



Kick-Off Limit Values for substances with limited human health-hazard information

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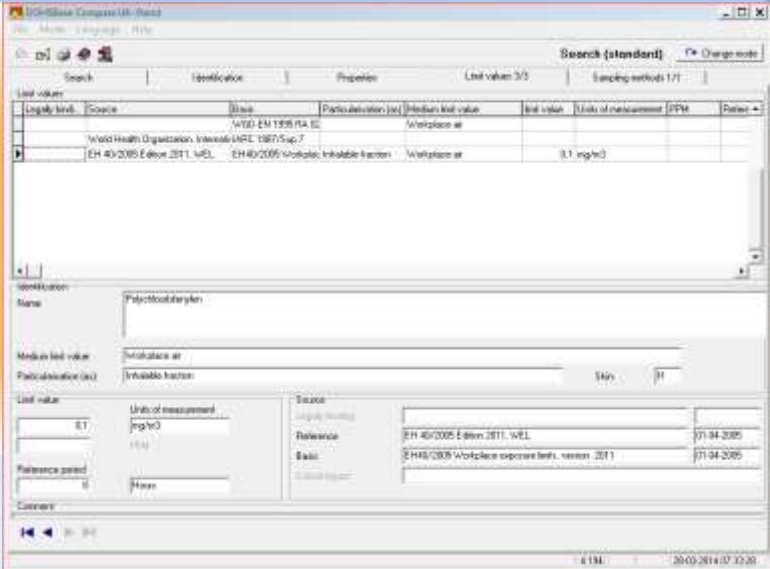
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How many substances within EU, with workplace exposure and no OELV?

- Worldwide: > 64 million substances (CAS-register)
- EINECS: approx. 140 thousand substances
- REACH: 12.399 unique substances disseminated (> 100 t/a or >10 t/a if CMR) (ECHA database of registered substances)
- about 2.600 substances: no workplace exposure
- # of 2018 registered substances (the REACH deadline for 1 – 10/100 t/a) with CSR/DNEL: unknown, may be zero
- Many workplace substances without REACH registration (wood dust, welding etc.)
- **Conclusion: workplace exposure in EU: at least 9800 substances**

How many substances within EU, with workplace exposure and no OELV?

- Substances with OELV (DOHSBase Compare): ~ 3800
- REACH-CSR substances with DNEL/DMEL: ~ 2000 (411 with both, see Theo's Ignite session)

Conclusion:

- Number of substances in EU with workplace exposure and no OELV or DNEL: at least 4400 (~ 45%!!)

Challenge:

- Establish limits (kick-off values) for these substances, using the relation between existing OELVs and Hazard Grouping



(Legal) status kick-off value

Paradigm shift in the Netherlands:

To work with chemicals the employer must:

1. Guarantee safe use (SDS) and
2. Must have a register for **all** substances, inclusive OELVs
3. Show compliance with OELV

No company limit → non-compliance!

Kick-off value is a starting point if no OELV/DNEL is available

In the Netherlands: kick-off values are accepted by Labour Inspectorate/law enforcement for substances with no formal OELV or DNEL

Philosophy behind kick-off values (1)

- Definition of kick-off value: 10%-tile of the OELV distribution of a Control Banding hazard group
- If this value is feasible in practice, no extensive toxicological research is needed to establish a health-based company limit

Philosophy behind kick-off values (2)

Target group:

- Substances with no OELV or DNEL, but with (limited) health-hazard information (H3###-statements)

Research group:

- Substances with OELV and at least one H3###-statement

Method to derive Kick-off values

Starting point: the OELV distribution hazard groups in 2 Control Banding Schemes:

- COSHH Essentials (HSE)
- GHS Spaltenmodell (DGUV IFA)

Establish the 10%-tile of the OELV distributions:

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

Number of substances used to calculate kick-off values

Substances with:

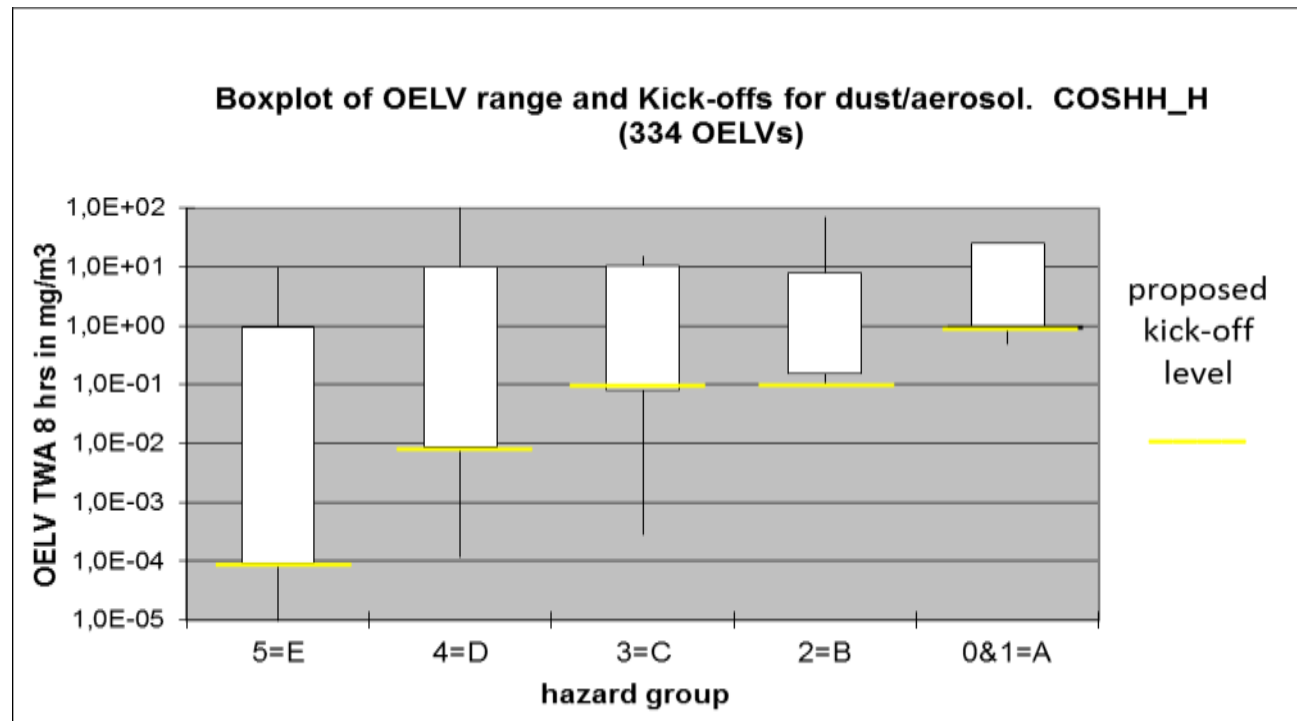
- A health-based TWA-8hrs OELV
- At least one harmonised H3##-statement
- Known physical state in workplace air:
gas/vapor or dust/aerosol

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

Results (1)

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

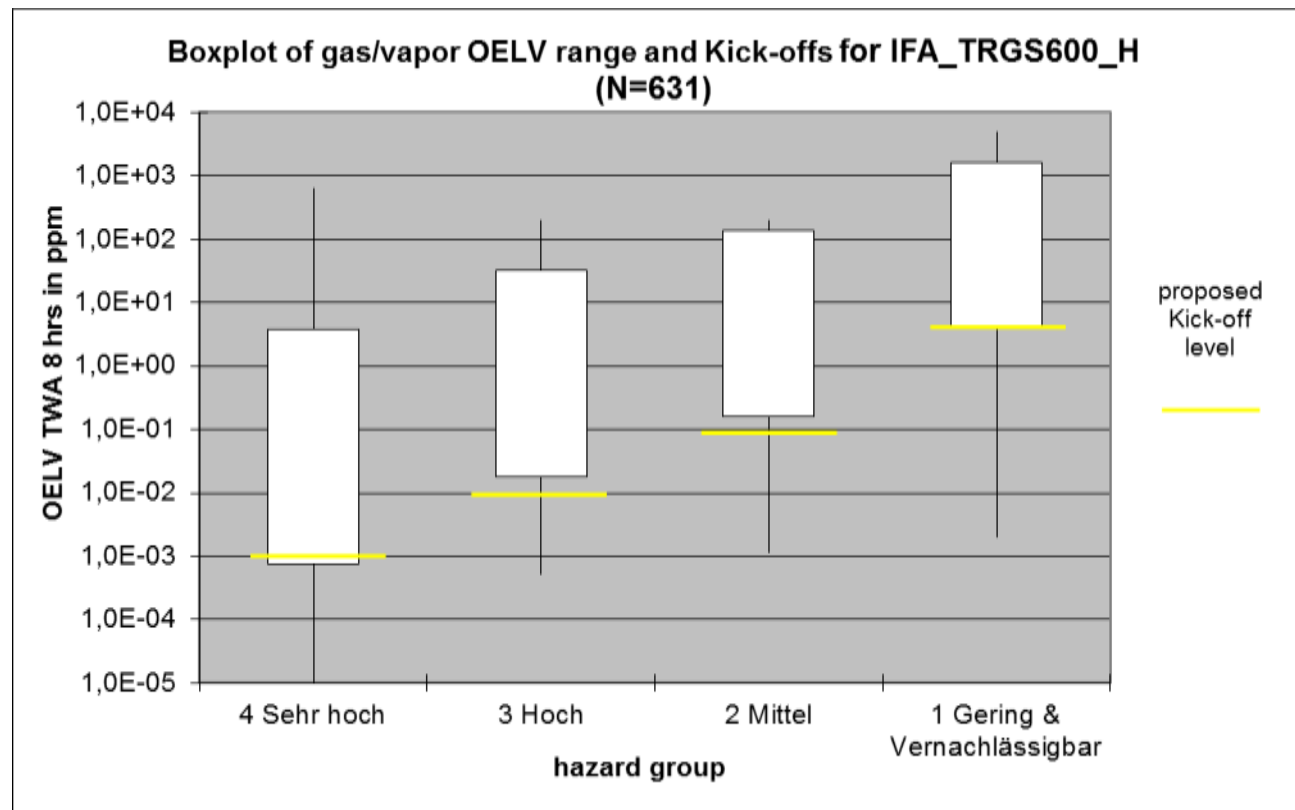
Hazard group	# subst.
A	8
B+C	31+54
D	93
E	148



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



Conclusions

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

(for more than over 4400 substances?)

A Kick-off value is an indispensable addition if no OELV or DNEs are available



Commentary Round

Invitation to comment on the kick-off values:

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

Mail to: consultancy@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 website www.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

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Dusts (mg/m³)	0,00001	0,01	0,1	1

Thank you!

Meet us   at the exhibition, booth 13

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