A New Regulatory Approach to Prevention of Occupational Cancers:
Boosting Exposure Minimization

EWHN Seminar on Prevention of Occupational Cancers

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Henning Wriedt
Beratungs- und Informationsstelle Arbeit & Gesundheit
Hamburg, Germany
wriedt@arbeitundgesundheit.de

Overview

- Rationale and objectives
- Structure and basic elements
- Interplay between risk limits and set of control measures
- From concept to application
- Developments (and expectations)

Rationale and objectives

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Starting point

- replacement (substitution) of a 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))

This 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 difficult to verify
- minimization "to zero" impossible in reality

Rationale and objectives

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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**

Structure and basic elements

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- **introduction of 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: grading of the individual measures according to the three risk bands**
- **quantified risks two substance-independent risk limits: "acceptable risk" and "tolerable risk"**
- for each carcinogen **derivation of two substance-specific concentration values** based on those two risk limits: **"acceptable concentration"** and **"tolerable concentration"**

Structure and basic elements

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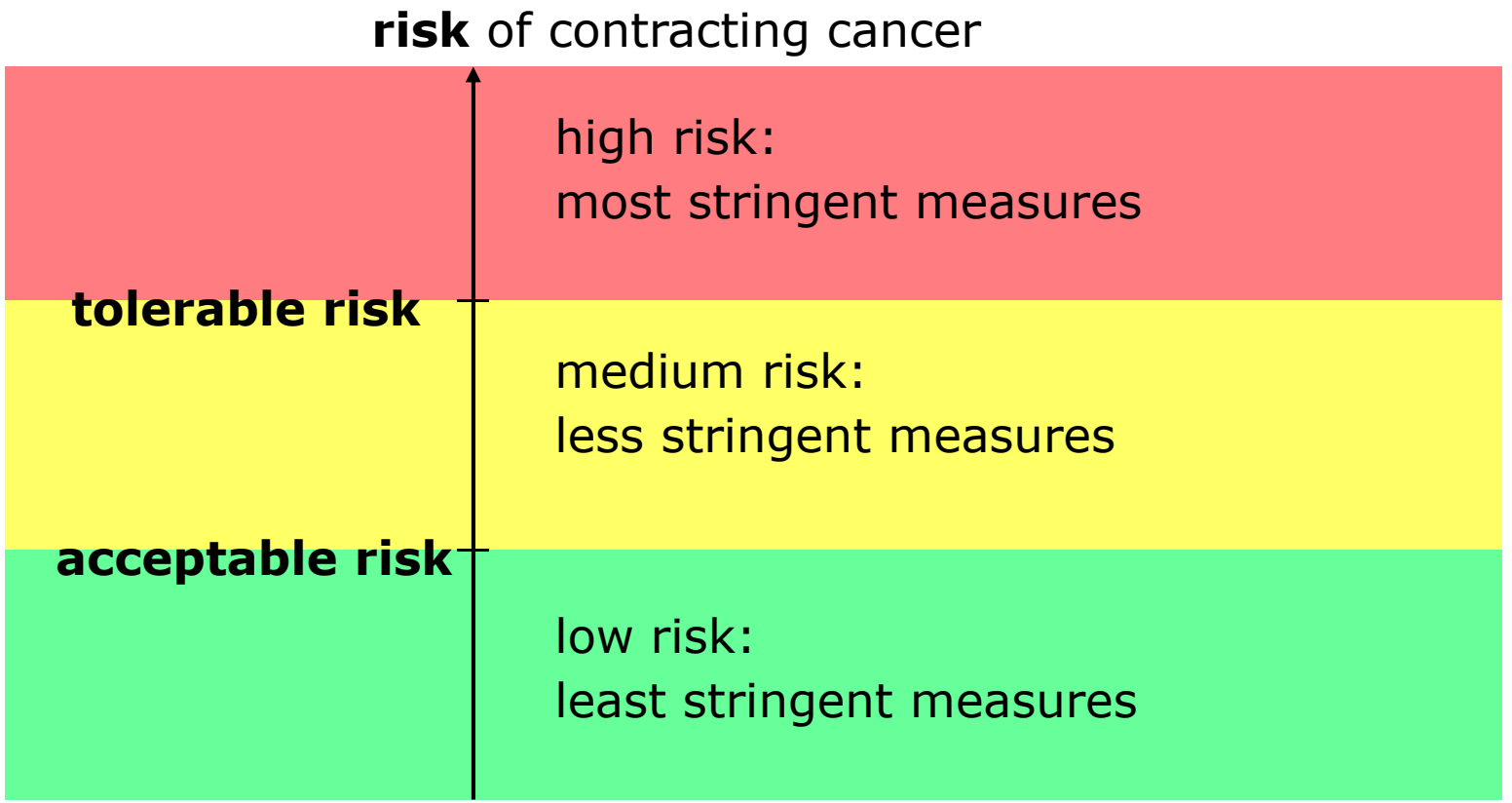
three bands (risks / control measures) – schematic view



Interplay between risk limits and set of control measures

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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
- not required for low risks

Interplay between risk limits and set of control measures

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Control measures – brief overview (1)

Obligations if exposure <u>above</u> "tolerable concentration"

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

plus

- list of additional control measures (not specified here)

Obligations if exposure <u>below</u> "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 graded control measures was precondition for consensus on numerical values of risk limits
- **What sort of risk?**
  - additional risk of developing cancer as a result of exposure at the workplace (extra cases of cancer; not mortality)
  - assumption for calculation of risk: continuous exposure during whole working life: 8 hours/day, 240 days/year, 40 years
- **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)

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**
- **Implementation support for enterprises**

From concept to application

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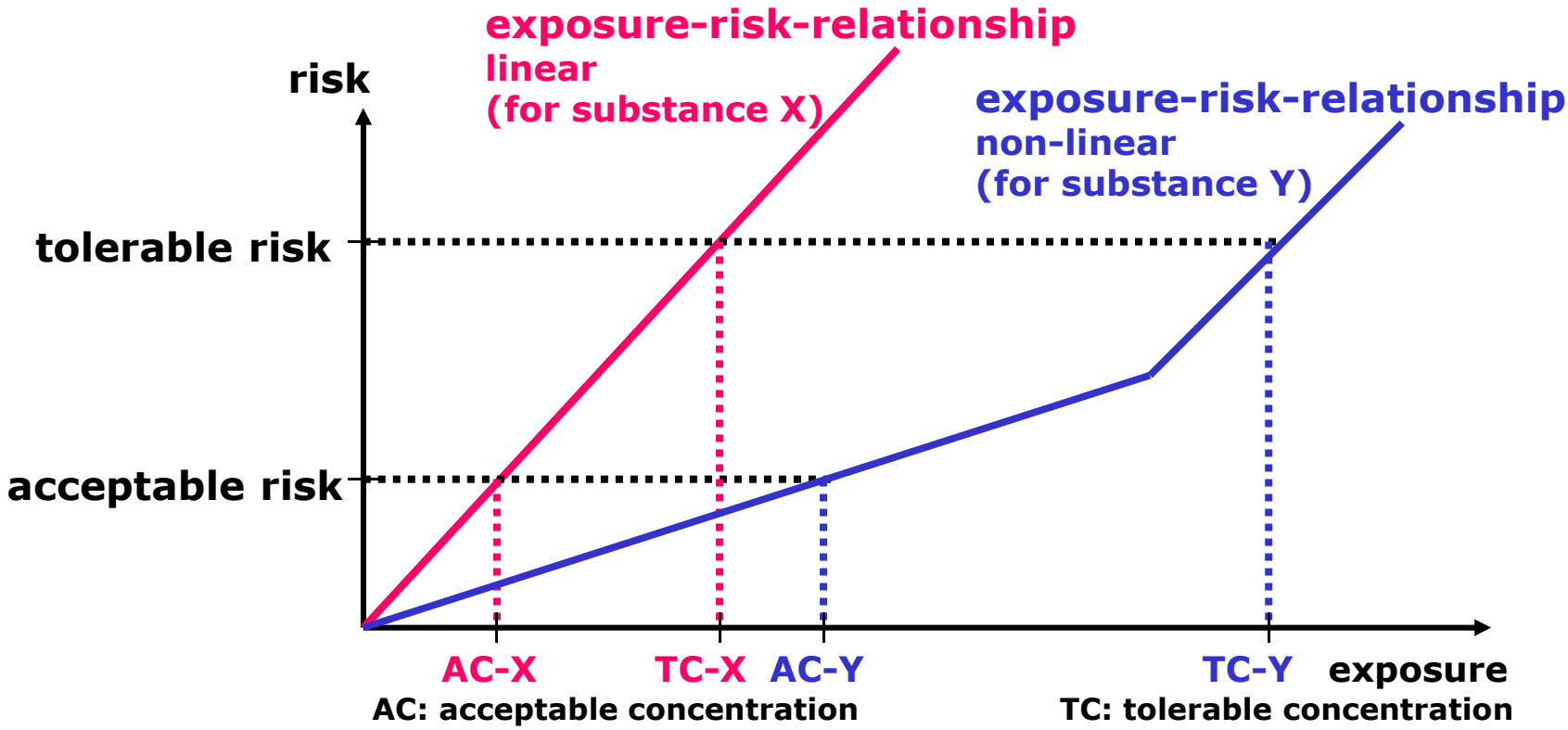
Exposure-risk-relationships – schematic view
(for substances X and Y)



From concept to application

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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 (MDA)**
- **Nitrosamines**
- **Trichloroethene**

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

From concept to application

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Consideration of additional factors: clarifications 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" ✓

From concept to application

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Implementation support for enterprises

Technical Rules for widely used carcinogens

- 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 set of graded control measures**
  - **integration of "acceptable" and "tolerable" concentration**

List of "Frequently asked questions"

- list of 25+ explanatory FAQs **to be published end of this year**

Guidance on consideration of "additional factors" in risk assessment

- detailed advice on inclusion of substance-specific issues (cf. previous slide) **to be available mid-2012**

Developments (and expectations)

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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

- derivation of additional ERRs

ERRs currently foreseen for 35 carcinogens in total

Provision of detailed guidance for risk assessment

- description on how to consider substance-specific factors in relation to both concentration values

Developments (and expectations)

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Resulting concentration values

- for a number of carcinogens the resulting concentration values are (or will be) far below the former technical-based values; thus, their achievement is posing a major challenge

carcinogen	concentration [µg/m³] at $4*10^{-3}$ (tolerable risk)	concentration [µg/m³] at $4*10^{-4}$ (acceptable risk)	former technical-based limit value [µg/m³]
Arsenic	*8 ?*	*0,8 ?*	100
Benzo(a)pyrene	0.7	0,07	2 / 5
Cadmium	*1 – 2 ?*	*0.1 – 0.2 ?*	15 / 30
Chromium (VI)	*< 5 ?*	*< 0.5 ?*	50 / 100
Hydrazine	*< 25 ?*	*< 2.5 ?*	130
Nickel	*< 5 ?*	*< 0.5 ?*	500
Trichloroethylene	60,000 (11 ppm)	33,000 (6 ppm)	270,000 (50 ppm)
Ceramic fibres	100,000 F/m³	10,000 F/m³	500,000 F/m³

Developments (and expectations)

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- Apart from "technical feasibility" at enterprise level, **limitations to minimization have to be envisaged for some carcinogens**

  Potential critical parameters
  - external background exposure
  - measurability (limit of detection)
    i.e. actual "state of technology" for measurements and analytics

  might indicate the **existence of practical limits** beyond which **minimization currently becomes meaningless**

- **NB: Those limits can, in principle, be lowered by a societal effort, yet not by an effort on the part of individual enterprises**