Minimizing Exposure to Carcinogens: Risk Limits and their Interplay with Risk Reduction Measures

Workshop
DMEL and risks in occupational exposure to carcinogenic compounds: The way forward
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Overview

- Aims of the German approach
- Background to the risk limits chosen
- Interplay between risk limits and set of control measures
- Deriving risk-based concentration values for specific carcinogens: initial experience
- Conclusions (in view of REACH)

Aims of the German approach

Reminder: **Scope**

- solely workers' health – **not** general population / consumers' health

Starting point

- replacement of carcinogen preferable
  (Dir. 2004/37/EC, Art. 4 (1))

Minimization of exposure

- where the replacement of a carcinogen is not technically possible, and where it cannot be manufactured and used in a closed system, the employer shall ensure that the level of exposure is reduced to as low a level as is technically possible
  (Dir. 2004/37/EC, Art. 5 (1) – (3))

Aims of the German approach

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Aim: to make the minimization obligation workable

- previous approach based on TRK values (technical values) resulted mainly in limiting exposure (i.e. by putting a lid on it), but rarely in a minimization beyond the TRK value
- reminder: other shortcomings of the TRK approach
  - it does not reflect differences in technical possibilities between different task or processes for the same carcinogen
  - it leads to wide differences for resulting risks (at respective TRK level) for different carcinogens – yet to identical legal consequences!

Aim: to provide general support for minimization efforts

Aim: to prioritize the minimization of high risks

Basic elements of the German approach

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- **introduction of three bands for both risks and control measures** (in comparison to two bands under the old system)
- **definition of a substance-independent set of control measures for minimizing exposure; each individual type of measure graded according to the three risk bands**
- **quantified risks as fundamental control parameters within the concept**
- **derivation of two substance-independent risk limits** ("acceptable risk" and "tolerable risk") **as basis for two substance-specific concentration values per carcinogen** ("acceptable concentration" and "tolerable concentration")

Basic elements of the German approach

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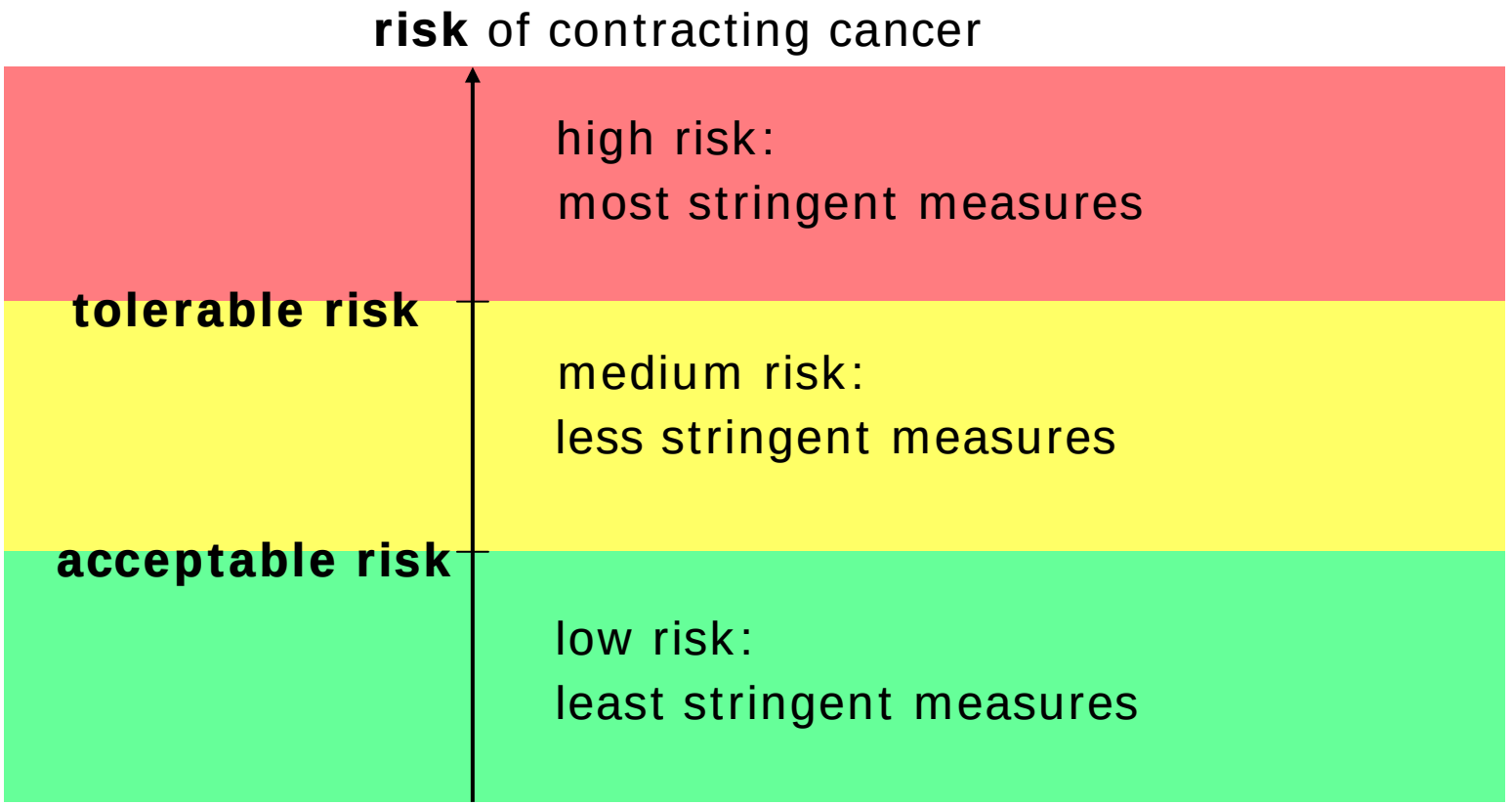
three bands (risks / control measures) – schematic view



Background to the risk limits chosen

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"risk" – short for: **additional risk** (precisely: additional probability) **of contracting cancer induced by exposure at the workplace**

- adverse health effects other than cancer not included
- focus on cancer incidence: morbidity, not mortality
- type or site of cancer not considered (i.e. neither possibilities of treatment, nor survival times, etc.)

Framing conditions for calculation of risks

- assumption of continuous exposure during whole working-life:
  - 8 hours/day, 240 days/year, 40 years

Background to the risk limits chosen

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Deliberations on numerical values of risk limits (1)

Upper risk limit

- comparison to other occupational health risks of similar severity
  - **probability of fatal work accident** (generally acknowledged aim: further reduction of accidents) **2 : 1,000** (average lifetime value for Germany – for further details see presentation by Prof. Bender)
- comparison to cancer-incidence in unexposed population (i.e. non-smokers, no occupational exposure)
  - **"background" lung-cancer risk for males:** about 0.4 % (rationale: occupational compensation is to set in when total risk is doubled (i.e. occupational risk higher than background risk) – upper risk limit should not exceed that limit)
- for other risk comparisons see presentation by Prof. Bender and section 3 in Annex 1 of "Announcement 910"

Background to the risk limits chosen

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Deliberations on numerical values of risk limits (2)

Lower risk limit

- consensus: no separate risk limit for work environment – instead use of identical target risk as applied for general population for “general” environment
- reason: ethical grounds – no valid arguments found for justification that workers should be submitted to a higher target risk than population in general

Gap-width between the two risk limits

- size of gap should extend over 1.5 to 2 orders of magnitude (i.e. factor 30 (logarithmic) / 50 (linear) to 100)
  - not too small to cope with the foreseeable uncertainties in the exposure-risk-relations
  - not too wide to justify the same control measures for the whole medium risk band

Interplay between risk limits and set of control measures

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Defining the consequences of the risk limits

No consensus on numerical values of risk limits without clarity on consequences

- agreement on control measures precondition for agreement on risk limits

Consensus on scope of measures and on their grading

- 19 individual types of control measures, graded into 3 steps
- sorted into five groups of measures
  (administrative, technical, organisational, medical, substitution)

Interplay between risk limits and set of control measures

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Control measures – three examples

Action plan

- requested for high and medium risks
- description of planned concrete measures for further exposure reduction:
  when, how, amount of expected reduction
- modelled after Dutch example

Minimization of exposure

- obligatory for high and medium risks
- optional for low risks (to be agreed at company level)

Use of respiratory protective equipment

- obligatory for high risks
- optional for medium risks; employer must always provide RPE
- not necessary for low risks

Interplay between risk limits and set of control measures

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Control measures – brief overview (1)

Obligations for exposure above "tolerable concentration"

- lowering of actual exposure below "tolerable concentration" within three years
- deriving an action plan
- informing of enforcement agency;
  yet no permission needed within those three years

plus

- list of additional control measures (not specified here)

Obligations for exposure below "acceptable concentration"

- (basic) occupational hygiene
- list of additional control measures (see next slide)
- further minimization of exposure not obligatory but desirable, to be achieved through agreements at company level

Control measures – brief overview (2)

Compilation of obligations for actual exposure below “acceptable concentration” / low risk	
(Basic) occupational hygiene	Yes
Minimization of number of exposed	Avoidance of unnecessary exposure of bystanders
Transparency of risk	Yes
Communication of risk	Yes
Written and oral instructions, training	Yes
Spatial separation	If possible, within reason
Minimization of amount of substance used	Yes
Technical control measures	No additional control measures demanded, but no reduction of control measures already implemented
Minimization of exposure	To be agreed at company level
Medical and toxicological advice	Yes
Entitlement to medical surveillance	Yes
(Repetition of) feasibility check on substitution	Reduced obligations on documentation
Substitution (substance and process), product type with lower exposure potential	If possible, within reason

Interplay between risk limits and set of control measures

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Numerical values of risk limits

- **Agreement on set of control measures foundation for consensus on numerical values of risk limits**

- **Resulting numerical risk values**
  - **upper risk-based limit** (“tolerable risk”)
    - **4 : 1,000**
  - **lower risk-based limit** (“acceptable risk”)
    - **4 : 100,000** (starting 2018 at the latest)
    - **4 : 10,000** (for a transitional period of at least until 2013, at most until 2018)

Interplay between risk limits and set of control measures

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Function of risk limits

Within the approach, the two risk limits have different functions regarding the minimization obligation

upper risk-based limit

- de facto starting point for risk reduction (higher risks avoided by obligatory use of RPE)
- de facto lifetime risk will be lower than 4 : 1,000 due to obligatory minimization

lower risk-based limit

- de facto target risk for risk reduction
- de facto lifetime risk will be higher than 4 : 100,000 for several reasons (higher initial risk, pace of minimization, optional minimization below 1 : 100,000)

Deriving risk-based concentration values for specific carcinogens: Initial experience

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Application of concept on individual carcinogens necessitates derivation of two concentration values per carcinogen

- tool: specifically developed general concept for the derivation of **exposure-risk-relations** (ERRs)
  - published as Annex 2 of "Announcement 910" – see: **http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/Announcement-910.html**
- current work programme: derivation of ERRs for 30+ carcinogens
  - 10 ERRs already published (in section 3 of the German version of "Announcement 910")

Deriving risk-based concentration values for specific carcinogens: Initial experience

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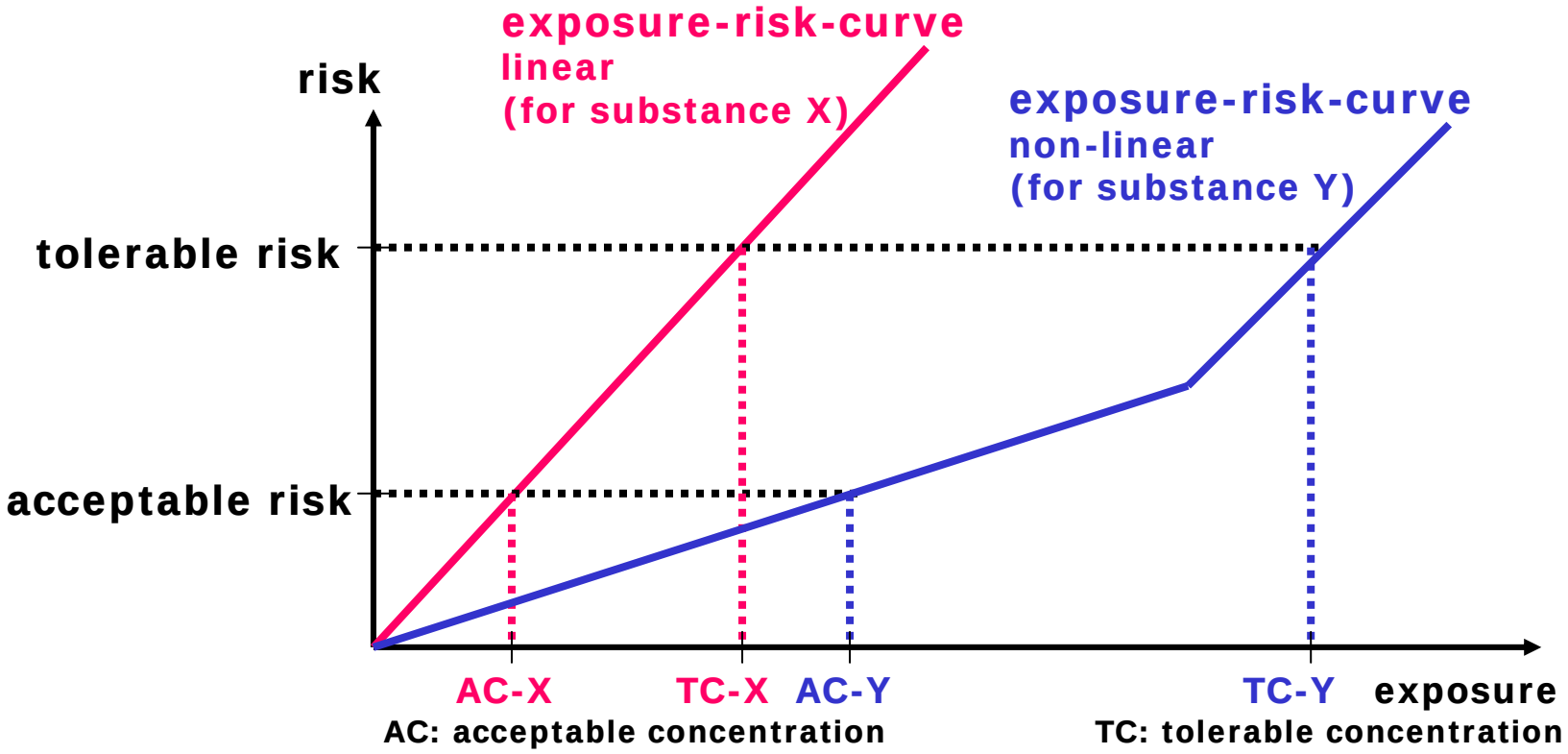
Exposure-risk-relations – schematic view (for substances X and Y)



Deriving risk-based concentration values for specific carcinogens: Initial experience

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Carcinogens (to be) covered by the approach

- **Acrylamide**
- **Acrylonitrile**
- **Aluminiumsilicate fibres (ceramic fibres)**
- **Asbestos**
- **Benzo(a)pyrene**
- **1,3-Butadiene**
- **Ethylene oxide**
- **4,4‘-Methylenedianiline**
- **Nitrosamines**
- **Trichloroethene**

- **Arsenic**
- **Benzene**
- **Beryllium**
- **Lead** (possibly OEL)
- **Cadmium**
- **Chromium (VI)**
- **Cobalt**
- **Diesel motor emissions**
- **Nickel**
- **Quartz** (possibly OEL)
- **Antimony trioxide**
- **Bitumen**
- **Epichlorohydrine**
- **Ethylene imine**
- **Hydrazine**

Deriving risk-based concentration values for specific carcinogens: Initial experience

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Clarifications needed for substance-specific issues

- approach for assessment of simultaneous exposure to several carcinogens **to be developed**
- approach for non-malignant toxic effects below the "tolerable concentration" with regard to the malignant effect
- approach for considering the previously described state of technology (i.e. the former technical-based limit values)
- approach for peak exposures and for dose considerations (in particular in cases of occasional exposure) **to be developed**
- approach for background exposure to a carcinogen above the "acceptable concentration"
- approach for limit of detection above the "acceptable concentration"

Deriving risk-based concentration values for specific carcinogens: Initial experience

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Potential critical parameters to be envisaged for some carcinogens

- background exposure
- measurability (limit of detection)
  - actual “state of technology” for measurement and analytics might define the current limit of minimization

Suggestion: these observations should also be taken into account when discussing DMELs

Conclusions (in view of REACH)

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Possible practical limitations

- don't underestimate "practical" limitations, in particular measurability

Common ground between the German approach and the DMEL approach

- both concepts employ the notion of an "acceptable risk limit"

Differences between the two approaches

- German approach prescribes a minimization concept, i.e. the transition from currently high exposures / risks to future low exposures / risks, considered by social partners as being "acceptable"
- DMEL approach defines an acceptable risk level without indicating how to achieve low risks in a real world of high risks, that is how to manage the transition from currently occurring risk levels