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

Henning Wriedt
Beratungs- und Informationsstelle Arbeit & Gesundheit
Hamburg, Germany
Content of working group “Cancer prevention”

Four complementary modes:

- **regulation**  
  this presentation
- **enforcement**  
  presentation 4
- **campaigns**  
  presentation 2
- **tools**  
  presentation 1
Regulatory context

Obligations of the CMD

- **Substitution** (art. 4 (1))
- **Closed system** (art. 5 (2))
- **Exposure minimization** (art. 5 (3))

Substitution is the preferred approach but ...
Regulatory context

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

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

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")
    - **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**

**risk** of contracting cancer

- **upper risk limit**
  - high risk: most stringent measures
  - medium risk: less stringent measures

- **lower risk limit**
  - low risk: least stringent measures
The approach in a nutshell

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

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

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

**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)

- **Linear** exposure-risk-relationship (for substance X)
- **Non-linear** exposure-risk-relationship (for substance Y)

Risk

Upper risk limit

Lower risk limit

AC: acceptable concentration

TC: tolerable concentration

AC-X  TC-X  AC-Y  TC-Y  exposure

From concept to application
## From concept to application

### Carcinogens (soon to be) covered by the German approach

<table>
<thead>
<tr>
<th>Left Panel</th>
<th>Right Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Acrylamide</td>
<td>- Arsenic</td>
</tr>
<tr>
<td>- Acrylonitrile</td>
<td>- Beryllium</td>
</tr>
<tr>
<td>- Aluminiumsilicate fibres (ceramic fibres)</td>
<td>- Cadmium</td>
</tr>
<tr>
<td>- Asbestos</td>
<td>- Chromium (VI)</td>
</tr>
<tr>
<td>- Benzo(a)pyrene</td>
<td>- Cobalt</td>
</tr>
<tr>
<td>- 1,3-Butadiene</td>
<td>- Diesel motor emissions</td>
</tr>
<tr>
<td>- Ethylene oxide</td>
<td>- Hydrazine</td>
</tr>
<tr>
<td>- 4,4′-Methylenedianiline (MDA)</td>
<td>- Lead (possibly OEL)</td>
</tr>
<tr>
<td>- Nitrosamines</td>
<td>- Nickel</td>
</tr>
<tr>
<td>- Trichloroethylene</td>
<td>- Quartz (possibly OEL)</td>
</tr>
<tr>
<td>- Benzene</td>
<td>- Antimony trioxide</td>
</tr>
<tr>
<td>- Epichlorohydrine</td>
<td>- Bitumen</td>
</tr>
<tr>
<td></td>
<td>- Ethylene imine</td>
</tr>
<tr>
<td></td>
<td>- Propylene oxide</td>
</tr>
<tr>
<td></td>
<td>- Vinyl chloride</td>
</tr>
</tbody>
</table>
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

Immediate progress (1)
- higher level of protection for selected carcinogens:

<table>
<thead>
<tr>
<th>carcinogen</th>
<th>former TRK [µg/m³]</th>
<th>tolerable concentration [µg/m³]</th>
</tr>
</thead>
<tbody>
<tr>
<td>acrylonitrile</td>
<td>7,000</td>
<td>2,600</td>
</tr>
<tr>
<td>benzene</td>
<td>3,200 (1 ppm)</td>
<td>1,900 (0.6 ppm)</td>
</tr>
<tr>
<td>benzo(a)pyrene</td>
<td>2 / 5</td>
<td>0.7</td>
</tr>
<tr>
<td>1,3-butadiene</td>
<td>11,000 / 34,000</td>
<td>5,000</td>
</tr>
<tr>
<td>refractory ceramic fibres</td>
<td>250,000 f/m³</td>
<td>100,000 f/m³</td>
</tr>
<tr>
<td>naphthalene</td>
<td>10 ppm</td>
<td>0.1 ppm (AGW)</td>
</tr>
<tr>
<td>N-nitrosamines</td>
<td>1 / 2.5</td>
<td>0.7</td>
</tr>
<tr>
<td>trichloroethylene</td>
<td>50 ppm</td>
<td>11 ppm</td>
</tr>
<tr>
<td>vinyl-2-pyrrolidone</td>
<td>500</td>
<td>50 (AGW)</td>
</tr>
</tbody>
</table>

AGW: health-based OEL
Immediate progress (2)

- focus on minimization of high-risk carcinogens:

<table>
<thead>
<tr>
<th>carcinogen</th>
<th>former TRK [µg/m³]</th>
<th>tolerable concentration [µg/m³]</th>
</tr>
</thead>
<tbody>
<tr>
<td>antimony trioxide</td>
<td>100 / 300</td>
<td>&lt; 10 (?) (AGW)</td>
</tr>
<tr>
<td>arsenic</td>
<td>100</td>
<td>8</td>
</tr>
<tr>
<td>cadmium</td>
<td>15 / 30</td>
<td>1.6 (respirable fraction)</td>
</tr>
<tr>
<td>chromium VI</td>
<td>50 / 100</td>
<td>&lt; 10 (?)</td>
</tr>
<tr>
<td>cobalt</td>
<td>100 / 500</td>
<td>&lt; 10 (?)</td>
</tr>
<tr>
<td>hydrazine</td>
<td>130</td>
<td>22</td>
</tr>
<tr>
<td>nickel compounds</td>
<td>500</td>
<td>&lt; 5 (?) (respirable fraction)</td>
</tr>
</tbody>
</table>

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

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

... in English can be found as:

**Announcement on Hazardous Substances 910**, the official text describing the new approach: