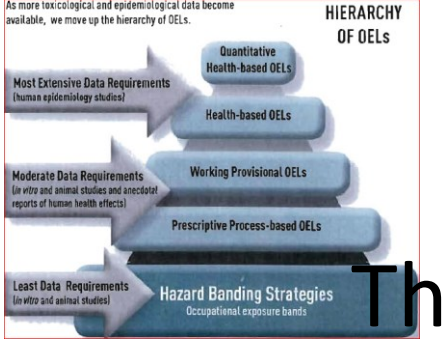
The most comprehensive database of OEL's and measurement methods

Kick-off limits.
For substances with no OELV/DNEL, but with GHS/CLP classification

Theo Scheffers, Geert Wieling

DOHSBASE v.o.f.



The wealth of workplace limit values

Status	US	Europe
Legal, Federal	PEL	BLV/IOLV
Legal, States/Nations	Califonia etc.	All
Health based (independent)	ACGIH	SCOEL, DFG etc.
Responsible Care/ Product stewardship	WEEL	AGS (Germany)
Product Liability		REACH

Substances with exposure & no OELV

- European REACH: > 12.500 substances traded > 10 ton/year
- Many workplace substances without REACH registration (wood dust, welding etc., smaller volumes, exclusions)
- DOHSBase: ~6000 substances with ≥ 1 OELV or DNEL

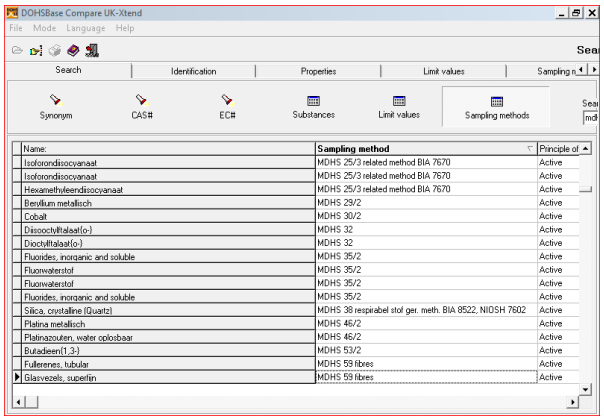
- Conclusion: EU ≥6500 substances with no OELV

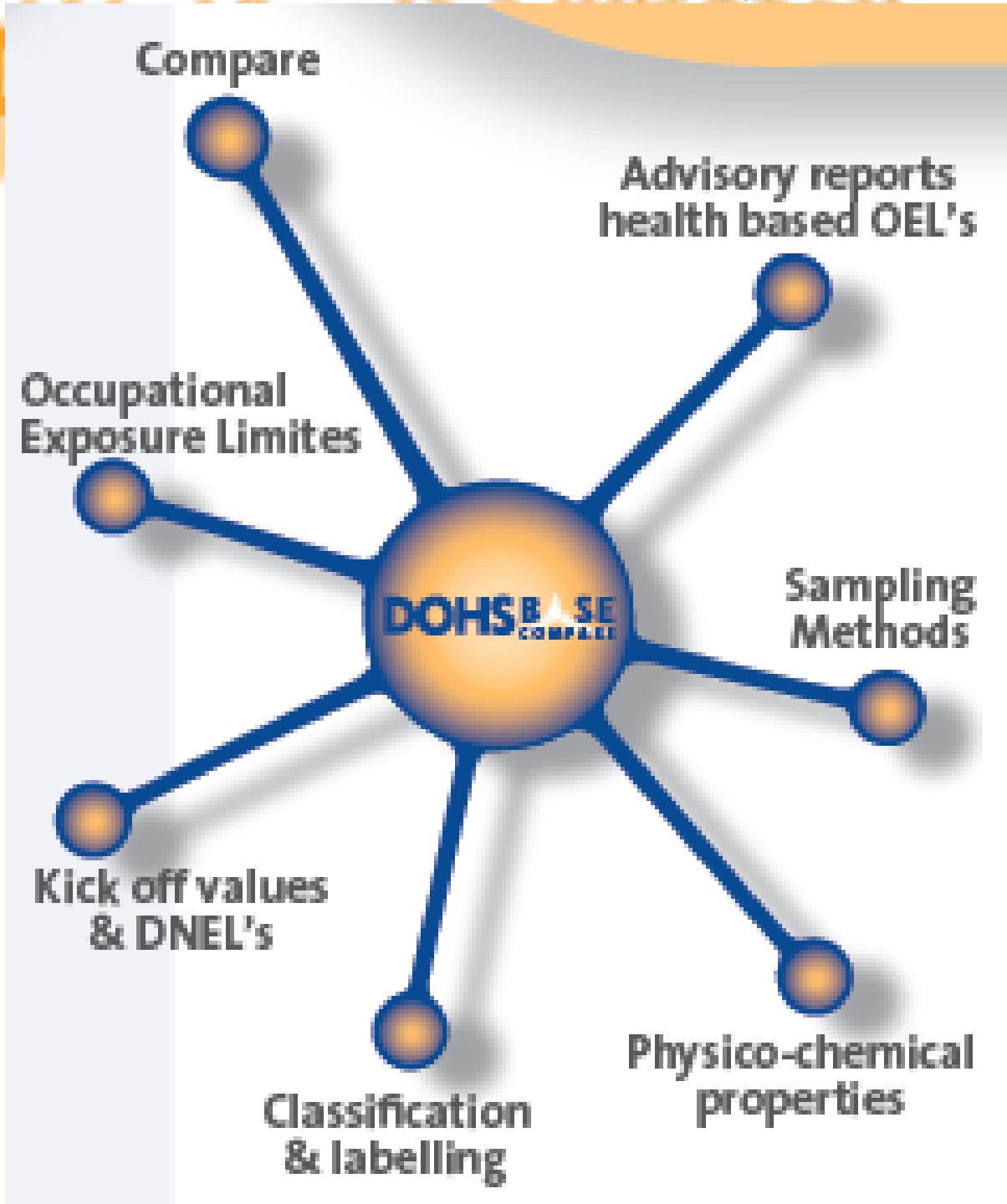
- NB: there are 100.000 substances EU notified as dangerous

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





4-6-2014 9:17:33

DOHSBase
US version

Paradigm shift in legislation

"License to operate":

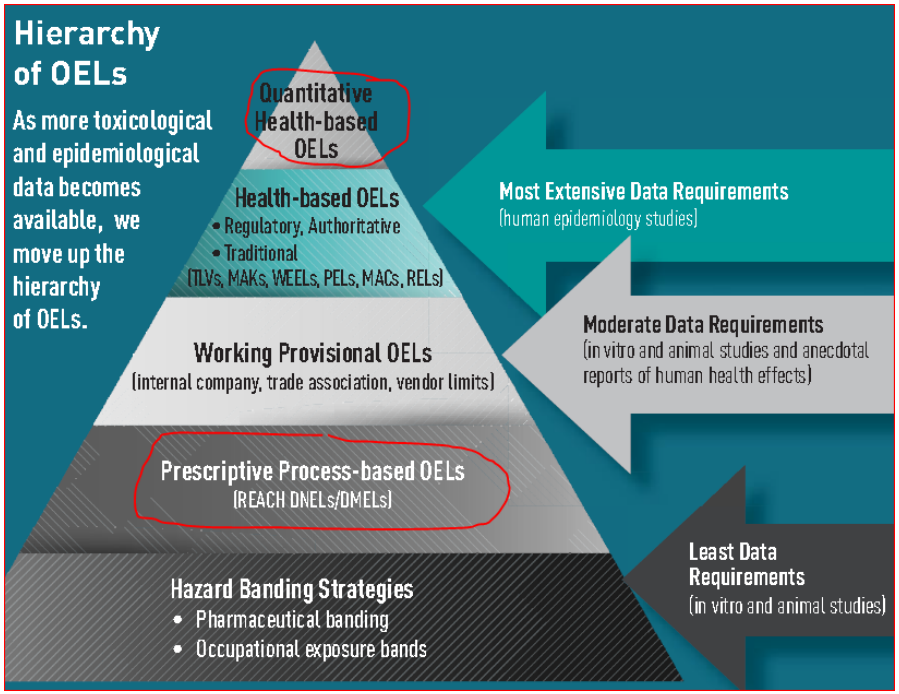
1. a substance register including workplace OELVs
2. guarantee safe use (SDS)

No limit → non-compliance!

How to establish an OELV if it's lacking?

- Data rich
- Data poor

Data rich OELV methods

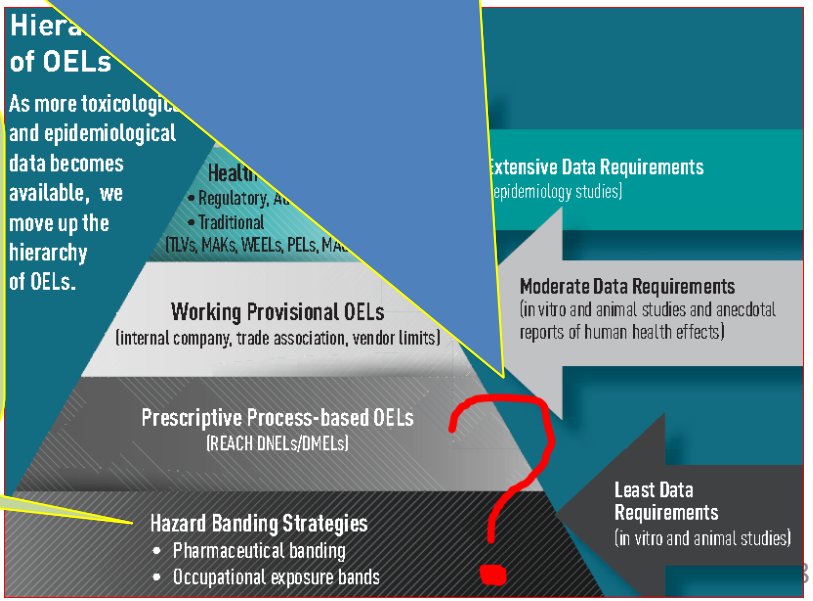


Multiple endpoint methods:

- Holistic health based approach (ACGIH, SCOEL, DFG, DECOS)
- Prescriptive Process-based (DNEL, DMEL)

The most comprehensive database of OEL's and measurement methods

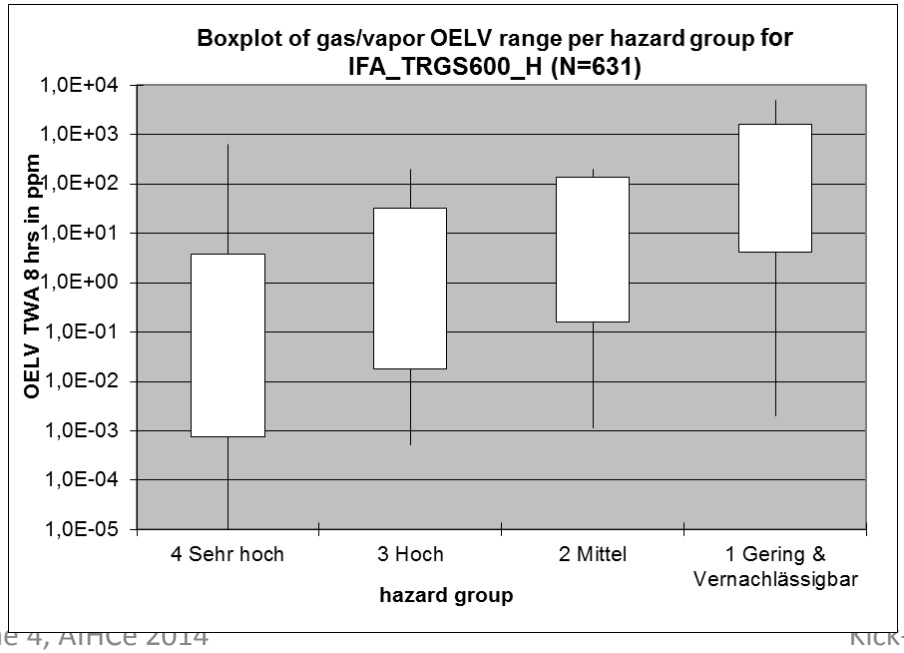
Data poor substance OELV methods

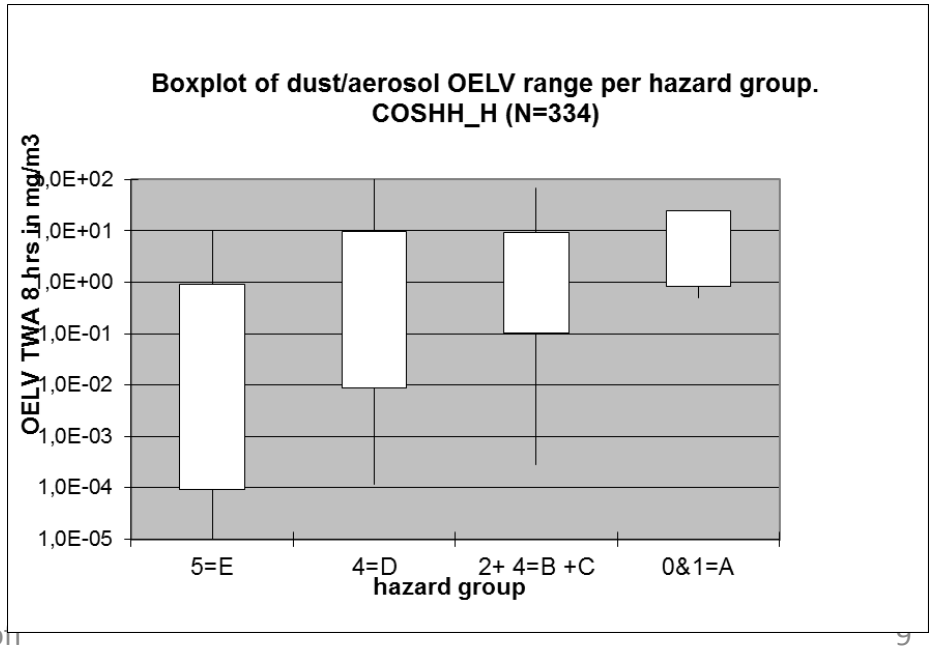


The most comprehensive database of OEL's and measurement methods

Approach

Based on the relation between OELVs and the Hazard Grouping in Control Banding schemes (later presentation)





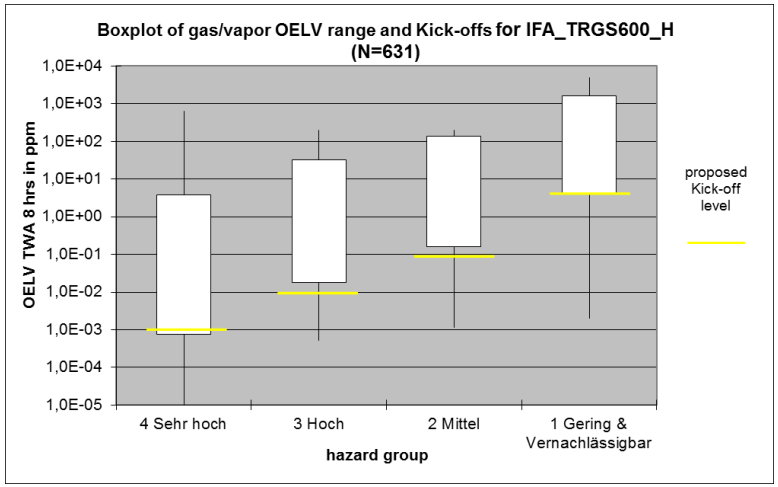
Substances used to calculate kick-off values

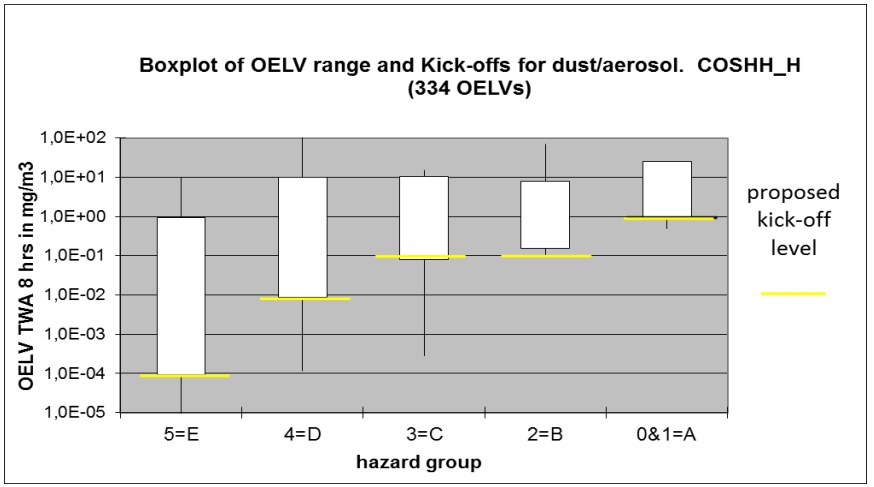
Substances with:

- A health-based TWA-8hrs OELV
- At least one harmonized H3##-statement
- Known physical state in workplace air: gas/vapor or dust/aerosol

CB-Scheme	Vapor/Gas	Dust/Aerosol
IFA Spaltenmodell	631	338
COSHH-Essentials	631	334

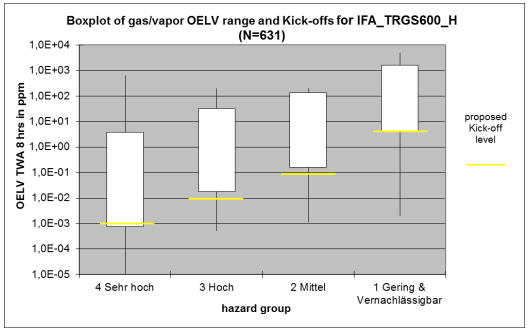
Philosophy behind kick-off values (1)

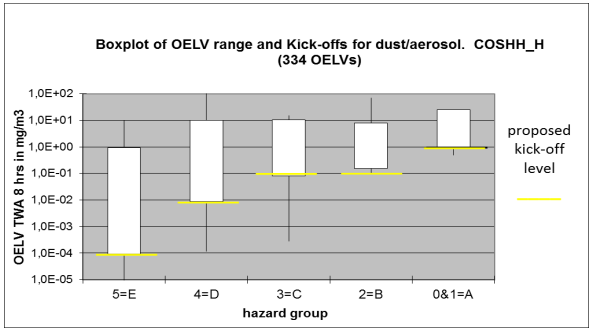




- Definition of kick-off value: 10%-tile of the OELV distribution of a Control Band hazard grouping
- Conservative estimate: 90% change the “real” OELV is higher
- If the kick-off is technically feasible, no extensive toxicological research is needed to establish a higher hierarchy limit

Calculation of the Kick-off values





10%-tile per OELV distribution (yellow bars).

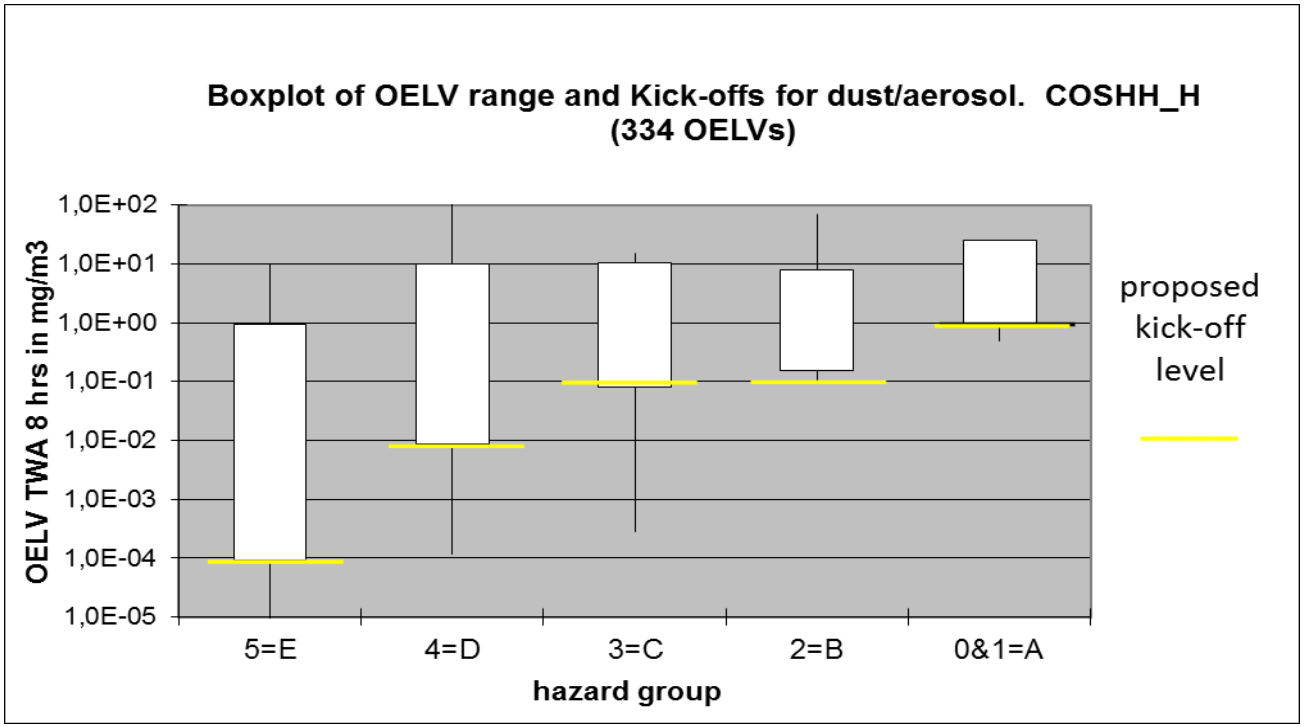
Established:

- Unbiased GM*GSD^[$k_{10\%}$*√((N+1)/N)], if approximate (censored) Lognormal
- Distribution free 10%-tile in other cases

Results (1)

- COSHH Essentials (2009) differentiates best the OELV distributions per hazard groups for dust/aerosol
- Hazard groups B and C are combined

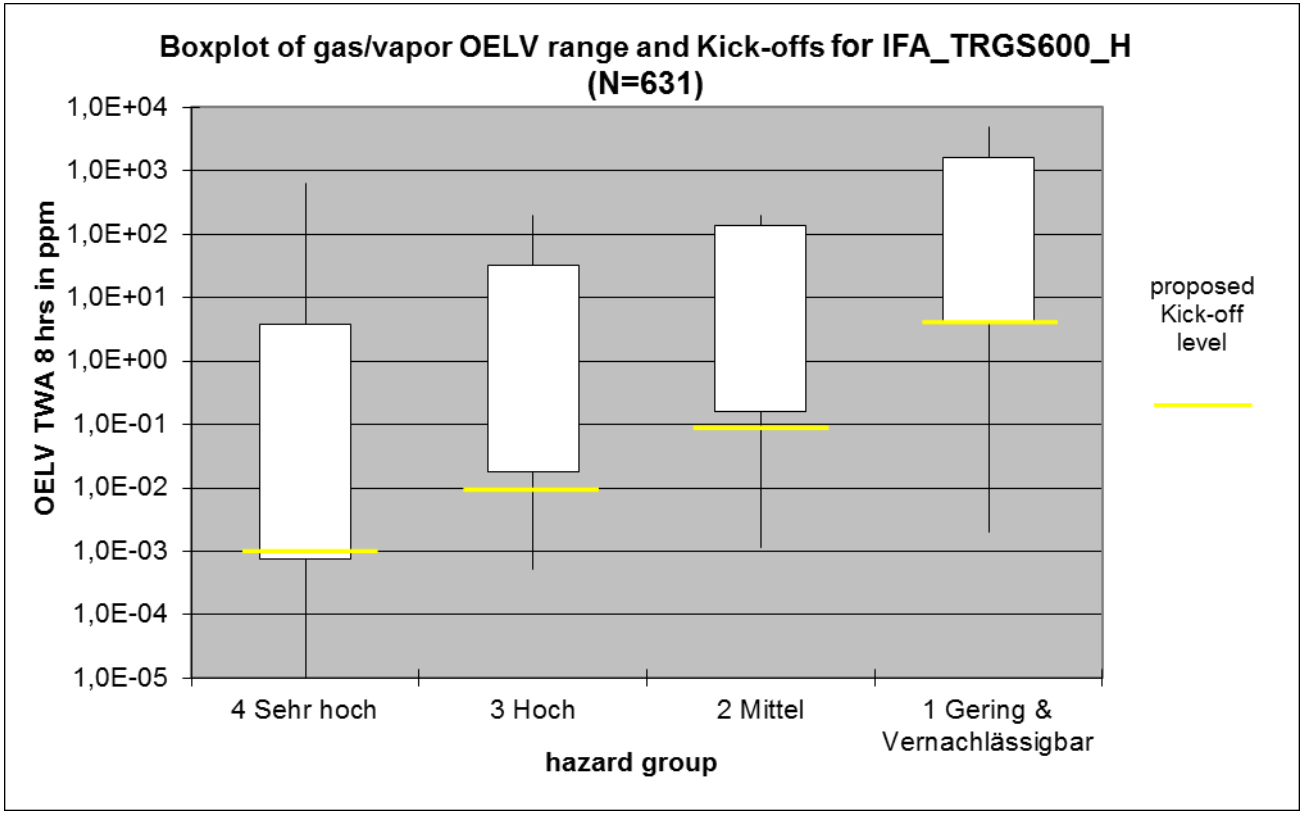
Hazard group	# subst.
A	8
B+C	31+54
D	93
E	148



Results (2)

IFA Spaltenmodell differentiates best the OELV distributions per hazard groups for vapor/gas

Hazard group	# subst.
1 (G&V)	84
2 (M)	119
3 (H)	246
4 (SH)	182



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

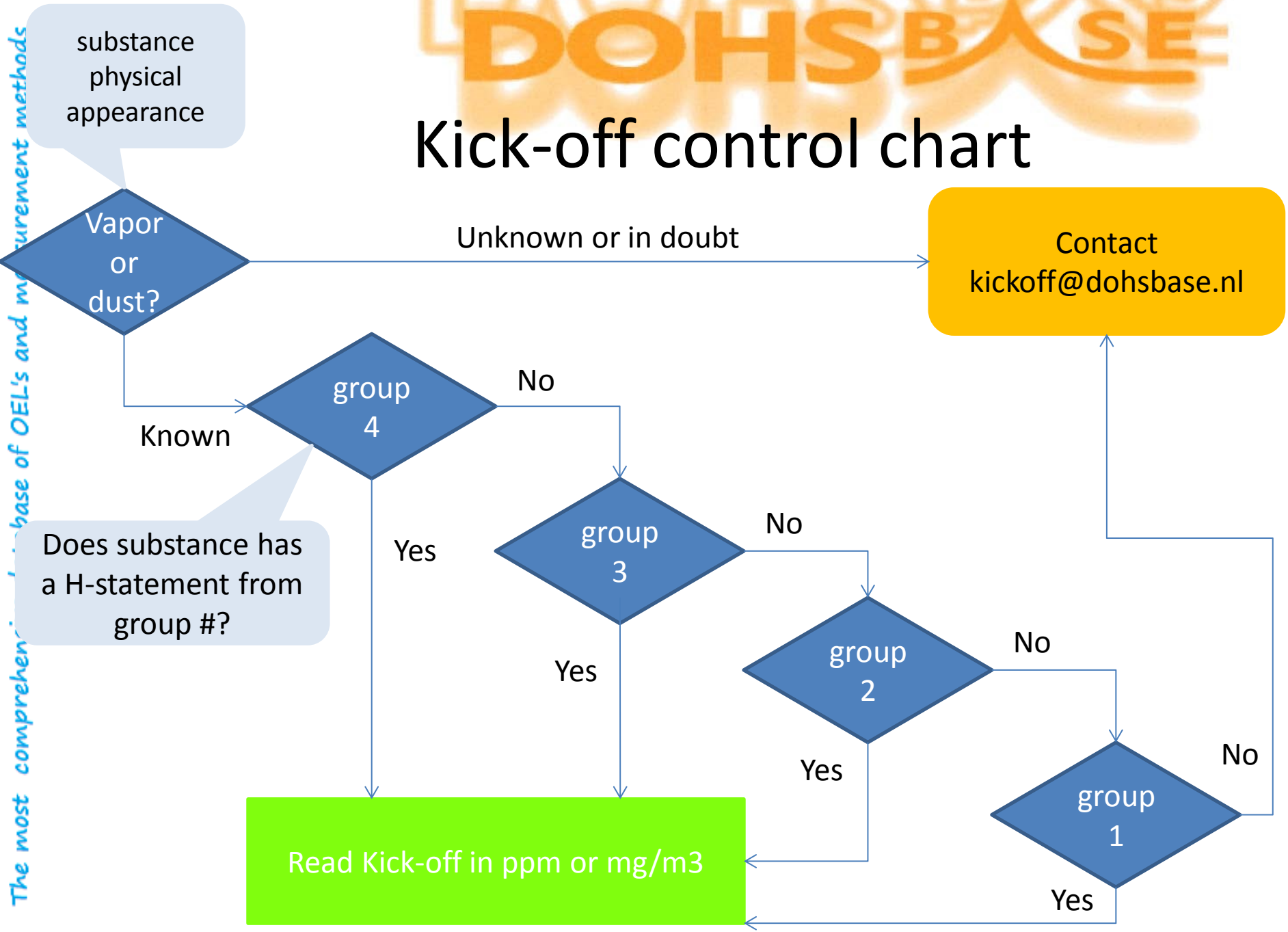
'*' Hazard Groups B+C combined

Proposed H3## based kick-off values for gases/vapors

Basis: DGUV IFA Spaltenmodell (TRGS600)

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



Final

Kick-off values can be derived for substances with harmonised **and** notified CLP-classification, without an OELV, but with known physical appearance and reliable H3##-statements

- at least 4400 substances
- (not for nano's: hazards unknown!)

A Kick-off value:

- if no OELVs or DNELs are available
- Does not replace existing OELV's !!!

The most comprehensive database of OEL's and measurement methods

(Legal) status kick-off

Kick-off value is a conservative starting point if an higher hierarchy OELV/DNEL is lacking.

If you don´t comply:

- Improve the limit (more data, better assessment) or
- Improve controls

- Authorized by Dutch law enforcement 2012

Commentary Round

Invitation to comment on the kick-off update 2014:

- Concept/idea
- Use of CB-schemes
- Statistics
- Values

Mail to: kickoff@dohsbase.nl

Or:

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

Follow up

- Draft publication and tables to derive draft H-Statement based kick-offs for CLP harmonised and notified substances on our websitewww.dohsbase.nl/en/content-2-2-2/draft-kick-off-values-2014/
- Evaluation of the received comments (Q3/4 2014)
- Establish definitive kick-off values (Q4 2014)
- (Scientific) publication
- Conversion of current R-phrase to H-statement kick-offs of harmonised substances in DOHSBase Compare (Dec 2014)

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/m^3)	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/

Theo.scheffers@dohsbase.nl