

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

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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



Exposure limits: types and characteristics

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



Exposure limits: types and characteristics

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



Exposure limits: types and characteristics

Health-based exposure limits (cont.)

■ Similarities and differences 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)



Exposure limits: types and characteristics

Health-based exposure limits (cont.)

■ Similarities and differences 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**



Exposure limits: types and characteristics

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)



Exposure limits: types and characteristics

Risk-based exposure limits (cont.)

Differences between DMELs and national approaches (1)

- 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?)
note: DMEL without information on level of reference risk
completely useless for OSH purposes
 - concentration values (NL, D):
correlation **transparent**



Exposure limits: types and characteristics

Risk-based exposure limits (cont.)

Differences between DMELs and national approaches (2)

■ 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: types and characteristics

Exposure limits for carcinogens and mutagens

■ **Binding OELs** (BOELs) according to art. 16, CMD; listed in Annex III:
“on the basis of the available information, **including scientific and technical data**”

■ **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
- caution (2): “technical feasibility” is strongly influenced by level of enforcement

observation: **currently no consensus on nature of BOELs across Europe**



Exposure limits: types and characteristics

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: types and characteristics

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
 - feasibility (state of technology)
 - cost-benefit-analysis (collective risk considerations)
 - individual risk (cf. NL / D approaches)
 - underlying question:
is any of these methods compatible with non-negotiable rights in the EU **Charter of Fundamental Rights**, in particular art. 1 – 3:
 - human dignity
 - right to life
 - 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: types and characteristics

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

■ Transparency on scientific reasoning behind published values

■ 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 substance-independent 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:

**Derived Minimal Effect Levels (DMELs): Shortcomings one
year after the REACH registration deadline**

http://www.auva.at/mediaDB/884917_DMELs_Shortcomings_one_year_after.pdf

