

# An evaluation of the between-user reliability of Tier 1 exposure assessment tools used under REACH

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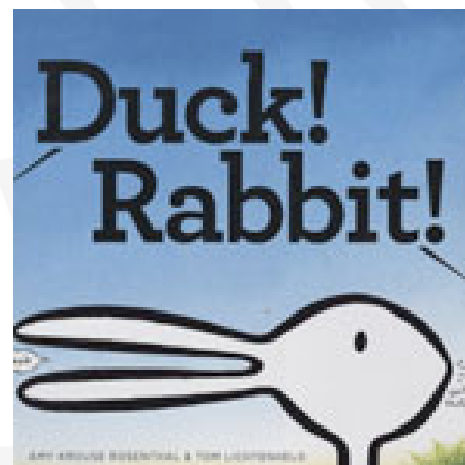
# Overview

- ❖ Background
- ❖ Method
- ❖ Results
- ❖ Main sources of variation in tools
- ❖ Ways forward...

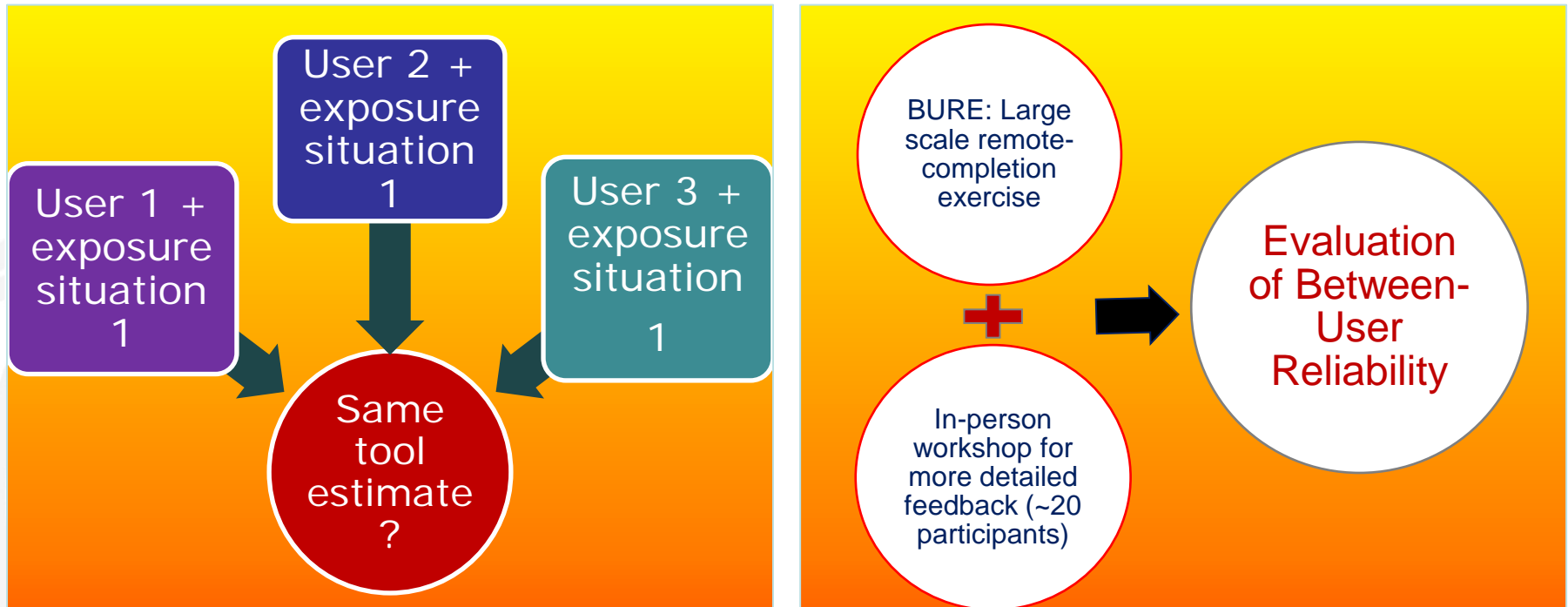


# Between-User Reliability?

- No matter how “good” a tool is, reliability between users is important
- As humans, we don’t always see the same things the same way as everyone else does!



**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



- ❖ Recruited 146 users: assessed 20 varied workplace situations using 6 tools
- ❖ Inhalation +/-dermal exposure potential
- ❖ Textual description of typical professional and industrial workplace exposure settings
- ❖ Information provided on standard factors
- ❖ Variable information on other exposure determinants e.g. RMMs, task duration, environment



# Results: BURE participant population



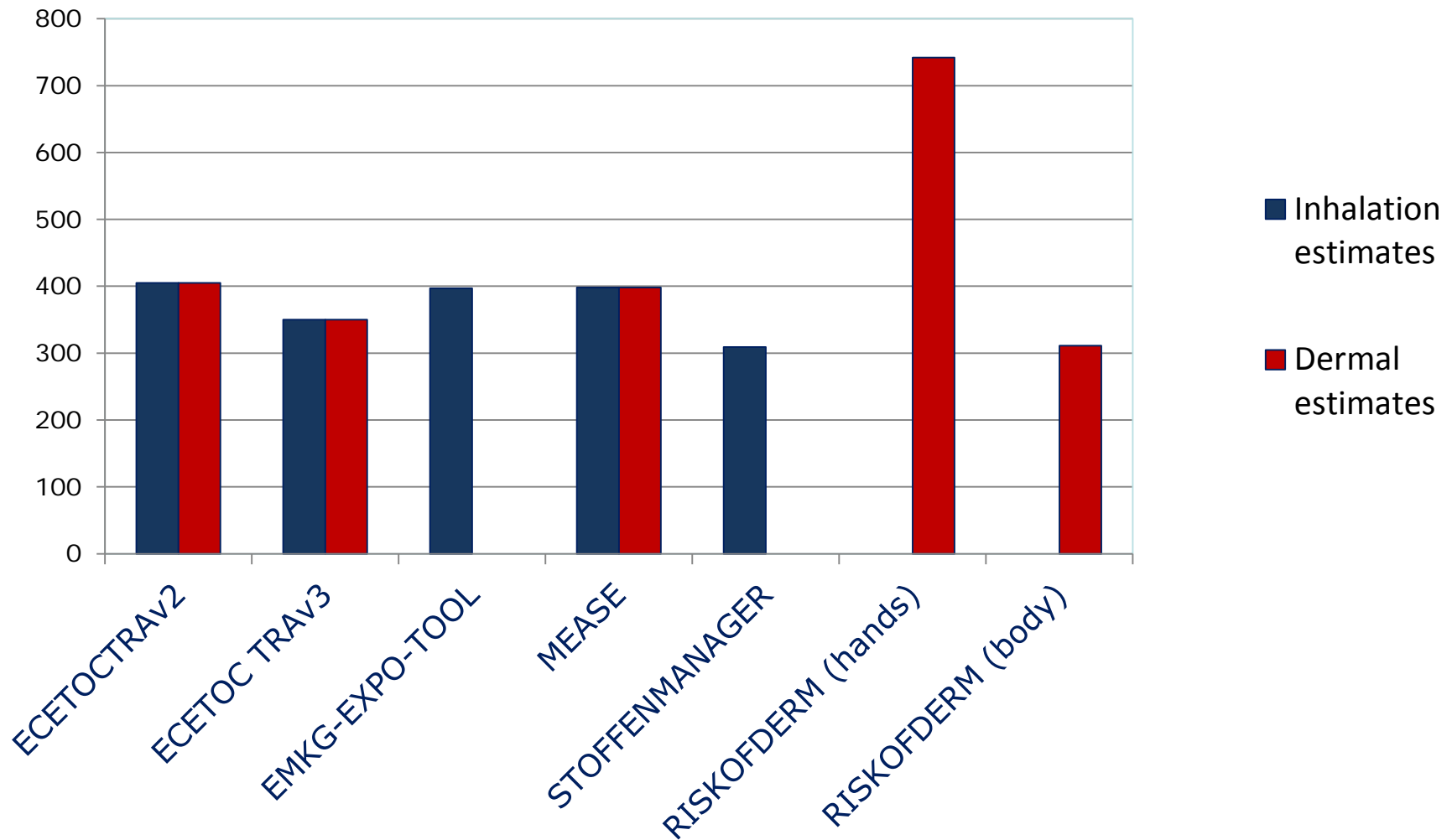
- ❖ Sector
  - majority consultancy/industry (57%)
- ❖ Location
  - mainly EU (84%)
- ❖ Main reason for carrying out exposure assessments
  - REACH exposure assessment (40%)
- ❖ English language ability
  - majority self-assessed as native/excellent/good
- ❖ Experience of tools
  - Most experience of 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>
<b>Inhalation exposure</b>				
ECETOC TRAv3 (mg/m <sup>3</sup> )	350	0.09	2.53	2.63
ECETOC TRAv2 (mg/m <sup>3</sup> )	405	0.28	1.91	2.19
MEASE (mg/m <sup>3</sup> )	398	0.35	6.07	6.43
EMKG-EXPO-TOOL (mg/m <sup>3</sup> )	397	0.28	3.72	4.00
STOFFENMANAGER(mg/m <sup>3</sup> )	309	0.60	1.59	2.20
<b>Dermal exposure</b>				
ECETOC TRAv3 (mg/kg/day)	350	0.47	1.59	2.06
ECETOC TRAv2 (mg/kg/day)	405	0.18	1.12	1.31
MEASE (mg)	398	0.78	3.69	4.47
RISKOFDERM (hands) (mg)	742	0.55	6.11	6.66
RISKOFDERM (body) (mg)	311	0.10	5.16	5.26



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



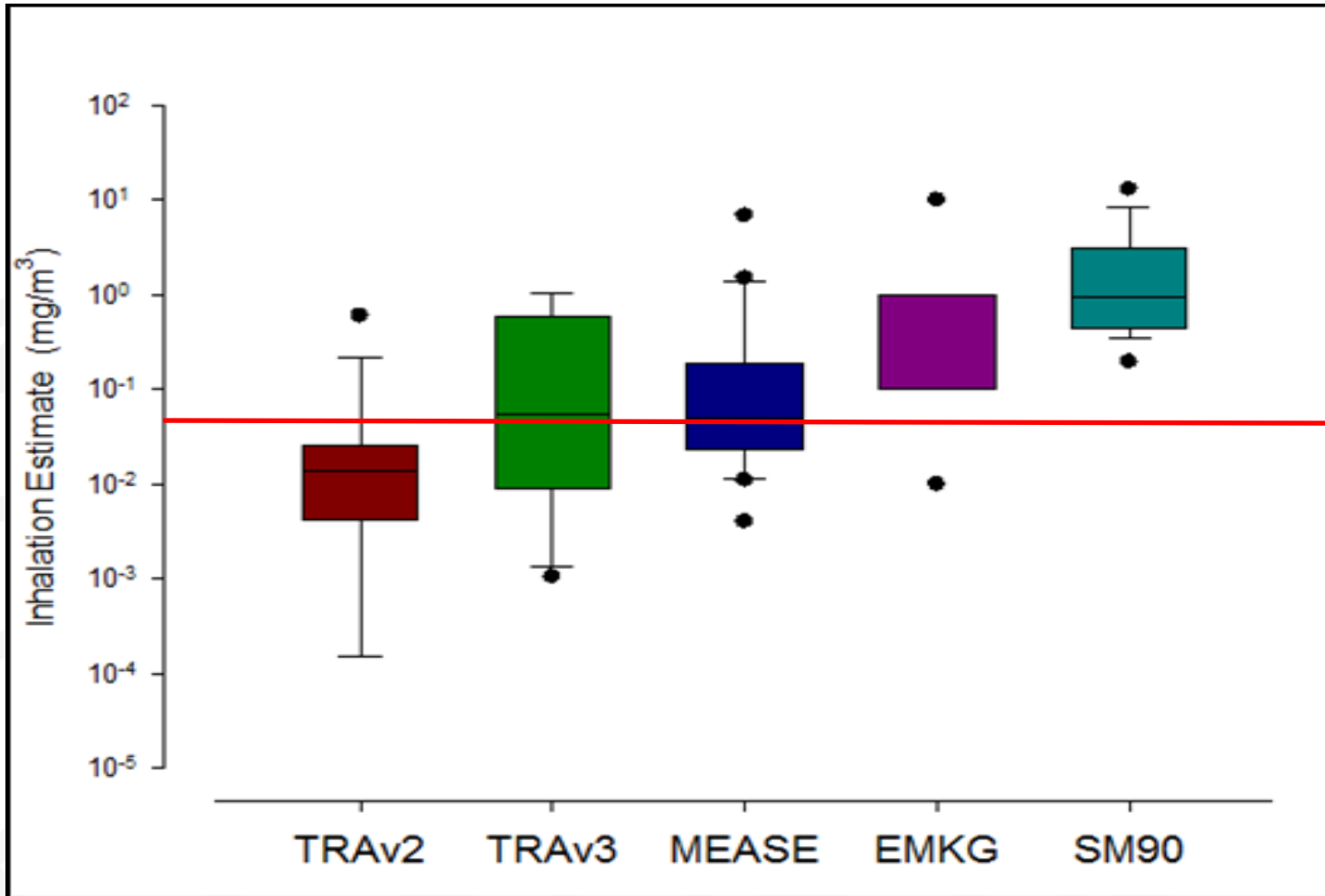
Tool	N	Var <sub>assessor</sub>	Var <sub>residual</sub>	Var <sub>Total</sub>
Inhalation exposure				
ECETOC TRAv3 (mg/m <sup>3</sup> )	326	<0.01	2.62	2.59
ECETOC TRAv2 (mg/m <sup>3</sup> )	365	0.30	1.99	2.28
MEASE (mg/m <sup>3</sup> )	151	0.80	3.63	4.44
EMKG-EXPO-TOOL (mg/m <sup>3</sup> )	313	0.14	3.08	3.23
STOFFENMANAGER(mg/m <sup>3</sup> )	280	0.52	1.25	1.77
Dermal exposure				
ECETOC TRAv3 (mg/kg/day)	326	0.30	1.63	1.93
ECETOC TRAv2 (mg/kg/day)	365	0.32	0.99	1.31
MEASE (mg)	151	0.68	3.98	4.66
RISKOFDERM (hands) (mg)	674	0.58	5.82	6.40
RISKOFDERM (body) (mg)	288	0.16	5.22	5.38

# 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, however not consistent
- ❖ People who do more REACH assessments are no more consistent than others

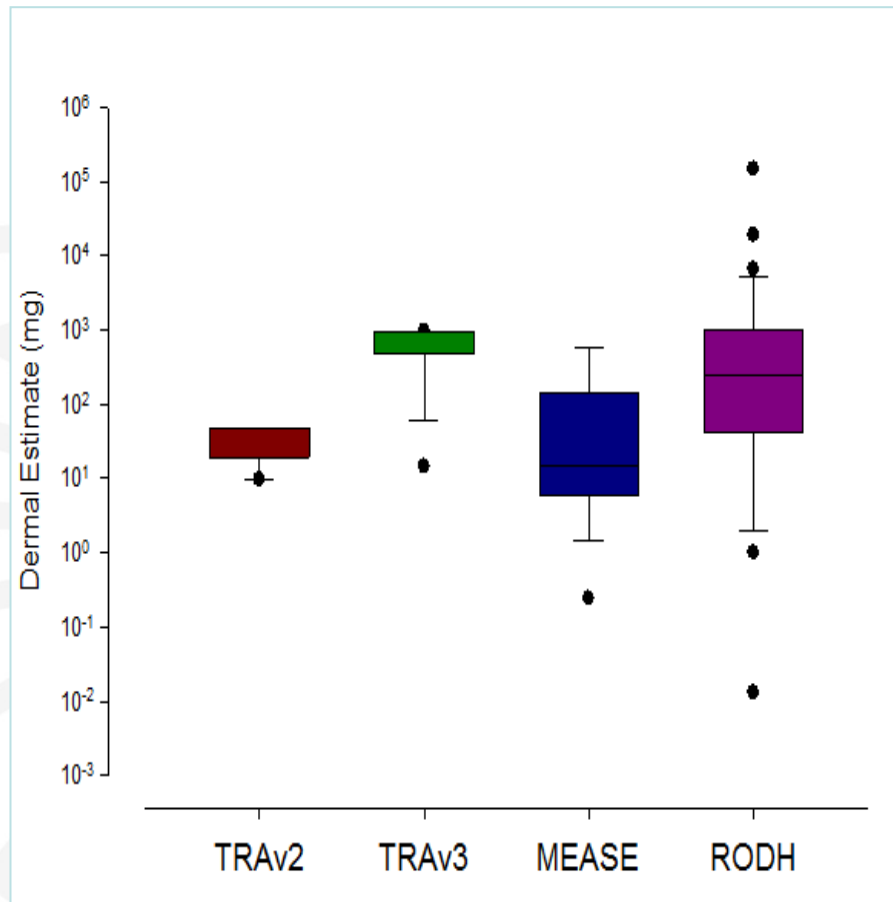


# Exposure to Nickel powder during packing- inhalation



DNEL = 0.05 mg/m<sup>3</sup>

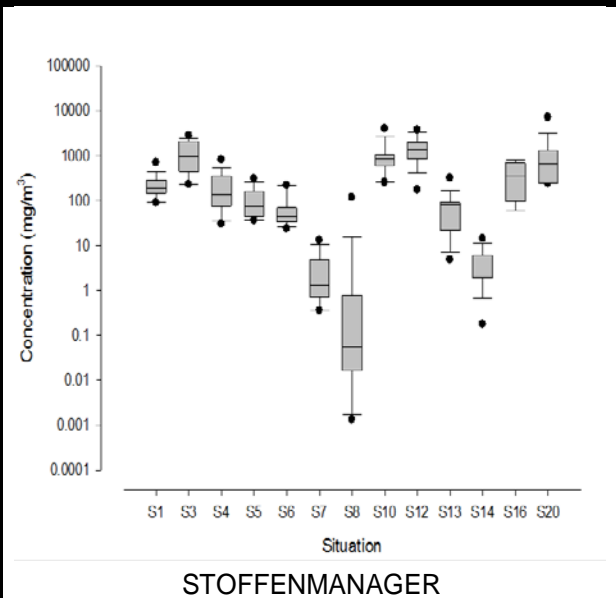
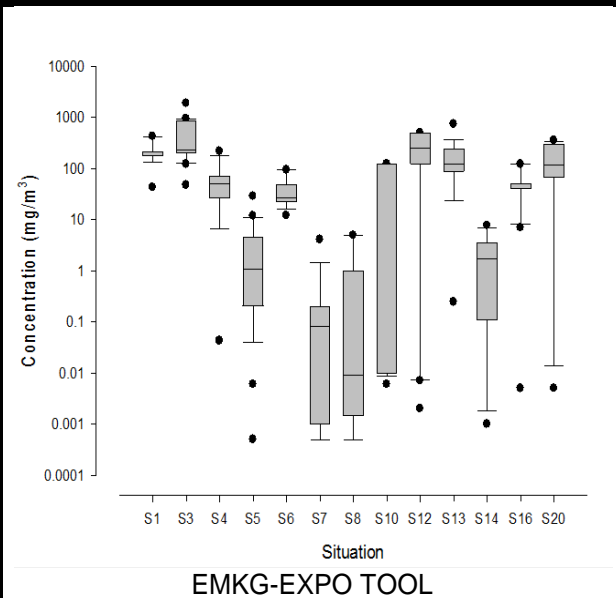
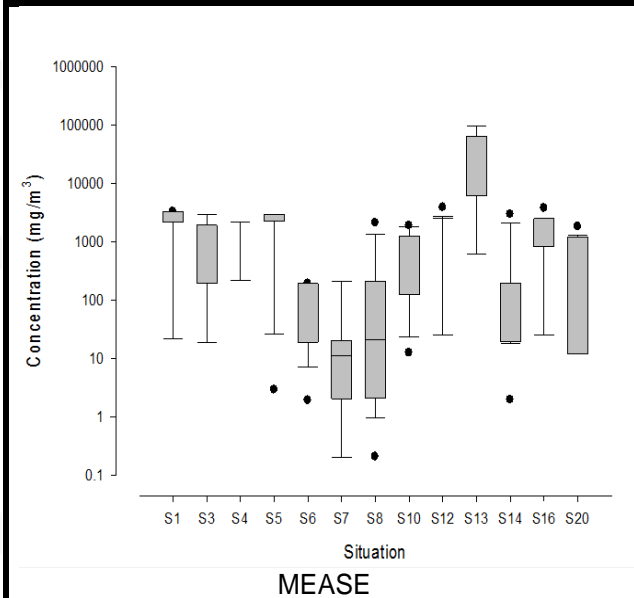
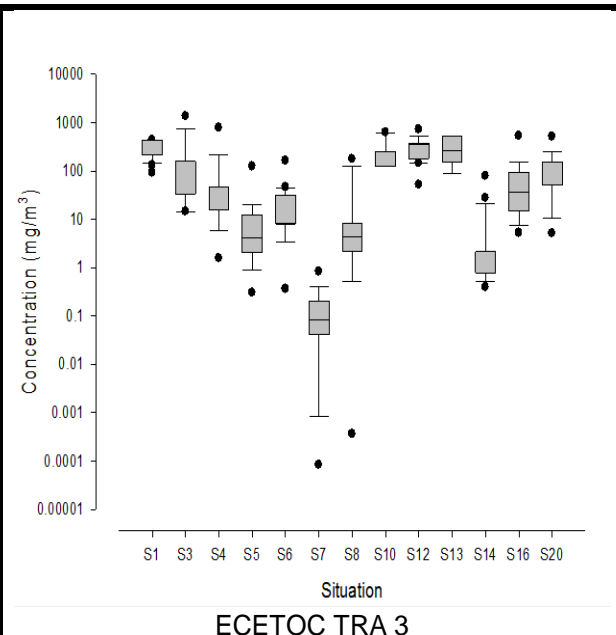
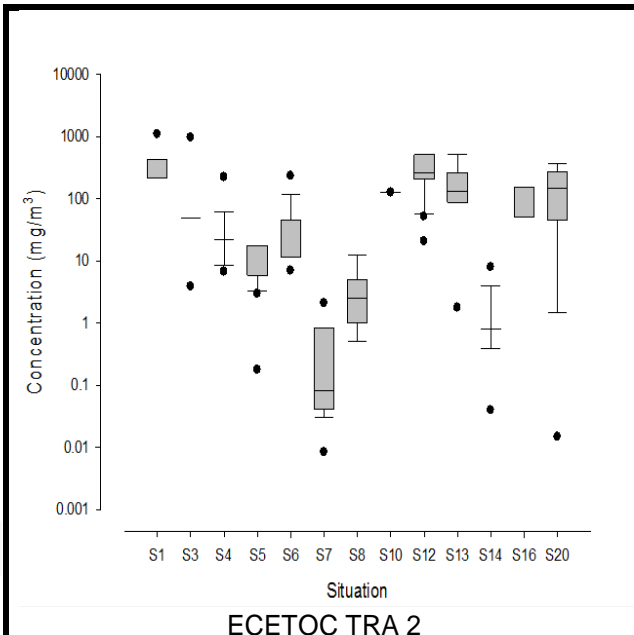
# Exposure to Nickel powder during packing- dermal

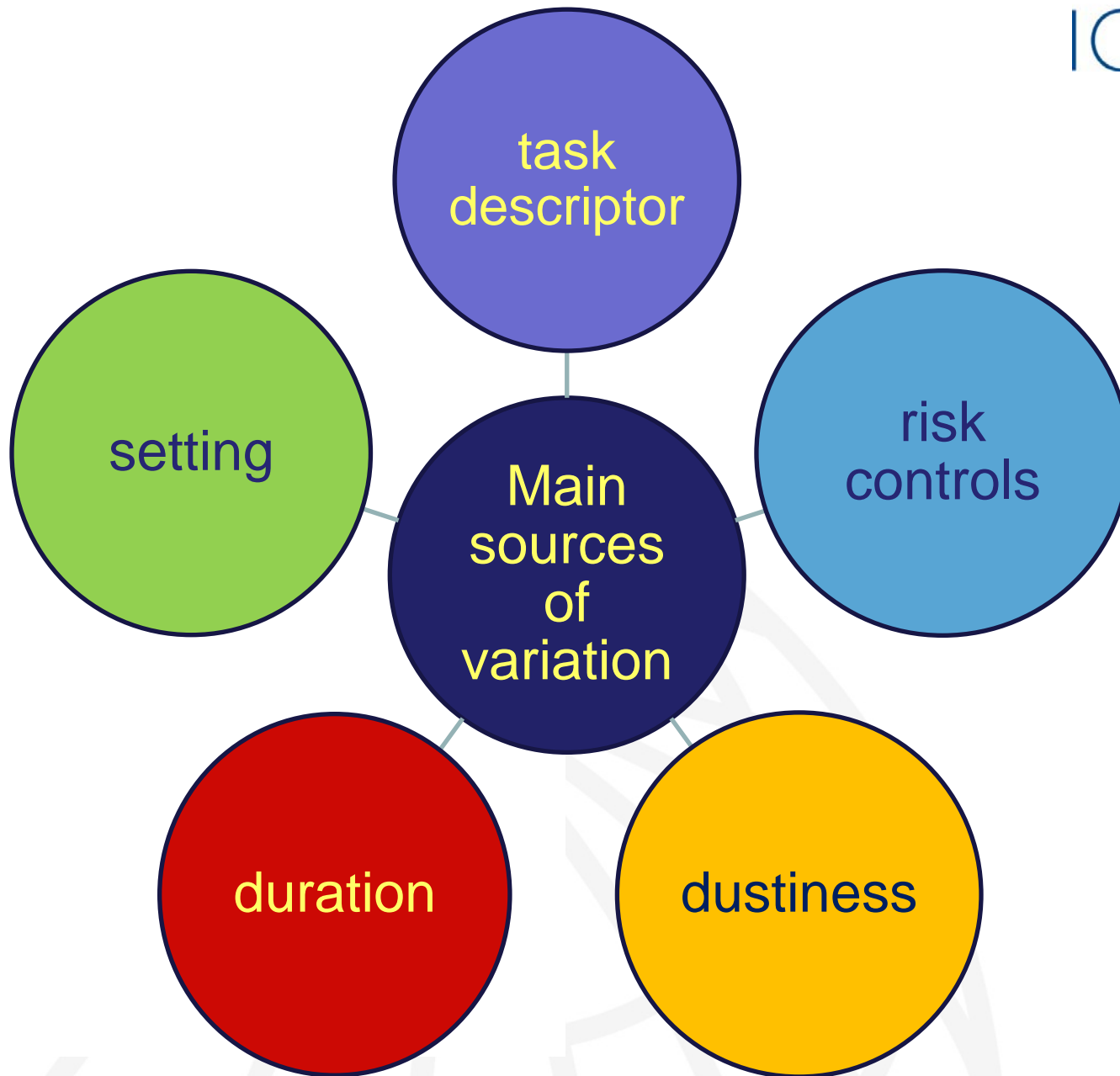


# Between-user variability - all tools



volatile liquids





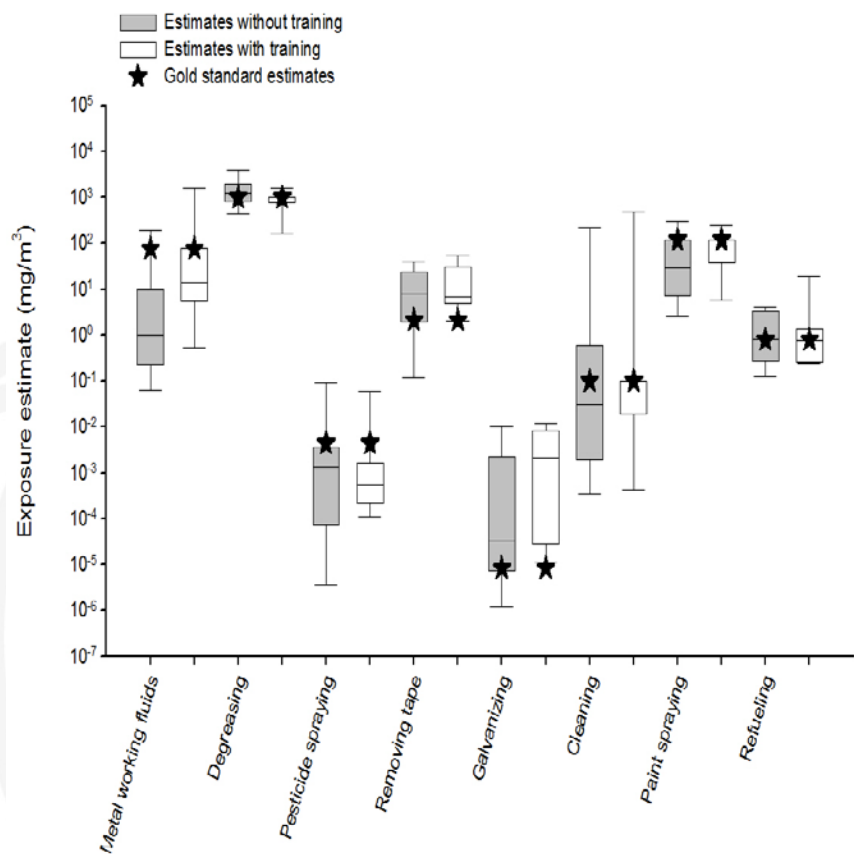
# Other sources of variation



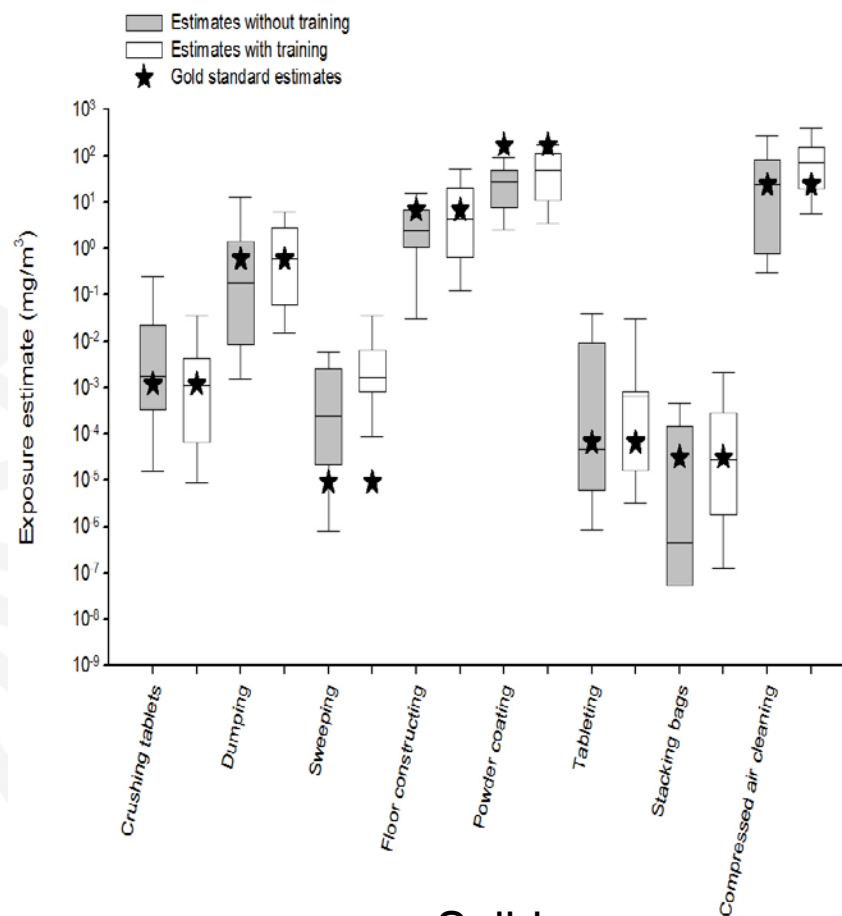
- ❖ Erroneous choices
  - physical form of molten metals
  - dermal exposure situations
- ❖ Differences in interpretation/ mis-reading of information
  - Inclusion/ exclusion of described risk management measures
- ❖ Lack of awareness of tool guidance
  - Tendency to use basic instructions provided rather than actual tool information
- ❖ Typographical/ transcription errors
- ❖ Some limitations but similar to findings in reliability studies for other assessment tools



# ART reliability and the effect of assessor training



Liquids



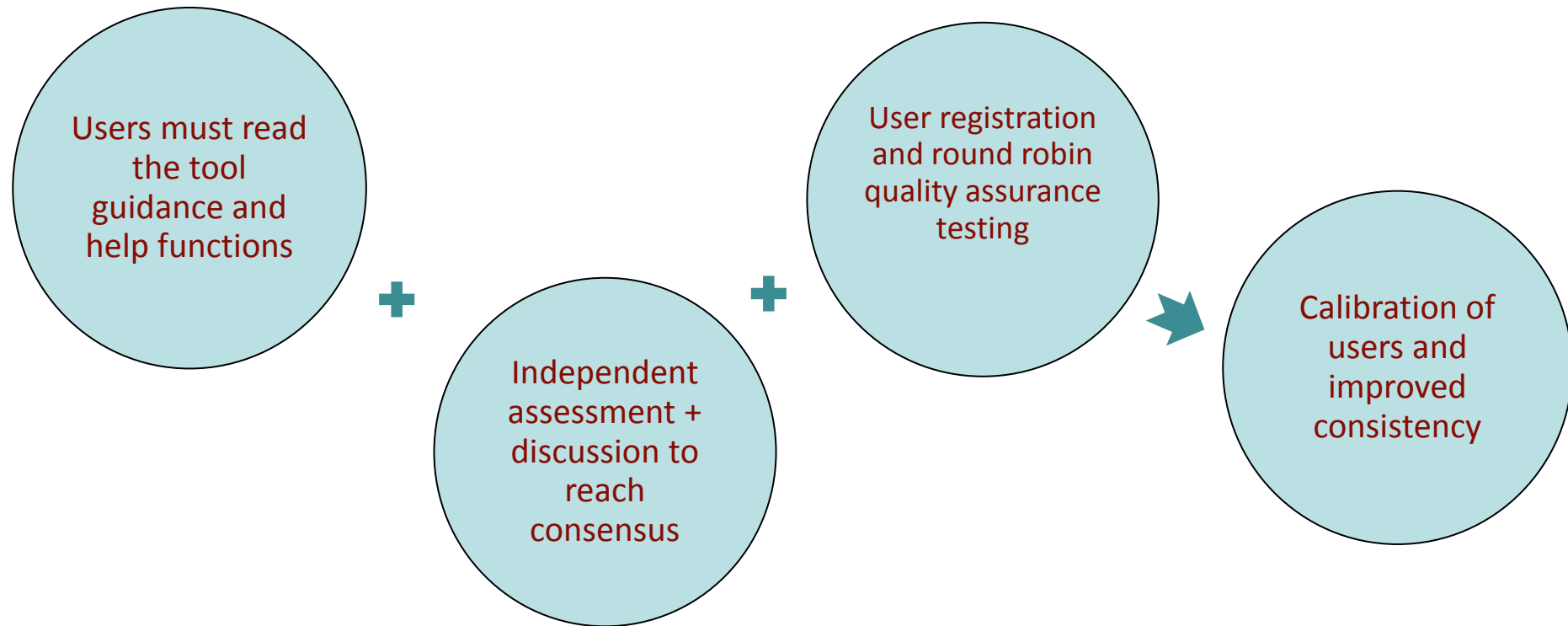
Solids

# Main 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
- ❖ Participants, on occasion, conflate determinants when allocating inputs which may affect variation and validity of the estimate
- ❖ 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
- ❖ Overall, the exercise suggests that between user variation in interpretation of exposure determinants could be an important issue for the standardisation of REACh processes across the EU

# Recommendations.....



# Acknowledgements



- ❖ Dr Martin Tischer and colleagues at BAuA
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