# Testing strength and validity of Hazard Band engines

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co-project/co-presentation

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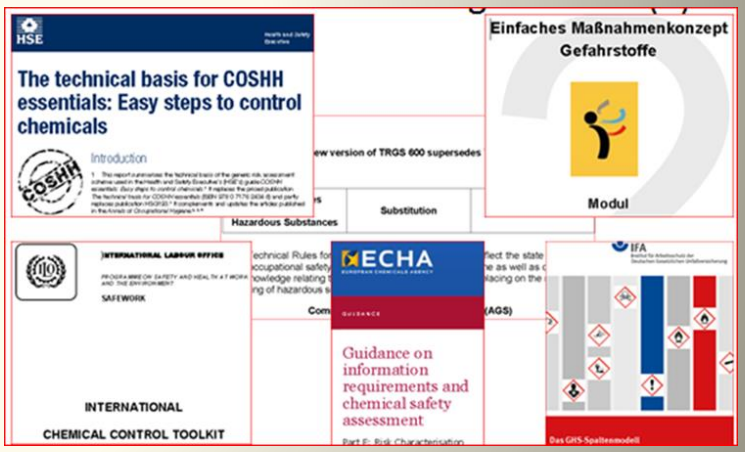
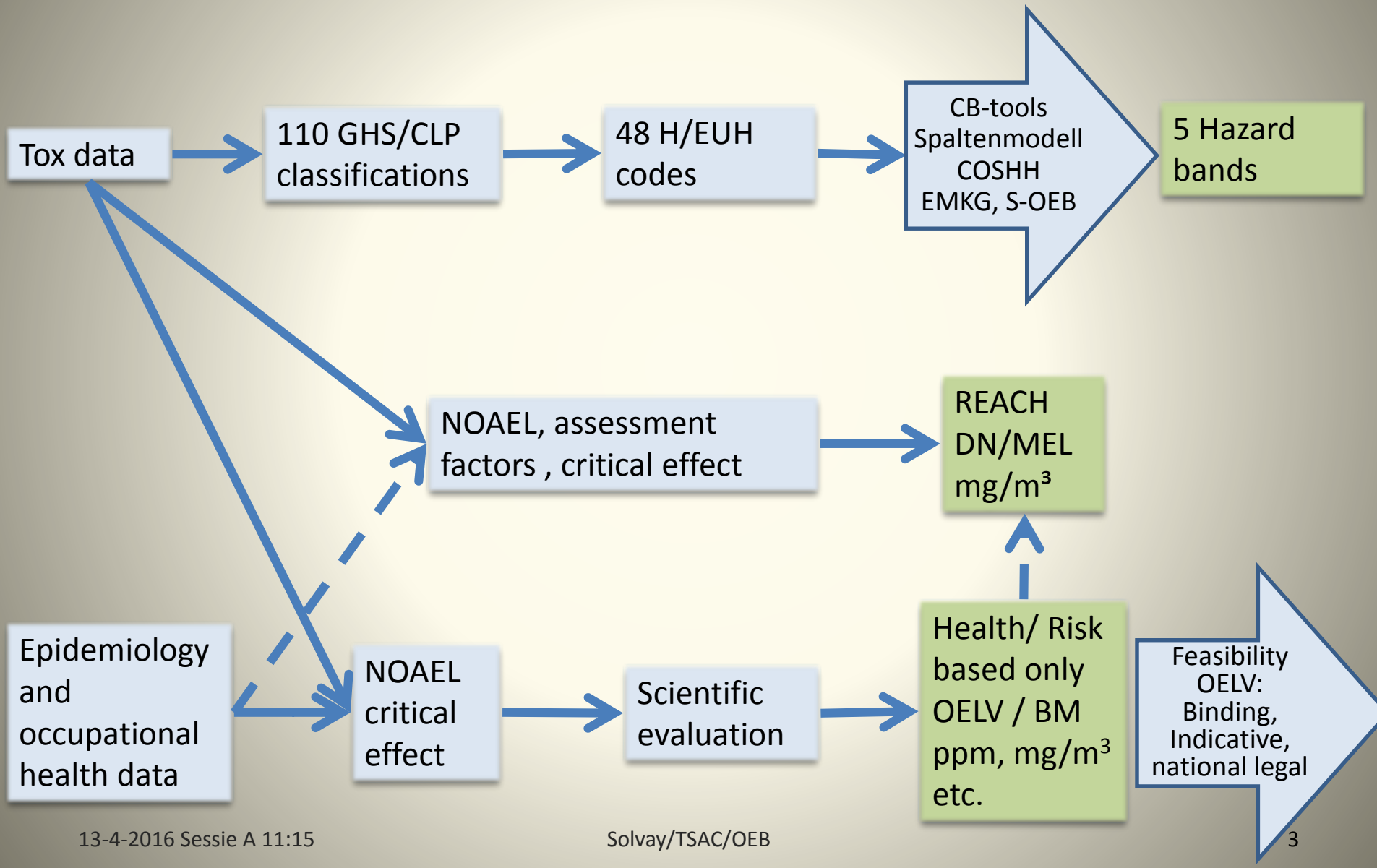
# Hazard band: if no OELV exists

- 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) ??

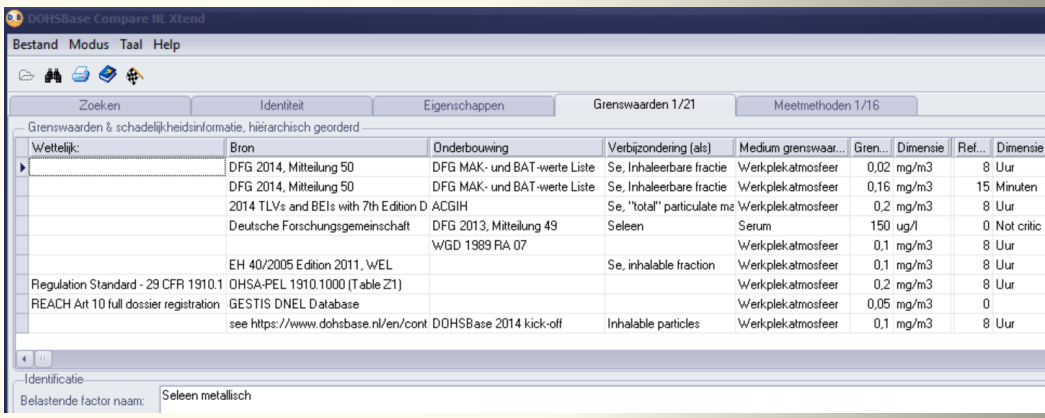


# Limit Value & Hazard Band

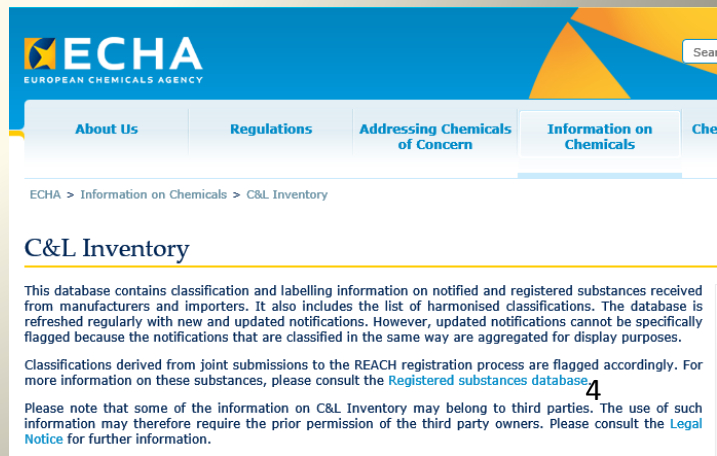


# Realm of hazard bands

- >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



# 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)<br>340, 350, 350i (CM)<br>EU032 (Tox gas release) | 340, 341, 350(i) (CM)<br>334 (S)<br>EU070 (Tox) | 340, 350, 350i (CM)<br>$360_F$ (R) | 372 (Tox)<br>340, 350 (CM)<br>334 (ICS) |
| D/4 | 301, 311, 331, 370, 372 (Tox)<br>341, 351, $360_{xy}$ (CMR)<br>EUH029, EUH031 (Tox gas release)<br>317, 334, 318, EUH070 (ICS) | 300, 310, 330, 372 (Tox)<br>351, $360_{xy}$, 361, 362 (CR) | 300, 330, 372 (Tox)<br>$360_D$ (R)<br>EUH032 (Tox gas release) | 300, 310, 330; 370, 373 (Tox)<br>314 (+ cat A), EUH071 (ICS),<br>341, 351, $360_{xy}$ (CMR) |
| C/3 | 302, 312, 332(Tox)<br>314 (pH ≥ 11,5, pH ≤ 2), 371, EUH071<br>361 $_{f/d}$, 373, 362<br>non-toxic gases which may cause asphyxiation | 301, 311, 331, 314, 370, 373 (Tox)<br>317, 318 , 335, EUH071 (IC) | 301, 331, 314, 370, 371, 373 (Tox)<br>334 (S)<br>341, 351, 361f/d (CMR)<br>EUH031 (Tox gas release) | 301, 311, 331; 371 (Tox)<br>304, EUH070 (lung, eye damage)<br>314 cat B and C, 317, 318, 335 (ICS)<br>361, 362 (R & Lact) |
| B/2 | 315, 319, 335, ** (I)<br>304, EUH066, 336 (solvents)<br>*** | 302, 312, 332, 371 (Tox) | 302, 332 (Tox)<br>318 (C) | 302, 312, 332, 336 (Tox)<br>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)<br>336 , EUH066 (solvents) and all H-numbers not otherwise listed | 319, 335 (I)<br>336 (solvent)<br>304 (Aspiration)<br>Non health hazard H-statement codes | 303, 313, 333 (GHS Tox 4)<br>305 (ICS)<br>316 (GHS-> noCLP),<br>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

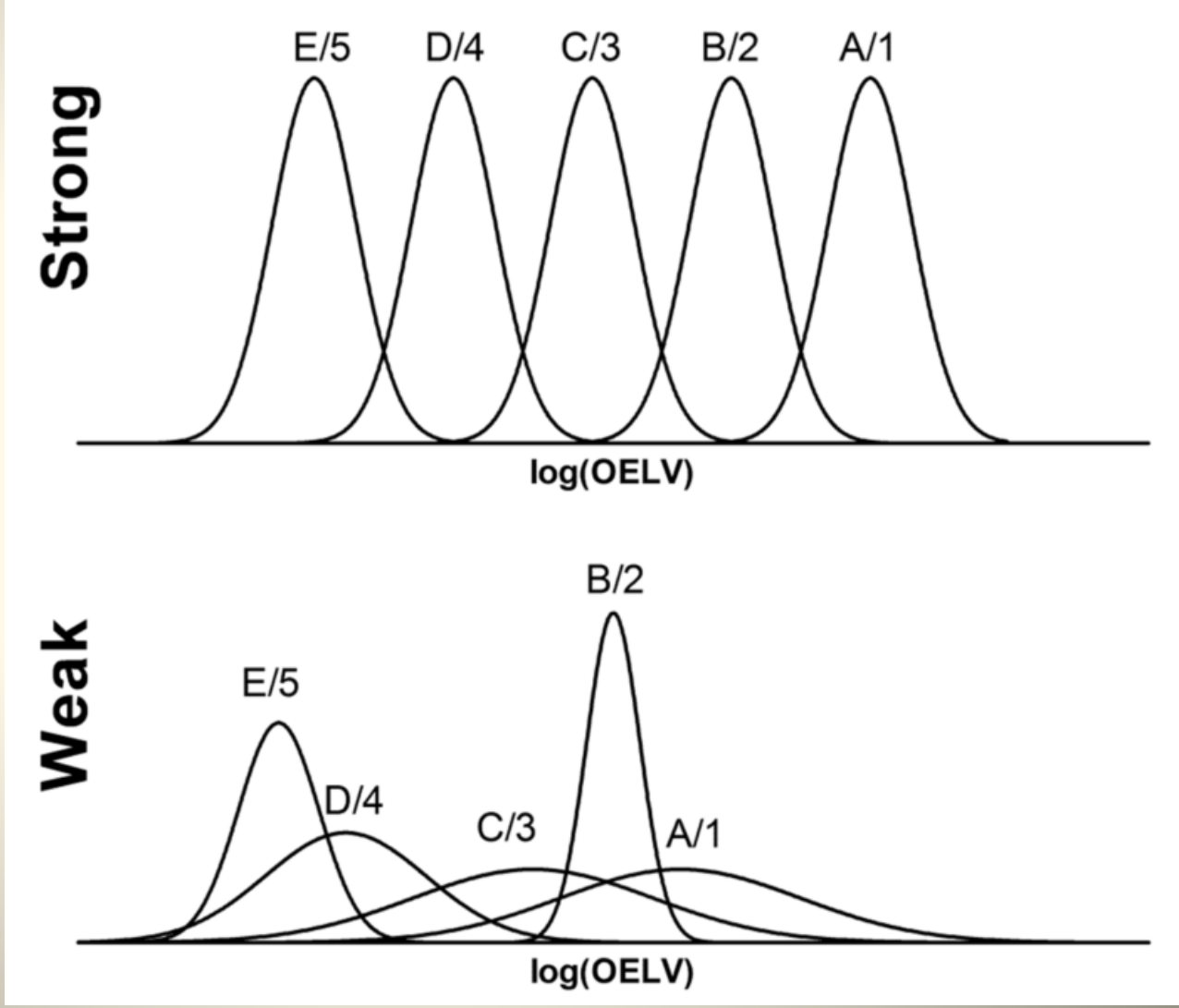
| Hazard band allocation | IFA Spaltenmodell (2011) | COSHH (2009) | EMKG-HOI (2009) | S-OEB |
|---|---|---|---|---|
| Eye Irrit. 2 H319 | 2 | 1 | 1 | 2 |
| Skin Sens. 1 H317 | 4 | 3 | - | 3 |
| **Final Hazard-Band** | **4** | **3** | **1** | **3** |



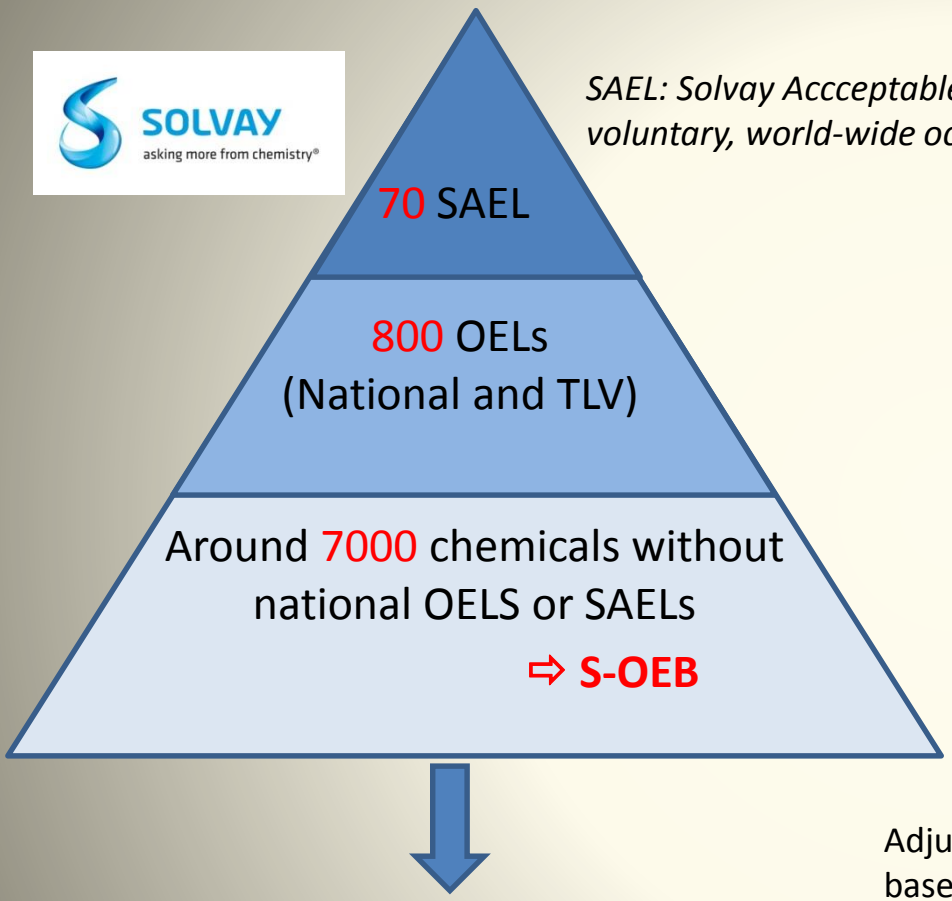
# Theo Scheffers question: how to maximize the HB-engine/OELV relation?

HB-engines:
COSHH
Spaltenmodell
EMKG
S-OEB

ILO
SEIRICHH
IFA (2015)
.....
.....



# Context




*SAEL: Solvay Accceptable Exposure Limits: voluntary, world-wide occupational exposure limit*

**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

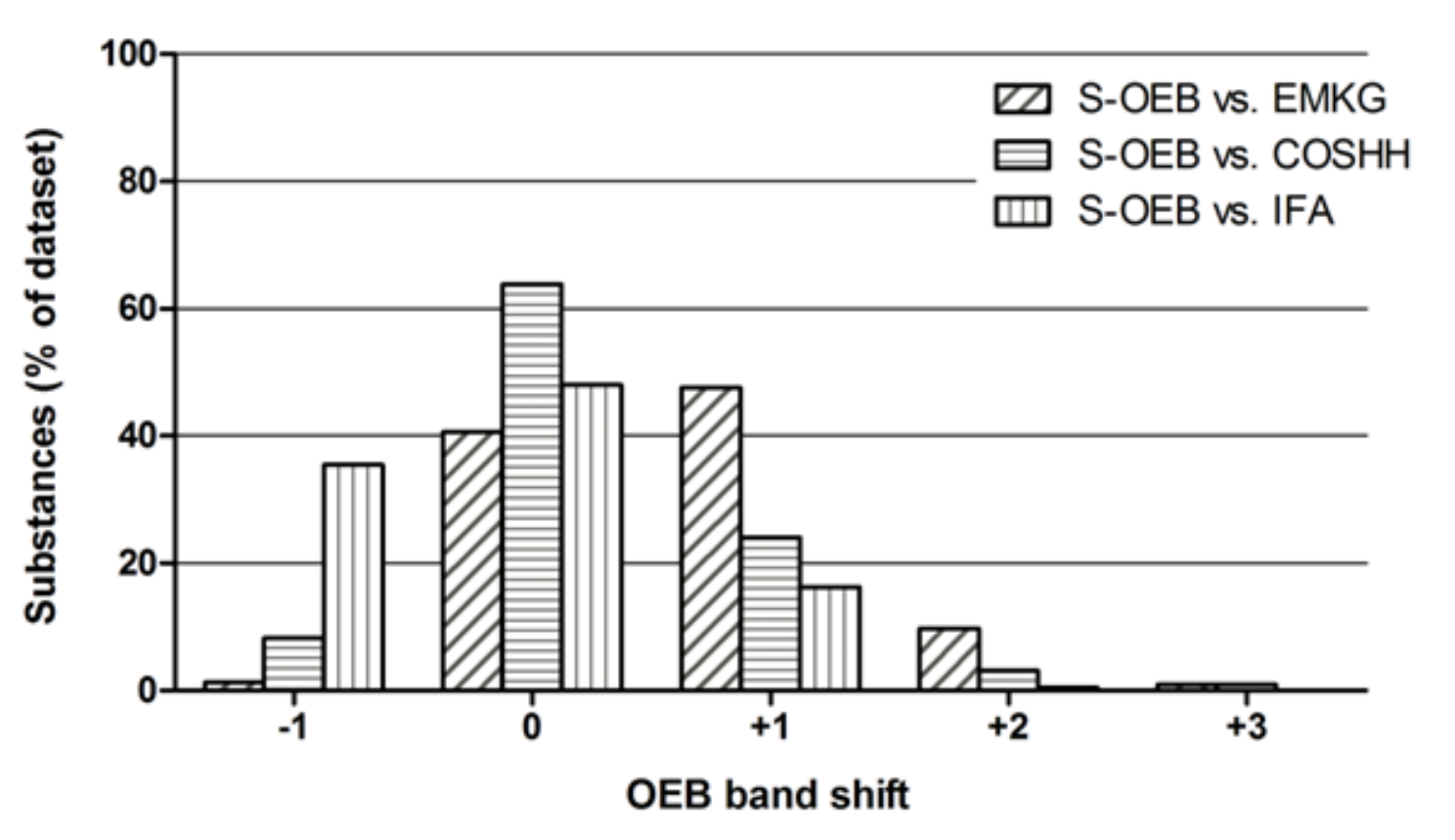
**Identification & application of adequate RMMs**

# 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

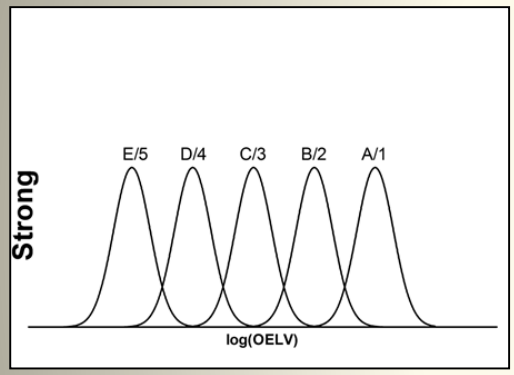


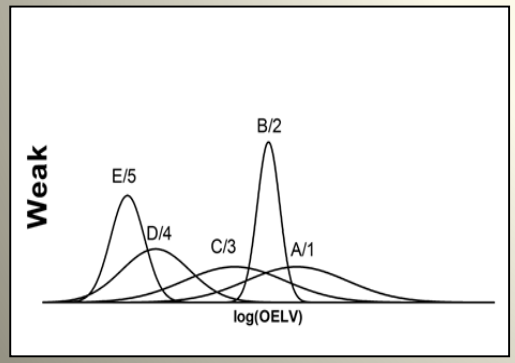

Relative to S-OEB, the 3 HB systems assign equal bands for at least 40% of the substances.
The remaining substances differ at least one band, with IFA placing more substances in a higher and EMKG doing the opposite

# Results:
# Strength of differentiation rel. to actual OELV

**Log-normal distribution**

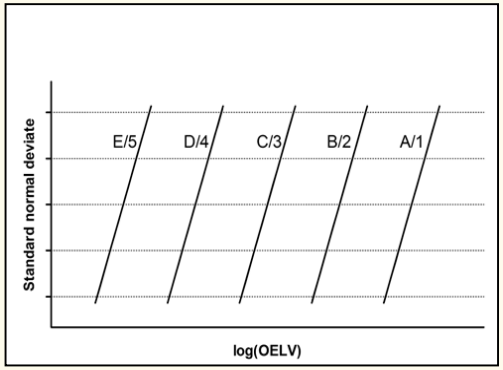
*Theory*

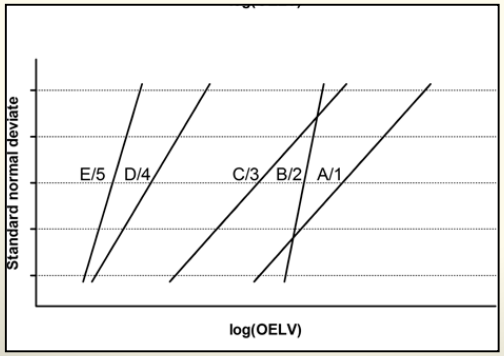



**Cumulative log-normalized probability plot**

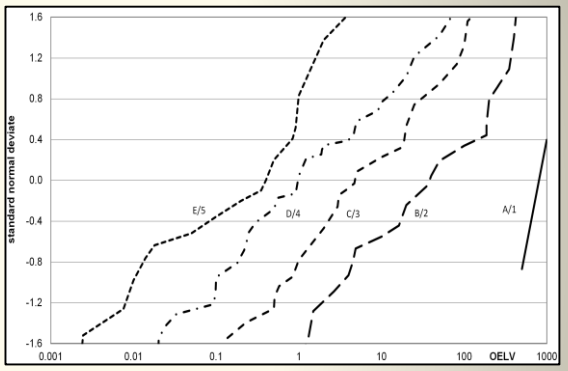
*Theory*

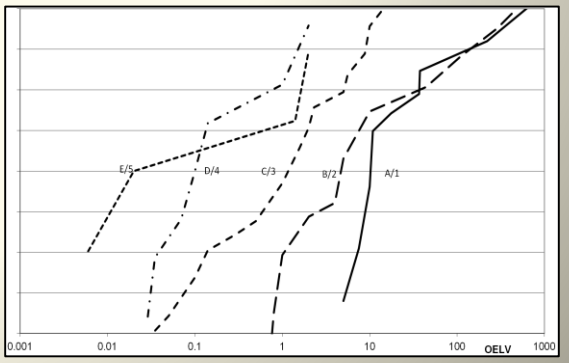



**Cumulative log-normalized probability plot**

*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** |

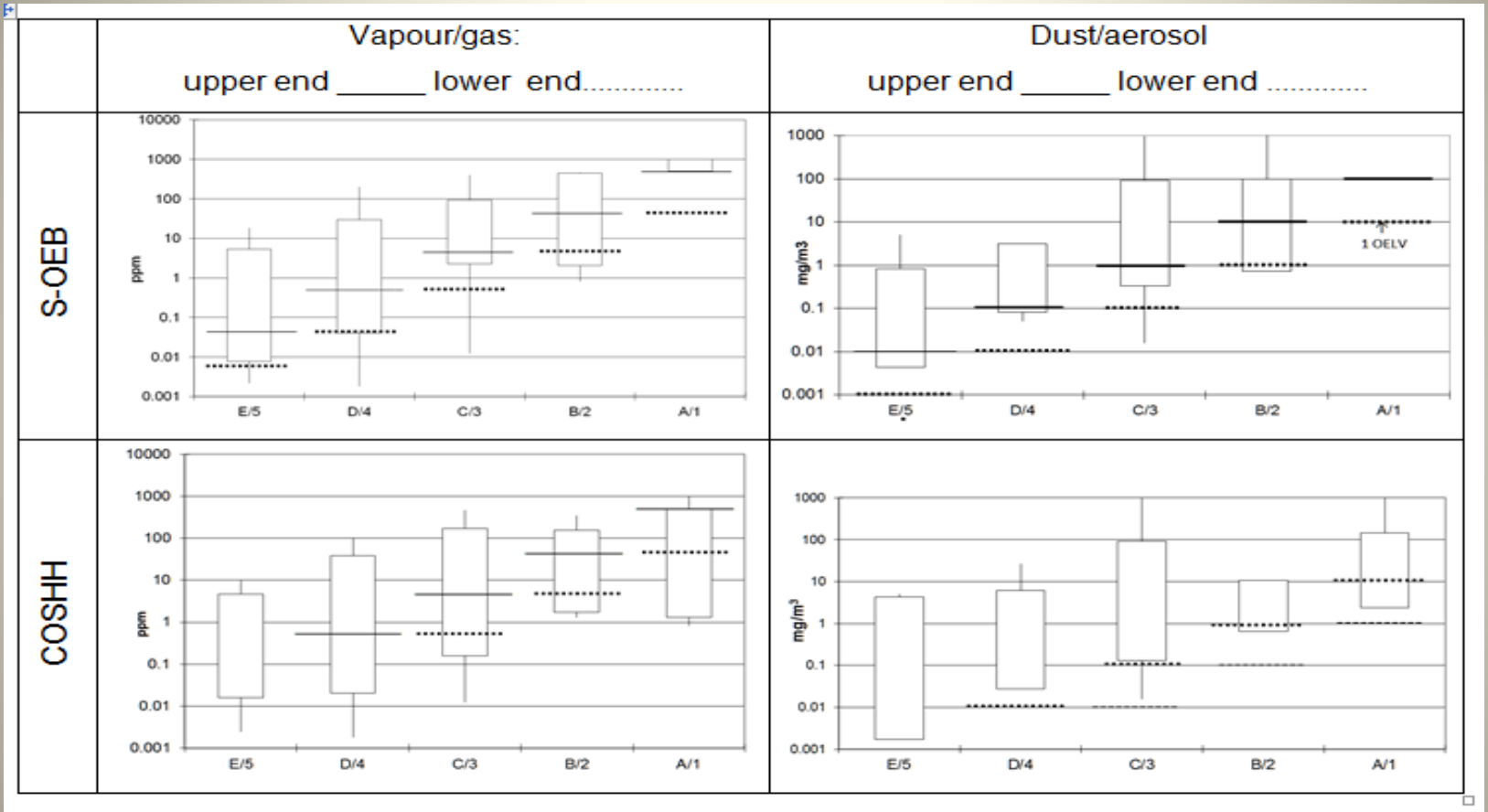
**S- OEB** relates at least as strongly to OELV as the other HB systems

# **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 that 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

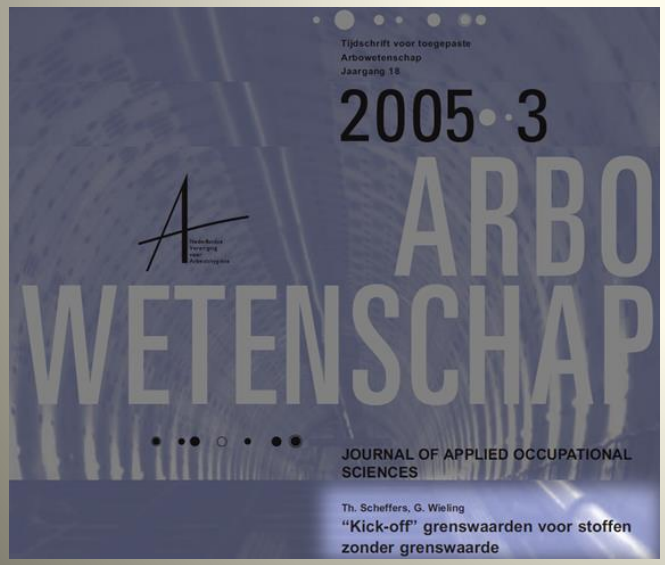
**Proposed kick-off values for dust/aerosols**
(basis: COSHH Essentials)

| 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/m³)** | **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

| 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** |