IOM

WORKING FOR A HEALTHIER FUTURE

eteam Project: Between-user reliability exercise

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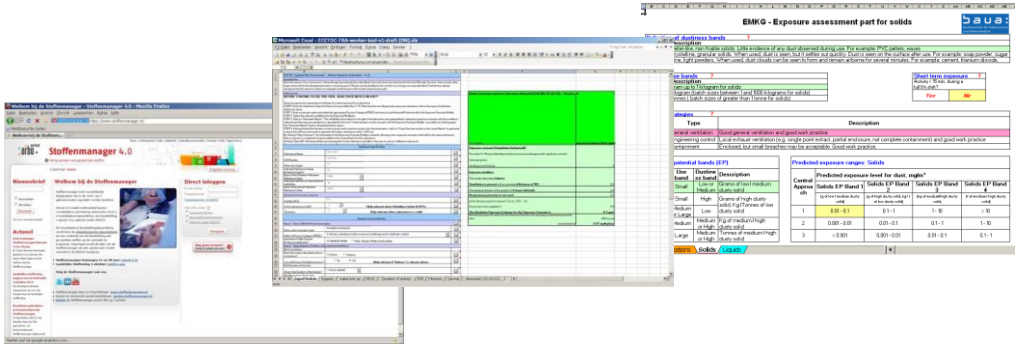
Overview

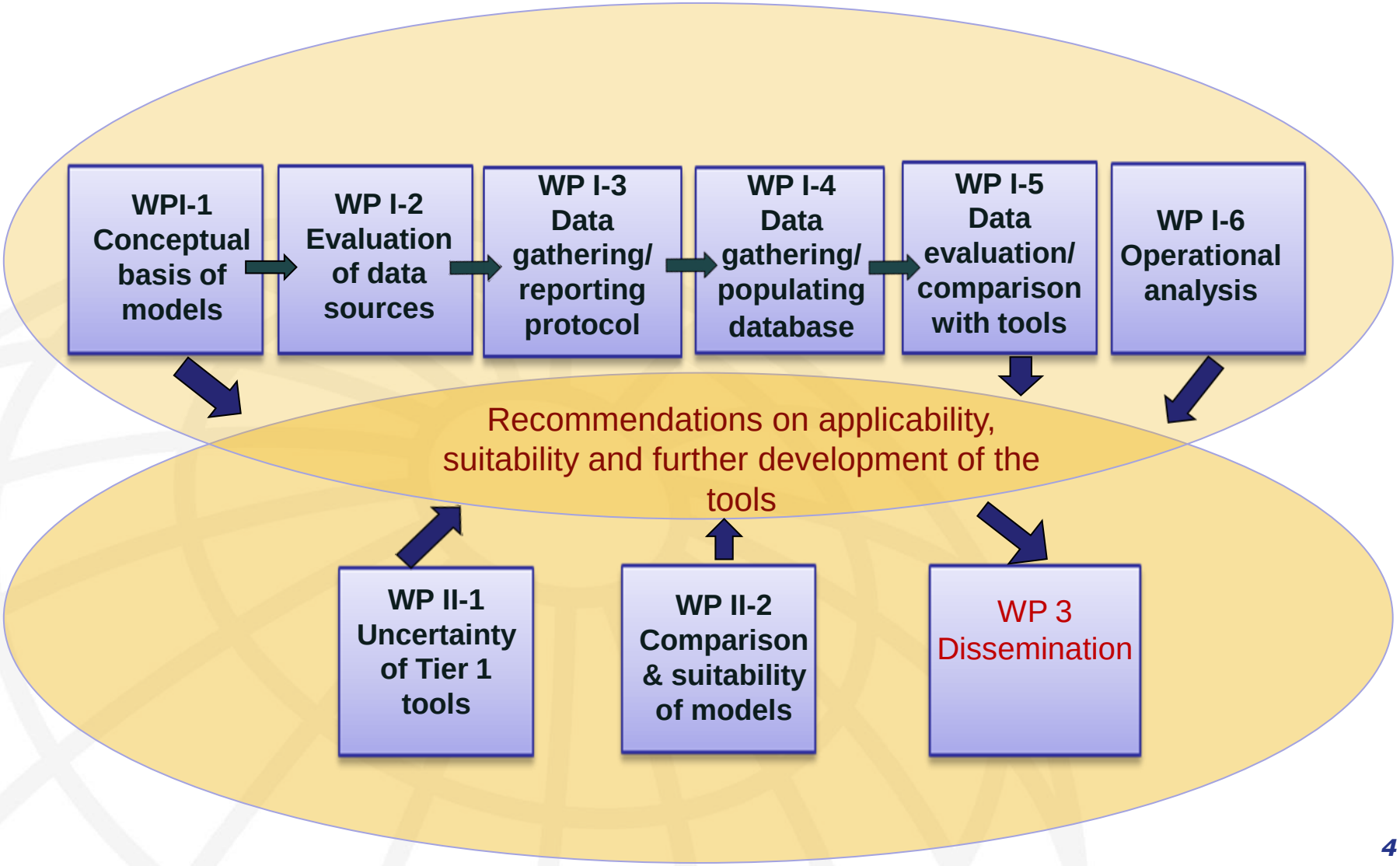
- eteam Project
- Background and aims
- Format
- Coverage
- Results
- Main sources of variation in tools
- Conclusions
- Recommendations

eteam Project



- Funded by BAuA
- Collaboration between IOM and Fraunhofer-ITEM
- Advisory Board, consisting of
  - Tool developers (ECETOC, TNO/ArboUnie, BAuA, EBRC)
  - Major data providers (IFA, NIOSH, HSE, SECO)
- Links with other projects (Switzerland, US, Sweden)

Project overview



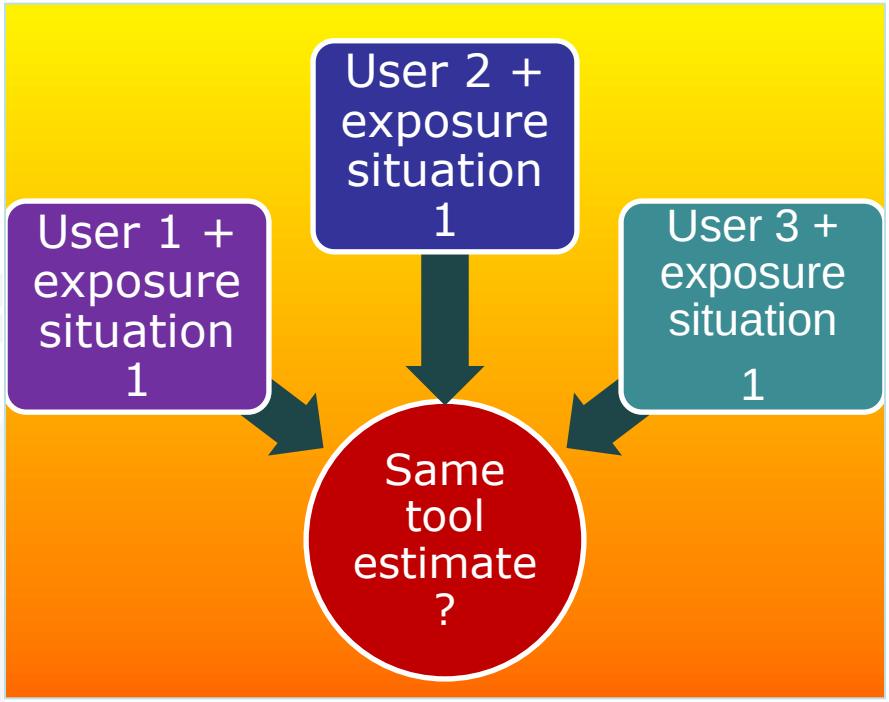
Tools

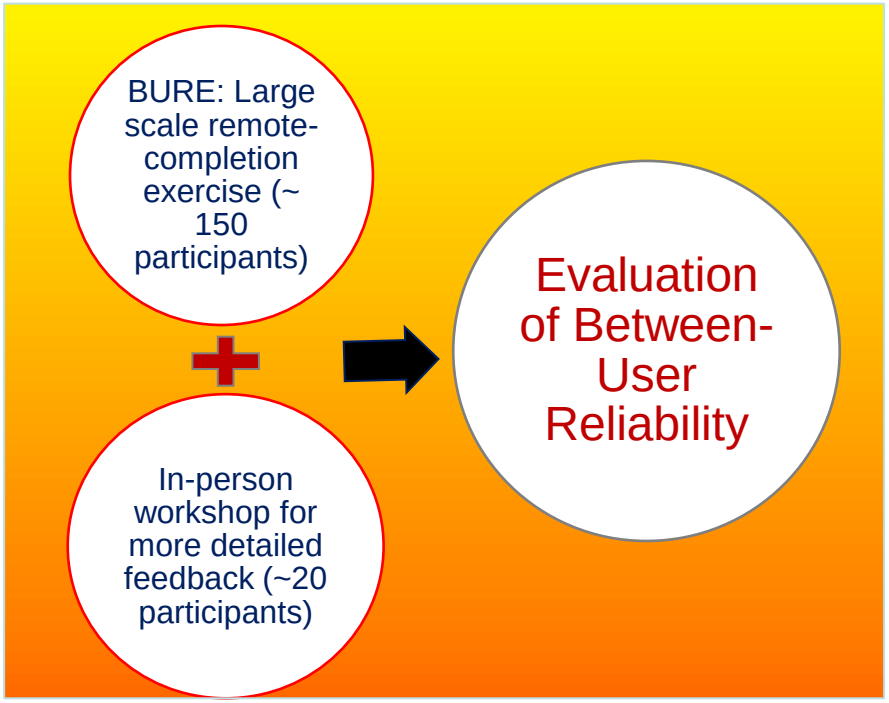
- ECETOC TRA Versions 2 & 3
- EMKG-EXPO-Tool
- MEASE Version 1.02.01
- Stoffenmanager Version 4.5
- RISKOFDERM Version 2.1
- EASE- conceptual evaluation process

Aims of eteam Project

- Evaluate the scientific basis of the tools
- Determine their user-friendliness
- Assess the between-user reliability
- External validation of tool estimates via comparison with measurement data
- Provide practical recommendations to developers, users and regulators on how to use the tools most effectively

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

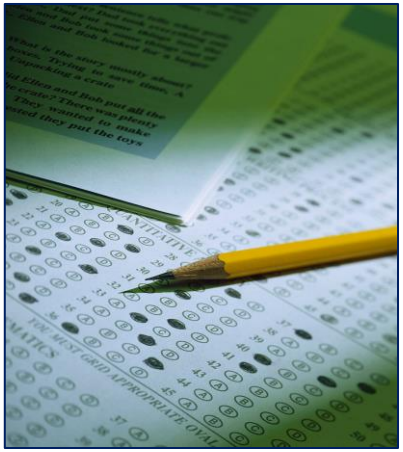




Confidence in a tool's predictions requires confidence in its reliability

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^{o}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.

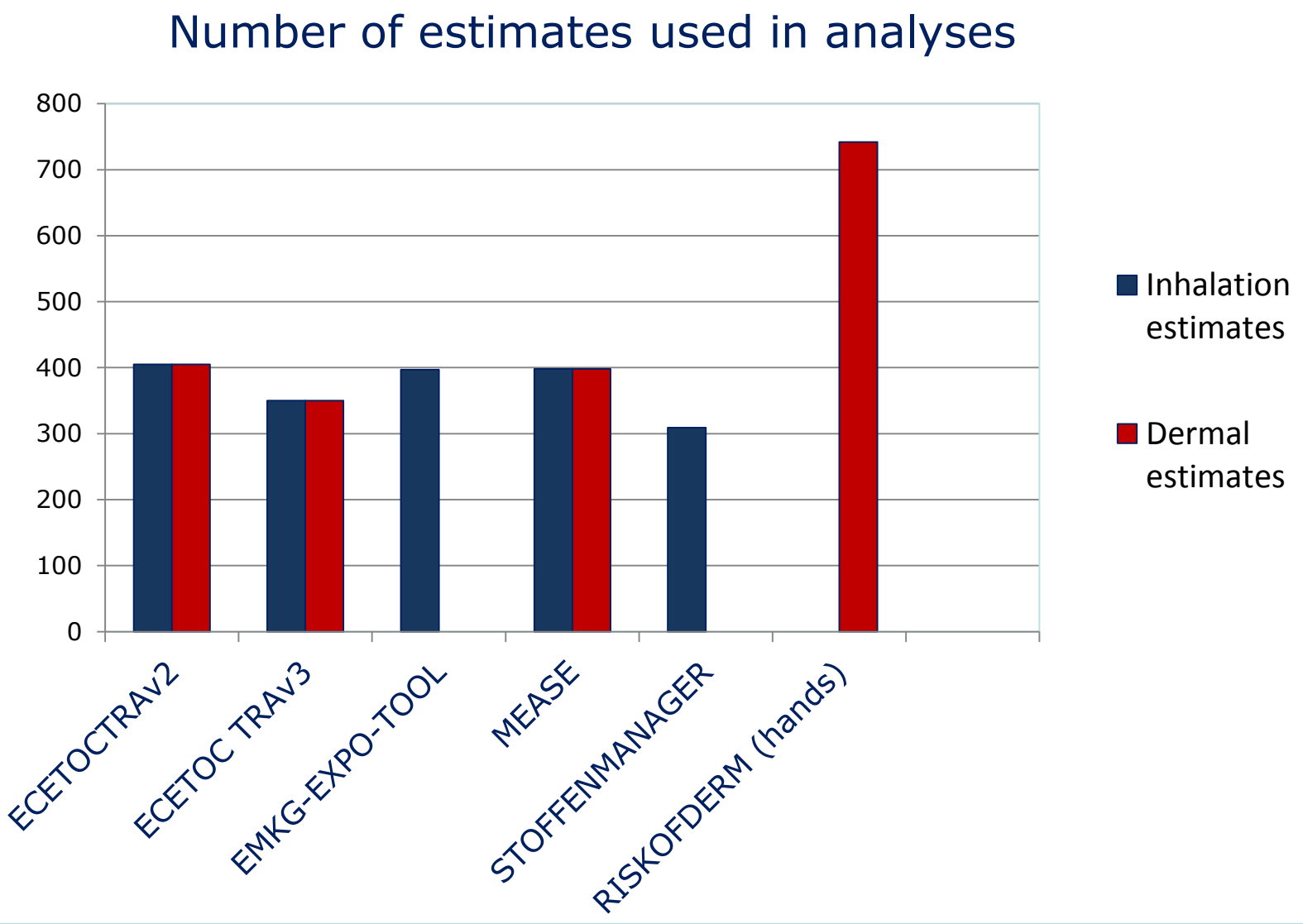
2. Product/ Substance Information

Product	Supplier	Substance Name	CAS Number	Molecular Weight/ gmol^{-1}	Vapour pressure at 20^{o}C/ Pa	Concentration of Xylene in Product D (%)
Product D	Supplier D	Xylene (mixed 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



Assessor-related variation/ total variation- all situations

Tool	N	Var_{Total}	Ratio (97.5%ile: 2.5%ile)
Inhalation exposure			
ECETOC TRAv3 (mg/m^3)	350	2.63	577
ECETOC TRAv2 (mg/m^3)	405	2.19	331
MEASE (mg/m^3)	398	6.43	20746
EMKG-EXPO-TOOL (mg/m^3)	397	4.00	2540
STOFFENMANAGER (mg/m^3)	309	2.20	335
Dermal exposure			
ECETOC TRAv3 (mg/kg/day)	350	2.06	278
ECETOC TRAv2 (mg/kg/day)	405	1.31	90
MEASE (mg)	398	4.47	3975
RISKOFDERM (hands) (mg)	742	6.66	24744

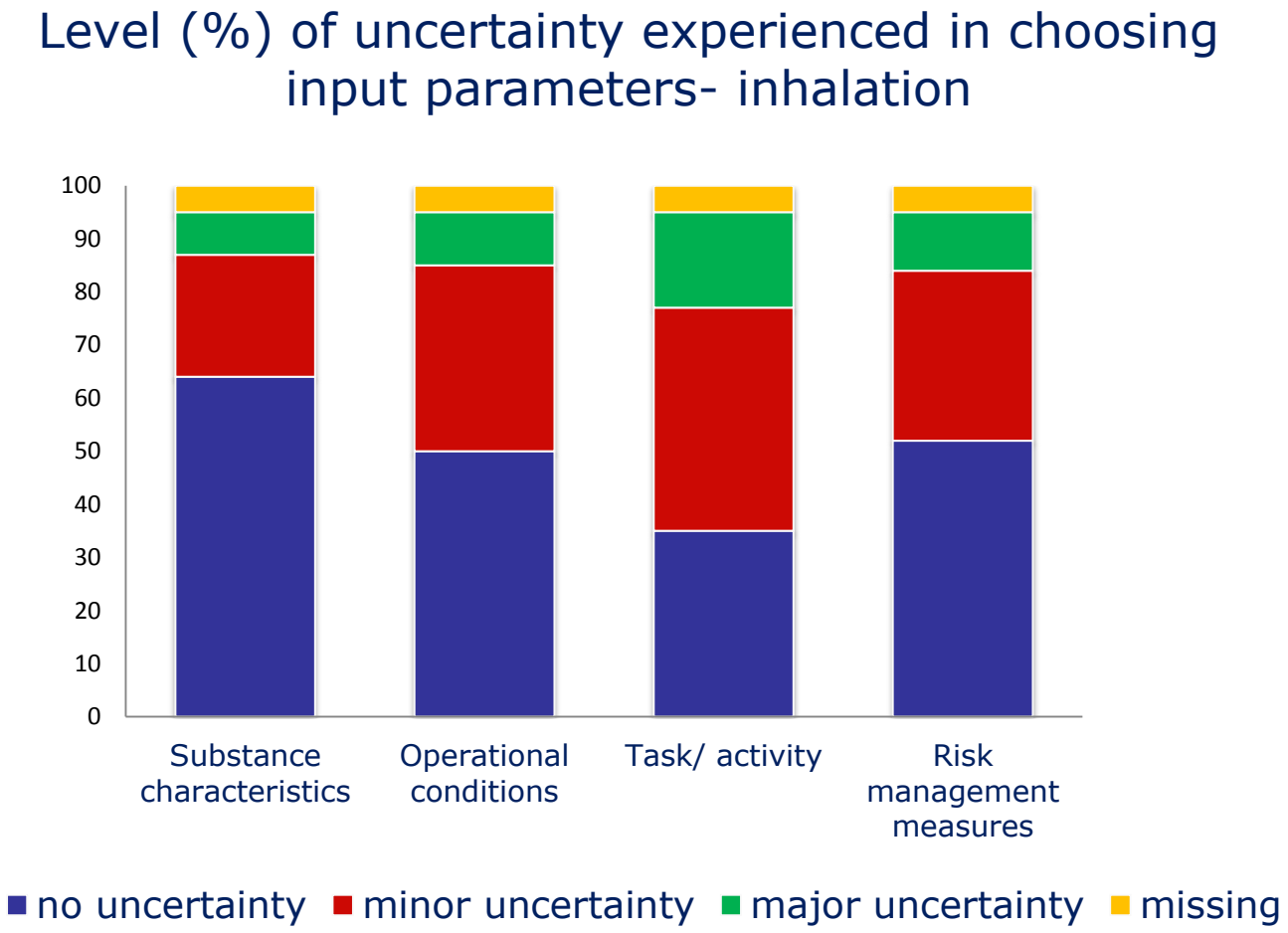
Assessor-related variation/ total variation- applicable situations only

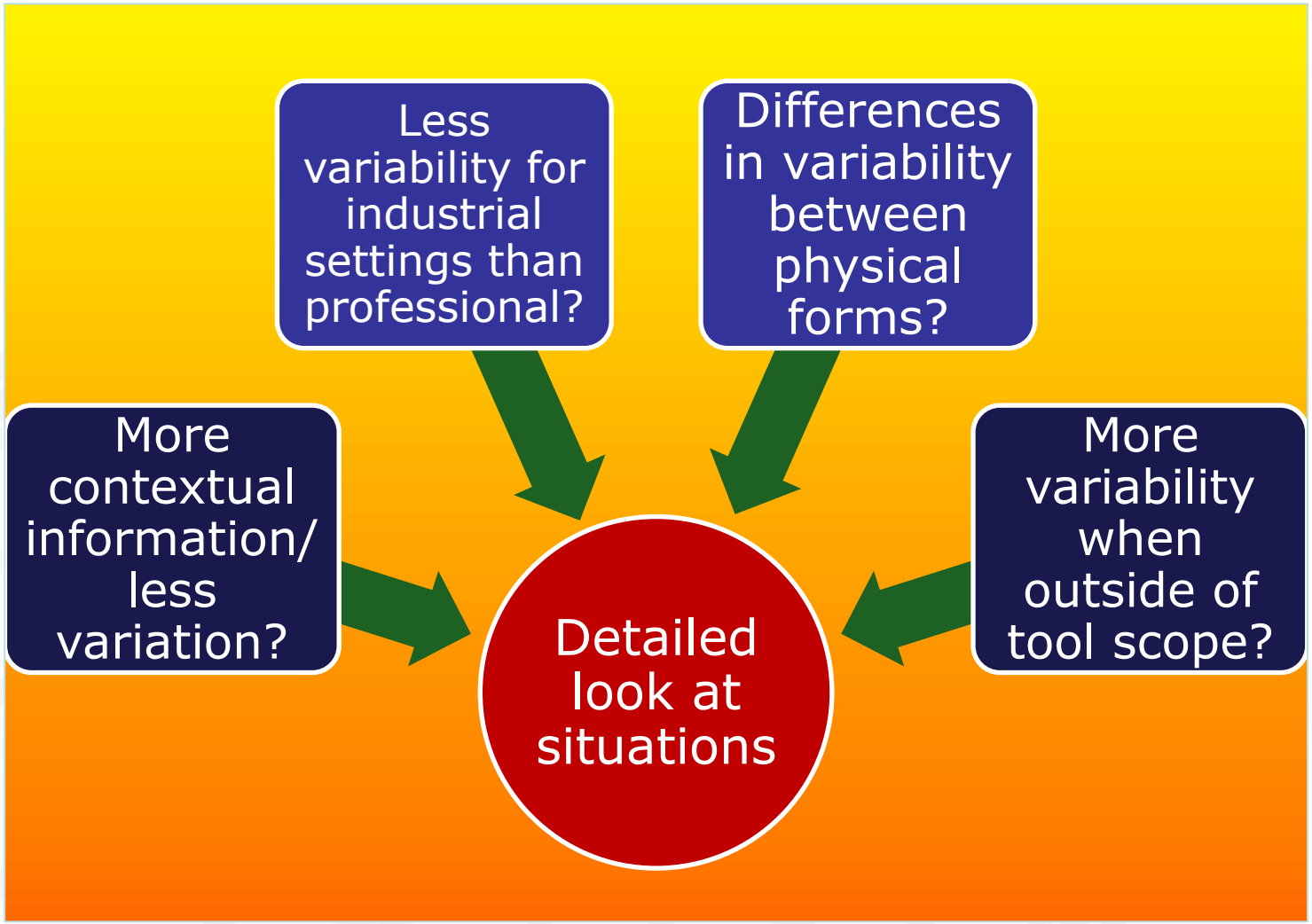
Tool	N	Var_{Total}	Ratio (97.5%ile: 2.5%ile)
Inhalation exposure			
ECETOC TRAv3 (mg/m^3)	326	2.59	549
ECETOC TRAv2 (mg/m^3)	365	2.28	372
MEASE (mg/m^3)	151	4.44	3866
EMKG-EXPO-TOOL (mg/m^3)	313	3.23	1147
STOFFENMANAGER(mg/m^3)	280	1.77	184
Dermal exposure			
ECETOC TRAv3 (mg/kg/day)	326	1.93	231
ECETOC TRAv2 (mg/kg/day)	365	1.31	88
MEASE (mg)	151	4.66	4732
RISKOFDERM (hands) (mg)	674	6.40	20270

Variation related to participants' characteristics

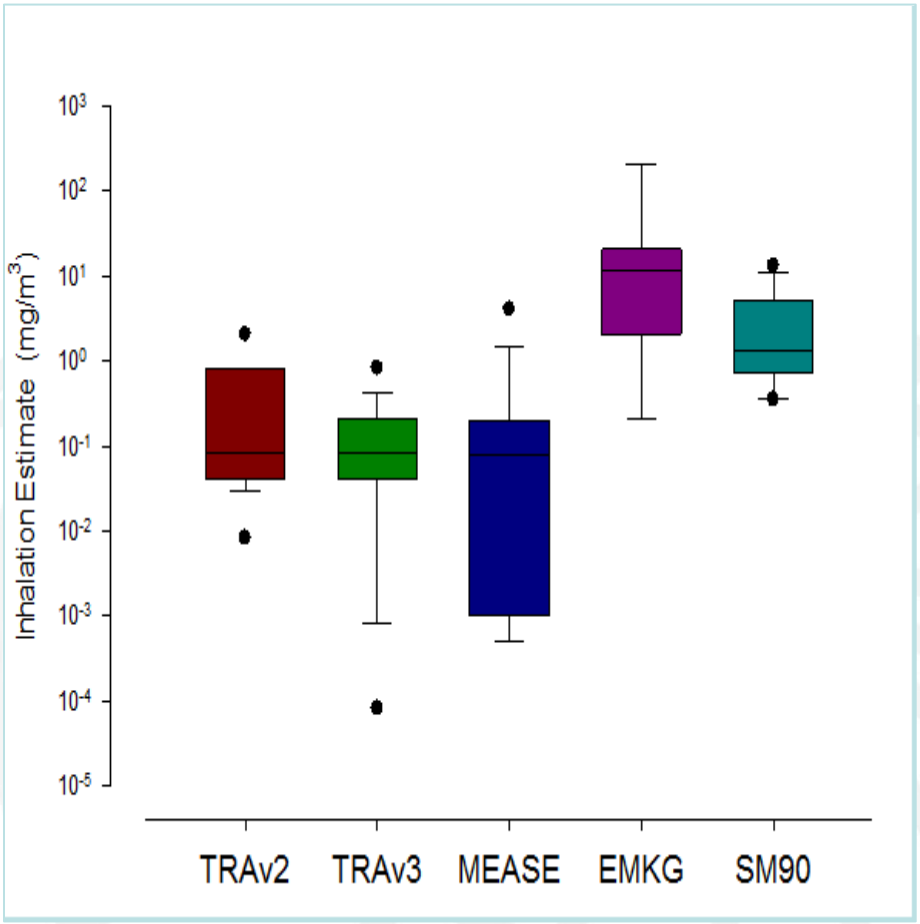
- Linear mixed effects statistical models used to calculate variance
- No obvious or consistent trends observed
- Systematic differences small in comparison with total between user variability
- More experience in assessing exposure does not lead to less variation
- People who do more REACh assessments are no more consistent than others
- Regulators are not obviously conservative, industry not obviously optimistic
- English language ability may have some small effect for MEASE, however not consistent

How uncertain were participants when choosing inputs?

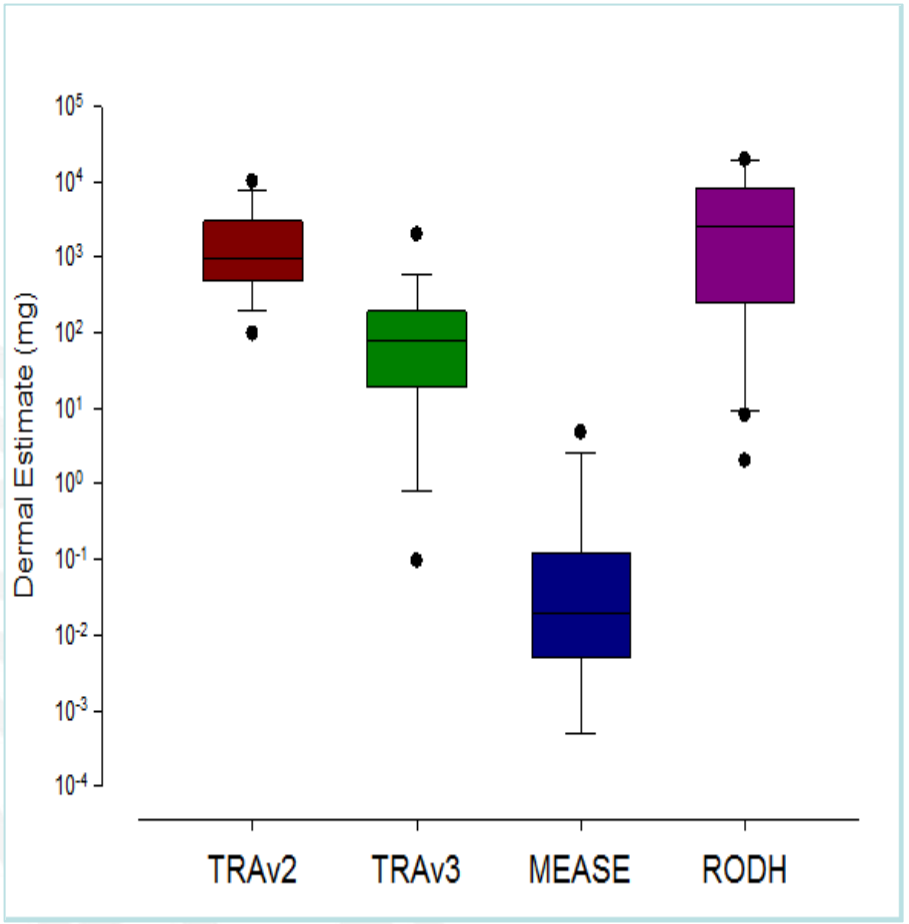



Less variability for industrial settings than professional?
Differences in variability between physical forms?
More contextual information/ less variation?
More variability when outside of tool scope?
Detailed look at situations

Situation 7:
Changing of filters in paint spray booth

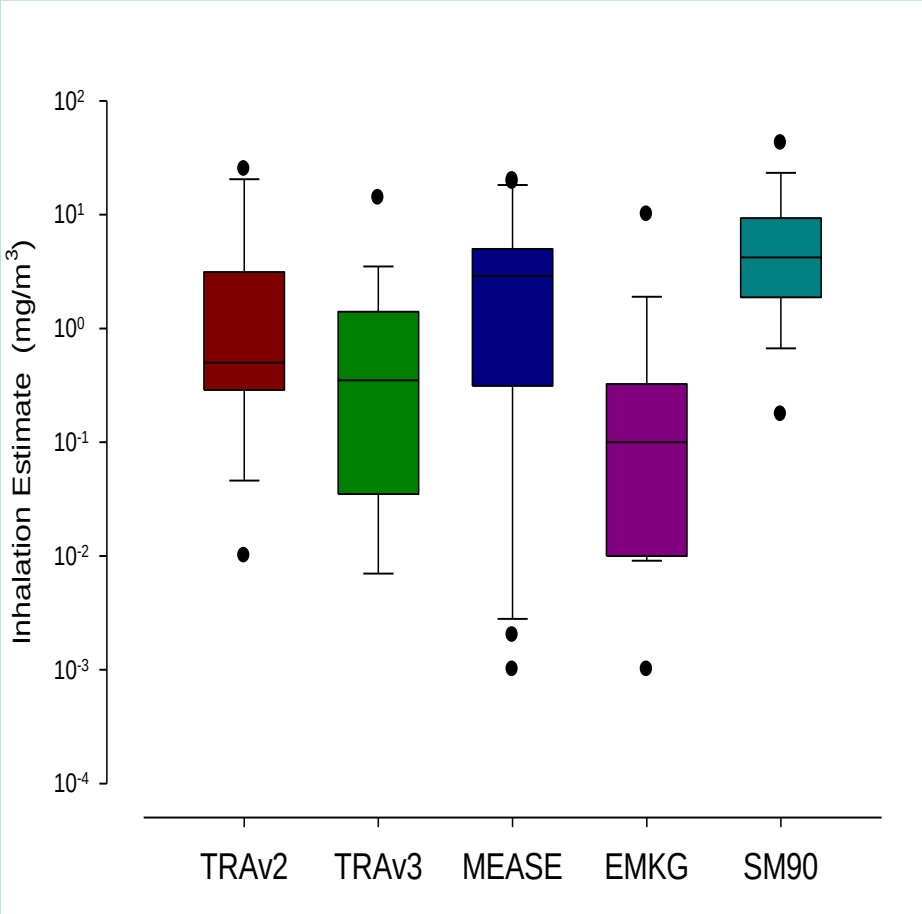


Inhalation estimates

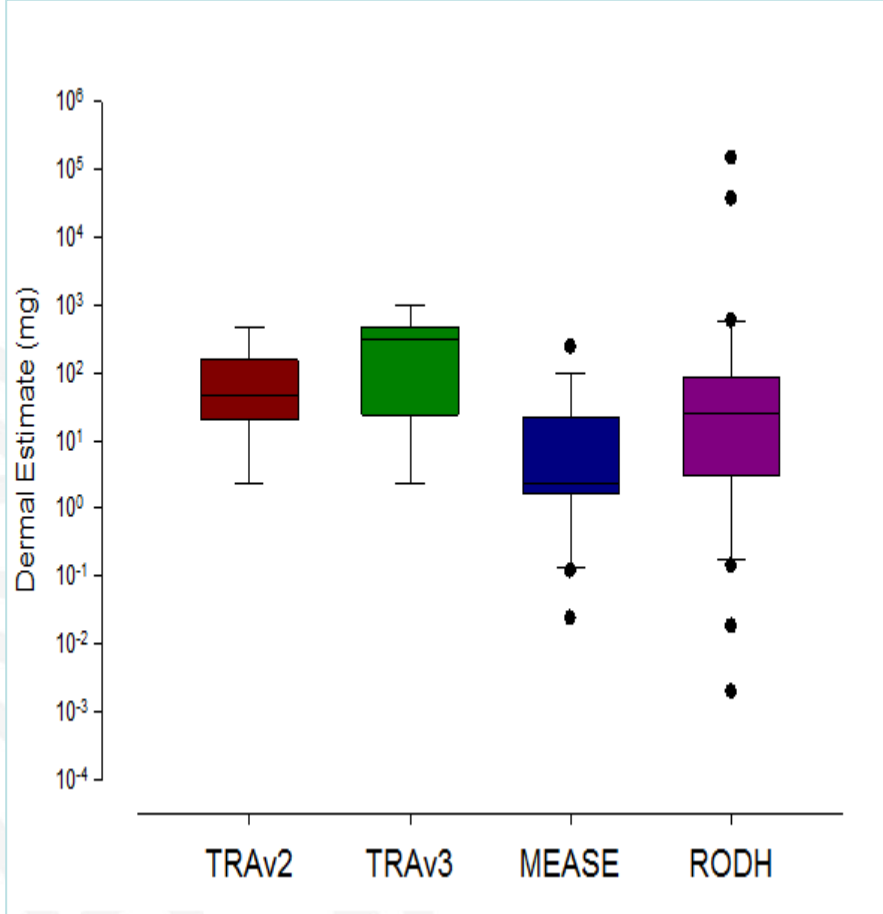


Dermal estimates

Situation 11:
Small scale weighing of amoxicillin powder



Inhalation estimates



Dermal estimates

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
  - Wide 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

Other sources of variation

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