

Is harmonisation an important and common objective?

Should all health-based values for a specific substance aiming at protecting workers be the same?

WORKSHOP ON BAUA-RESEARCH PROJECT F2437

## **TOPIC 8: Open questions and steps towards implementation**

---

### **Derivation of occupational exposure limits for airborne chemicals - Comparison of methods and protection levels**

Klaus Schneider - FoBiG, Forschungs- und Beratungsinstitut Gefahrstoffe GmbH, [www.fobig.de](http://www.fobig.de)

# Open questions regarding the database

- Applicability of POD modifications for locally acting irritants?
- Time extrapolation:
  - Distributions based on defined endpoints or based on guideline-conform studies (with differences in depth of investigation)?
- Intraspecies extrapolation
  - Difference between inhalation and oral data for TK?
  - TD: Limitations of the data from Abdo et al. (2015)

## Open questions regarding tools and methods

- What should be the role of the benchmark approach in deriving OELs?
- Should allometric scaling be applied whenever no substance-specific data on species differences is available?
- Specific rules for locally irritating substances (respiratory toxicity and sensory irritation)?
- How to assess deposition and clearance of particles in the respiratory tract (HEC procedure, with deposition modelling)?

# Methodological descriptions

To further increase transparency methodological descriptions should be expanded to include more information on

- **Data searches:** type of data to be searched, sources, documentation of search criteria and results
- **Data quality evaluation:** procedure to evaluate the quality and suitability of data (while keeping the workload manageable)
- **Weight-of-evidence:** considerations whether and how to use it
- **Human versus experimental animal data:** considerations and criteria on the weighing of human and animal data
- **Updates:** information on criteria for and frequencies of assessment updates
- **Point of departure:** Selection of suitable POD, specifically on the BMD approach
- **Modification of the POD:** rules to account for exposure conditions of workers
- **Assessment factors:** Step-by-step application of assessment factors and conditions for deviating from defaults

# Steps towards harmonisation

- Do we want to harmonise?
  - There might be reasons for differing approaches: e.g. biocides assessments focus on systemic absorbed dose from several routes
  - If yes, which parts of the assessment procedure?
- If harmonisation is a goal: Harmonise methods first, not values
  - Define values with regard to coverage and probability
  - Agree on empirical data informing extrapolation steps
  - Agree on key methodological steps required for deriving OELs / OEL-analogue values
  - Provide detailed guidance

