



10th IOHA International
Scientific Conference

Conceptual evaluation and uncertainty of Tier 1 Exposure Assessment Models used under REACH

Susanne Hesse
28.04.2015

Conceptual evaluation vs. Tier 1 model



Concepts for exposure modelling, for example:

- Cherrie et al., 1996,
- Schneider et al., 1999,
- Tielemans et al., 2008.

Tier 1 models

- do not have to fulfil all details included in these publications (ECHA guidance R14)

➔ General evaluation:

- Transparency, Algorithm and Parameters,
- Usemap,
- Applicability matrix

Applicability matrix (1/2)

| Applicability | EMKG-EXPO-TOOL | Stoffen-manager v.4.5 | ECETOC TRA v2 | ECETOC TRA v3 | MEASE | RISKOFDERM |
|-------------------------------|--|--|---|---|--|---|
| Route | Inh. | Inh. | Inh.+derm. | Inh.+derm. | Inh.+derm. | Derm. |
| Covered physical state | solid liquid | solid liquid | solid liquid = volatile | solid liquid = volatile | solid liquid gaseous | solid liquid |
| Beyond Scope | Dusts by abrasive techniques, open spray, gases, pesticides, fumes, wood dusts, CMR substances | Fibres, gases or hot working techniques (welding, soldering); abrasion and impact of solid objects not recommended | Fibres, liquid aerosols or emissions from hot processes (e.g. fumes). Solids in liquids. Caution recommended for CMRs | Fibres, liquid aerosols or emissions from hot processes (e.g. fumes). Solids in liquids. Caution recommended for CMRs | Organic substances & some restrictions concerning special combinations of PROC/physical properties | Sometimes restrictions due to original data set (e.g. "only on manual tasks for powders") fumes not covered |

Applicability matrix (2/2)

| Applicability | EMKG-EXPO-TOOL | Stoffen-manager v.4.5 | ECETOC TRA v.2 | ECETOC TRA v.3 | MEASE | RISKOFDERM |
|--------------------------------------|-------------------------|---|---------------------------|-----------------------------|---------------------------|---------------------------------------|
| Type of enterprises | SME | industrial & professional | industrial & professional | industrial & professional | industrial & professional | industrial & professional |
| Use categories process or task based | task | task | process | process (+ „peak exposure“) | process | task |
| Farfield factors | partly included via cgs | same task by other workers | Not included | Not included | Not included | Not included |
| Other information | | only model which covers stone / wood dust | | | | only model which covers body exposure |



Not all models are applicable for all situations !

Summary / Conclusion (1)



- **different types of algorithms and designs**
 - logic tree \leftrightarrow initial concentration + modifiers \leftrightarrow linear mixed effects models
 - Excel-tool \leftrightarrow web based tool \leftrightarrow program
 - **internal validation / model development**
 - fitting procedures to measured data \leftrightarrow expert judgement
 - **varying number of determinants and level of detail \rightarrow different scopes, e.g.**
 - RISKOFDERM covers body exposure
 - MEASE, Stoffenmanager offer more RMM options
 - only ECETOC TRA, MEASE offer gloves
- \rightarrow** Concerning concept, choice of „best“ tool depends on situation & user



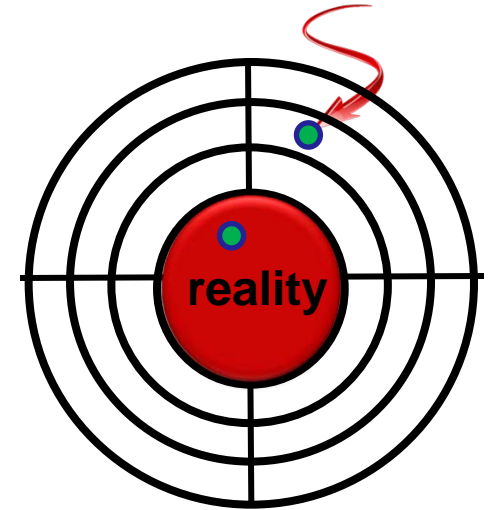
10th IOHA International
Scientific Conference

IOHA London 2015, 27-30 April
2015, Hilton London Metropole

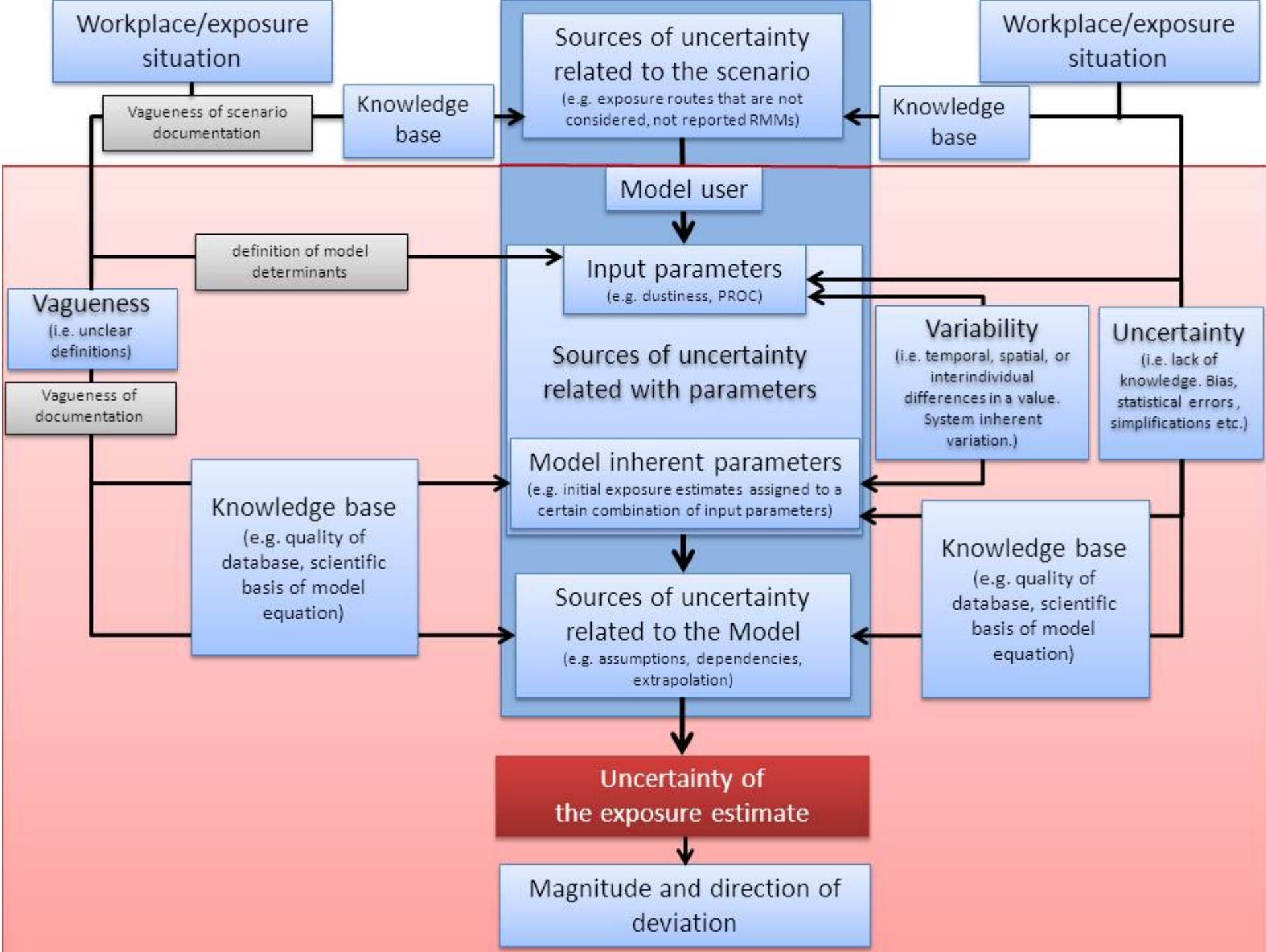


Uncertainty of tier 1 models:

“Lack of or imperfect knowledge concerning the present or future state of an organism, system, or (sub)population under consideration, which may affect its accuracy or relevance. Uncertainty can be reduced, at least in principle, by improving the quality and/or amount of information.” (WHO)



- Uncertainty of the exposure estimate and the sources of this uncertainty (uncertainty/variability of parameters, assumptions etc.)
- Evaluation of the uncertainty of tier 1 models in a qualitative way:
 - REACH Guidance R19
 - WHO guidance document on characterising and communicating uncertainty in exposure assessment.



Approach: What has been done?



- List sources of uncertainty (parameter uncertainty, model uncertainty)
 - Set of categorisations:
 - **Transparency**: What background information is published?
 - **Knowledge base**: Quality of documented background information (experimental data vs. „expert knowledge“)
 - **Quality of input parameter definition** (vagueness, level of detail)
 - (If possible, **magnitude and direction of uncertainty**)
- ➡ Report: Evaluation matrix + discussion / conclusion
- ➡ In this presentation: Examples / comparison + conclusion



10th IOHA International
Scientific Conference

IOHA London 2015, 27-30 April
2015, Hilton London Metropole



Examples

Knowledge base:

- no published datasets (EMKG-EXPO-TOOL) vs. partly published datasets (MEASE, ECETOC TRA) vs. published datasets (STOFFENMANAGER®, RISKOFDERM)

Input parameter quality:

- Overlap with BURE: Low quality → misassignments.
- High deviations are possible.
- Examples: Dustiness (mostly qualitative except in MEASE), use descriptions (varying level of detail but always high variation).

Model inherent parameter reflections:

- Varying between models, situations (e.g. DEO units, PROCs)
- Example: LEV efficiencies range from ~50% (STOFFENMANAGER) to 95% (MEASE, ECETOC TRA)
- Possible reasons for differences: different routes, datasets / underlying assumptions

General considerations

- Tier 1 estimates are meant to be conservative → A tendency to overestimate exposure is therefore not considered to be a disadvantage
- If a risk is determined at Tier 1 level, sometimes refinements at higher Tier levels are possible
- REACh obliges the downstream user to follow the scenario used for exposure estimation → errors or vagueness during the documentation of the exposure situation / errors during model input are expected to have less influence
- However, correct interpretation of scenario by downstream user necessary
 - ➔ More than one point at the chain of communication, where uncertainty due to parameter definitions/assignment may happen

Conclusion / summary (2)

- There is always some (situation dependant) uncertainty
 - Model uncertainty has to be seen in REACH context and in relation to other eteam work packages:
 - User friendliness ↔ many parameters may increase variability
 - Available quantitative information, uncertainty of measurements ↔ vague input parameters
 - Uncertainties ↔ error compensation (→ validation exercise)
 - Correlation with BURE – some input parameters induce large variability, e.g.:
 - use category (e.g. PROC), intrinsic dustiness, type of setting, RMMs
- ➔ Improvement of model / parameter definitions
- ➔ „Improvement of model user“



10th IOHA International
Scientific Conference

LONDON 2015



April 25th-30th 2015
London Metropole Hotel

Dr. Susanne Hesse
Chemical risk assessment
susanne.hesse@item.fraunhofer.de

Fraunhofer-Institute for Toxicology and
Experimental Medicine
Nikolai-Fuchs-Strasse 1
30625 Hannover

IOHA & BOHS 2015

London: Building on Occupational Hygiene Together

BOHS
The Chartered Society for
Worker Health Protection



April 25-27-30 April
London Metropole

www.iohalondon2015.org