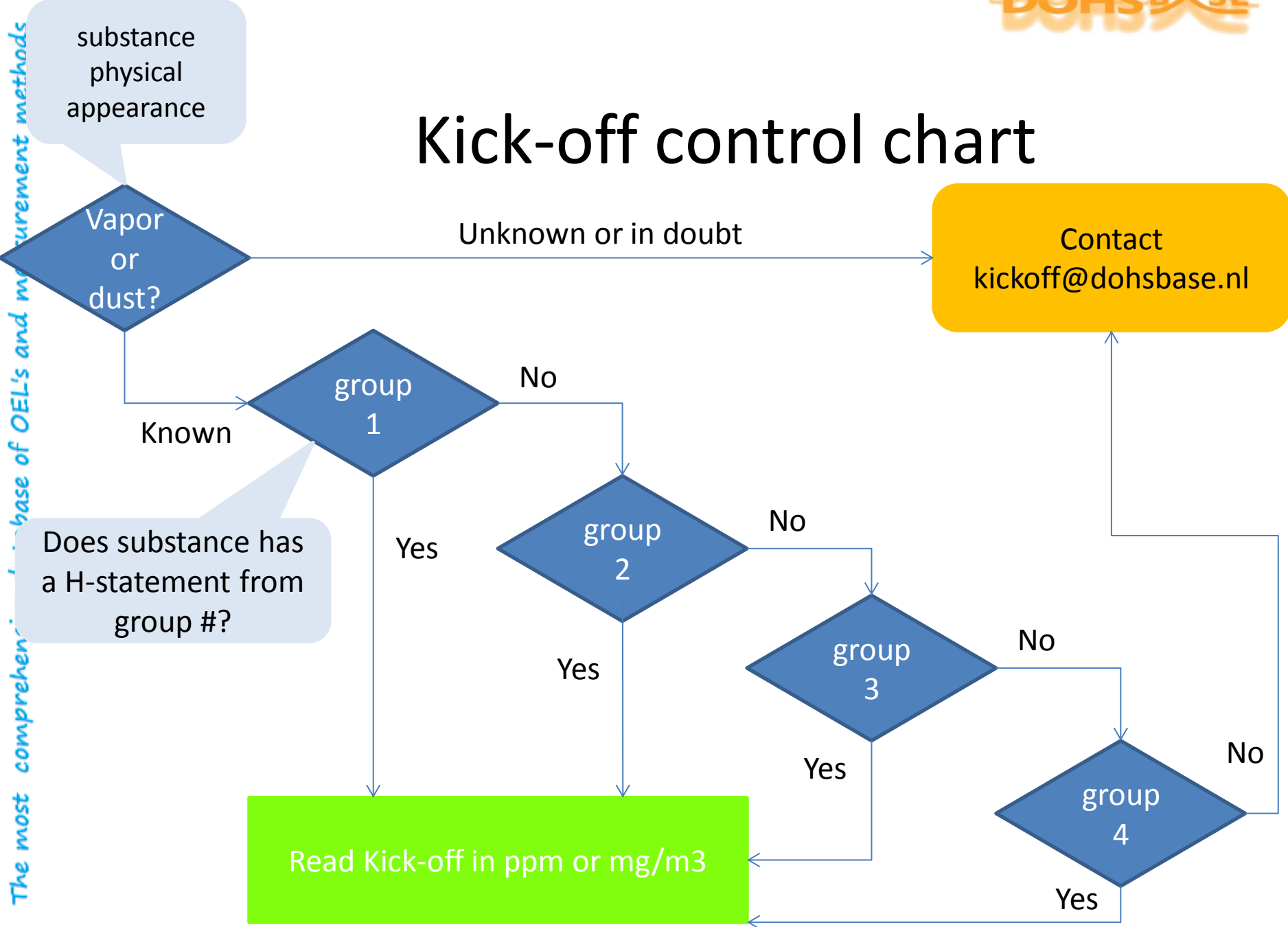
*: COSHH Essential Groups B+C combined

Proposed based kick-off values for gases/vapors

(basis: DGUV IFA Spaltenmodell)

Hazard Group	1	2	3	4
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

Kick-off control chart

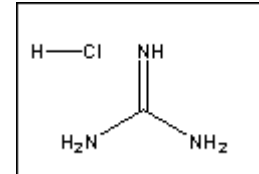


Example

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

Hazard Group	1	2	3 *	4
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)	0,00001	0,01	0,1	1

*: COSHH Essential Groups B+C combined



- Guanidine monohydrochloride $C_{sat} < 0.01 \text{ mg/m}^3$
- 100-1000 t/a. Registration 2013. no DNEL
- H319 & H315: hazard group 4
- H302: hazard group 3 => kickoff level $0,1 \text{ mg/m}^3$ (which is higher than the old R-phrase based kick-off)

Summary

Kick-off values for substances:

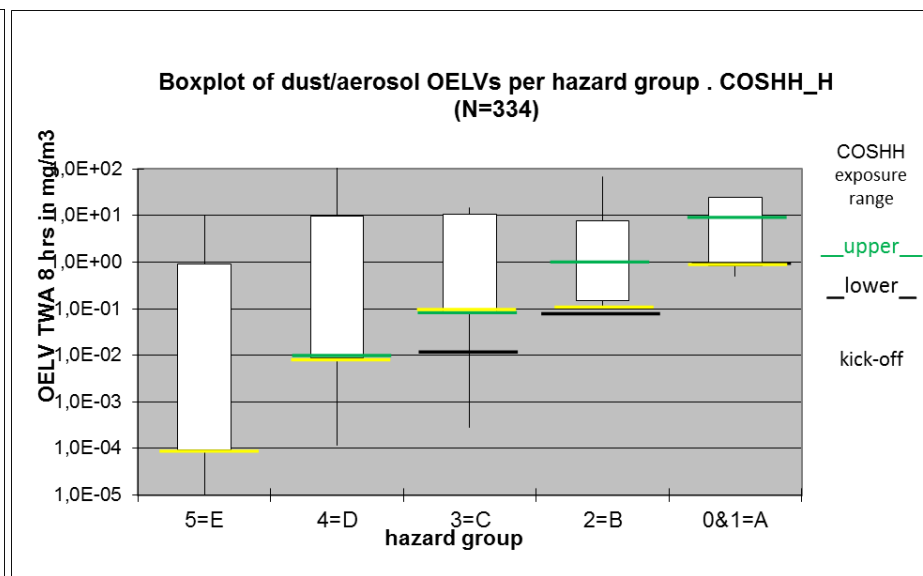
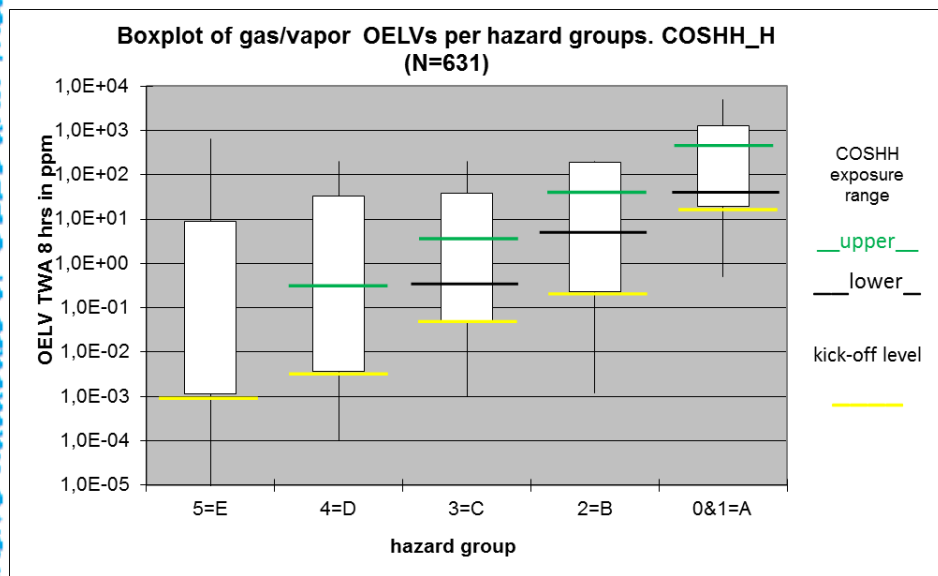
- with harmonised, notified or derived H3##-statements, or low or non-dangerous
- with known physical state
- without a higher hierarchy OELV or DNEL,

~ 110.000 notified substances

<http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>

Not for nano's

COSHH control measures based exposure ranges



Compliance testing with hazard group Kick-off level

- Noncompliance for all ppm
- Compliance for C & D mg/m³



Improving Control bands

Develop a most powerful, health hazard Control banding

- an optimized number of bands
- international accepted H3## allocation

This may lead to:

- The most robust relation between OELV & hazard banding
- The best Kick-off levels

Hazard Group	1	2	3	4
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, all other H3##-statements
Gases/vapors (ppm)	0,001	0,01	0,1	5

Hazard Group	1	2	3 *	4
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, all other H3##-statements
Dusts (mg/m³)	0,00001	0,01	0,1	1

Comments and more info see:

www.dohsbase.nl/en/content-2-2-2/draft-kick-off-values-2014/



Consultancy@dohsbase.nl

Recommendation: Let's harmonize !!!

Control Banding



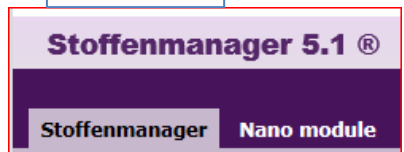
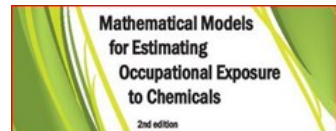
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Compliance statistics

BW
stat



Exposure modelling



Hazard classifications

CLP

GHS



mixtures

XLUNIFAC

$$\sum_{i=1}^{i=n} \left(\frac{C_i}{OELV_i} \right) \leq 1$$

Lead substance

OELV

