Filling the OELV gap: Optimize Hazard Banding

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Session 4c Hazard banding
BOSH OH2017 14:30

Application of Hazard Banding

I. No OELV:

1. Hazard Banding
   - Pharma, Painting in
   - COSHH essentials (
   - Currently 10+ look-

hazard band	harm
E/5	Carcinogens, Very Toxic Sensitizers
D/4	Reprotoxic Corrosive
C/3	Toxic
B/2	Irritant
A/1	non-hazardous

2. Tiered approach for OELV development
   - DOHSBase Kick-off (2005)
   - NIOSH OEB approach (2017)

II. Compare & substitution

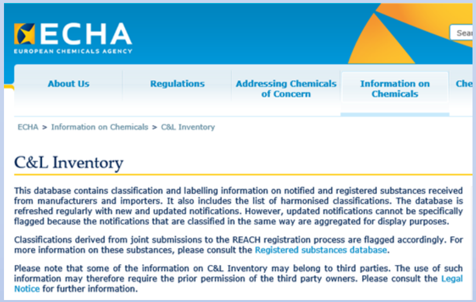
- DOHSBase compare (2006)
- ECHA, IFA Spalten (2015), Seirich (2016)

Hazard banding when an OELV is lacking:

- 6.000.000 CAS# chemicals
- 150.000-200.000 with some occupational relevance
- substances with:
  - ≥1 OELV: 6000
  - DNEL: 2500
  - ‘DOHSBase Kick-off levels: ≈1200

Public health hazard classifications:

- harmonized’ (EU, AUS, Korea,…): 8500
- Echa notifications: >100.000 substances



The development of a Hazard Band engine

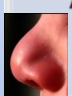
GHS process

Tox data → 110 GHS/CLP classifications → 48 H-codes → Hazard 4/5 Band engine

expert judgement

H301 - Fatal if swallowed
H302 - Toxic if swallowed
H303 - Harmful if swallowed
H304 - May be harmful if swallowed
H305 - May be fatal if swallowed and enters airways
H306 - May be harmful if swallowed and enters airways
H310 - Fatal in contact with skin
H311 - Toxic in contact with skin
H312 - Harmful in contact with skin
H313 - May be harmful in contact with skin
H314 - Causes severe skin burns and eye dar
H315 - Causes skin irritation
H316 - Causes mild skin irritation
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H319 - Causes serious eye irritation
H320 - Causes eye irritation
H330 - Fatal if inhaled
H331 - Toxic if inhaled
H332 - Harmful if inhaled
H333 - May be harmful if inhaled

Allocation of H-codes of 4 HB-engines

Hazard band	DGUV IFA Spaltenmodell	HSE COSHH	BAUA EMKG (inhalation)*	Solvay OEB
 E/5	300, 310, 330 (Tox) 340, 350, 350i (CM) EU032 (Tox gas release)	340, 341, 350(i) (CM) 334 (S) EU070 (Tox)	340, 350, 350i (CM) 360_{F} (R)	372 (Tox) 340, 350 (CM) 334 (ICS)
D/4	301, 311, 331, 370, 372 (Tox) 341, 351, 360_{xy} (CMR) EUH029, EUH031 (Tox gas release) 317, 334, 318, EUH070 (ICS)	300, 310, 330, 372 (Tox) 351, 360_{xy}, 361, 362 (CR)	300, 330, 372 (Tox) 360_{D} (R) EUH032 (Tox gas release)	300, 310, 330; 370, 373 (Tox) 314 (+ cat A), EUH071 (ICS), 341, 351, 360_{xy} (CMR)
C/3	302, 312, 332(Tox) 314 (pH ≥ 11,5, pH ≤ 2), 371, EUH071 $361_{f/d}$, 373, 362 non-toxic gases which may cause asphyxiation	301, 311, 331, 314, 370, 373 (Tox) 317, 318 , 335, EUH071 (IC)	301, 331, 314, 370, 371, 373 (Tox) 334 (S) 341, 351, 361f/d (CMR) EUH031 (Tox gas release)	301, 311, 331; 371 (Tox) 304, EUH070 (lung, eye damage) 314 cat B and C, 317, 318, 335 (ICS) 361, 362 (R & Lact)
B/2	315, 319, 335, ** (I) 304, EUH066, 336 (solvents) ***	302, 312, 332, 371 (Tox)	302, 332 (Tox) 318 (C)	302, 312, 332, 336 (Tox) 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) 336 , EUH066 (solvents) and all H-numbers not otherwise listed	319, 335 (I) 336 (solvent) 304 (Aspiration) Non health hazard H-statement codes	303, 313, 333 (GHS Tox 4) 305 (ICS) 316 (GHS-> noCLP), 320 (GHS eye irr 2b->CLP 319)

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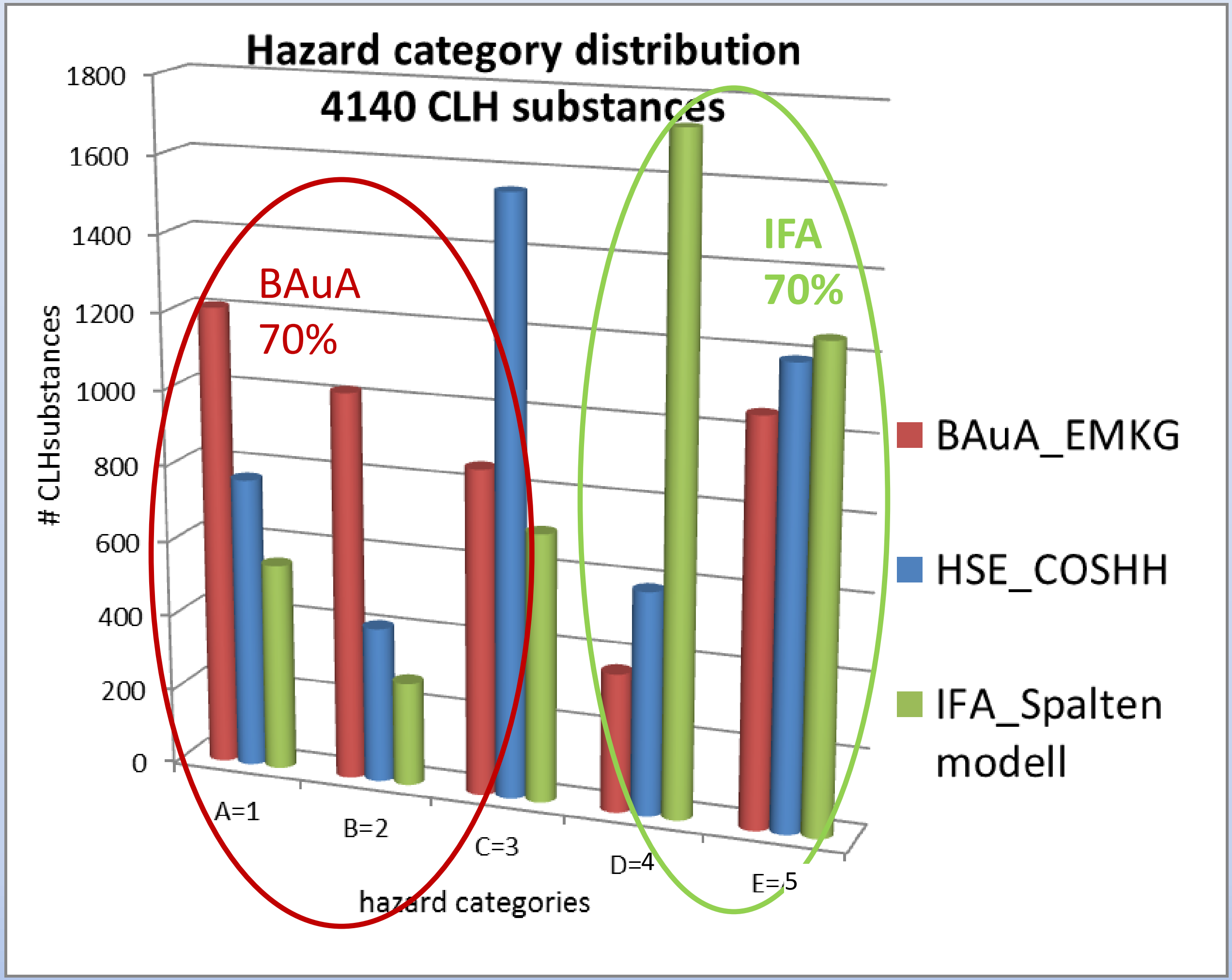
HB-engines variability

Substance	H-codes	Band# per HB-engine		
		IFA	COSHH	EMKG
Maleic anhydride 108-31-6	H302 H314 H334 H317	4	5	3
Diisobutylene (DIB) 25167-70-8	H304 H336	2	1	1
Cumene 98-82-8	H304 H335	2	3	1
Ethanol 64-17-5	(H225) (IARC 1)	-	-	-

In red: the H-code determining the band #

Band# determines control regime

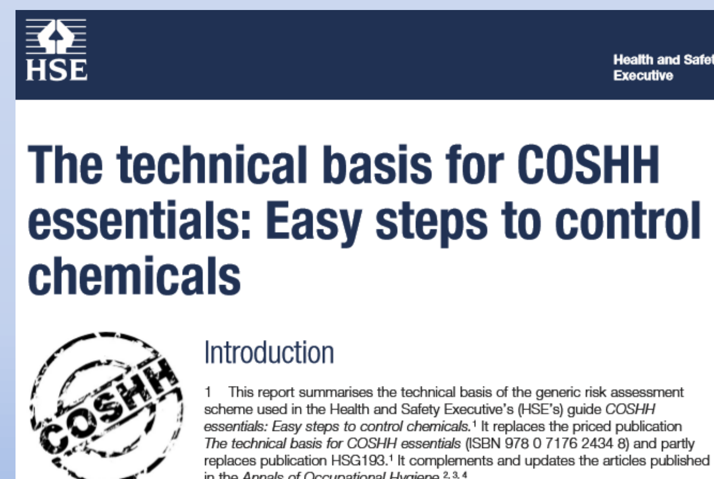
Comparing 3 Hazard Banding Engines



Validation of single HB engines

- COSHH, Annals 2017
- IFA Spaltenmodell, Reg Tox & Pharm 2015

- Both seems robust within their own realm


HSE

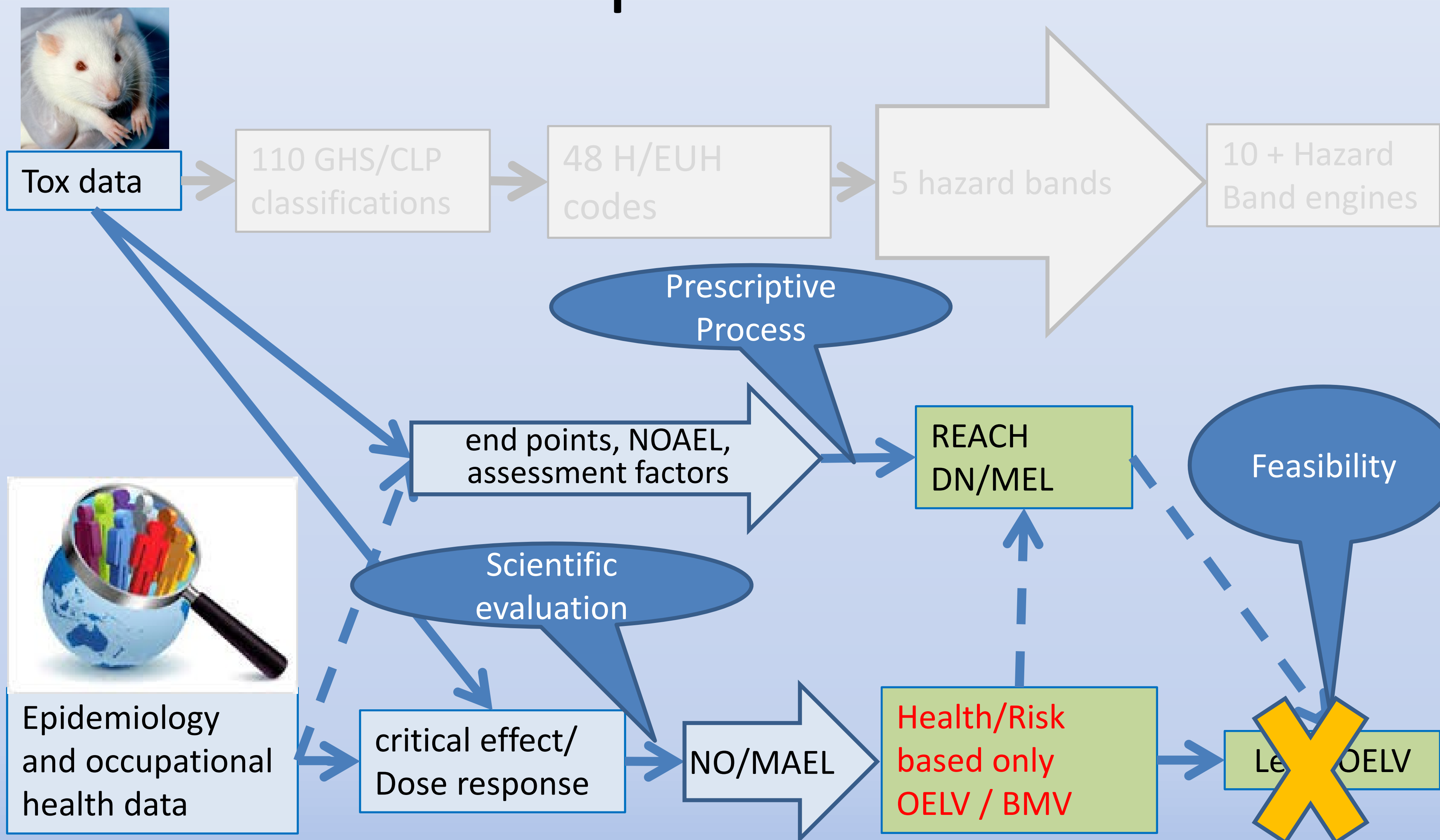
Health and Safety Executive

The technical basis for COSHH essentials: Easy steps to control chemicals

Introduction

1 This report summarises the technical basis of the generic risk assessment scheme used in the Health and Safety Executive's (HSE's) guide *COSHH essentials: Easy steps to control chemicals.*[1] It replaces the priced publication *The technical basis for COSHH essentials* (ISBN 978 0 7176 2434 8) and partly replaces publication HSG193.[1] It complements and updates the articles published in the *Annals of Occupational Hygiene.*[2, 3, 4]

OELV production



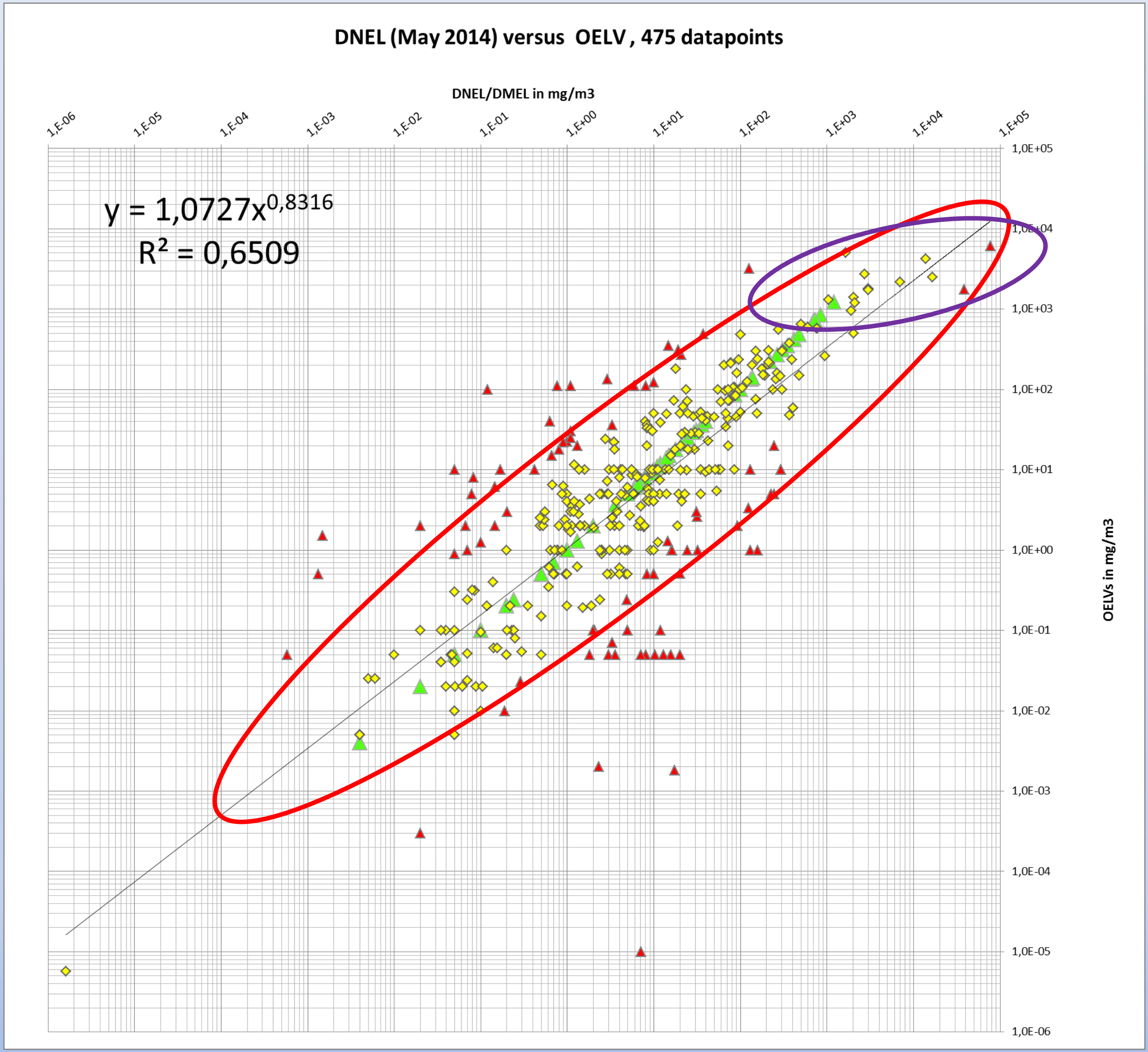
OELV variability (mg/m3)

substance	UK-WEL	ACGIH TLV	DFG	DNEL	OARS WEEL
Maleic anhydride 108-31-6	1	0,01 (S)	0,41	0,19	-
Diisobutylene (DIB) 25167-70-8	-	-	-	**14.7**	344
Cumene 98-82-8	125	246	200	100	-
Ethanol 64-17-5	-	1884	960	950	-

OELV 90%-range: 0.001 through 1000 mg/m3

Red: socio-economic feasibility included

DNEL



OELV

BOHS-exposure-2014-06. Take care of that DNEL Occupational Hygienist!

HB-engines vs OELV

Hazard Banding

Advantages	Disadvantages
Simple procedure	Subjective expert judgement
> 100.000 cas# with H-codes	Limited end points
public available	High between HB variation

OELV

Advantages	Disadvantages
tox & epidemiology	Expensive, time consuming
Reliable safe level, if feasibility is excluded	Rich dataset required

Conclusion and recommendations:

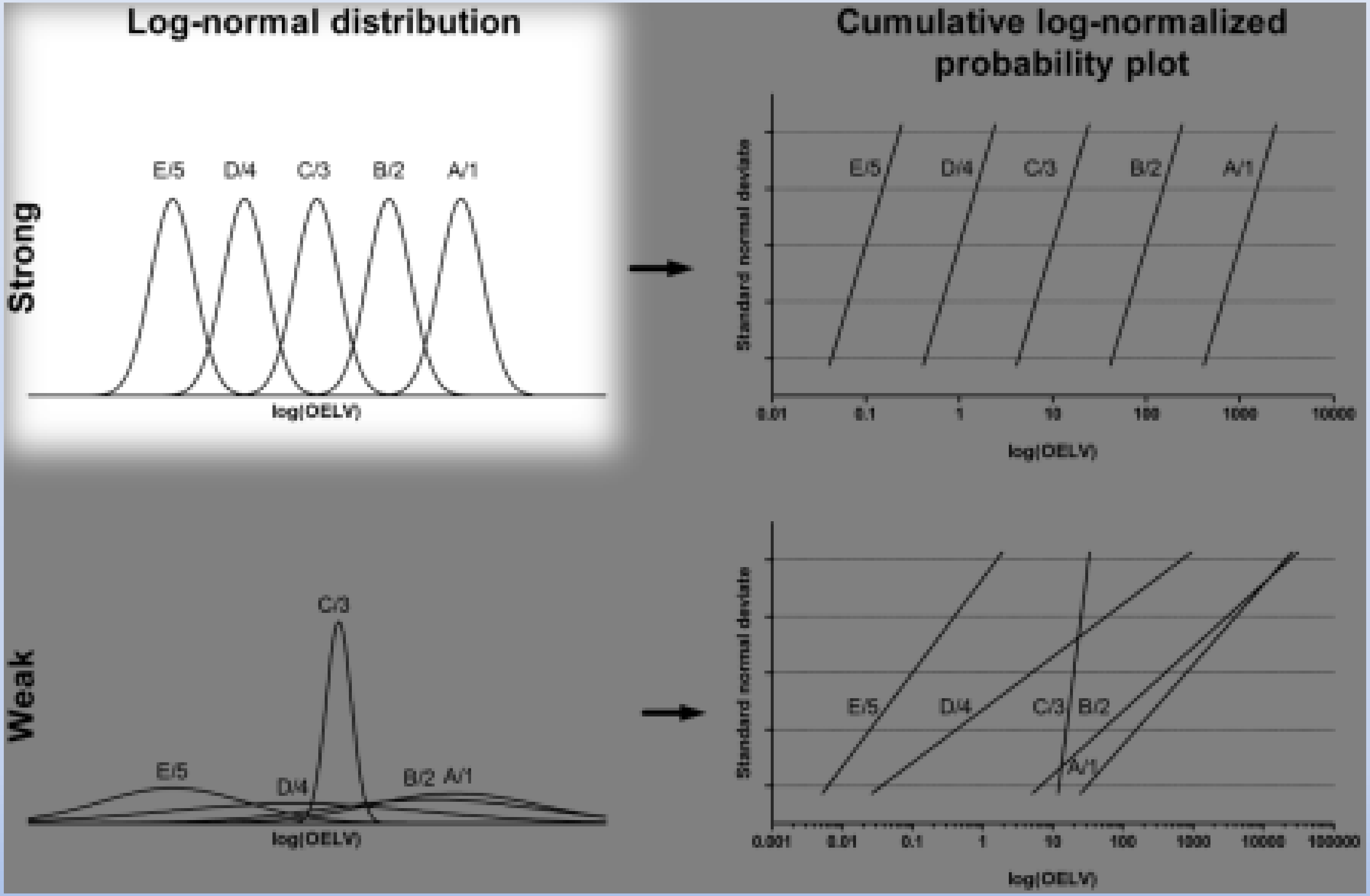
Too many HB engines differ globally too much, therefore:

- Align & improve HB-engines
- Use ‘health-based-only’ OELV as ‘golden’ standard

How to align and improve the HB engines?

Technical
Organization

HB-engine strength to fill the OELV gap



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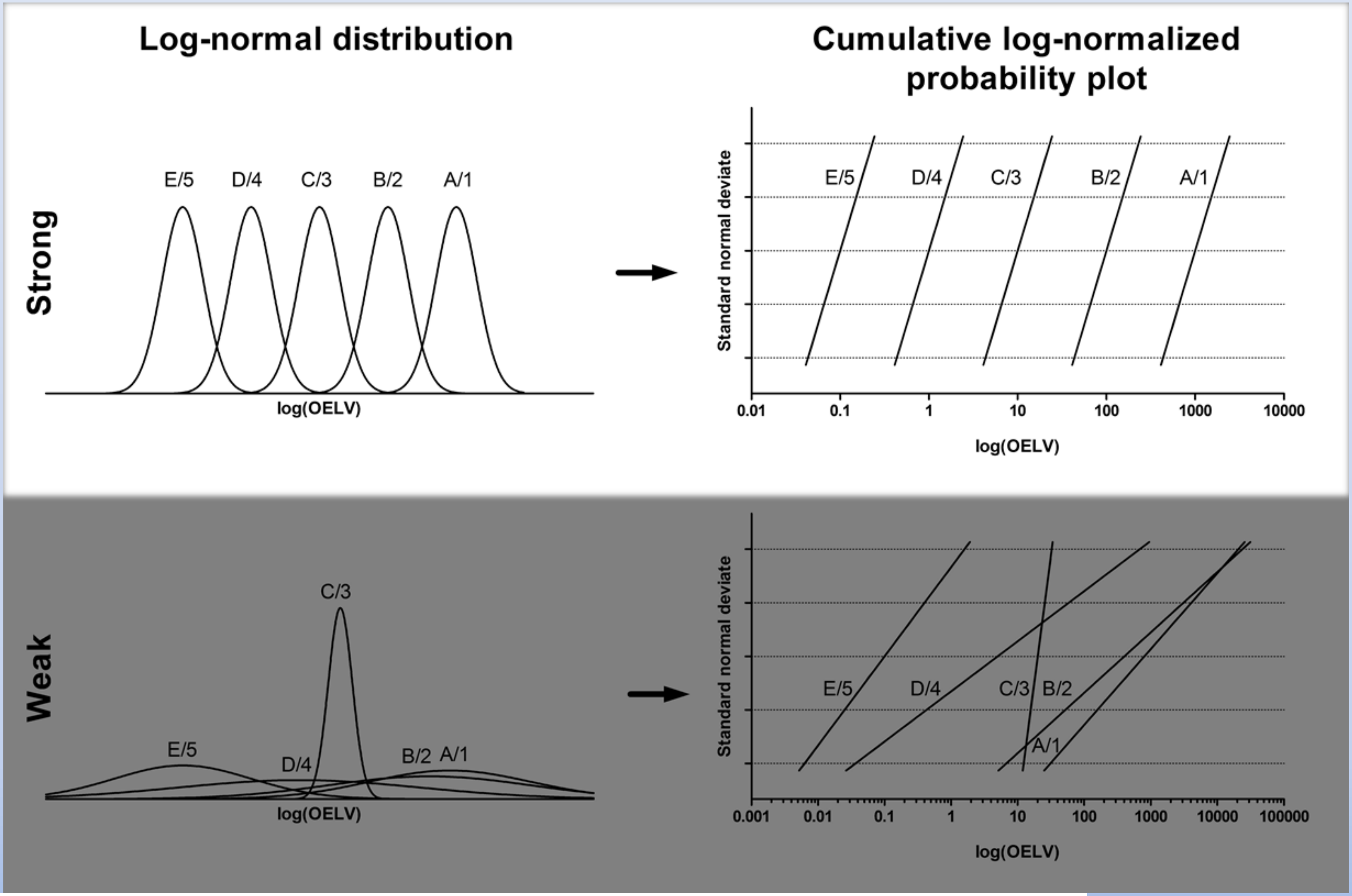
Strong HB-engine strength



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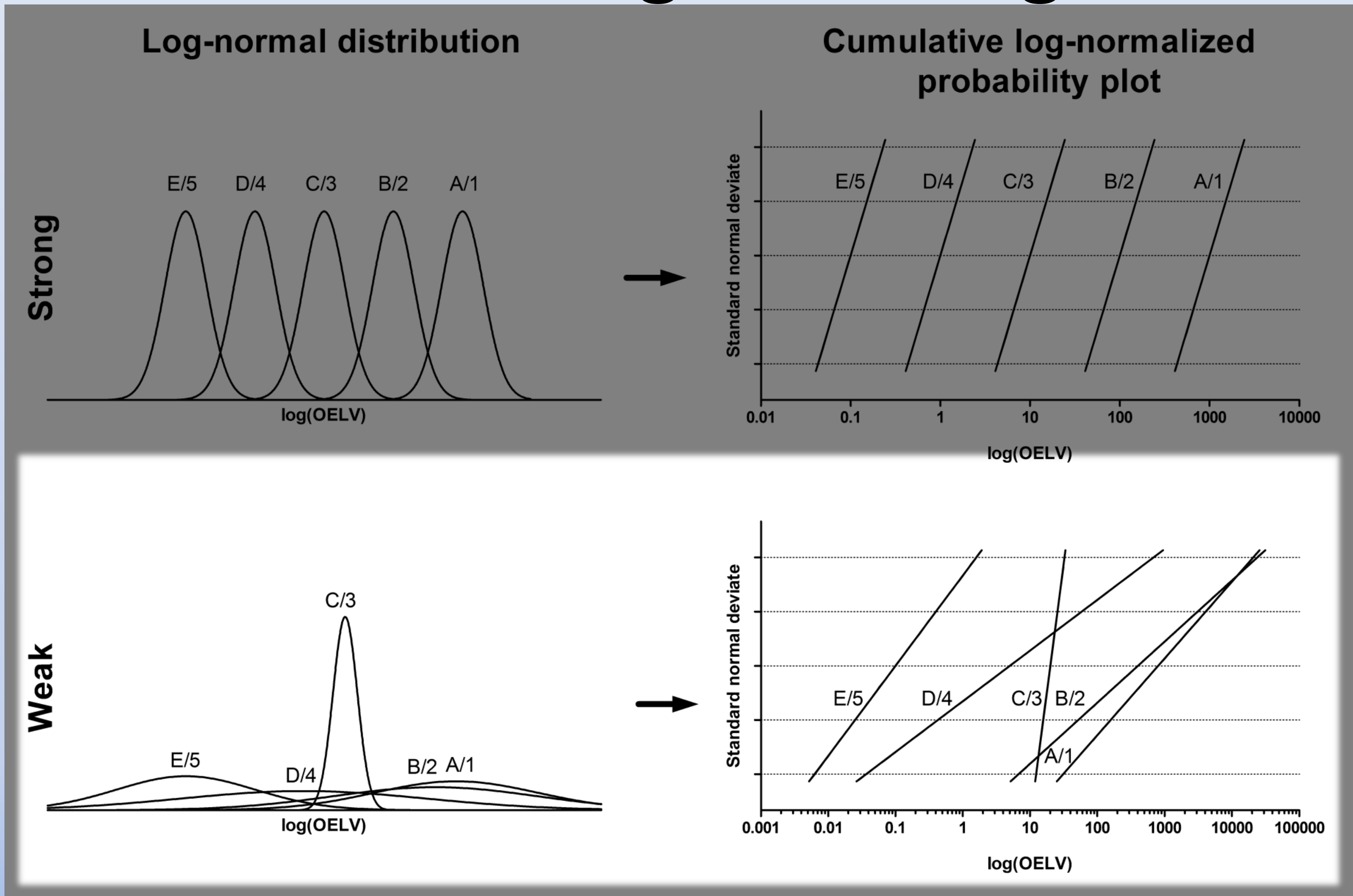
Weak HB-engine strength



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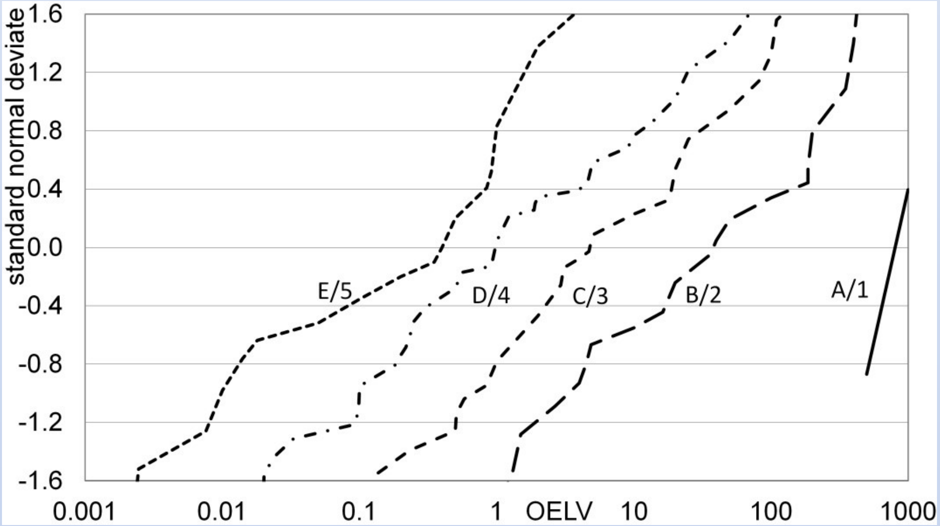
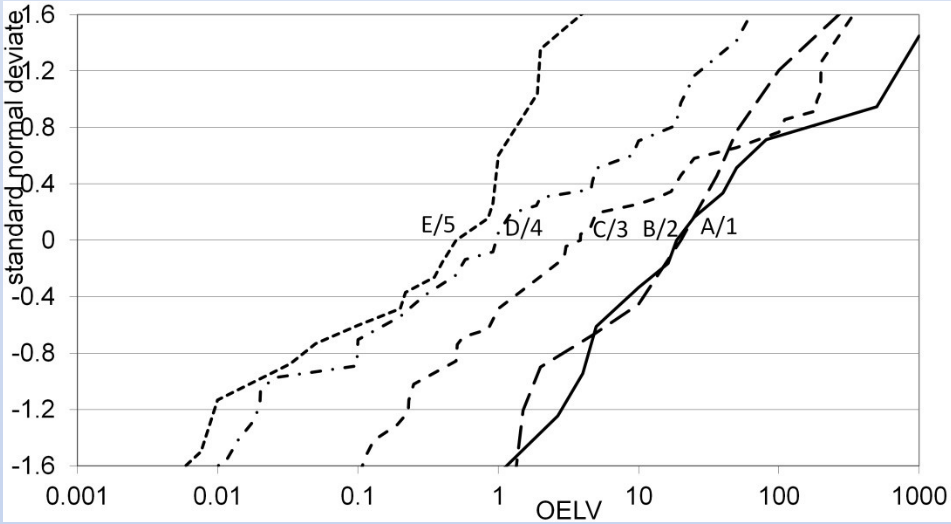
strength of 2 HB-engines (vapour)





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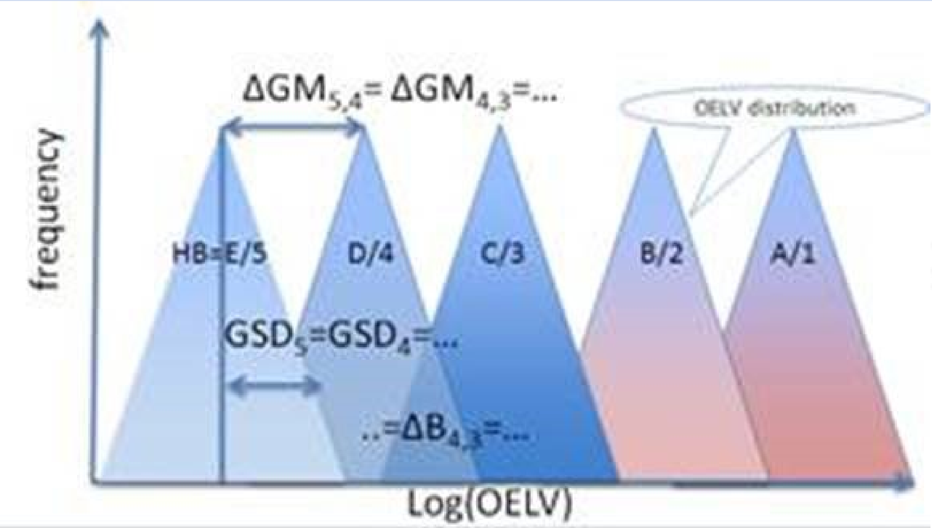
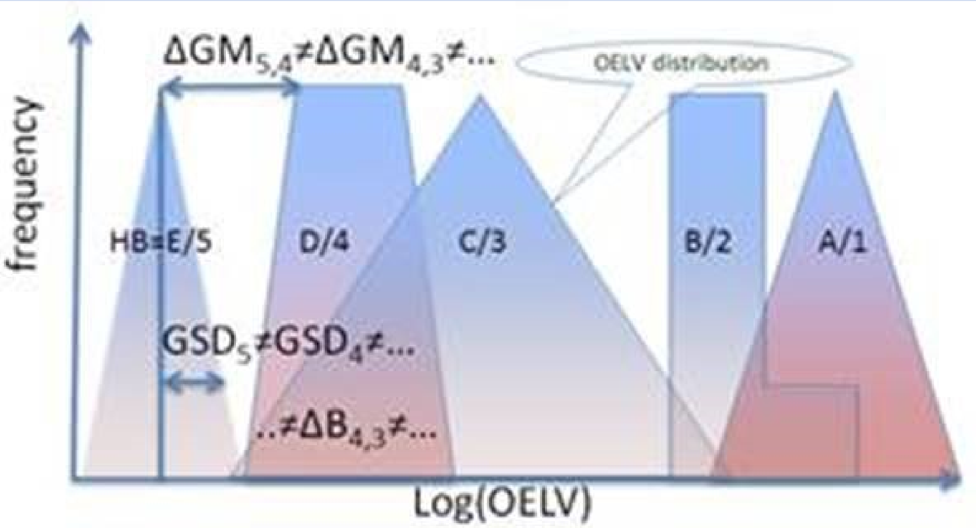
HB Overall Strength Score

- Combines equidistance, equal shape, minimal variance and overlap in one measure





Overall Strength Score=OSS

HB-engines	1) Lognormal shape p(S-W)	2) variability explained by hazard banding	3) Homogeneity of variance	4) Equidistant means	5) pairwise independent log(OELV) means	OSS = sum 1 -> 5
Vapour/gas (n=158)						
S-OEB	3 (0.526)	3 (38%)	2 (0.187)	4 (0.722)	4 (4 out of 4)	16
COSHH	1 (0.040)	1 (25%)	1 (0.043)	2 (0.535)	1 (1 out of 4)	6
EMKG	4 (0.909)	4 (41%)	3 (0.281)	1 (0.055)	2 (2 out of 4)	14
IFA	2 (0.129)	2 (36%)	4 (0.338)	3 (0.701)	3 (3 out of 4)	14
Dust/aerosol (n=71)						
S-OEB	1 (0.003)	4 (50%)	4 (0.793)	2 (0.078)	3 (2 out of 3)	14
COSHH	2 (0.025)	2 (41%)	2 (0.160)	3 (0.174)	1 (1 out of 3)	10
EMKG	3 (0.029)	3 (49%)	1 (0.127)	4 (0.640)	3 (2 out of 3)	14
IFA	4 (0.042)	1 (38%)	3 (0.427)	1 (0.007)	3 (2 out of 3)	12

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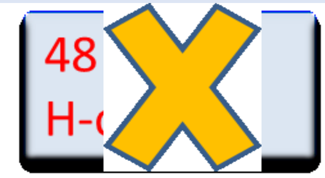
Conclusions

- Current HB engines seem sub-optimal
- A method to objectively align and improve HB-engines exist see doi:10.1093/annhyg/mew050

A global optimized HB engine (1)

HB	IFA	COSHH	EMKG (inhalation)	Global
OSS=	12	10	14	Maximal
E/5	300, 310, 330_(Tox) 340, 350(i) (Car, M) EU032 (Tox gas release)	EU070 (Tox) 340, 341, 350(i) (Car, M) 334 (S)	340, 350(i) (Car,M) 360F (R)	
D/4	301, 311, 331, 370, 372 (Tox) 341, 351, 360xy (Car,M,R) EUH029, EUH031 (Toxic gas release) 317, 334, 318, EUH070 (I,C,S)	300, 310, 330,_372 (Tox) 351, 360xy, 361, 362 (Car,R) EUH070 (I,C)	300, 330, 372 (Tox) 360D (R) EUH032 (Toxic gas release)	
C/3	302, 312, 332, 371, 373 (Tox) 361 f/d, 362 (R) 314 (pH ≥ 11,5, pH ≤ 2), EUH071 (I,C) non-toxic gases which may cause asphyxiation	301, 311, 331, 314, 370, 373 (Tox) 317, 318 , 335, EUH071 (I,C)	301, 331, 314, 370, 371, 341, 351, 361f/d (Car,M,R) 373 (Tox) 334 (S) EUH031 (Toxic gas release)	
B/2	315, 319, 335 (I) 304, EUH066, 336 (solvents)	302, 312, 332, 371 (Tox)	302, 332 (Tox) 318 (C)	
A/1	substances for which experience showed them to be harmless (e.g. water, sugar, paraffin etc.)	303, 313, 333(Tox) 315, 319,316,320(I) 304, 305 (Aspiration hazard) 336 (Tox) , EUH066 (solvent effect) and all H-numbers not otherwise listed	319, 335 (I) 336 (Tox) 304 (Aspiration hazard) non health hazard H-codes	

A global optimized HB engine (2)



Tox data

110 GHS/CLP classifications

Hazard 4/5 Band engine

OSS

Health Hazards

- Acute Toxicity
- Skin Corrosion/Irritation
- Serous Eye Damage/Eye Irritation
- Respiratory or Skin Sensitization
- Germ Cell Mutagenicity
- Carcinogenicity
- Reproductive Toxicology
- Target Organ Systemic Toxicity – Single Exposure
- Target Organ Systemic Toxicity – Repeated Exposure
- Aspiration Toxicity

Table 3.8 Acute Toxicity

Acute toxicity	Cat. 1	Cat. 2	Cat. 3	Cat. 4	Category 5
Oral (mg/kg)	≤ 5	> 5 ≤ 50	> 50 ≤ 300	> 300 ≤ 2000	Criteria: • Anticipated oral LD50 between 2000 and 5000 mg/kg; • Indication of significant effect in humans;* • Any mortality at class 4;* • Significant clinical signs at class 4;* • Indications from other studies.* *If assignment to a more hazardous class is not warranted.
Dermal (mg/kg)	≤ 50	> 50 ≤ 200	> 200 ≤ 1000	> 1000 ≤ 2000	
Gases (ppm)	≤ 100	> 100 ≤ 500	> 500 ≤ 2500	> 2500 ≤ 5000	
Vapors (mg/l)	≤ 0.5	> 0.5 ≤ 2.0	> 2.0 ≤ 10	> 10 ≤ 20	
Dust & mists (mg/l)	≤ 0.05	> 0.05 ≤ 0.5	> 0.5 ≤ 1.0	> 1.0 ≤ 5	

Next steps

- Alignment of OH tools is recognized by IOHA as an important issue
  - Alignment ambassador ?
- Involve WHO/OECD/ILO/NIOSH/ICCA.. ISSA/CEFIC/EU/Bilbao/ECHA/…
- Bring key players/stakeholders together at IOHA 2018
  - Alignment Award ?
- Fund raising to develop a global HB-engine

Thanks!
Questions & suggestions?

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