

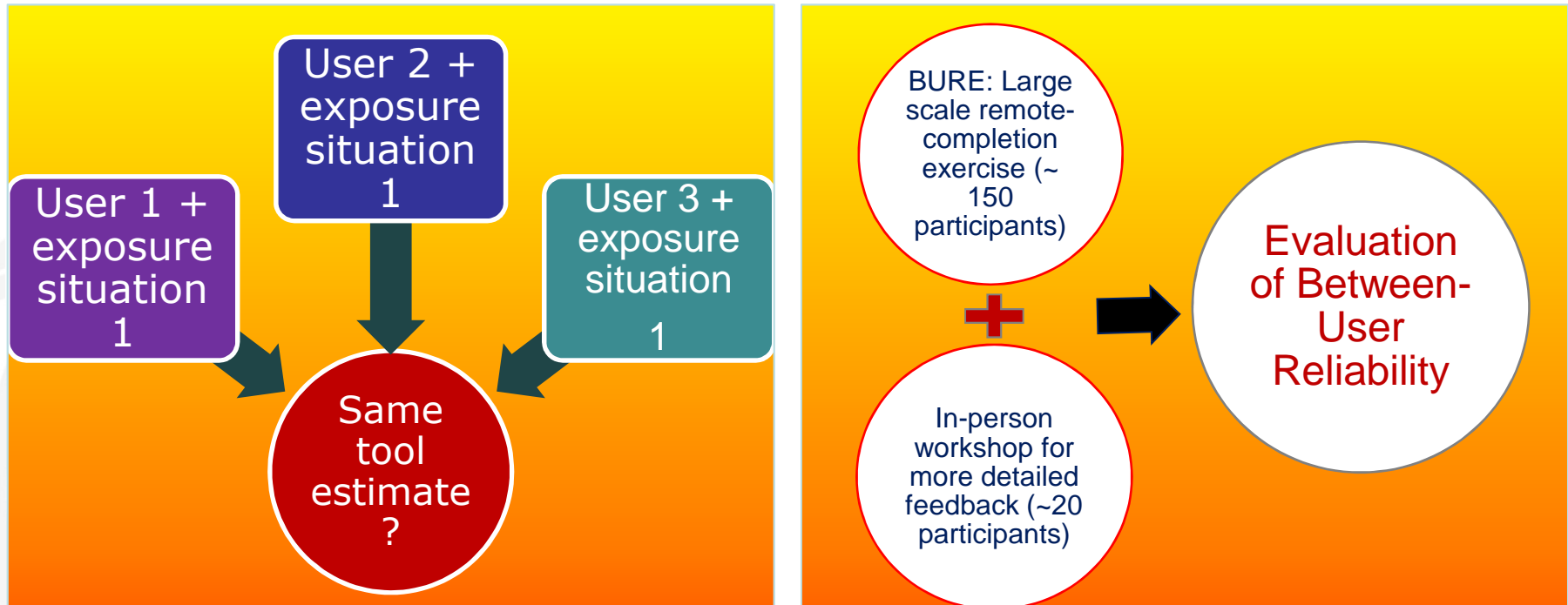
# eteam Project: Between-user reliability exercise

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# Overview

- ❖ Background and aims
- ❖ Format
- ❖ Coverage
- ❖ Results
- ❖ Main sources of variation in tools
- ❖ Conclusions
- ❖ Recommendations

**Aim:** Examine how consistent tool users are in making choices in comparison with other users

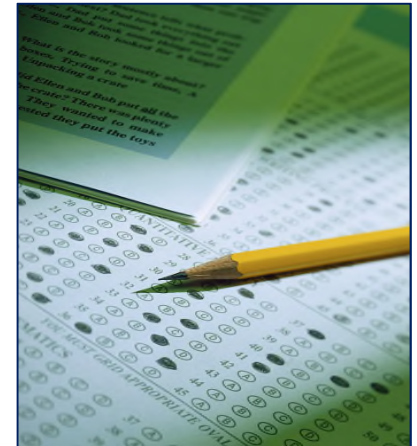


Confidence in a tool's predictions requires confidence in its reliability

# BURE Format

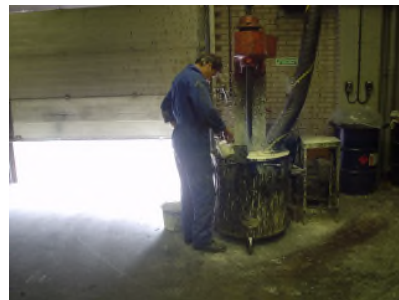


- ❖ Collect tool estimates from multiple users for a selection of common exposure situations
- ❖ 6 tools: participants asked to generate inhalation & dermal estimates for each tool- situation combination
- ❖ Simple guides on tool installation and use
- ❖ Standard worksheets used to collect results
- ❖ Background questionnaire
- ❖ Final feedback questionnaire



# Exposure situations

- 20 varied workplace situations: inhalation +/- dermal exposure potential
- Standard 1 page A4 format
- Textual description of typical workplace exposure settings
- Professional & industrial settings
- Information provided on
  - ✓ Vapour pressure
  - ✓ Molecular weight
  - ✓ CAS number
- Variable information on other exposure determinants e.g. RMMs, task duration, environment
- Powders, liquids and fumes



## Situation 4: Use of Xylene in Formulations- Mixing of chemicals in an Open Vessel



Please assess inhalation and dermal exposure to **xylene** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure xylene (mixed isomers)**) given in the table below.

### 1. General Description of Exposure Situation

This situation involves industrial mixing of liquid chemicals, including xylene. The operator stands on a platform above the vessel to mix the raw materials for the process, which takes place in Work Area D.

The mixed product (Product D) contains 60% xylene (mixed isomers). Product D is mixed in 50 litre batches.

The process takes place at room temperature (20°C).

There are fixed capture hoods above the mixing process and adequate general ventilation.

The activity takes place for 5 hours per 8 hour shift.

There is no personal protective equipment and no respiratory protective equipment worn during the activity.

### 2. Product/ Substance Information

| Product   | Supplier   | Substance Name               | CAS Number | Molecular Weight/<br>gmol <sup>-1</sup> | Vapour pressure at<br>20°C/ Pa | Concentration<br>of Xylene in<br>Product D (%) |
|-----------|------------|------------------------------|------------|---|--------------------------------|--|
| Product D | Supplier D | Xylene<br>(mixed<br>isomers) | 1330-20-7  | 106                                     | 1200                           | 60   |

# Results: BURE participant population



## ❖ Sector

- majority consultancy/industry (57%)

## ❖ Location

- mainly EU (84%)

## ❖ Main reason for carrying out exposure assessments

- REACH exposure assessment (40%)

## ❖ English language ability

- majority self-assessed as native/excellent/good

## ❖ Experience of tools

- Most experience of ECETOC TRAv2/v3, then Stoffenmanager

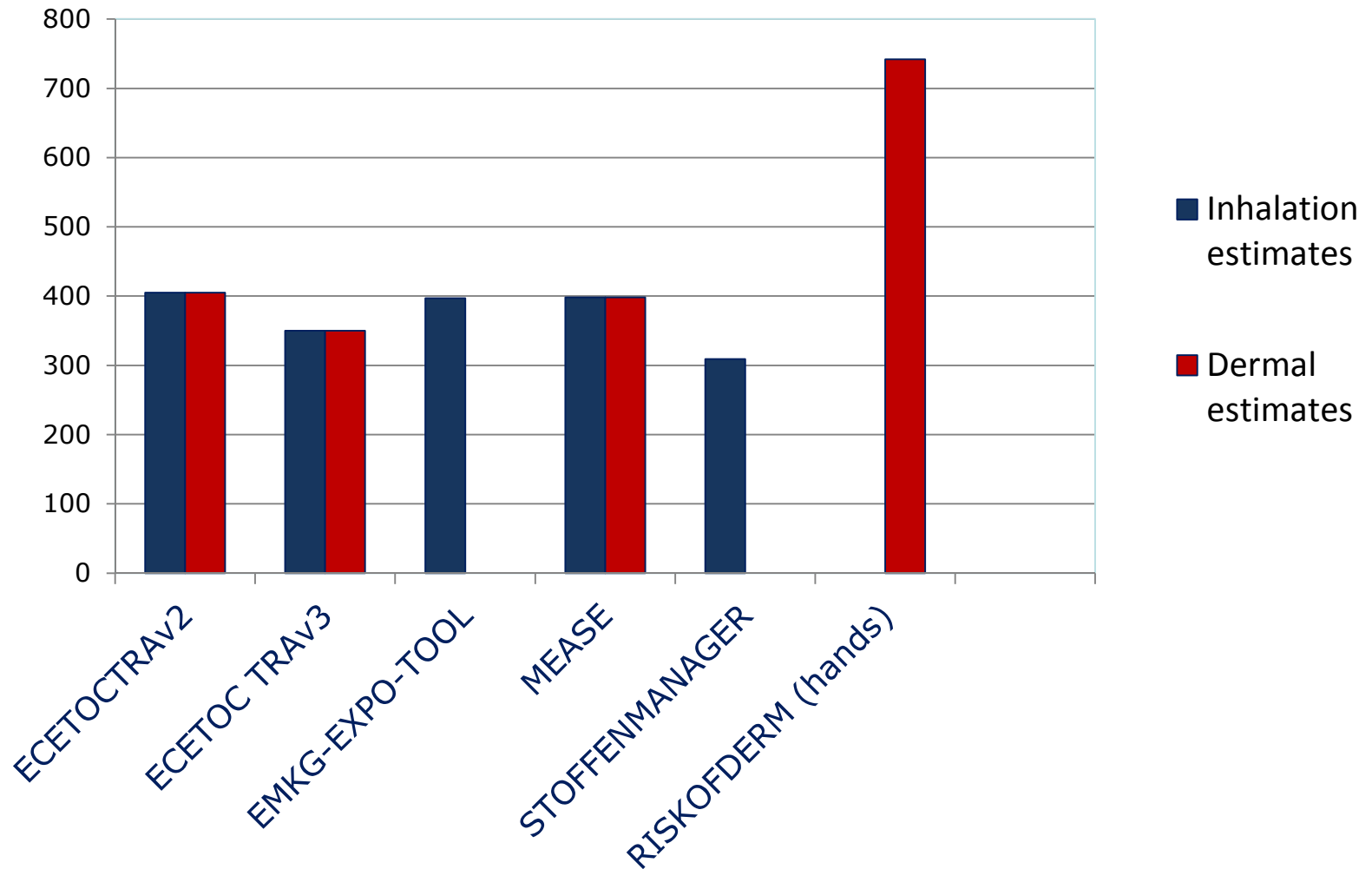
## ❖ Exposure assessment experience

- even split across all categories (~20% each category)



# Final dataset

## Number of estimates used in analyses





# Assessor-related variation/ total variation- all situations



| Tool                                   | N   | Var <sub>assessor</sub> | Var <sub>residual</sub> | Var <sub>Total</sub> | Ratio<br>(97.5%ile:<br>2.5%ile) |
|--|-----|-------------------------|-------------------------|----------------------|---------------------------------|
| Inhalation exposure                    |     |                         |                         |                      |                                 |
| ECETOC TRAv3 (mg/m <sup>3</sup> )      | 350 | 0.09                    | 2.53                    | 2.63                 | 577                             |
| ECETOC TRAv2 (mg/m <sup>3</sup> )      | 405 | 0.28                    | 1.91                    | 2.19                 | 331                             |
| MEASE (mg/m <sup>3</sup> )             | 398 | 0.35                    | 6.07                    | 6.43                 | 20746                           |
| EMKG-EXPO-TOOL<br>(mg/m <sup>3</sup> ) | 397 | 0.28                    | 3.72                    | 4.00                 | 2540                            |
| STOFFENMANAGER<br>(mg/m <sup>3</sup> ) | 309 | 0.60                    | 1.59                    | 2.20                 | 335                             |
| Dermal exposure                        |     |                         |                         |                      |                                 |
| ECETOC TRAv3<br>(mg/kg/day)            | 350 | 0.47                    | 1.59                    | 2.06                 | 278                             |
| ECETOC TRAv2<br>(mg/kg/day)            | 405 | 0.18                    | 1.12                    | 1.31                 | 90                              |
| MEASE (mg)                             | 398 | 0.78                    | 3.69                    | 4.47                 | 3975                            |
| RISKOFDERM (hands) (mg)                | 742 | 0.55                    | 6.11                    | 6.66                 | 24744                           |

# Assessor-related variation/ total variation- applicable situations only



| Tool                                | N   | Var <sub>assessor</sub> | Var <sub>residual</sub> | Var <sub>Total</sub> | Ratio<br>(97.5%ile:<br>2.5%ile) |
|-------------------------------------|-----|-------------------------|-------------------------|----------------------|---------------------------------|
| <b>Inhalation exposure</b>          |     |                         |                         |                      |                                 |
| ECETOC TRAv3 (mg/m <sup>3</sup> )   | 326 | <0.01                   | 2.62                    | 2.59                 | 549                             |
| ECETOC TRAv2 (mg/m <sup>3</sup> )   | 365 | 0.30                    | 1.99                    | 2.28                 | 372                             |
| MEASE (mg/m <sup>3</sup> )          | 151 | 0.80                    | 3.63                    | 4.44                 | 3866                            |
| EMKG-EXPO-TOOL (mg/m <sup>3</sup> ) | 313 | 0.14                    | 3.08                    | 3.23                 | 1147                            |
| STOFFENMANAGER(mg/m <sup>3</sup> )  | 280 | 0.52                    | 1.25                    | 1.77                 | 184                             |
| <b>Dermal exposure</b>              |     |                         |                         |                      |                                 |
| ECETOC TRAv3 (mg/kg/day)            | 326 | 0.30                    | 1.63                    | 1.93                 | 231                             |
| ECETOC TRAv2 (mg/kg/day)            | 365 | 0.32                    | 0.99                    | 1.31                 | 88                              |
| MEASE (mg)                          | 151 | 0.68                    | 3.98                    | 4.66                 | 4732                            |
| RISKOFDERM (hands) (mg)             | 674 | 0.58                    | 5.82                    | 6.40                 | 20270                           |

# Variation related to participants' characteristics



- ❖ No obvious or consistent trends observed
- ❖ Regulators are not obviously conservative, industry not obviously optimistic
- ❖ More experience in assessing exposure does not seem to reduce the amount of variation
- ❖ English language ability may have some small effect for MEASE, however not consistent
- ❖ People who do more REACH assessments are no more consistent than others



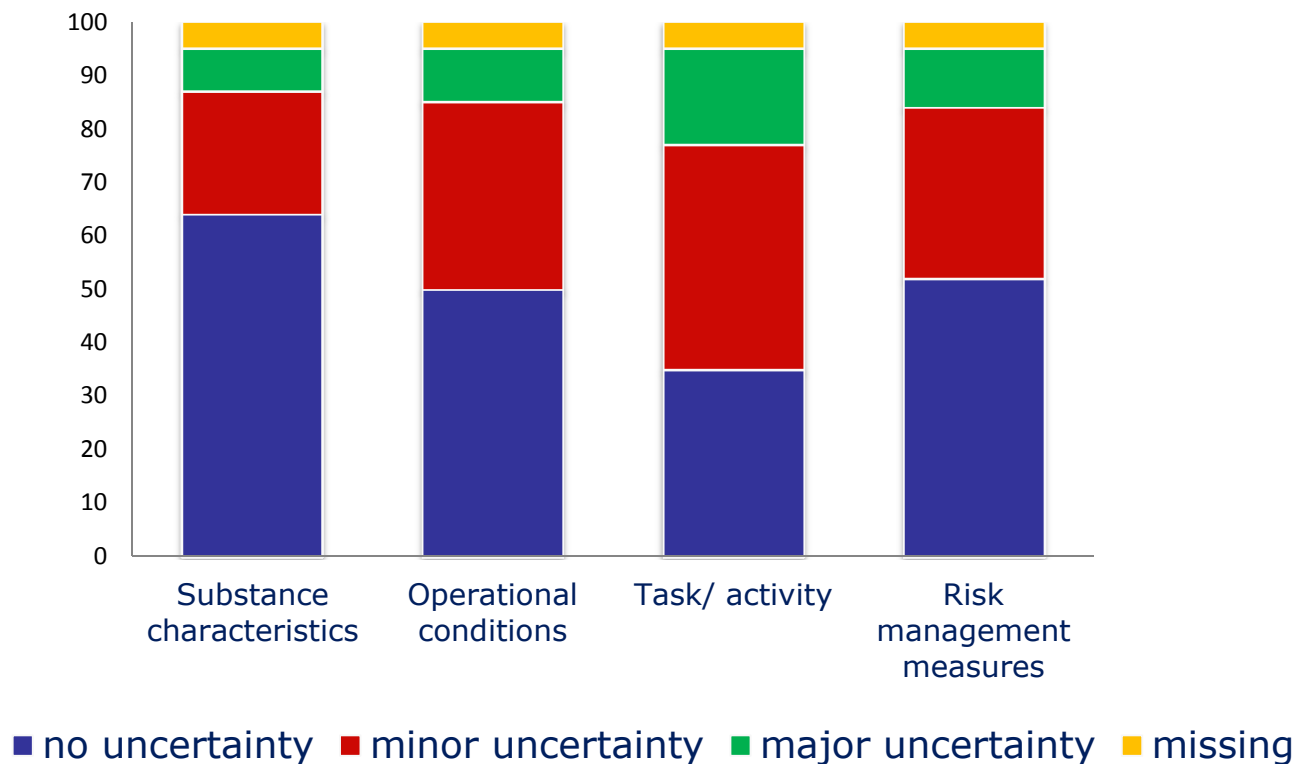
Participants generally had less experience of:

- ❖ Professional/ end use vs industrial situations
- ❖ Solids vs liquids
- ❖ Inhalation vs dermal



# How uncertain were participants when choosing inputs?

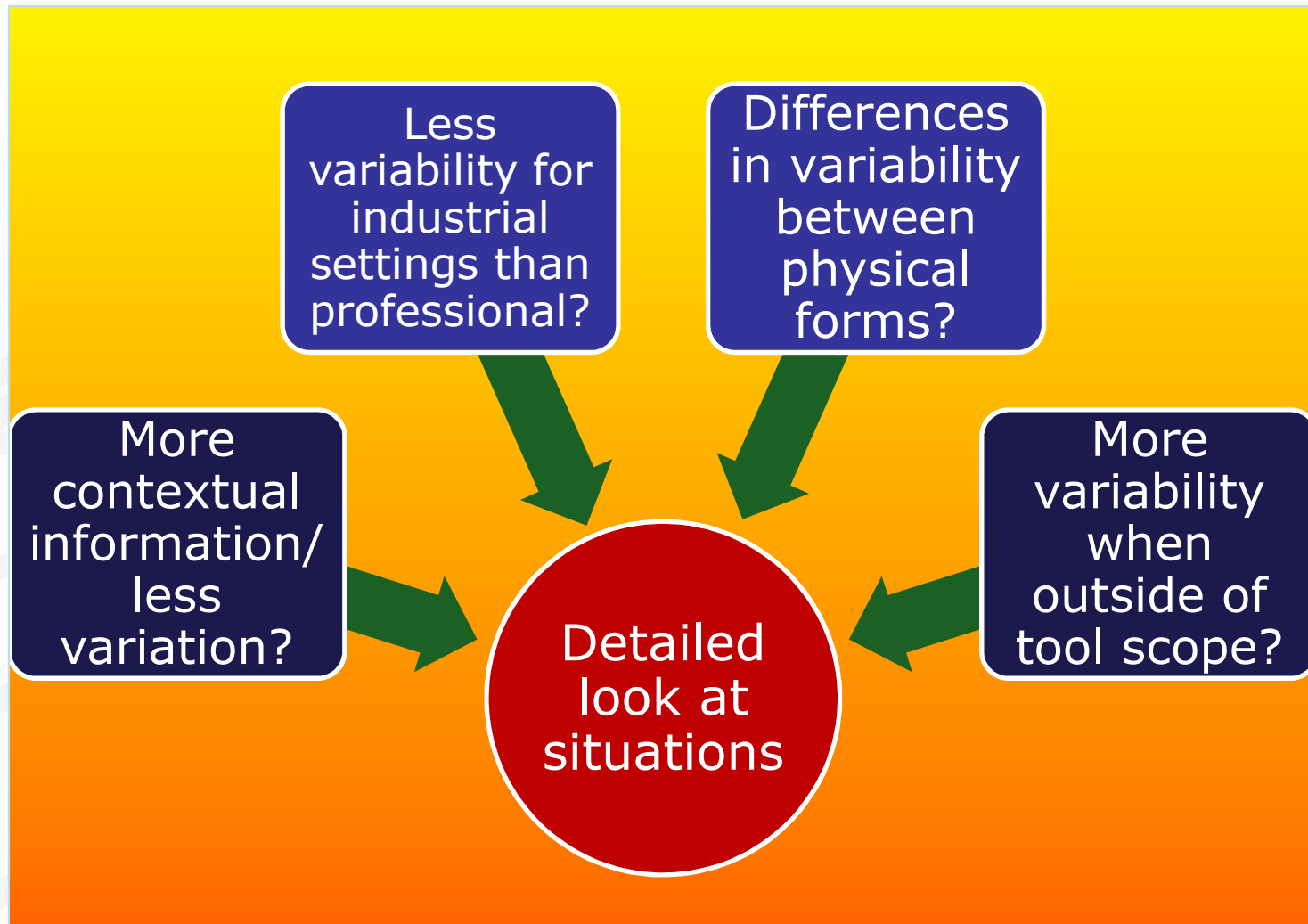
Level (%) of uncertainty experienced in choosing input parameters- inhalation



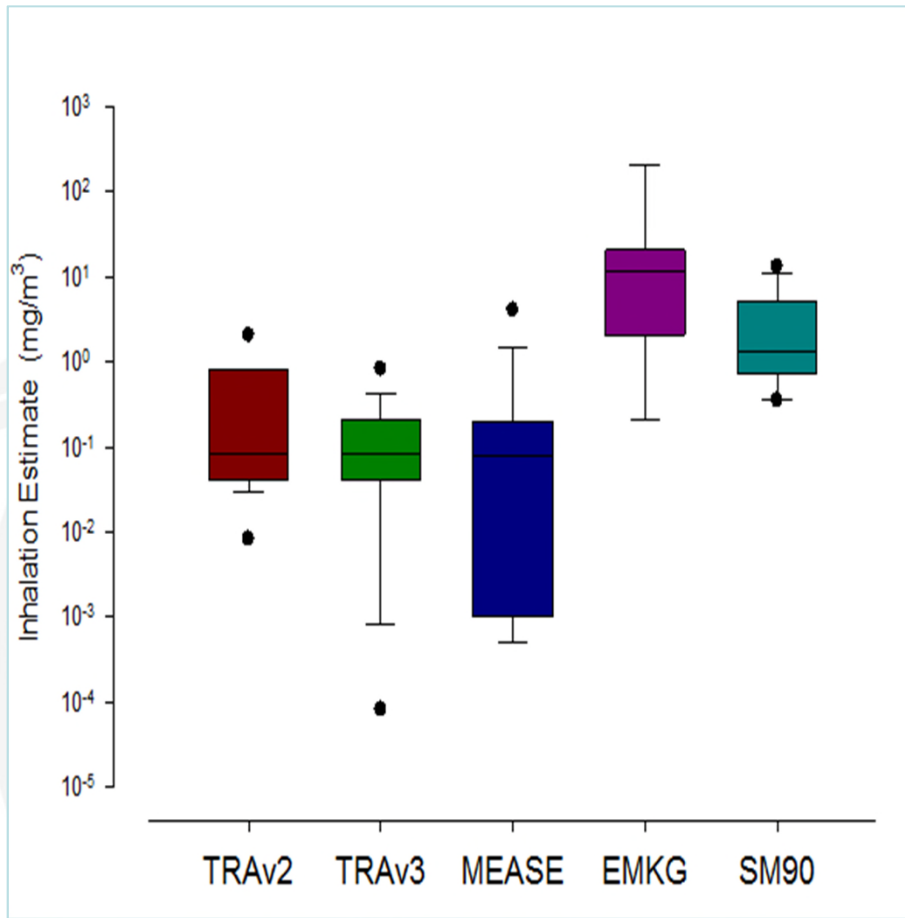
# How easy did participants find translation of situations into tool inputs?



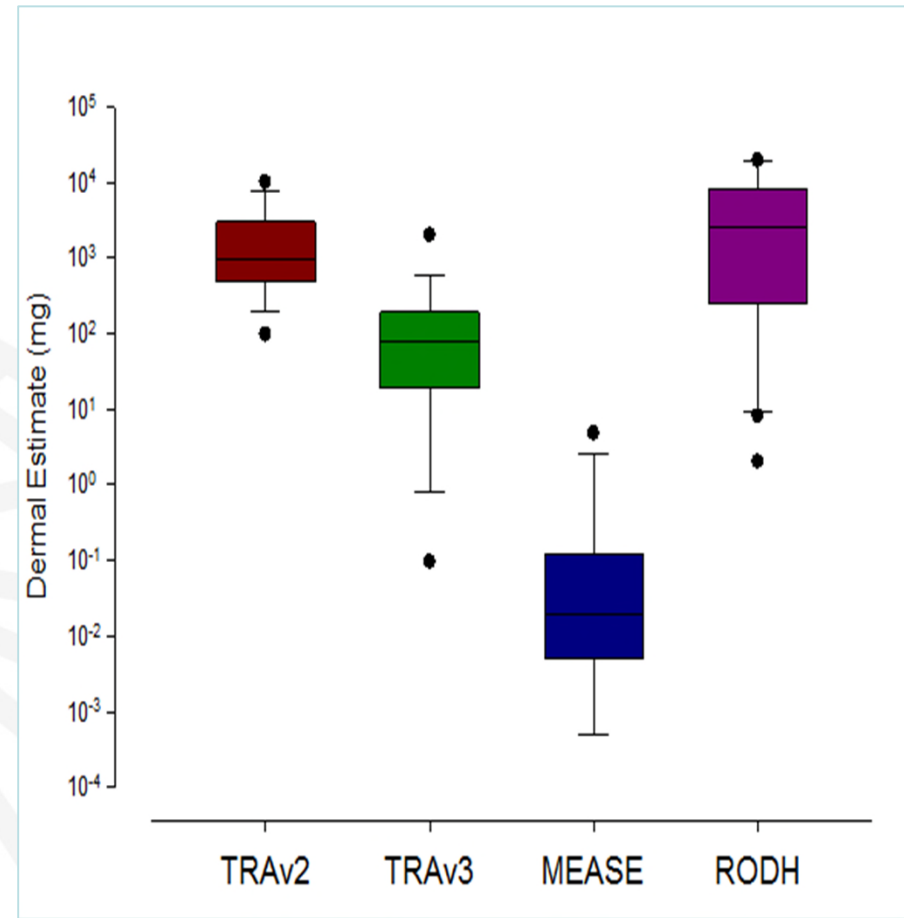
| Inhalation Tool       | Ease of Translation into Tool Parameters (%) |                                  |                              |         |
|-----------------------|--|----------------------------------|------------------------------|---------|
|                       | Very easy/<br>easy                           | Neither easy<br>nor<br>difficult | Difficult/<br>very difficult | Missing |
| <b>ECETOC TRAv2</b>   | 49   | 16                               | 6                            | 28      |
| <b>ECETOC TRAv3</b>   | 36   | 23                               | 10                           | 30      |
| <b>EMKG-EXPO-TOOL</b> | 45   | 18                               | 8                            | 29      |
| <b>MEASE</b>          | 42   | 21                               | 9                            | 28      |
| <b>STOFFENMANAGER</b> | 27   | 29                               | 14                           | 30      |



# Situation 7: Changing of filters in paint spray booth



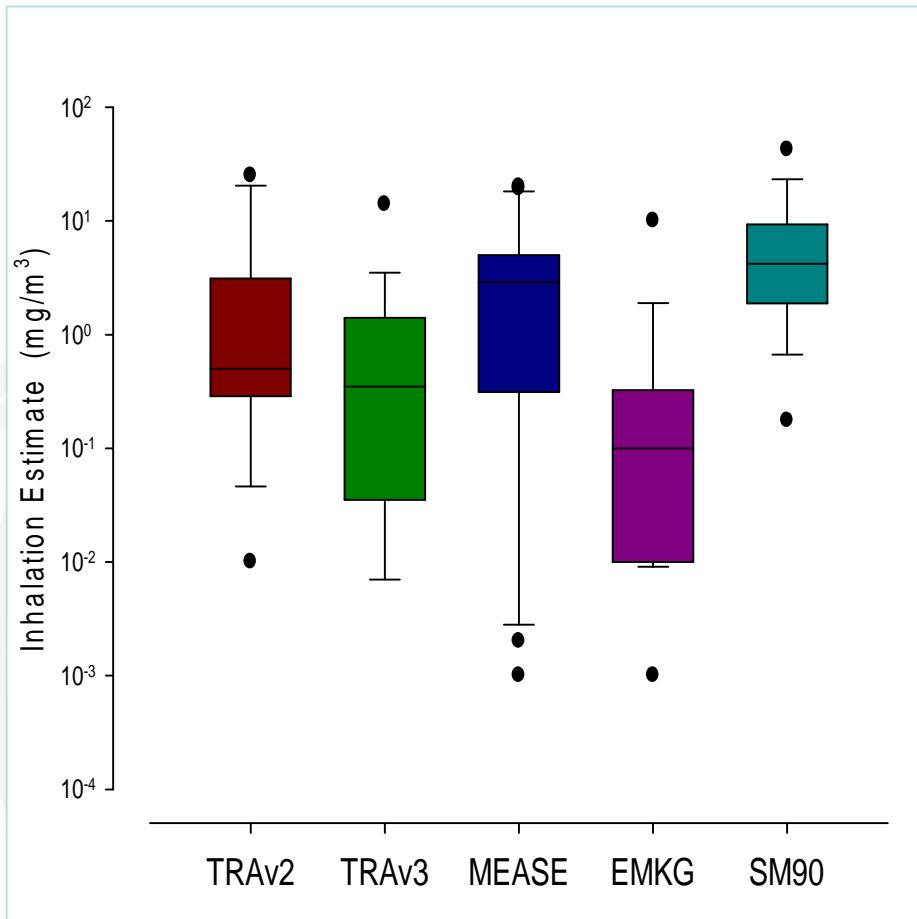
Inhalation estimates



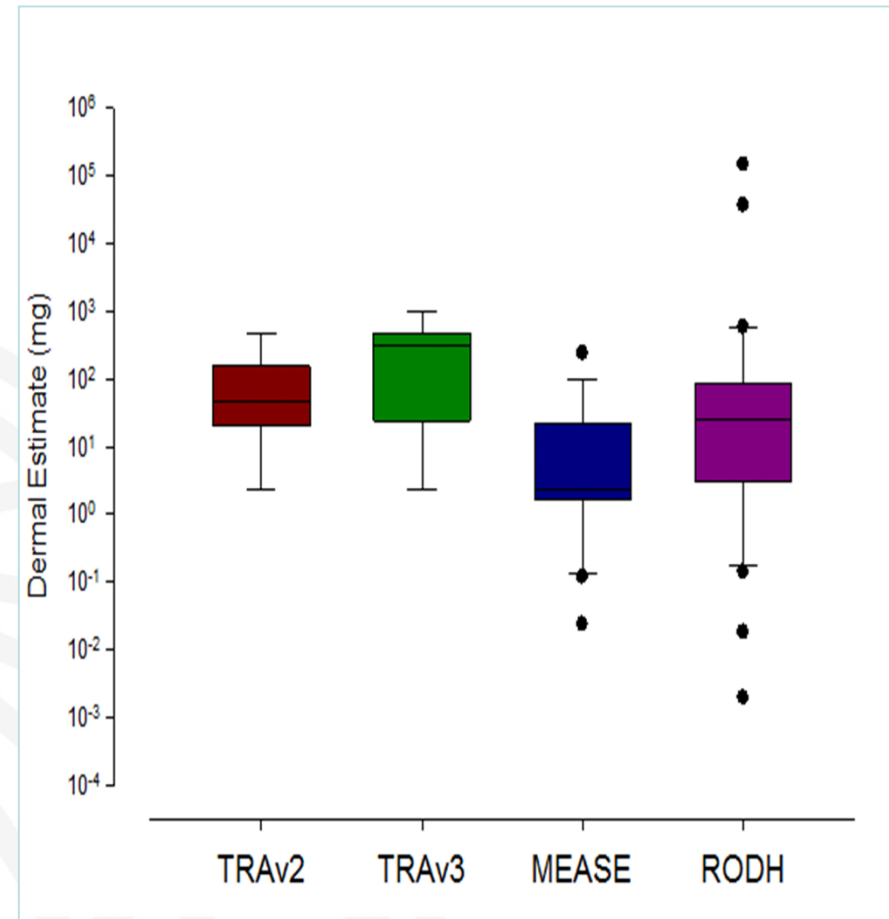
Dermal estimates



# Situation 11: Small scale weighing of amoxicillin powder

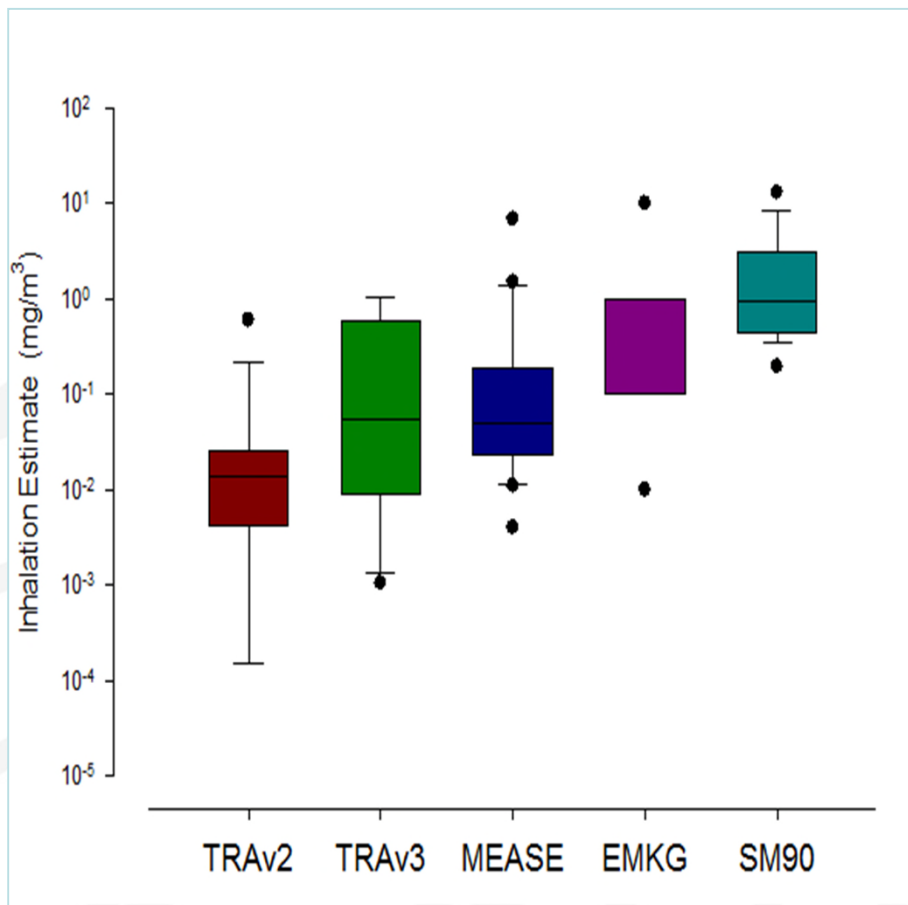


Inhalation estimates

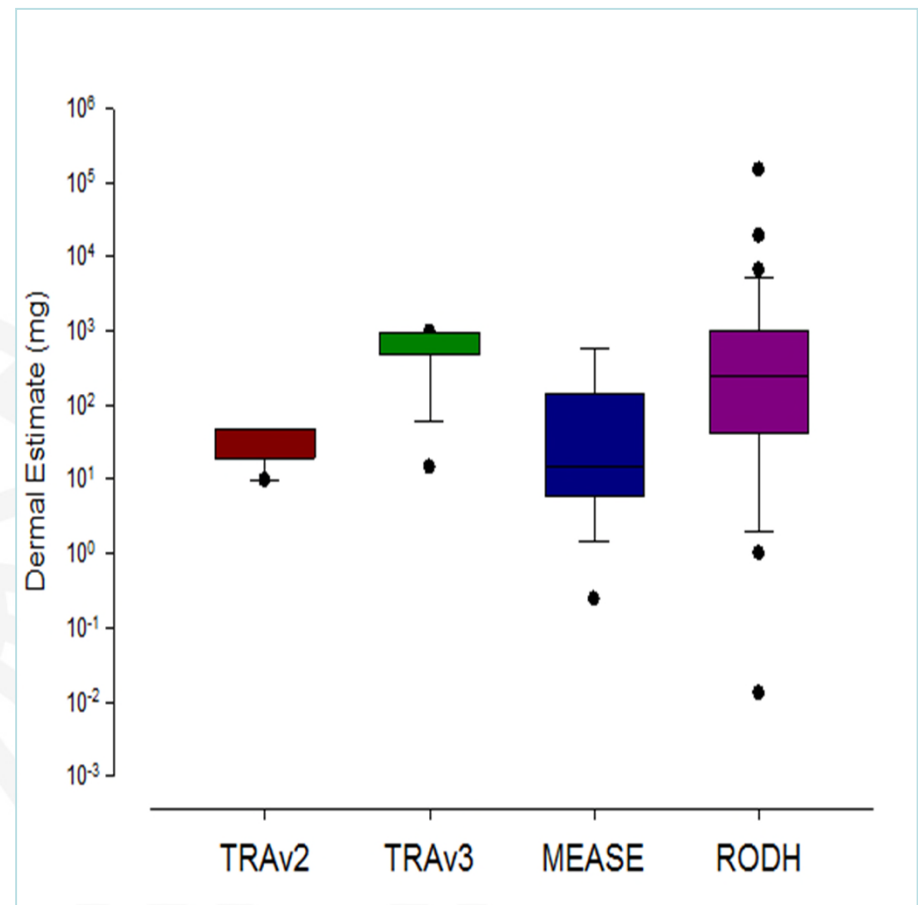


Dermal estimates

# Situation 15: Packing of nickel powder



Inhalation estimates



Dermal estimates

# Common Sources of variation



- ❖ Choice of PROC code/  
handling description
  - Assessing main process or subtask?
  
- ❖ Dustiness
  - Intrinsic dustiness or linked to energy in process
  - Difficult to assess non-visually

- ❖ Risk management measures
  - Variety within situation
  
- ❖ Choice of industrial vs professional
  - Participants and delegates seemed to struggle with this
  - No consistent determining factor
  
- ❖ Duration of activity
  - “borderline” times

# Sources of variation: ECETOC TRAv3 & ECETOC TRAv2



- ❖ Choice of PROC code
  - Assessing main process or subtask?
  - Handling/ transfer activities: 8a/8b/9 (TRAv3) and PROC 1/4/8a for liquid transfer (TRAv2)
  - Provision of guidance/ examples mentioned at workshop
  - Inconsistency of PROC choice between two tool versions for same situation
- ❖ Choice of industrial vs professional
- ❖ Duration of activity
- ❖ Dustiness

# Sources of variation: EMKG-EXPO-Tool



## ❖ General

- Fewer inputs but still large amount of variation
- No in-tool task parameter so more uncertainty when trying to translate activity
- More uncertainty re liquid characteristics than other tools: absence of concentration factor

## ❖ Volatility

- some discrepancies in allocation- reading ability!

## ❖ Scale of use

- Limited information given so judgement required- higher levels of variation

## ❖ Dustiness

## ❖ Control approach

# Sources of variation: MEASE



## ❖ Physical form

- Majority of situations outside scope of tool
- Aqueous solution instead of liquid- in BURE more variation if chosen erroneously
- Dustiness

## ❖ PROC code

- Large variation in choice
- Awareness of tool metal/inorganic-specific options / glossary

## ❖ Contact level

- Difficulty in separating out frequency of contact from intrinsic dustiness

## ❖ Pattern of exposure control

- Awareness/ use of tool guidance?

## ❖ Scale of operation

## ❖ Duration of activity

# Source of variation: Stoffenmanager



## ❖ Activity description

- Choice between similar descriptions: e.g. agreement that small quantities but which handling type?

## ❖ Room size

- Little information given therefore judgement needed - some variation noted

## ❖ Control measures

### ❖ Dustiness

- Similar reasons for variation to other tools
- More choices but balanced by use of descriptions?

# Sources of variation- RISKOFDERM



## ❖ DEO- task

- Less variation than other tools- more delineation between categories

## ❖ Application rate

## ❖ Cumulative duration

- Information given but interpreted very differently

## ❖ Contact

- Observed variation in level of contact
- Difficulty in separation of likelihood of contact from frequency?

## ❖ Dustiness

- Estimates much higher than for other dermal tools



# Other sources of variation



- ❖ **Erroneous choices**
  - physical form of molten metals
  - dermal exposure situations
- ❖ **Lack of awareness of tool guidance**
  - Tendency to use basic use instructions provided rather than actual tool information
- ❖ **Differences in interpretation/ mis-reading of information**
  - Inclusion/ exclusion of described risk management measures
- ❖ **Typographical/ transcription errors**

# Limitations of BURE



- ❖ Recruitment may not have reached typical tool users
- ❖ Self-selection regarding English language
- ❖ Different to iteration process used under REACH
  - Workplace specific situations used vs sector generic scenarios
  - Assessment outputs are the estimate and the tool parameter choices

# Conclusions



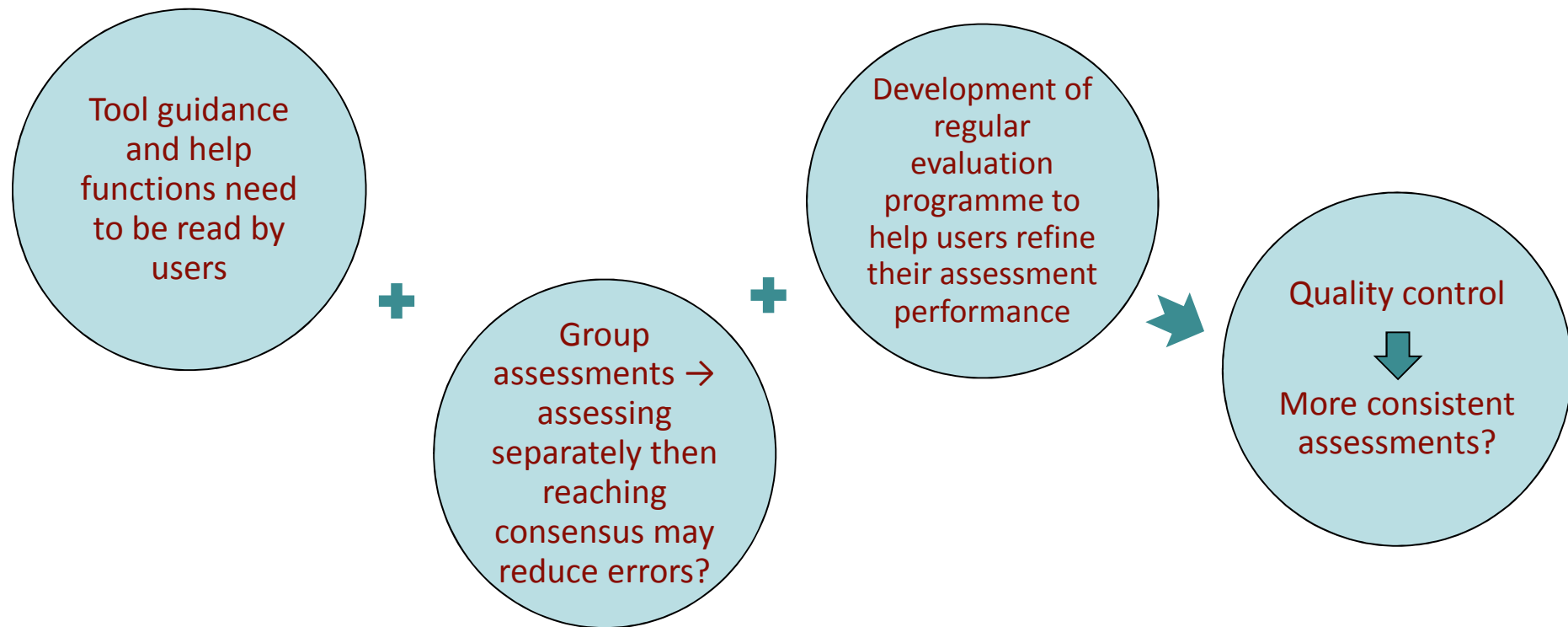
- ❖ Most variation between users is not obviously attributable to their personal characteristics
- ❖ Ease of translation and level of uncertainty are not predictors of level of variation
- ❖ Perceived level of uncertainty greater for dermal assessments and for solids- general levels of experience of these tasks?
- ❖ Participants, on occasion, conflate determinants when allocating inputs which may affect variation and validity of the estimate
- ❖ Assessment of overall process type rather than described exposure-prone task

# Conclusions (2)



- ❖ Professional situations gave rise to more variation in estimates- lower familiarity with these activities?
- ❖ Allocation of level of dustiness seems to be challenging and variable
- ❖ For all tools, the choice of task/ activity for a given situation showed great variation between people who were assessing the same, reasonably well-described exposure settings
- ❖ Similar findings in reliability studies for other assessment tools
- ❖ Overall, the exercise suggests that between user variation in interpretation of exposure determinants could be an important issue for the standardisation of REACh processes

# Recommendations.....



# Acknowledgements



- eteam Project Advisory Board
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- BURE and workshop participants