

New insights on exposure limits – DNELs / DMELs and OELs / BOELVs

ECHA Workshop"Chemicals at the workplace: REACH and OSH in practice"

Helsinki, 3 October 2012

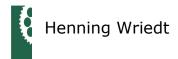
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Overview

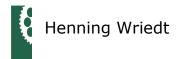
- Objectives
- **Application of exposure limits**
- Exposure limits: types and characteristics
- Conclusions





Objectives

- Exposure limits prescribed by different pieces of legislation (REACH, OSH) and applied for risk assessment at the workplace (i.e. from an OSH point of view):
 - How useful are the existing types of occupational exposure limits (OELs) for employers and workers?
 - Can the usefulness of OELs be improved?
 - If so, how?





Application of exposure limits in the workplace

DNELs / DMELs

indirect application -

by prescribed risk management measures (control measures) which additionally have to rely on

- exposure estimates and
- assumptions on efficacy of RMMs

basic weakness: uncertainties in estimates and assumptions

IOELVs / BOELs

direct application -

as benchmark for assessing

- the efficacy of implemented (self-derived) control measures
- when (if) true exposure has been determined

basic weakness:

direct application reliant on exposure determination





Application of exposure limits in the workplace

DNELs / DMELs

also direct application in the same way as for IOELVs / BOELs for existing uses with already established control measures – as benchmark for assessing

- the efficacy of implemented control measures
- when (if) true exposure has been determined

IOELVs / BOELs

also indirect application in a similar way as for DNELs / DMELs primarily for new uses with control measures to be derived -

as an aid to process design and choice of RMMs

needs both prediction of future exposure and validation of appropriateness of control measures by determination of true exposure





Types and methodologies for their derivation

health-based exposure limits (for substances with effect threshold)

DNELs: REACH guidance

IOELVs: SCOEL methodology

national OELs national methodology

(e.g. German TRGS 901)

risk-based exposure limits (for substances without effect threshold)

DMELs: REACH guidance

national risk-based OELs (Netherlands, Poland, Germany)

national methodology

(e.g. German BekGS 910, Annex 2)

exposure limits for carcinogens and mutagens (cf. slide 13)

BOELs (according to art. 16, Dir. 2004/37/EC)

as yet without defined methodology for

derivation





Health-based exposure limits

Similarities and differences

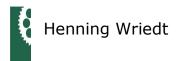
between DNELs and IOELVs/OELs

(focus on DNELs for workers: long-term exposure – systemic effects)

- prescribed methodology for derivation published (cf. previous slide)
- methods structurally similar, yet certain technical differences
 - prescribed assessment factors vs. role of scientific judgement

Caveat (re. national OELs)

national OELs derived under a variety of approaches,
 e.g. in some MS consideration of socio-economic aspects





Health-based exposure limits (cont.)



between DNELs and IOELVs/OELs (1)

sponsors structurally different

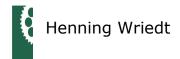
DNELs: company (manufacturer / SIEF)
 IOELVs: state-like body (EU Commission)

deriving bodies ("contractor") structurally different

• DNELs: in-house expertise / commercial contractor

IOELVs: SCOEL (international body of experts;

formalized, recorded meetings, i.e. open to external scrutiny)





Health-based exposure limits (cont.)



between DNELs and IOELVs/OELs (2)

quality control of derivation structurally different

DNELs: selective quality control (small sample) by REACH

evaluation mechanisms

IOELVs: review process (6 months external consultation)

period); plus workability discussion in ACSH/WPC

(in-)transparency on reasoning behind resulting values

DNELs: no publicly available documentation –

results not accessible to **public** scientific criticism

(cf. also different DNELs for the same substance)

IOELVs: scientific documentation publicly available –

results easily accessible to scientific criticism

publicly accessible scientific documentation:

cornerstone for additional layer of quality control





Risk-based exposure limits (primarily for carcinogens)

Risk: statistical probability for an individual of contracting cancer

DMELs: not an element of the legal text of the regulation;

solely recommended in guidance;

reference risk level not pre-determined,

only recommendations given

national risk-based approaches (NL, D)

based on two risk limits with different functions:

upper risk limit: 4: 1,000

lower risk limit: 4: 100,000

(accumulated risk for working life of 40 years)

- basis for two substance-specific concentration values
- no EU-OSH equivalent in Carcinogens and Mutagens Directive (CMD – 2004/37/EC)





Risk-based exposure limits (cont.)

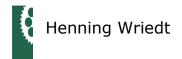


- transparency on correlation between limit values and risk
 - DMELs: correlation unknown, unless reference risk is communicated

(are there any examples yet of the reference risk being communicated together with the DMEL in the eSDS?)

<u>note</u>: DMEL without information on level of reference risk completely useless for OSH purposes

 concentration values (NL, D): correlation transparent





Risk-based exposure limits (cont.)



function of limit values

• DMELs: **conventional limit values** which have to be

achieved; no mechanisms for transition from

current exposure level foreseen

• NL: **conventional limit values** (in the range

between upper and lower risk limit); derived

according to **technical feasibility**; successive

lowering until lower risk limit is reached

• D: **not conventional limit values**;

upper concentration values: de facto starting points for minimization; minimization obligation

limited by lower concentration values,

further minimization voluntary





Exposure limits for carcinogens and mutagens



nature of BOELs

- legal text: "including scientific and technical data"
- "technical data": to be interpreted as "what is technically feasible"?
- caution (1): "technical feasibility" is determined not primarily by

the substance, but rather by the industry it is applied

in or the process it is used for

→ for same substance a number of different BOELs might be applicable

inight be applicable

caution (2): "technical feasibility" is strongly influenced by level of

enforcement

observation: currently no consensus on nature of BOELs

across Europe





Exposure limits for carcinogens and mutagens (cont.)



- state of BOELs
 - to date, BOELs for 3 substances available (derived 20 years ago)
 - currently, 25 BOELs under discussion (revision of 2 existing BOELs, proposals for 23 additional substances)



Exposure limits for carcinogens and mutagens (cont.)



methodology for derivation of BOELs

- no pre-determined methodology existing;
 dissenting views on methodology to apply
- ad-hoc solution (?): use of diverse methodologies
 - o feasibility (state of technology)
 - cost-benefit-analysis (collective risk considerations)
 - o individual risk (cf. NL / D approaches)
- underlying question:
 is any of these methods compatible with non-negotiable rights in
 the EU Charta of Fundamental Rights, in particular art. 1 3:
 - o human dignity
 - o right to life
 - o right to the integrity of the person
- serious doubts that CBA as a method based on collective risk considerations might conform to these Fundamental Rights





Exposure limits for carcinogens and mutagens (cont.)



Structural incompatibility between BOELs and DMELs

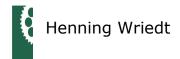
exposure minimization

BOELs: exposure minimization obligatory below BOEL

DMELs: exposure minimization not required below DMEL

(or, rather, no further improvements on

recommended RMMs required)





Conclusions

Regulatory improvements re. DNELs and IOELVs



- DNELs
 - underlying critical health effects should be made transparent;
 - derivation of values should be made accessible to public scrutiny
- IOELVs

no improvements identified

Further relevant issues re. DNELs and IOELVs – only mentioned as a reminder

Consistency between OELs

- between DNELs and IOELV for the same substance
- between DNELs for substances from the same substance class

Resources for derivation of exposure limits

will be an issue for IOELVs if larger number of IOELVs is required





Conclusions

Regulatory improvements re. exposure limits for carcinogens



Might a long-term convergence of the REACH and OSH worlds be a possible way forward?

OSH world:

- agree on methodology for risk-based BOELs including substance-independent reference risk, preferably at a level comparable with the NL / D upper risk limit
- maintain minimization obligation below BOEL; limit minimization obligation by DMEL

REACH world:

- find political agreement on pre-determined substanceindependent reference risk for DMEL, preferably at a level comparable with the NL / D lower risk limit
- introduce mechanisms for manageable transition from current exposure levels to DMEL levels (for carcinogens not included yet in Annex XIV [substances subject to authorisation])



More detailed information



... on DMELs can be found in the following article by Joe Püringer from Austria:



http://www.auva.at/mediaDB/884917 DMELs Shortcomings one year after.pdf

