Stoffenmanager

Working safely with hazardous substances

# The scientific basis of Control Banding

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RETURN ON SUSTAINABILITY

# This presentation

1. The need for a scientific basis
2. Three building blocks scientific basis
   - Validation of exposure models
   - Reliablity of tools
   - Transparancy
3. New developments
4. Summary and discussion

# The need for a scientific basis

- Goal of all control banding tools is to protect worker health
- Any screening tool should have an ‘appropriate level of conservatism’[1]
- Key question:

  “Are workers sufficiently protected when the outcome of a Control Banding tool is implemented at workplace level?”


1 Tielemans et al. 2007. Tools for regulatory assessment of occupational exposure: development and challenges. J Exp Anal Environ Epi; 17:S72-80

# The need for a scientific basis

- Science might help to answer this question
- This presentation is starting point for the discussion on:
  - The scientific basis of control banding, and
  - The lessons that we can learn from it
  - Possible action points ITG “Control Banding”

☑ Hazard assessment

☑ Exposure assessment

Risk = Hazard x Exposure

# Building blocks scientific basis

- To ensure worker protection CB tools need to be:

1. Valid
- "Sufficient discriminatory power and sufficiently – but not overly - conservative"

2. Reliable
- "Do users of the tool come to the intended results 'developer's gold-standard'?"

3. Transparant

# Example: validation of exposure models

- Possible definition:

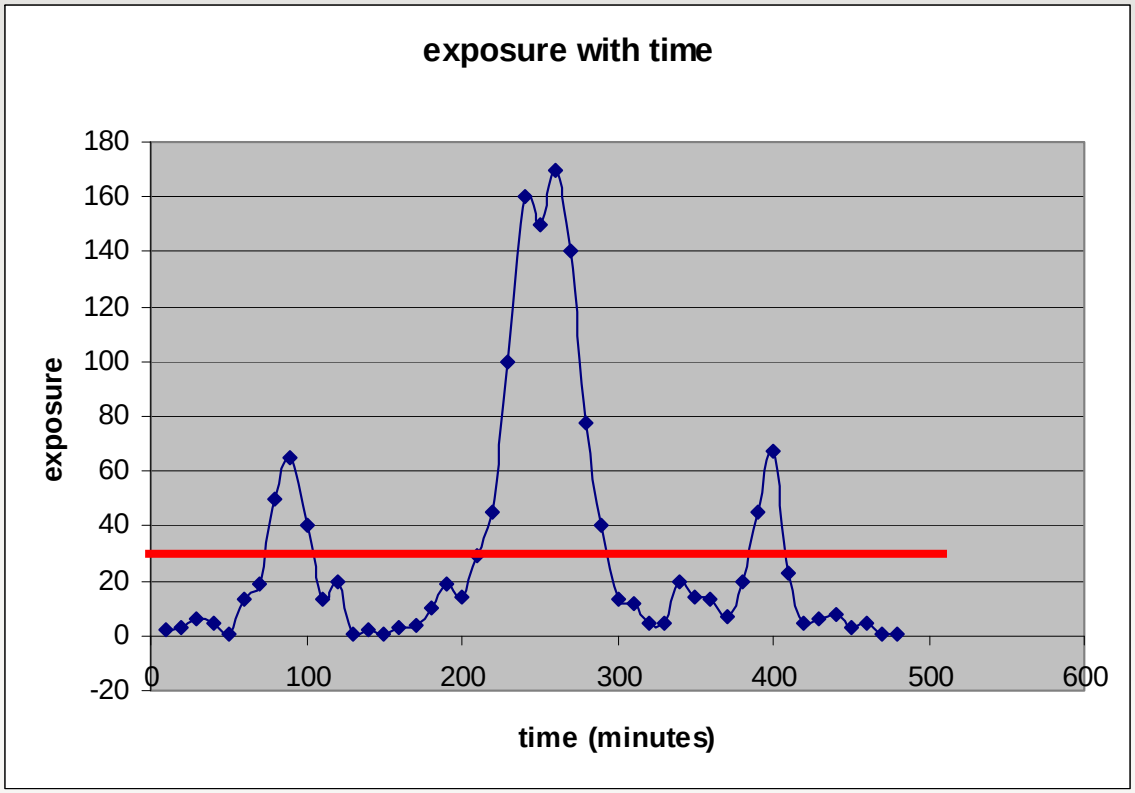
"Validation of an exposure model is limited to a demonstration that in a specific application, the model output agrees with measured data (WHO; 2005)[1]

- For exposure models this is crucial because exposure levels have been demonstrated to show significant variability
- Models can never explain full variability → Substantial uncertainty remains
- Only few validations of exposure models in open literature (Bredendiek-Kamper; 2001)[2]

1. WHO/ILO IPCS project on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals. 2005. PRINCIPLES OF CHARACTERIZING AND APPLYING HUMAN EXPOSURE MODELS
2. Bredendiek-Kamper S. 2011. Do EASE scenarios fit workplace reality? A validation study of the EASE model. Appl Occup Environ Hyg; 16:182-7

# Exposure variablity

- Variability in one working day (example)



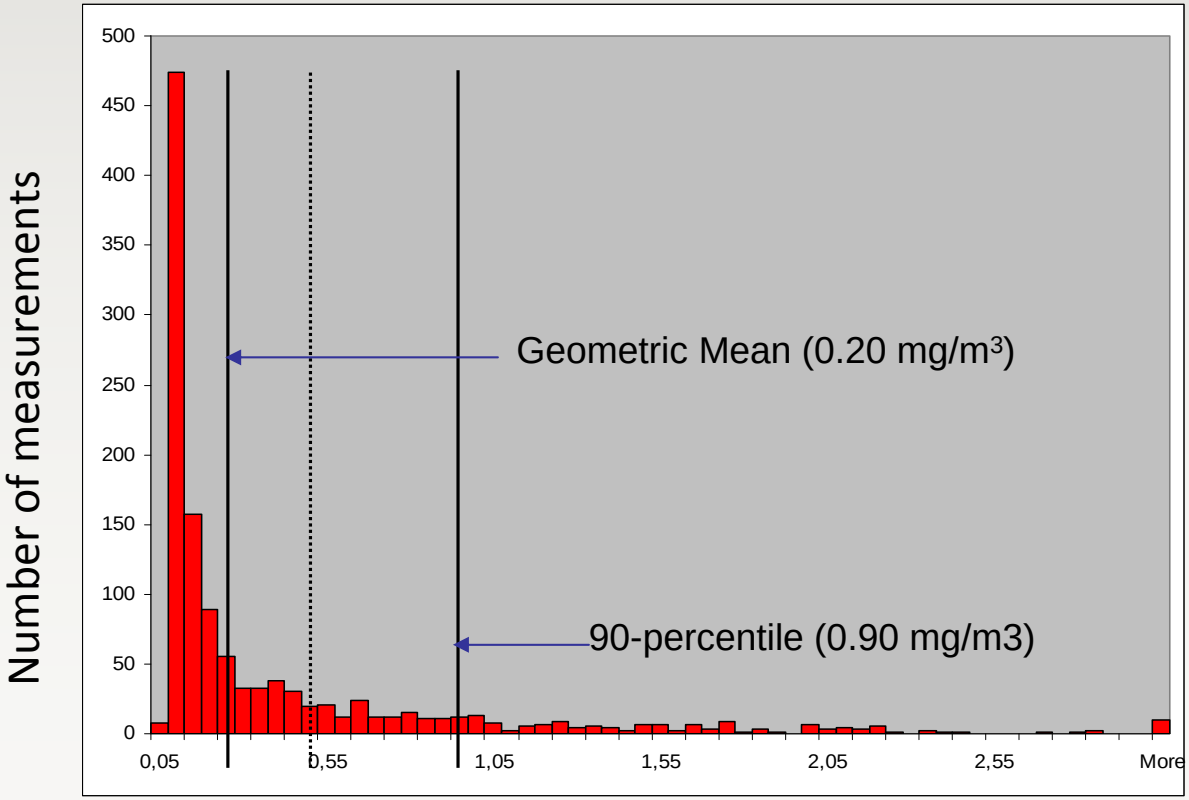
# Model uncertainty

- Two different worker performing the same task:
  - Same model outcome
  - (Very likely) different measured values
  - Unexplained variability

No CB tool differentiates between these two workers!

# Exposure variablity

- Multiple workers at one workplace
- Typically a log normal distribution



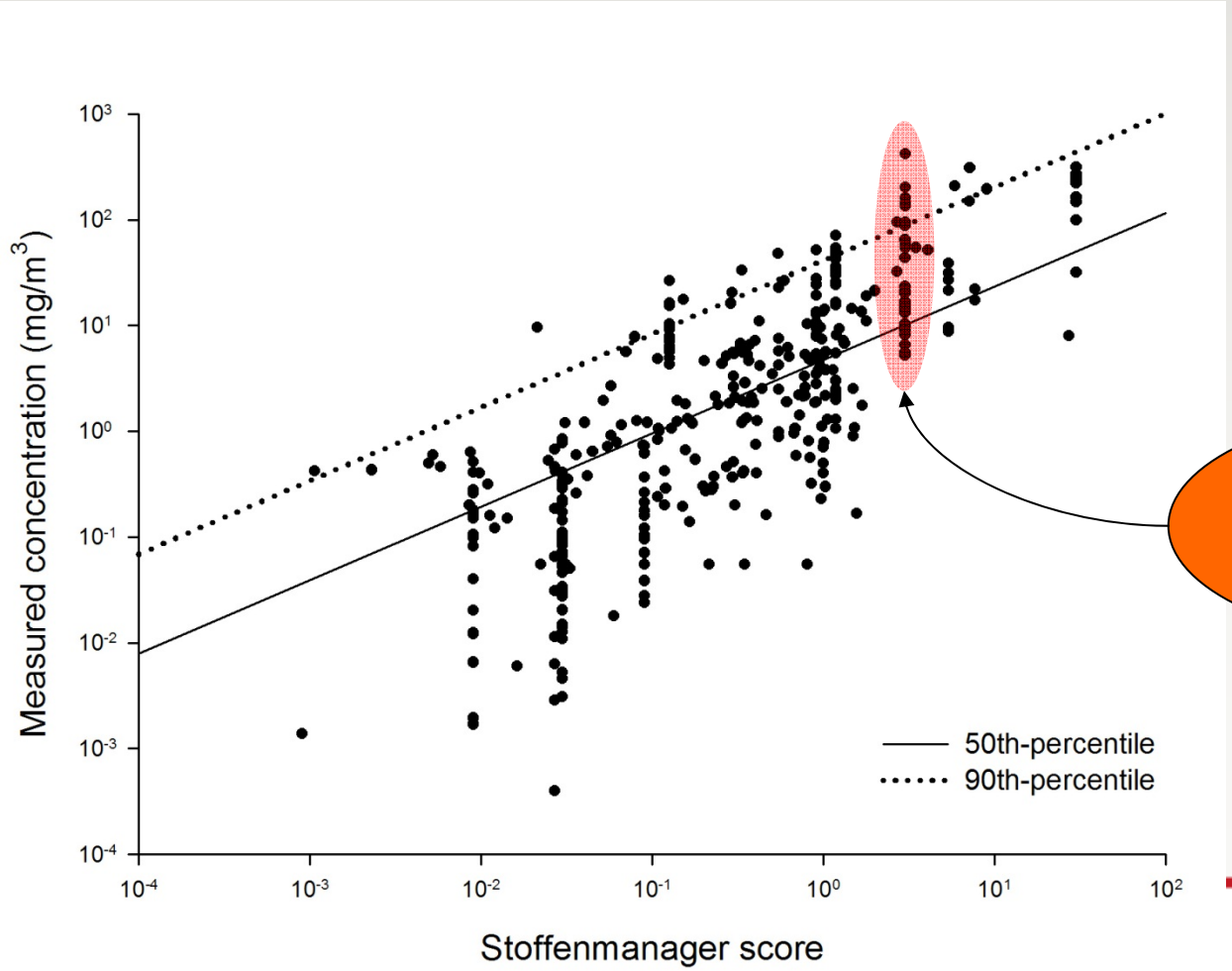

# Exposure variability

- Variability between workers
  - Differences in work protocol (good vs. bad practice)
  - Differences in use of LEV
- Variability within workers (day-to-day variation)
  - Differences in temperature / air humidity
  - Differences in production volume
- Variation within workers > variation beween workers [1]
- Also historical trends: exposure tends to decrease over time
- Geographical differences?

[1] Amongst others: Spaan et al. 2007. Exposure to endotoxins; Kromhout et al. 1993. Exposure to chemicals; Kromhout and Vermeulen. Dermal exposure to chemicals; Kromhout et al. 2004. Dermal exposure to chemcials

# Use of measured data for calibration

More on this in session 2!




Same Stoffenmanager exposure, different measured results

# Conclusions validity

- Model = simplified picture of reality
- Work from assumptions and generalisations
  - R- and H-phrases as substitutes for OELs and DNELs
- Crucial to take into account variablity of exposure
- Need to be sufficiently conservative (worst-case)

To be discussed (session 2):

- "The validity of the predictions of any model should be evaluated before results can be used safely and effectively in the risk assessment process"[1]

1. WHO/ILO IPCS project on the Harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals. 2005. PRINCIPLES OF CHARACTERIZING AND APPLYING HUMAN EXPOSURE MODELS

# Reliability of CB Tools

- Possible definition of reliability
  *'A measure of the consistency of assessments or of the ability of assessors to reach the same conclusions about a specific case'* (Kunac, 2006).

- Lack of reliability can have consequences for worker health and for financial situations of organisations
  - Eg purchase of high tech exhaust ventilation when not stricktly needed
- Limited amount of reliability studies on CB Tools

# Reliability: the example of ART

Investigate with 18 health and safety professionals:

1. Do participants agree with ‘gold-standard’ per determinant?

- Do participants agree with each other (inter-rater agreement)?
- Do participants come to the same exposure estimate as ‘gold standard’ exposure estimate?
- The effect of providing information related to ART on participant ’s agreement with gold-standard

# Difficult choice? Substance Emission Potential (dustiness)

| Category | Relative weight |
|---|---|
| Firm granule | 0.01 |
| Granule | 0.03 |
| Coarse dust | 0.1 |
| Fine dust | 0.3 |
| Extremely fine dust | 1.0 |

# Conclusions ART & reliability

- After introduction and demonstration:
- Correlation between the rater's exposure estimates and gold-standard exposure estimate increased
- Improved agreement per determinant with the gold-standard (ranged from 53-99%)
- No differences regarding years of experience of raters!

# Conclusions reliabilty

- Exposure Assessment is an *ART* and a *science*
- More research on reliability tools much needed!
- Own limited experience shows that training might help:
  - Use of CB tool is not just pressing buttons
  - Need to know what you are doing and why...


- How true is this for tier 1 tools?
- More on this in session 3!

# Scientific transparency

- An informed society is one that can reach conclusions from a sound ethical and knowledgeable base [1]

- But what does this mean for Control Banding tools?
- No formal definition nor guidelines for transparency CB Tools
- Should all CB Tools be published in peer-reviewed articles?
- If not, what is a minimum level of description?
  - Scientific basis
  - Justification of choices
  - Applicability domain
  - Etc

# Example: STM applicability domain

| Activity \ Product | Gas | Volatile liquids | Non-volatile liquids | Powders | Fibers | Objects |
|---|---|---|---|---|---|---|
| Moving and agitating | | | | | | n.a. |
| Gravitational transfer | | | | | | n.a. |
| Spreading and immersion | | | | | | n.a. |
| Air dispersive techniques | | | | | | n.a. |
| Hot work techniques | | | | | | n.a. |
| Abrasion and impact | n.a. | n.a. | n.a. | n.a. | n.a. | |

# New developments

- Control Banding Tools for nano materials
  - Based on very limited information
  - What does this mean for validity and reliability?
- European SME are starting to receive extended SDS
  - Quantified levels of exposure plus control measures and DNELs
  - What does this mean for qualitative CB tools?
- BAUA validation study of REACH tier 1 models
  - E-team
  - More on this in session 2

# Summary and conclusions

- Scientific basis CB tools could be based on:

1. Validity
2. Reliability
3. Scientific transparency

- Benefits of a uniform scientific basis of CB Tools:
  - Trust amongst the user group (“risk governance”)
  - Clear focus future developments

# Discussion points (session 2)

- What are the building blocks for a scientific basis for CB tools?
- Can we come to definitions of these building blocks?
- Can CB Tools be safely used before validation?
- How strong does a scientific basis need to be?
- Etc

- Thank you for your attention!

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