IOM

WORKING FOR A HEALTHIER FUTURE

# eteam Project: Results of external validation exercise and implications

Martie van Tongeren, Judith Lamb, Brian Miller, Laura MacCalman, Susanne Hesse, Stefan Hahn, John Cherrie

# Aim of external evaluation

1. Determine whether Tier 1 tools are predictive of measured exposures over a range of situations
2. Determine whether Tier 1 tools are conservative

# Data sources

- Exposure measurement data and descriptive contextual information were collected from a wide variety of data providers
  - Advisory Board members (BAuA, EBRC, HSE, IFA, NIOSH, SECO)
  - Lund University, BEAT dermal database
  - Project team: ITEM and IOM
- Personal samples
  - Powders/ liquids/ metal processing fumes/ metal abrasion
  - Mix of task-based and time weighted average representative samples
  - REACh-relevant where possible
- Inhalation and dermal data sought, however dermal data limited in scope and quality

# Coding of situations into the tools

- Team of experienced exposure scientists
- Quality control manual
  - "Best" option chosen in first instance
  - Agreed defaults where the description was unclear - "middle" option chosen
  - Recorded level of uncertainty in choice
- Coding meetings
- Data checking
  - Data checking
    - Outliers
    - Consistency checks across tools and scenarios
    - Blind recoding of 10% of situations

# Some differences between tools

- ECETOC TRAv2
  - Concentration adjustment for liquids only (not for dusts)
  - Exposure duration taken into account
- ECETOC TRAv3
  - Concentration adjustment for solids and liquids
  - Exposure duration taken into account
- MEASE
  - Concentration adjustment for solids, liquids & aqueous solutions
  - Exposure duration taken into account

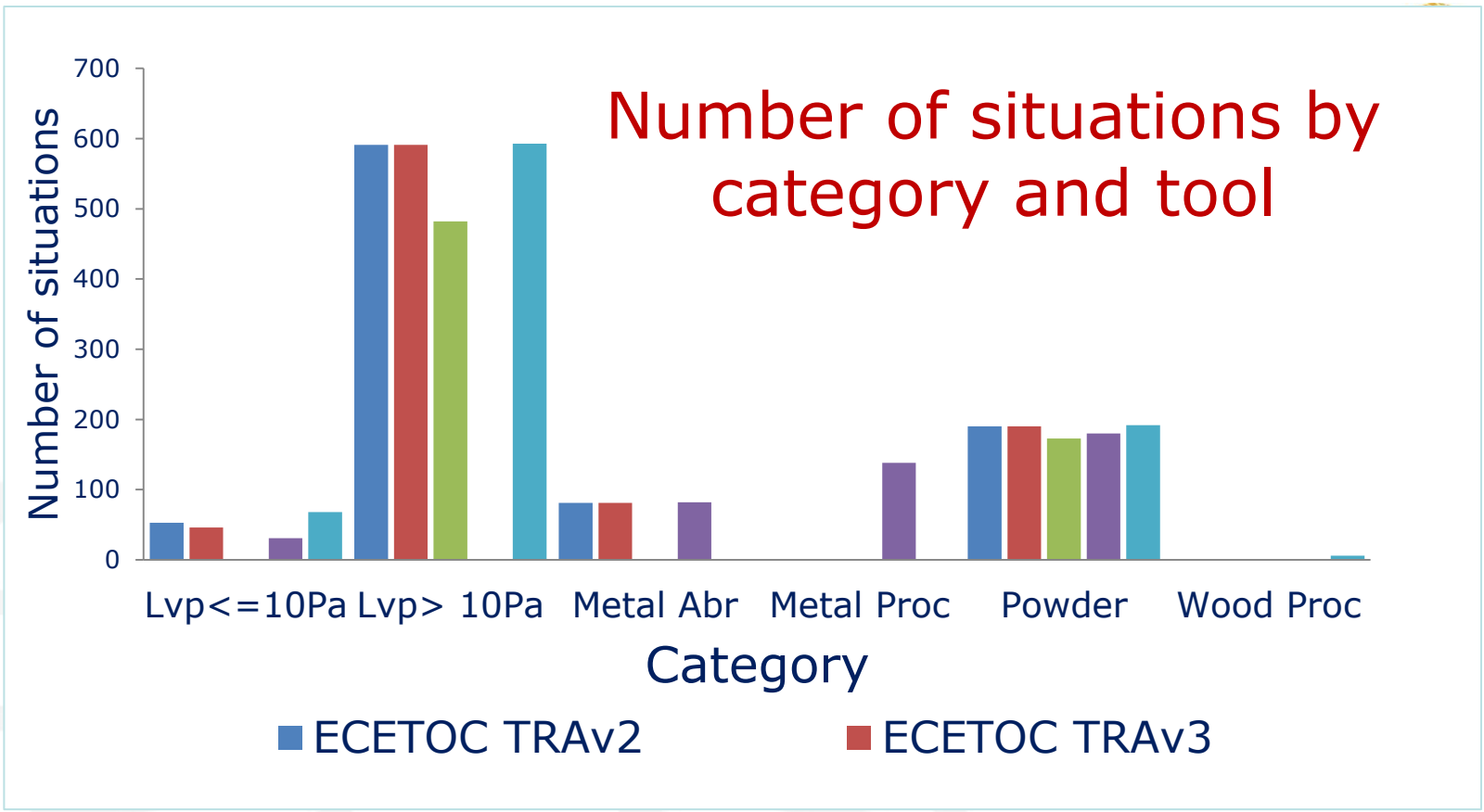
# Some differences between tools

- EMKG-EXPO-tool
  - No concentration adjustment
  - No adjustment duration of exposure
  - No option for absence of RMMs. If none present, lowest control approach was chosen (general ventilation)
- Stoffenmanager v 4.5
  - Concentration adjustment for liquids only (not for dust)
  - No adjustment for duration of exposure

# eteam database

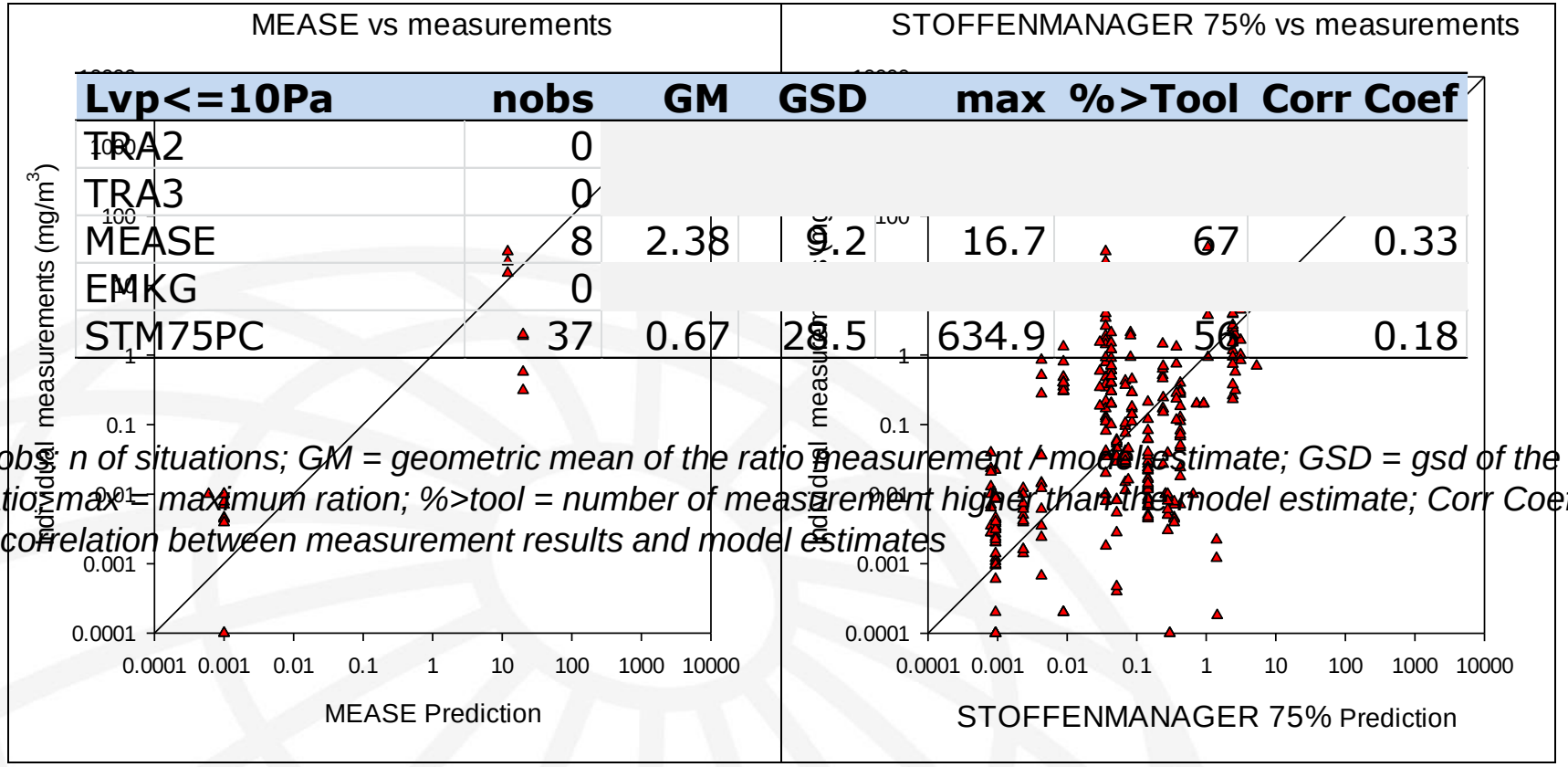
- Microsoft Access: based on ART exposure database

- Multifunctional
  - contextual information on exposure situations
  - results from related exposure measurements
  - coded parameters for all the tools and
  - procedures for applying the tools and storing the resultant exposure estimates




Individual measurements: n = 2098
Aggregated measurements: 148 situations with 1843 measurements

# Tool comparison for low volatile liquids

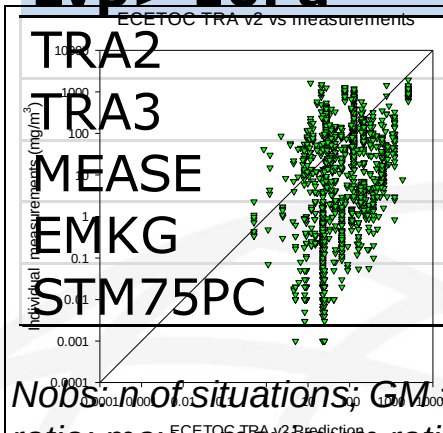


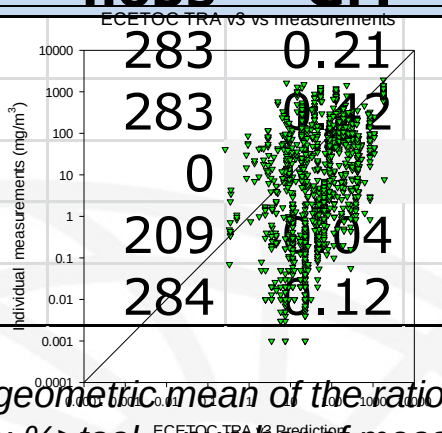

| Lvp<=10Pa | nobs | GM | GSD | max | %>Tool | Corr Coef |
|---|---|---|---|---|---|---|
| TRA2 | 0 | | | | | |
| TRA3 | 0 | | | | | |
| MEASE | 8 | 2.38 | 9.2 | 16.7 | 67 | 0.33 |
| EMKG | 0 | | | | | |
| STM75PC | 37 | 0.67 | 28.5 | 634.9 | 56 | 0.18 |

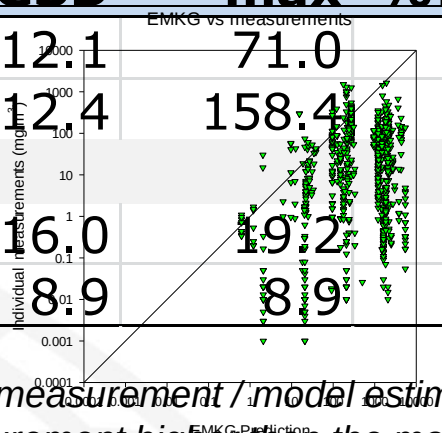
*Nobs: n of situations; GM = geometric mean of the ratio measurement / model estimate; GSD = gsd of the ratio;max = maximum ration; %>tool = number of measurement higher than the model estimate; Corr Coef = correlation between measurement results and model estimates*

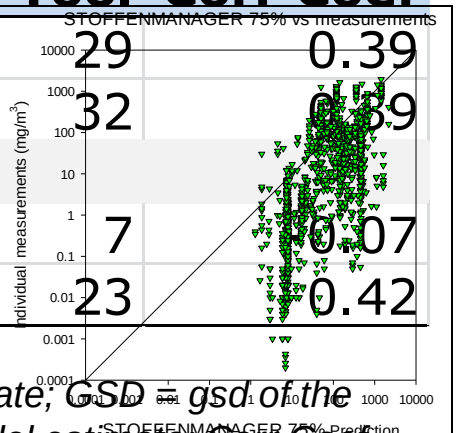
# Tool comparison for volatile liquids

| Lvp> 10Pa | nobs | GM | GSD | max | %>Tool | Corr Coef |
|---|---|---|---|---|---|---|
| TRA2 | 283 | 0.21 | 12.1 | 71.0 | 29 | 0.39 |
| TRA3 | 283 | 0.12 | 12.4 | 158.4 | 32 | 0.39 |
| MEASE | 0 | | | | | |
| EMKG | 209 | 0.04 | 16.0 | 19.2 | 7 | 0.07 |
| STM75PC | 284 | 1.12 | 8.9 | 8.9 | 23 | 0.42 |



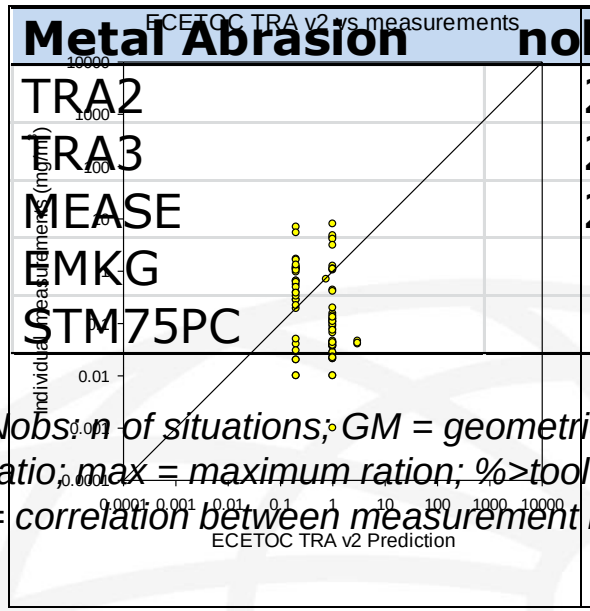



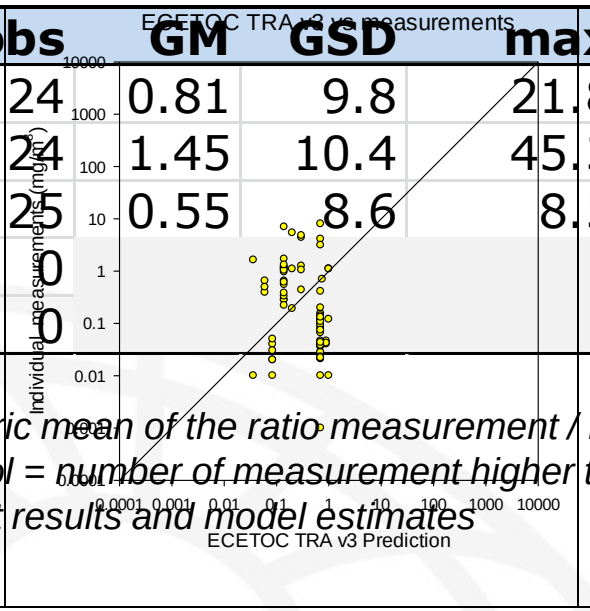



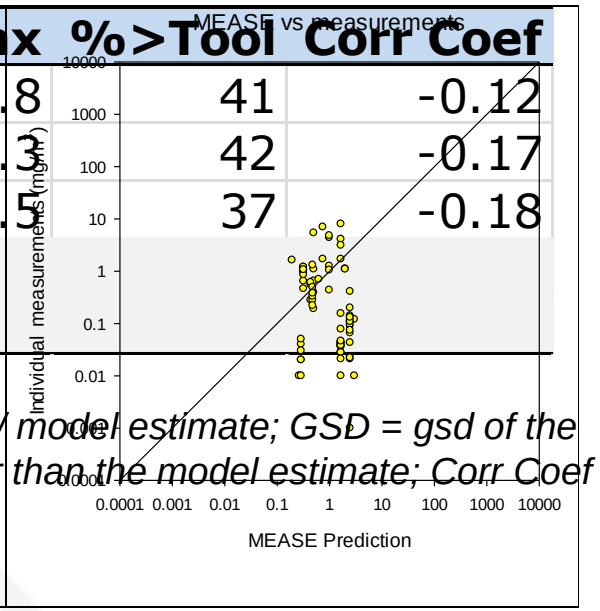

*Nobs: n of situations; GM = geometric mean of the ratio measurement / model estimate; GSD = gsd of the ratio; max = maximum ration; %>tool = number of measurement higher than the model estimate; Corr Coef = correlation between measurement results and model estimates*

# Tool comparison for metal abrasion

| Metal Abrasion | nobs | GM | GSD | max | %>Tool | Corr Coef |
|---|---|---|---|---|---|---|
| TRA2 | 24 | 0.81 | 9.8 | 21.8 | 41 | -0.12 |
| TRA3 | 24 | 1.45 | 10.4 | 45.3 | 42 | -0.17 |
| MEASE | 25 | 0.55 | 8.6 | 8.5 | 37 | -0.18 |
| EMKG | 0 | | | | | |
| STM75PC | 0 | | | | | |



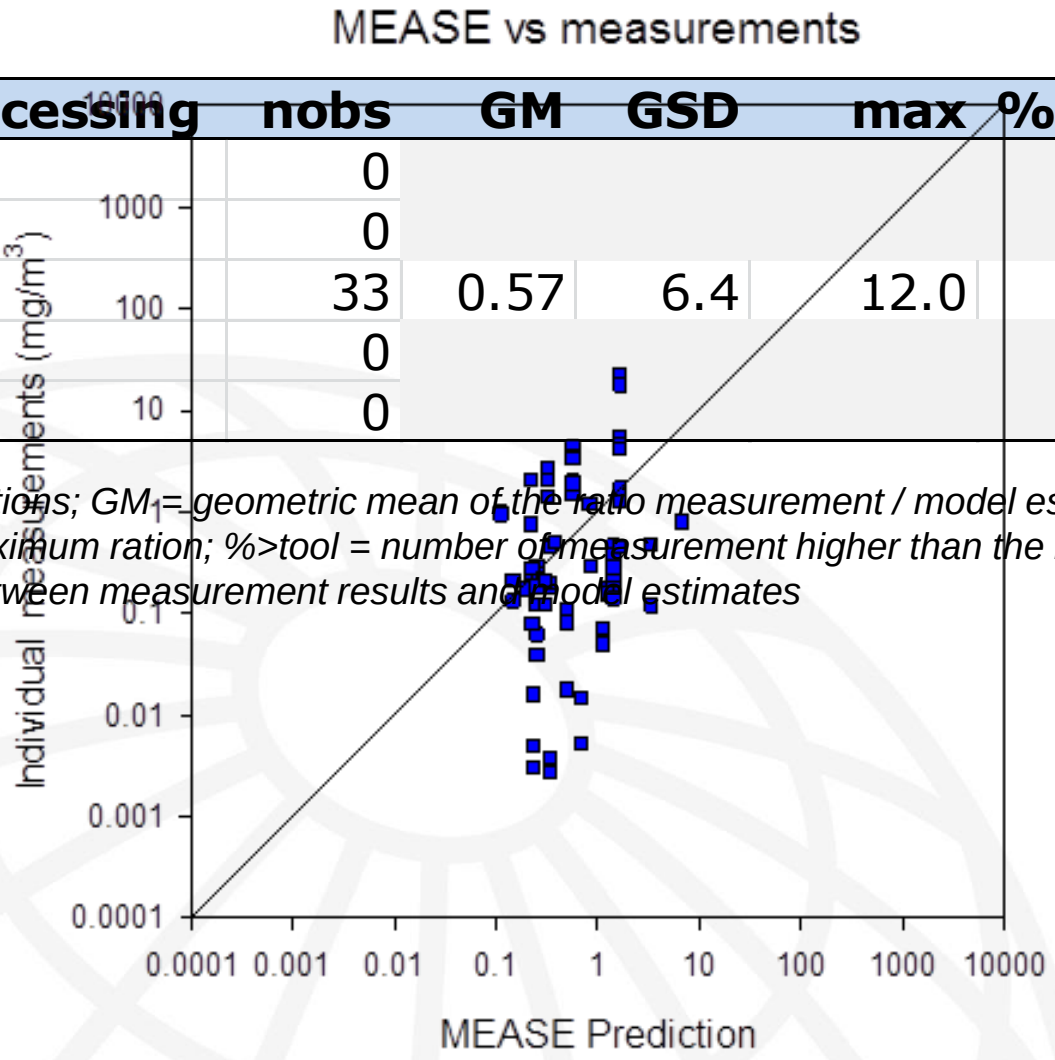




*Nobs: n of situations; GM = geometric mean of the ratio measurement / model estimate; GSD = gsd of the ratio; max = maximum ration; %>tool = number of measurement higher than the model estimate; Corr Coef = correlation between measurement results and model estimates*

# Tool comparison for metal processing

| Metal processing | nobs | GM | GSD | max | %>Tool | Corr Coef |
|---|---|---|---|---|---|---|
| TRA2 | 0 | | | | | |
| TRA3 | 0 | | | | | |
| MEASE | 33 | 0.57 | 6.4 | 12.0 | 38 | 0.15 |
| EMKG | 0 | | | | | |
| STM75PC | 0 | | | | | |

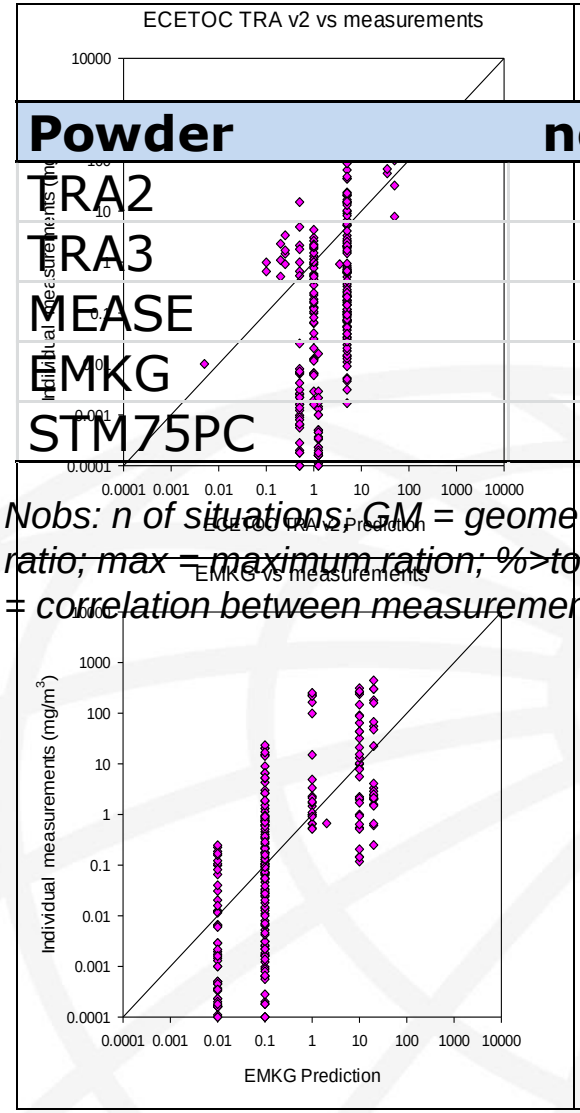
*Nobs: n of situations; GM = geometric mean of the ratio measurement / model estimate; GSD = gsd of the ratio; max = maximum ration; %>tool = number of measurement higher than the model estimate; Corr Coef = correlation between measurement results and model estimates*

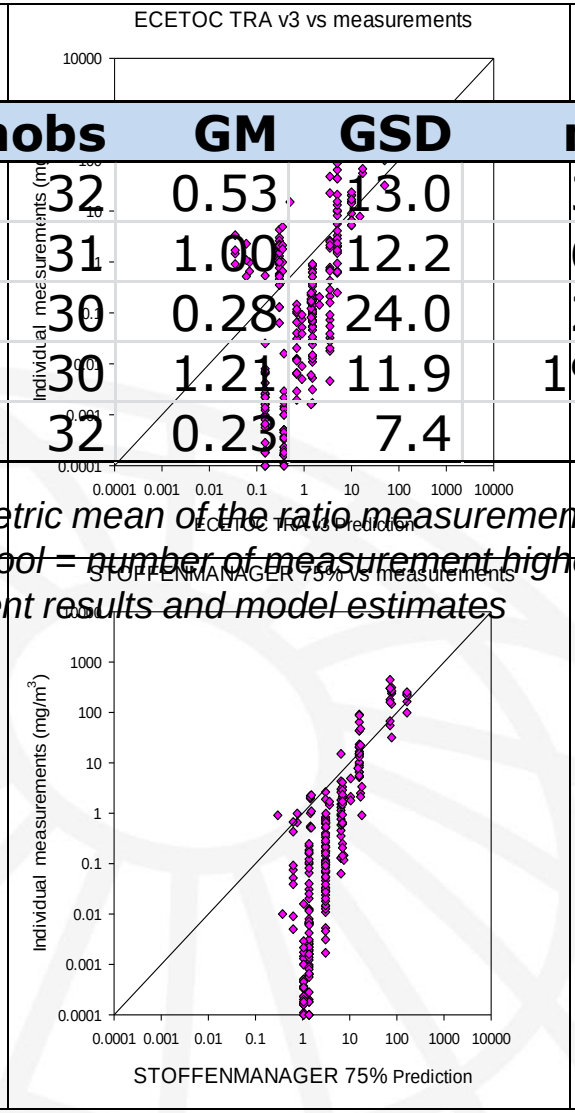


# Tool comparison for powders

| Powder | nobs | GM | GSD | max | %>Tool | Corr Coef |
|---|---|---|---|---|---|---|
| TRA2 | 32 | 0.53 | 13.0 | 30.2 | 28 | 0.83 |
| TRA3 | 31 | 1.00 | 12.2 | 61.0 | 29 | 0.78 |
| MEASE | 30 | 0.28 | 24.0 | 26.0 | 23 | 0.09 |
| EMKG | 30 | 1.21 | 11.9 | 199.9 | 45 | 0.35 |
| STM75PC | 32 | 0.23 | 7.4 | 3.1 | 14 | 0.80 |

*Nobs: n of situations; GM = geometric mean of the ratio measurement / model estimate; GSD = gsd of the ratio; max = maximum ration; %>tool = number of measurement higher than the model estimate; Corr Coef = correlation between measurement results and model estimates*



# Conclusions – non-volatile liquids

- Limited data, only comparison with MEASE and STM
- No evidence that these tools are conservative
- Low correlation between tool estimates and exposure

# Conclusions – volatile liquids

- Reasonable amount of data
- Based on individual measurements the tools are conservative (but ECETOC TRAv3 less so than others)
- Some evidence from the aggregate data that the ECETOC TRAv2, ECETOC TRAv3 and STM are less conservative
- Correlation between tools estimates and measurement results
  - ~0.4 for ECETOC TRAv2, ECETOC TRAv3 and STM
  - No correlation for EMKG-EXPO-Tool

# Conclusions – Metal abrasion

- Limited data
- Only for ECETOC TRAv2, ECETOC TRAv3 and MEASE
- No evidence that these tools are conservative
- No correlation with measured results

# Conclusions – Metal processes

- Limited data
- Only for MEASE
- No evidence that MEASE is sufficiently conservative
- Little or no correlation with measured results

# Conclusions – Powders

- Reasonable amount of data
- Tools appear to be conservative, although EMKG-EXPO-Tool less so than others
- Good correlation with measurement results for ECETOC TRAv2, ECETOC TRAv3 and STM (~0.8)
- Less correlation for EMKG-EXPO-Tool and no for MEASE

# Summary

- Tools appear to be conservative, however:
  - not for all exposure categories
  - Is the level of conservatism is sufficient?
  - Impact of measurement uncertainty?
  - What is the likelihood that false-negative conclusions are drawn?
  - For some tools (eg STM, EMKG) estimates were not corrected for concentration of the agent in the mixture and duration of the exposure (relative to the measurement duration). If this were to be included, the levels of conservatism will be reduced!

# Summary

- Strong correlation between tool estimates from TRAvs2 and vs3 and STM for powders and measurement results
- Other tools and exposure categories correlation was low or absent.
- In particular, more data required for
  - non-volatile
  - metal abrasion
  - hot metal processes
  - but our results suggest that tools should be used very cautiously for these exposures (or not at all?)

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# Implications from the results and practical recommendations

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# Uncertainty

- Tier 1 tools and hence a relatively high level of uncertainty is expected
- This is addressed by ensuring the tools are conservative, although what this means in practice is unclear
- Sources of uncertainty include
  - Scenario uncertainties: probably high impact
  - Parameter uncertainties
    - Vagueness of parameter definition
  - Model uncertainty
    - Assumptions, dependencies, etc
    - Omitted parameters
    - Model basis (knowledge base and transparency)

# User-friendliness

- Tools were found to be very user-friendly (perhaps too user-friendly?)
- Generally meet the requirements and demands of users
- Perhaps some suggestions that more could be done with regard to training in the use of tools

# Between-user reliability

- Some very large differences in predicted exposures were observed between users
- This could not be explained by expertise, experience, language, sector, etc.
- Similar to results from other studies looking at exposure judgement, ART etc.
  - Notion that tool simplicity reduces between-user variability does not seem to be correct

# External validation

- Generally tools were conservative for powders and volatile liquids
  - but what is sufficiently conservative?
- Difference between exposure categories
  - Powders: TRAv2, TRAv3 and STM were highly correlated with measurement results
  - Correlations were lower or non-existent for other exposure categories/tools
- No evidence from the eteam project that any tools is conservative for metals and low volatility liquids

# Implications

- Are the tools sufficiently conservative?
  - Depends on what is considered to be sufficiently conservative
  - No evidence from the eteam project that they are conservative for low volatility liquids, metal abrasion or hot metal processes
- Can the tools predict exposure?
  - For powders there is a strong correlation with individual measurements for TRAv2, TRAv3 and STOFFENMANAGER
  - Not so much for other tools and exposure categories
  - Would it be possible to improve this?
- Between user reliability
  - In our view, this is the main cause for concern
  - Need to improve the Quality Assurance and training

# Recommendations: Tool users

1. Do not rely on just one tool when estimating exposure, but apply several, and use conservatively unless good reason to do otherwise
2. Test the sensitivity of the tool estimates for choice of parameters
3. If exposure data are available, use these too
4. Make sure you read all documentation related to the tool and supporting documents
5. Seek out good quality training in the use of your chosen tool

# Recommendations: Tool developers

1. Increase training in use of exposure tools and visibility of guidance documents
   - For example, ask tool user to tick box in the tool if training followed and guidance documents read

2. Carry out specific data gathering exercise for metals and low volatility liquids and for certain PROCs to improve the calibration of the tools
   - Share data/collaborate?

3. Develop a protocol / Standard Operating Procedure (SOP) for tool users, including data collection, data interpretation, sensitivity analyses, verification, etc.

# Recommendations- Regulators

1. Quality assurance:
   - Require evidence of training
   - Consideration of use of multiple tools / use of exposure measurement data
   - Consideration of sensitivity to choice of model parameters
   - Encourage development and use of protocols / SOPs for tool applications
   - Round robin testing for exposure assessors using Tier 1 tools
2. Encourage further validation and calibration exercises
   - Exposure is variable over time and location!
3. Provide clarity on the level of conservatism that is required from the tools
4. More data on dermal exposure is required

# Acknowledgements


- Advisory Board
  - BAuA (funding)
  - Tool developers (TNO/Arbo-Unie, ECETOC, BAuA, EBRC)
  - Major data providers (IFA, NIOSH, HSE, SECO)
- Other data providers (Lund University)
- BURE and workshop participants
- Participants in user-friendliness survey
- Various IOM staff