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Session 1C: Cancer prevention: action plans and campaigns to prevent occupational cancer

The German exposure risk management model

Workshop on Carcinogens and Work-related Cancer

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Content of working group "Cancer prevention"

Four complementary modes:

- **regulation** — this presentation
- **enforcement** — presentation 4
- **campaigns** — presentation 2
- **tools** — presentation 1

Regulatory context

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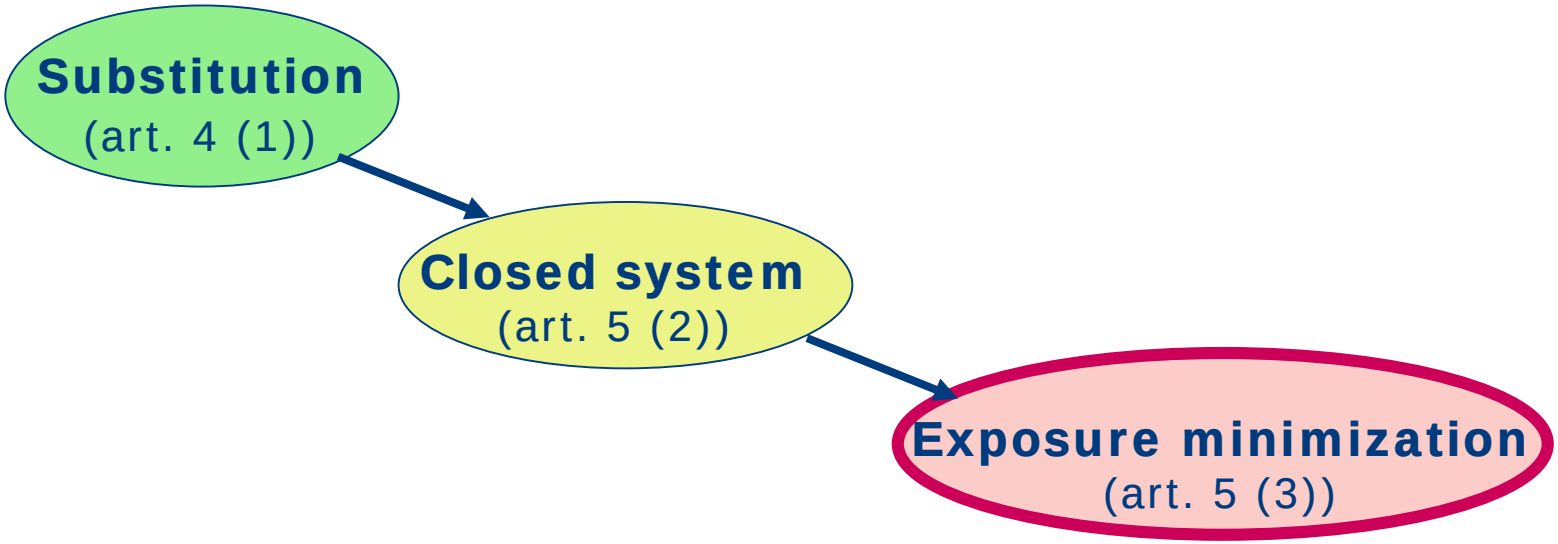
Obligations of the CMD



Substitution is the preferred approach but …

Regulatory context

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Substitution is the preferred approach **but ...**

... it has to be **complemented by a**

strategy on exposure minimization

for tasks with, and uses of, carcinogens during the period in which substitution is not yet feasible.

What might be an effective strategy?

➔ **addressed in this presentation**

Overview

- Rationale and objectives
- The approach in a nutshell
- From concept to application
- Advantages and outlook

Rationale and objectives

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Exposure minimization is not a new obligation – so why introduce a new concept?

- minimization of carcinogens with the former TRK concept did not work in practice: overall cap – yes
  further reduction below the TRK value – no
- minimization progress at workplaces is difficult to verify
- technical-based OELs do not reflect differences in technical possibilities between different tasks or processes for the same carcinogen

Objectives

- **verifiable implementation of minimization requirement**
  (if substitution is not or not yet possible)
- **assistance in carrying out minimization**
- **priority for minimization of high risks**

The approach in a nutshell

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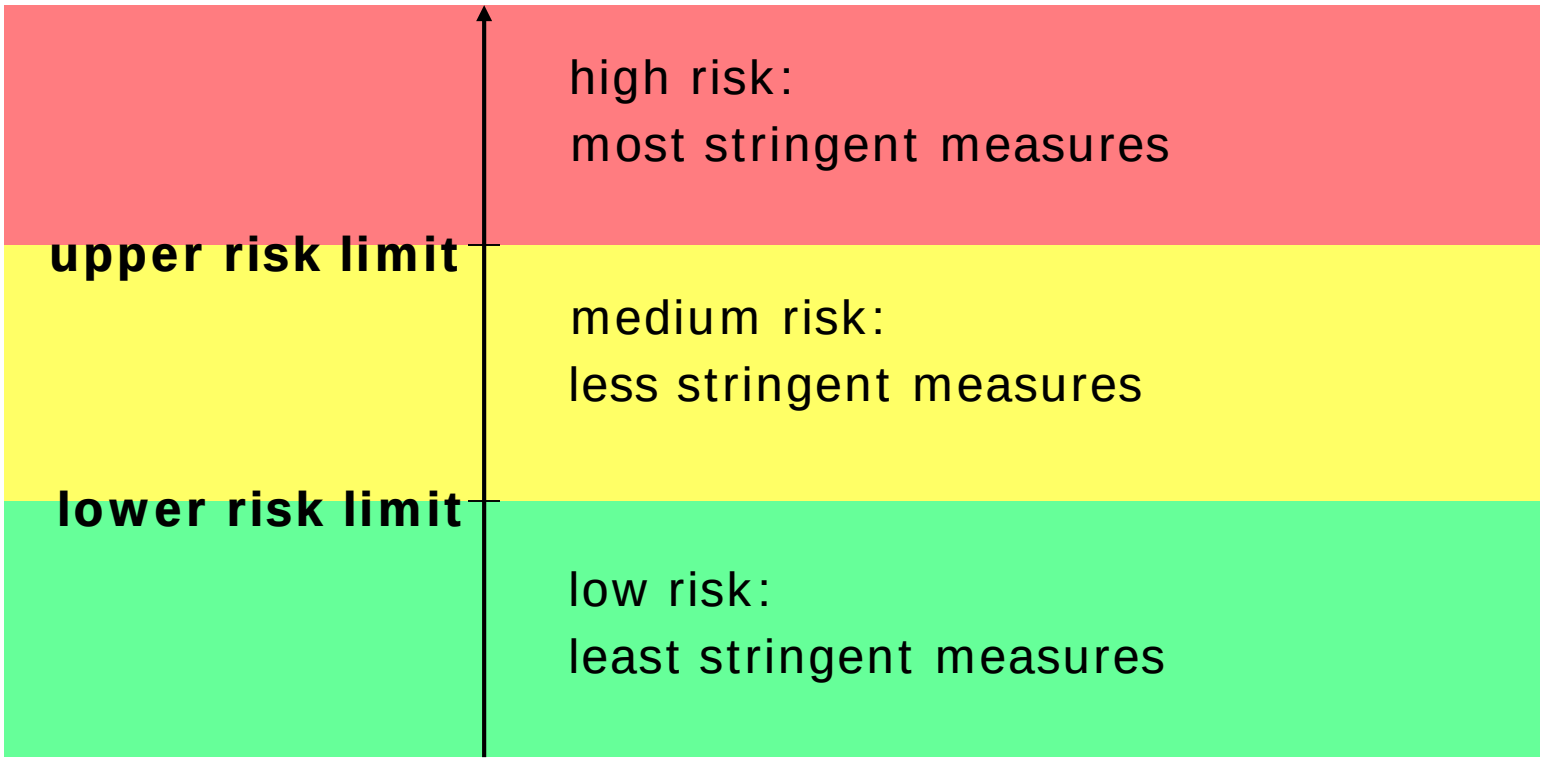
Structure and basic elements

- **three bands for both risks and control measures**
  (in comparison to two bands in the former TRK concept)
- **substance-independent tiered control scheme to minimize exposure** (19 individual control measures), each one graded according to the three risk bands
- **quantified individual risk**
  two substance-independent risk limits:
  lower limit ("acceptable risk")
  and **upper limit** ("tolerable risk")
- for each carcinogen **derivation of two substance-specific concentration values** based on those two risk limits ("acceptable concentration" and "tolerable concentration")

The approach in a nutshell

three bands (risks / control measures) **– schematic view**



The approach in a nutshell

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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 4 : 100,000)**

The approach in a nutshell

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Grading of control measures – three examples

Action plan

- mandatory 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

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

Use of respiratory protective equipment

- mandatory for high risks
- optional for medium risks: employer must always provide RPE, worker may decide whether to use it or not
- not required for low risks

The approach in a nutshell

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Control measures – brief overview

Obligations if exposure above upper risk limit

- lowering of actual exposure below upper risk limit ("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 if exposure below lower risk limit

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

From concept to application

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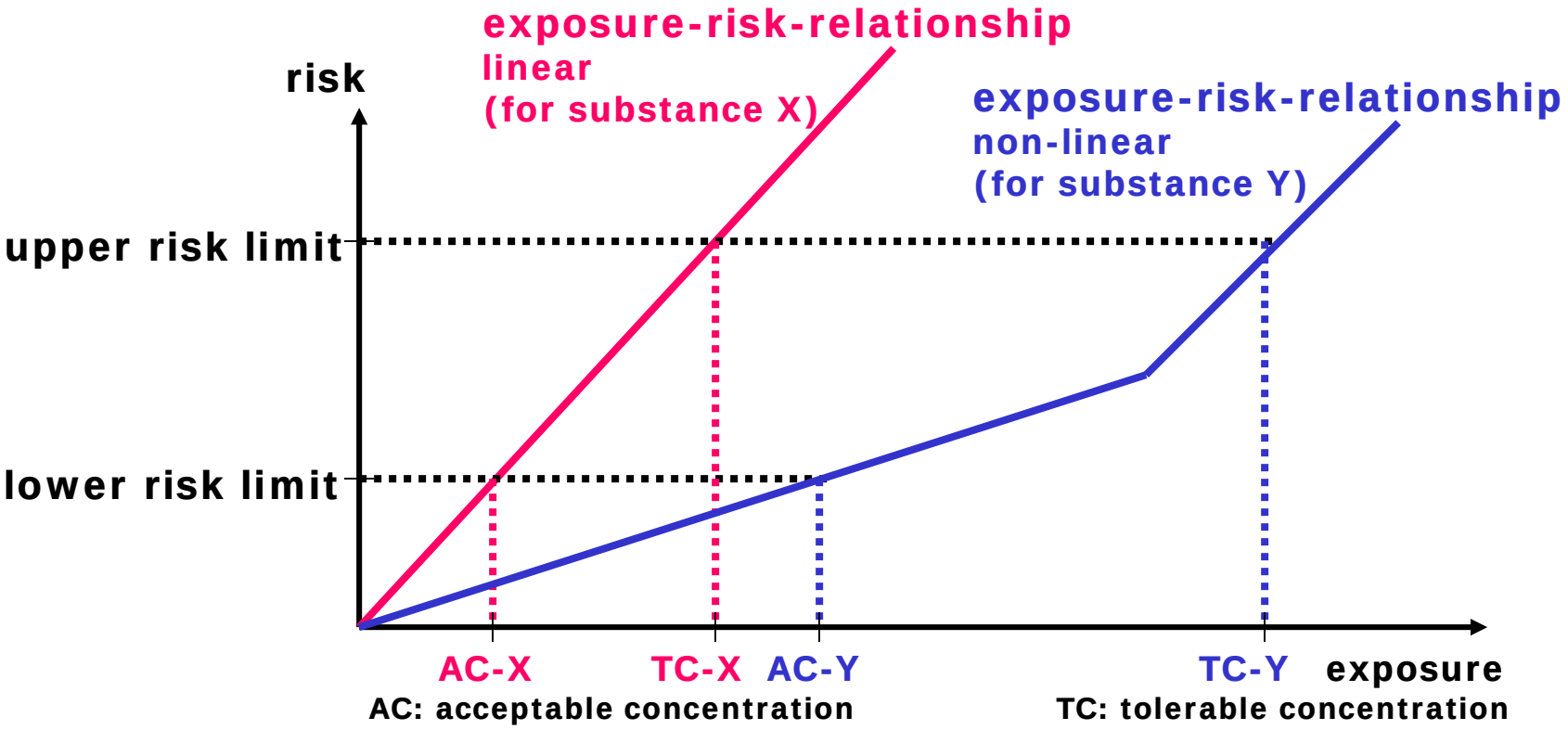
- **Derivation of two concentration values per carcinogen**
  - **risk limits:** preset and identical for all carcinogens
  - **for each substance its specific exposure-risk-relationship (ERR) has to be determined**
  - **from the ERR both the substance-specific acceptable concentration and the tolerable concentration are derived**
- **Consideration of additional factors**
  (cf. presentation Herbert Bender)
- **Implementation support for enterprises**

From concept to application

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



From concept to application

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Carcinogens (soon to be) covered by the German approach

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

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

From concept to application

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Implementation support for enterprises

Technical Rules for carcinogens in widespread use, or when the tolerable concentration is technically not feasible for certain relevant uses

- adaptation of already existing Technical Rules or drafting of new ones
  (e.g. Asbestos, Benzo(a)pyrene, Ceramic fibres, Diesel motor emissions, N-Nitrosamines, Welding of stainless steel)
  - **adaptation of control measures to the tiered control scheme**
  - **integration of "acceptable" and "tolerable" concentration**
  - **if necessary, "phasing-in" of challengingly low tolerable concentrations including socio-economic considerations**

List of "Frequently asked questions"

- list of 25 explanatory FAQs **published early this year**

Advantages and outlook

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Immediate progress (1)

- higher level of protection for selected carcinogens:

carcinogen	former TRK [µg/m³]	tolerable concentration [µg/m³]
acrylonitrile	7,000	2,600
benzene	3,200 (1 ppm)	1,900 (0.6 ppm)
benzo(a)pyrene	2 / 5	0.7
1,3-butadiene	11,000 / 34,000	5,000
refractory ceramic fibres	250,000 f/m³	100,000 f/m³
naphthalene	10 ppm	0,1 ppm (AGW)
N-nitrosamines	1 / 2.5	0.7
trichloroethylene	50 ppm	11 ppm
vinyl-2-pyrrolidone	500	50 (AGW)

AGW: health-based OEL

Advantages and outlook

Immediate progress (2)

- focus on minimization of high-risk carcinogens:

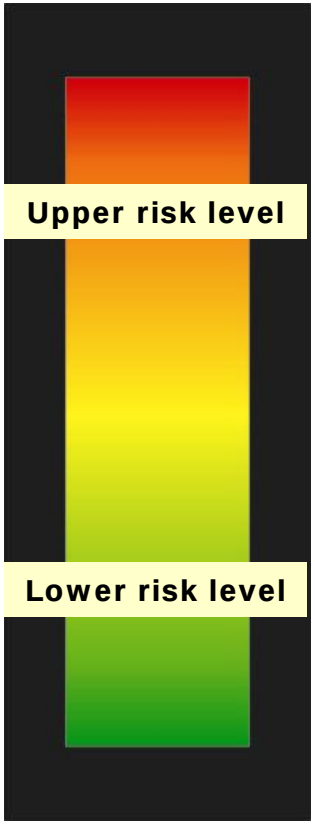
carcinogen	former TRK [µg/m³]	tolerable concentration [µg/m³]
antimony trioxide	100 / 300	*< 10 (?) (AGW)*
arsenic	100	8
cadmium	15 / 30	1.6 (respirable fraction)
chromium VI	50 / 100	*< 10 (?)*
cobalt	100 / 500	*< 10 (?)*
hydrazine	130	22
nickel compounds	500	*< 5 (?)* (respirable fraction)

AGW: health-based OEL

Advantages and outlook

Advantages of the approach

- limitation of individual cancer risk
- thresholds for other detrimental health effects are also covered
- focus on minimization of high risks: the higher the risk, the more urgent further exposure reduction
- identification of uses with particularly high risks
- guidance on selection and application of control measures provided, in particular on the use of respiratory protective equipment



Advantages and outlook

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Implementation of the general approach

- early 2011: start of official test phase
- mid-2015: formal legal inclusion in Ordinance on Hazardous Substances foreseen

Enlarging the scope

- inclusion of additional carcinogens by deriving their ERRs

ERRs currently foreseen for 35 carcinogens in total

Provision of detailed guidance on consideration of substance-specific factors in risk assessment

- under development; publication foreseen for mid-2013

More detailed information

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… in English can be found as:

Announcement on Hazardous Substances 910, the official text describing the new approach:
http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/Announcement-910.html