Evaluation of Tier 1 tools for estimating occupational exposure

Martie van Tongeren

background

- ❖ REACH advocates at tiered approach for the safety of use of chemicals.

- ❖ REACH heavily relies on efficient, simple tools for exposure assessment (tier 1 tools)

- ❖ However, despite being used heavily within REACH, little independent evidence exist on the performance of these tools.

- ❖ BAuA initiatated and funded the eteam project

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)**

Tools

IOM
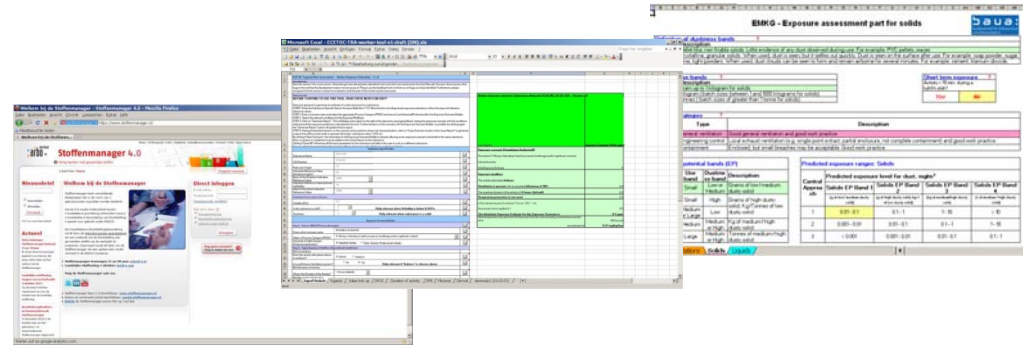
- ❖ ECETOC TRA Versions 2 & 3

- ❖ EMKG-EXPO-Tool

- ❖ MEASE Version 1.02.01

- ❖ Stoffenmanager Version 4.5

- ❖ RISKOFDERM Version 2.1

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

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

BURE study

IOM

- ❖ To determine the reliability of the tool or tool users

- ❖ Recruited 150-200 tool users in Europe and elsewhere

- ❖ Each participant was asked to assess inhalation and dermal exposure for 20 scenarios

  - ❖ Standard 1 page A4 format

  - ❖ Textual description of typical workplace exposure settings

  - ❖ Professional & industrial settings
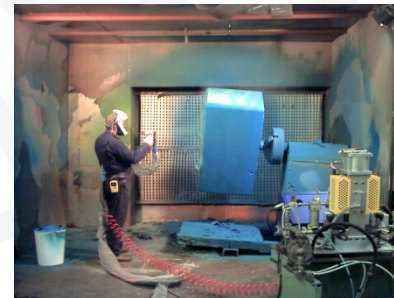
Results: BURE participant population

- ❖ 146 participants, performing in total 4066 assessments
  - 57% were consultants or industry
  - 84% from EU
- ❖ Experience of tools
 - Most experience of ECETOC TRAv2/v3, then Stoffenmanager

# 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

Situation 7:
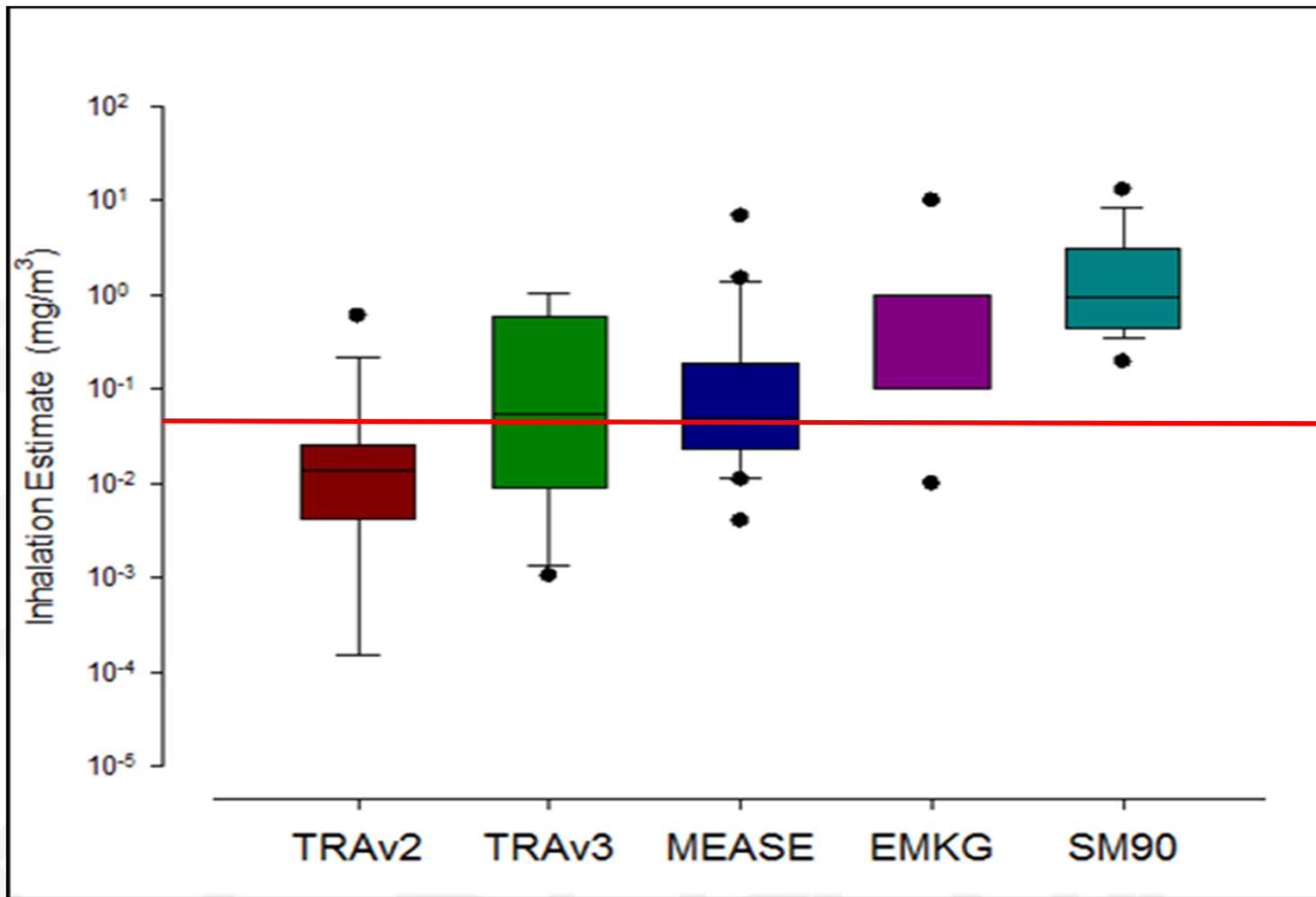## Changing of filters in paint spray booth
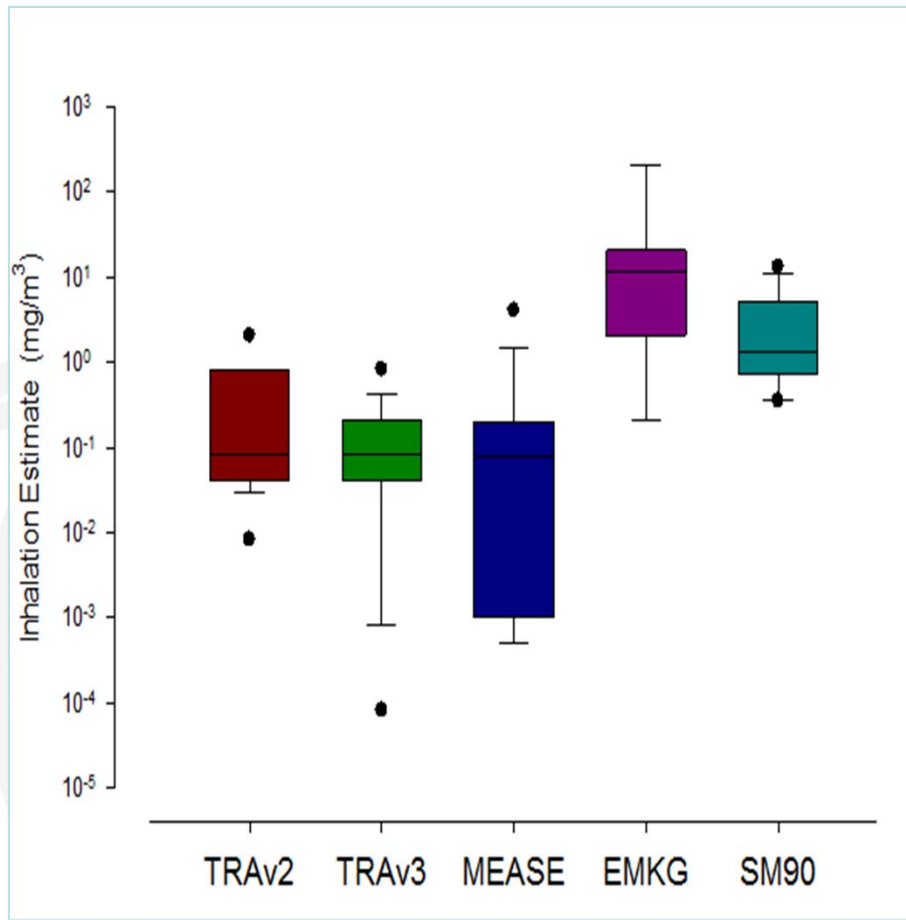
Inhalation
estimates
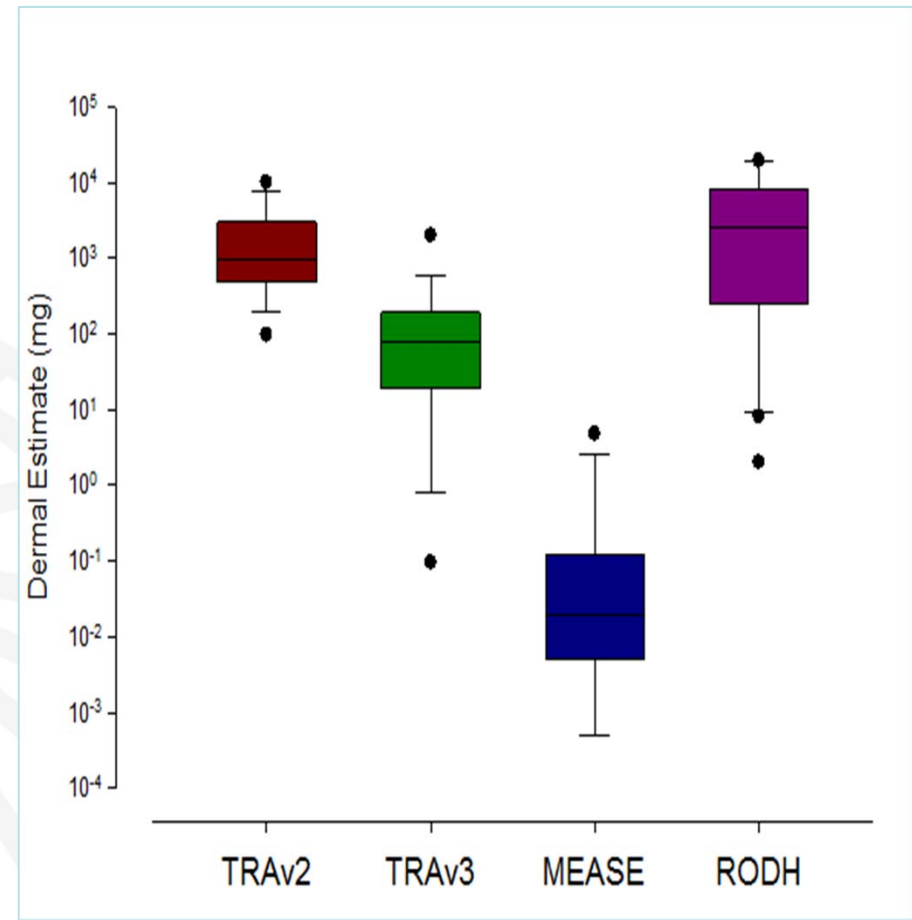
Dermal
estimates

Exposure to Nickel during packing

DNEL = 0.05 mg/m3

External validation

IOM

- ❖ 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

IOM

- ❖ 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

Summary tool performance for volatile liquids

	Individual data		Individual and aggregated data		
	R_{ind}	GM_{ratio}	nM	nM>T	%M>T
ECETOC TRAv2	0.35	0.1	1842	485	26
ECETOC TRAv3	0.34	0.2	1842	586	32
EMKG-EXPO-TOOL	0.28	0.03	1372	70	5
STM 75th percentile	0.54	0.1	1854	359	19
STM 90th percentile	0.54	0.04	1854	209	11

Tool comparison for volatile liquids
(individual data only)
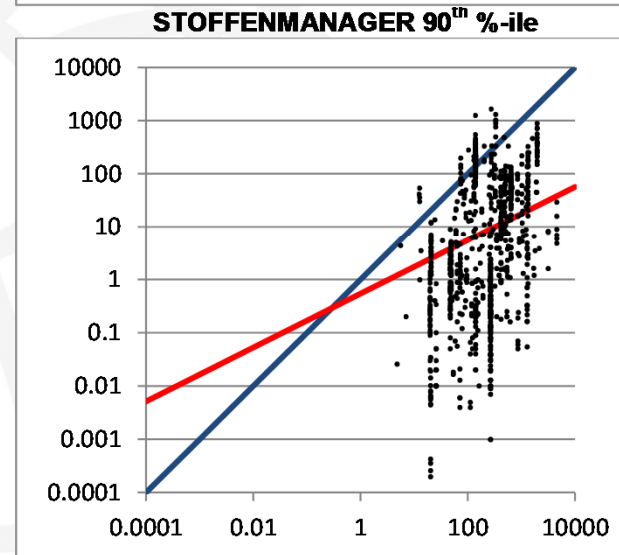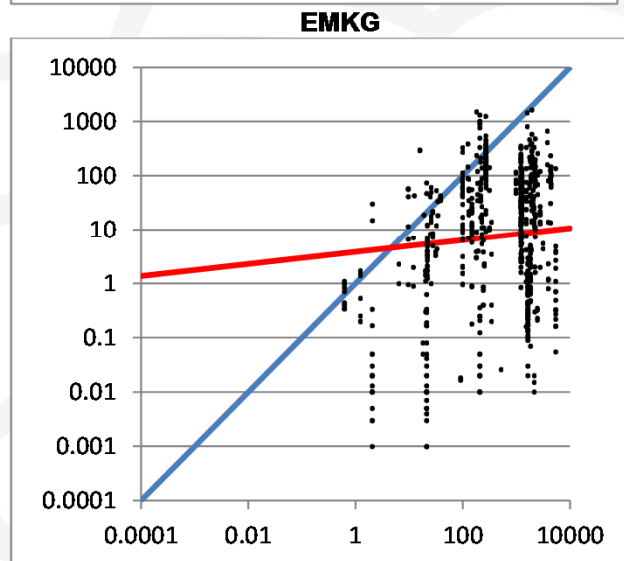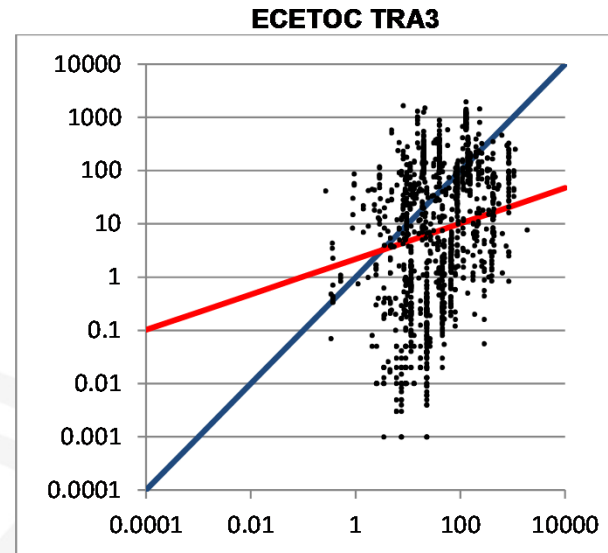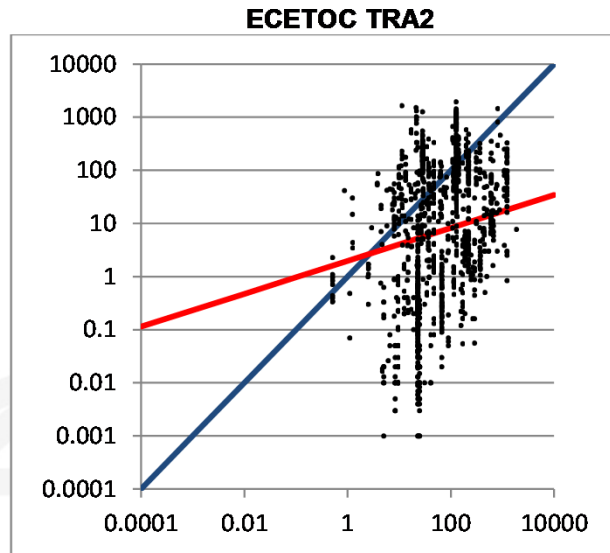
Summary tool performance for powders

	Individual data		Individual and aggregated data		
	R_{ind}	GM_{ratio}	nM	nM>T	%M>T
ECETOC TRAv2	0.59	0.05	1101	180	16
ECETOC TRAv3	0.69	0.1	1101	231	21
MEASE	<0	0.02	1081	115	11
EMKG-EXPO-TOOL	0.7	0.6	1063	184	17
STM 75th percentile	0.83	0.04	1101	90	8
STM 90th percentile	0.83	0.01	1101	33	3

Tool comparison for powders
(individual data only)

ECETOC TRA2

ECETOC TRA3

MEASE

EMKG-EXPO

STOFFENMANAGER 90th %-ile
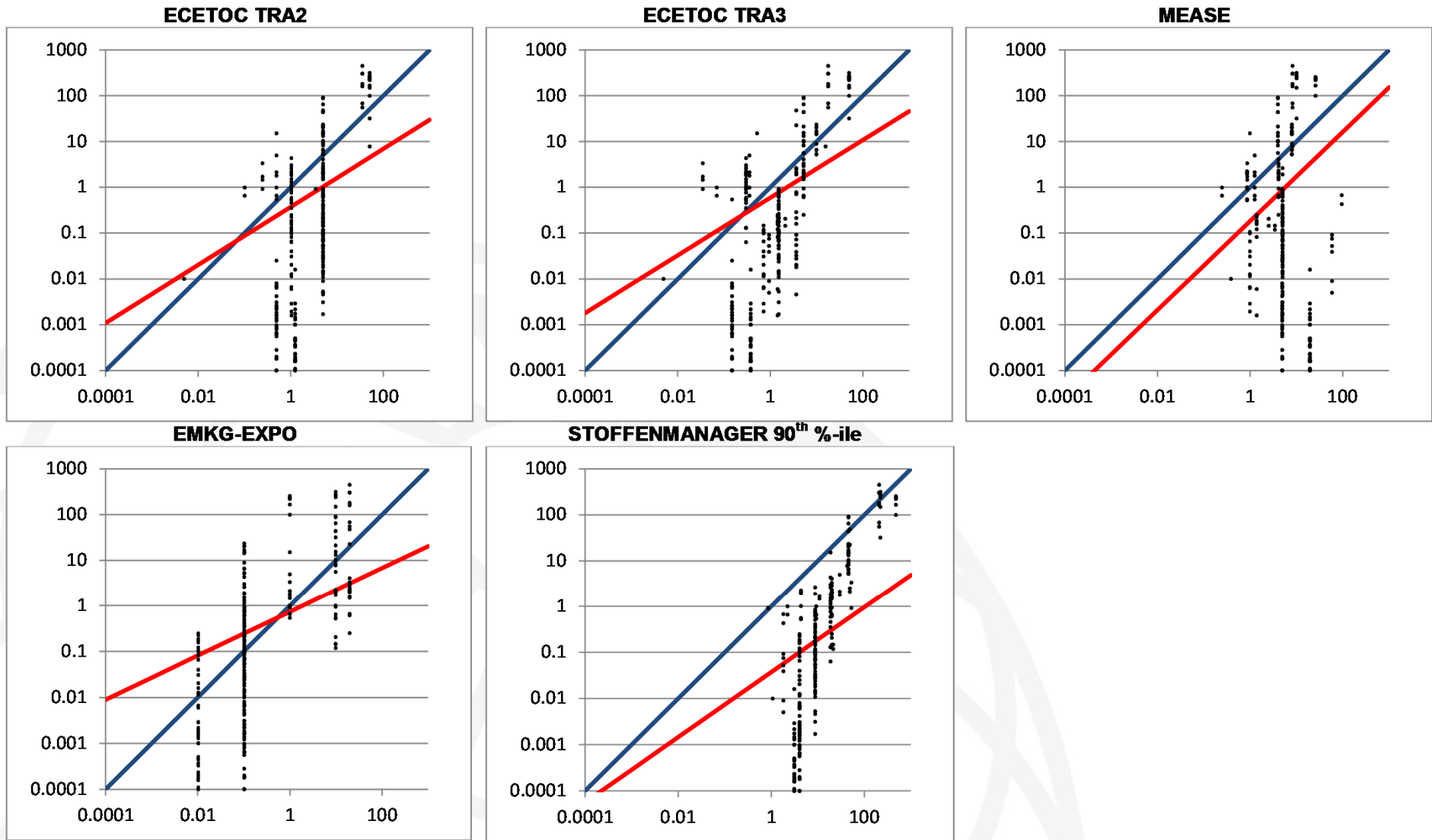
Conclusions – volatile liquids

- Reasonable amount of data
- Tools appear to be reasonably conservative, in particular when estimating high exposure levels
    - EMKG, ECETOC TRAv2 and v3 less than MEASE and STOFFENMANAGER
- Model estimates appear to follow exposure measurements pretty well (better than for volatile liquids)

Conclusions – Powders

- Reasonable amount of data
- Tools appear to be conservative, again in particular for high exposures
- lthough 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

Discussion/Conclusions IOM

- Limitations of the study
  - Data representativeness
  - Coding of exposure scenarios perhaps not done as Industry would do under REACH
- However, large between-user reliability remains a concern
  - Requires efforts to improve use of models
  - Training, certification, team coding, etc
- Tools appear conservative for volatile liquids and powders, in particular for high exposures levels
- However, in particular for TRAvs2 and vs3 care should be taken when using these tools for estimating exposure levels < 100 mg/m3

Acknowledgements

- IOM: Judith Lamb, John Cherrie, Karen Galea, Laura MacCalman, Brian Miller, Shaz Rashid

- Fraunhofer ITEM: Susanne Hesse, Stefan Hahn

- 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