National approach in Germany: OELs based on working procedures and substance-specific criteria (Ausschuss für Gefahrstoffe AGS)

OEL-setting seminar
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(occupational carcinogens)

Former approach in Germany

Technical guidance values
TRK (Technische Richtkonzentrationen)

- **not (primarily) health-related**
- **value linked to an agreed level of achievability (state-of-the-art)**
- **associated risk usually not known; often high**
- **no dynamics towards further reduction**

Integrated 3 pillar approach

Methodology:

Guidance to describe the exposure/risk relationship for carcinogens

[range], no point estimate!

Application:

Risk quantification: exposure/risk relationship for a substance

[range of possible exposures]

Risk management + stakeholders framework:

➔ **Select: risk level for OEL (general)**

➔ **Describe: risk management measures**

➔ **Describe: current technical status**

1

2

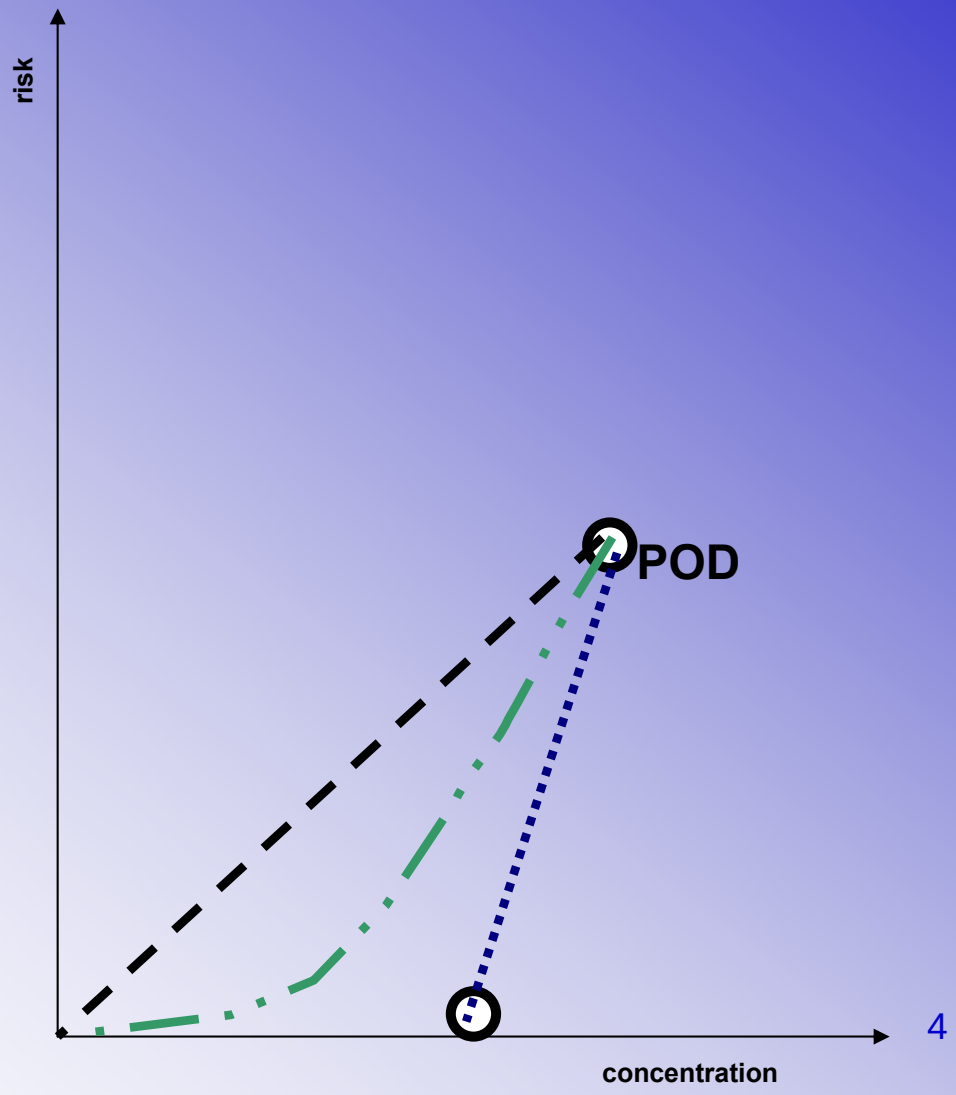
3

Elements of the methodology

- Determine “point of departure“ (benchmark BMD_{05} / T25)
- Characterise “mode of action“:
- ➔ if clear threshold: handle similar to other threshold substances

  ➔ if “mode of action“ well understood and substantial indications of sublinearity: account for sublinearity

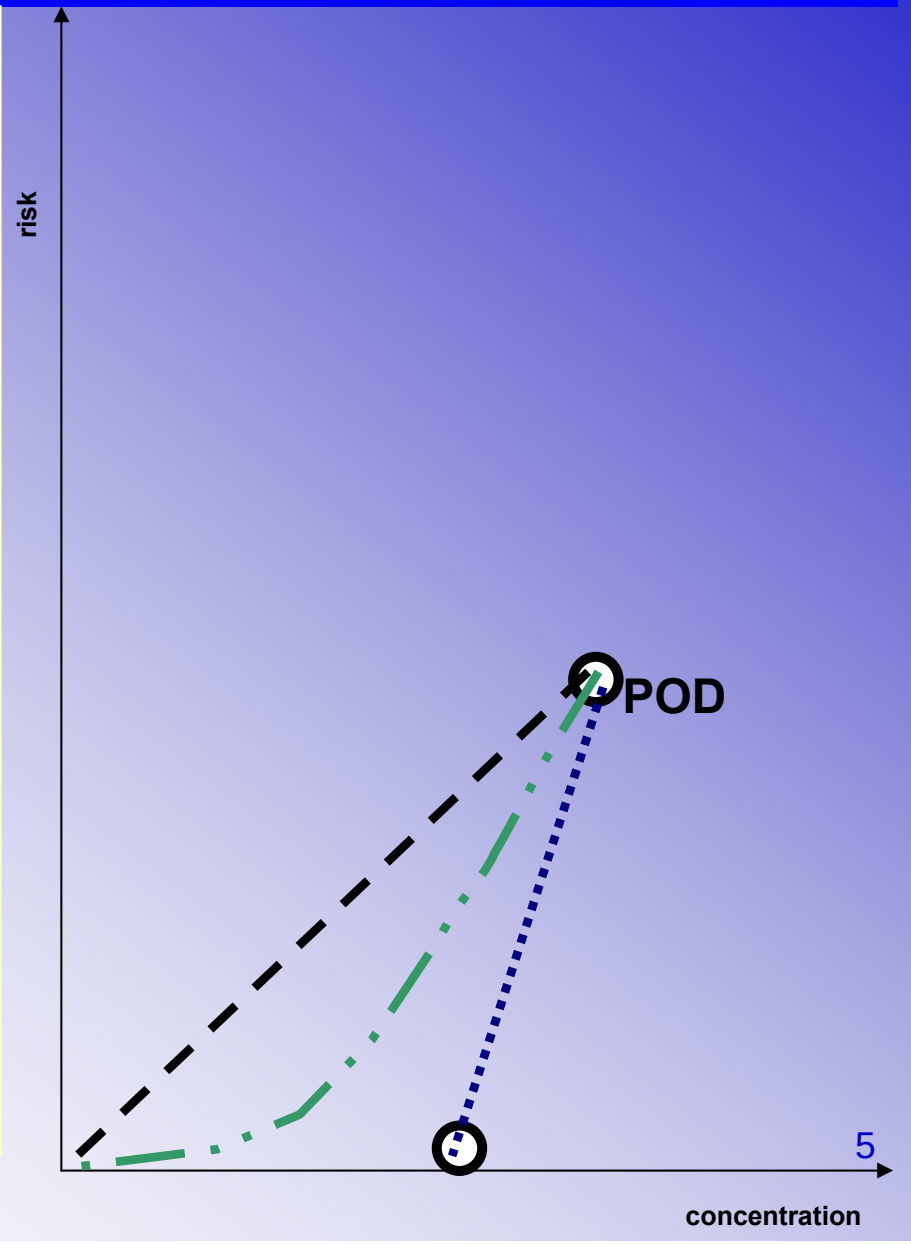
  ➔ if “mode of action“ not sufficiently clear or if supportive of linear exposure/risk relationship: extrapolate linearly



Understanding of the term “risk“ within this framework

- No “real“ risk, but “nominal“ risk under defined side constraints

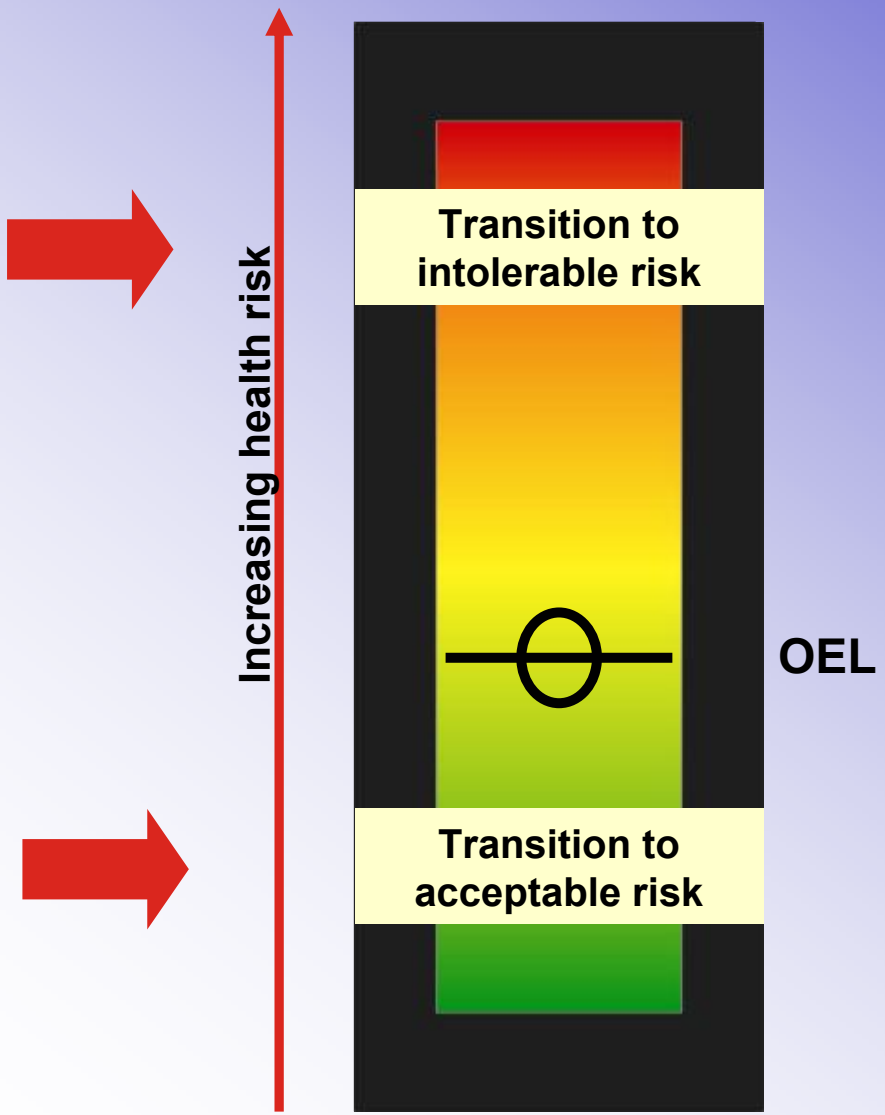
  (“bias towards potential overestimation of risk“)
- often linear scale
- open to scientific input and progress
- Set OEL at defined nominal risk level



The traffic light approach

Instead of single spots….

…. risk areas



- communicate transition points
- communicate nominal risk level at OEL
- crucial: select risk management measures
- communicate current exposure (state-of-the-art)
- establish priorities (more than ALARA)
- few requirements in green region
- ban in red region

Compatibility with REACH

REACH – risk-based philosophy

Risk of the various activities should be identified ***ARTICLE 59 (4a)***

Discriminates concern / very low concern (DMEL) ***ARTICLE 59(2)***

Authorisation ➔socio-economic benefits ***ARTICLE 59 (4b)***
Follow ALARA ***ARTICLE 59 (10)***

Similar results: modified EFSA approach

EFSA: Multidimensional safety factors amount
to similar total factor as (proposed) risk extrapolation

Conclusions

- Approach is still under discussion
- Provide methodology (guidance document)
- Interpretation of term “risk“ (nominal, high uncertainty, conservative)
- Approach separates risk assessment from risk management (traffic light)
- Risk comparison at supra- or sub-OEL level
- Largely compatible with other approaches (ALARA, MoE, REACH, mod. EFSA)

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ABSTRACT

Recently, the regulatory framework has changed in Germany with major consequences for standard setting on carcinogens. Whereas historically OELs for carcinogens (called TRK: Technische Richtkonzentrationen) were technically based (i.e. a level of exposure that was achievable for most of the companies was used as guidance with limited influence of the associated health risk), new OELs should be health (or risk) based. However, a specific guideline how to establish a “new” OEL for carcinogens has not yet been established. Thus, all considerations including those in this presentation are preliminary. This new (and preliminary) philosophy asks for: a) the determination of a “point of departure” (POD) at the low end of observed cancer incidences (as a benchmark dose or T25), b) the extrapolation of the assumed dose-response relationship to the low risk area, c) defined risk levels which are explicitly characterised as acceptable or tolerable (based on a public risk communication process), d) the establishment of an OEL at a (not yet) defined risk level, in combination with risk management provisions if the tolerable risk level or the acceptable risk level is exceeded. The assumed shape of the dose-response relationship and the resulting risk for certain exposure concentrations may differ depending on the substance specific “mode of action” for carcinogenicity. The concept is more precise than the ALARA-approach (…it accounts for the different potencies of carcinogenic substances), it is compatible with the current specifications intended for REACH and it may provide similar results as a modified EFSA-approach (as currently considered for carcinogenic food contaminants). However, the very uncertain risk extrapolation procedure to the low risk area necessitates some pragmatic default-assumptions as long as no more precise data are available. The resulting risk figure may thus often not resemble the “real” risk but is taken as a conservative approximation for risk management purposes on a comparative scale. The approach should be accompanied by a guidance document in order to harmonise all steps of this risk quantification approach. The integration of expert judgement is an essential element of this procedure with some explaining narrative in order to increase transparency.