



Evaluation of the Tier 1 tools used for exposure assessment under REACH (E- TEAM)



This session

Introduction in Tier 1 exposure assessment (Dr. Jody Schinkel, TNO, 10 minutes)

Results of the E-TEAM project:

- **Between user variability** (Judith Lamb, IOM, 20 minutes)
- **Comparison of Tool estimates with measurement results** (Dr. Martie van Tongeren, IOM, 20 minutes)
- **Summary and implications** (Dr. Martie van Tongeren, IOM, 10 minutes)

Discussion (Dr. Henri Heussen, Arbo Unie, 30 minutes)



REACH: Tiered approach

- Under REACH an enormous burden of risk assessments need to be done in a few years.
- In order to get this done, a tiered approach is proposed:
 - 1st tier: relative simple screening tools
 - 2nd tier: more sophisticated exposure models
 - 3th tier: exposure measurement survey
- The higher the tier, the more complex the assessment and the more certain the estimate should be.
- First tier should be simple and conservative.
- The development of first tier exposure models has given exposure assessors the opportunity to deal with the enormous burden of risk assessments under REACH .

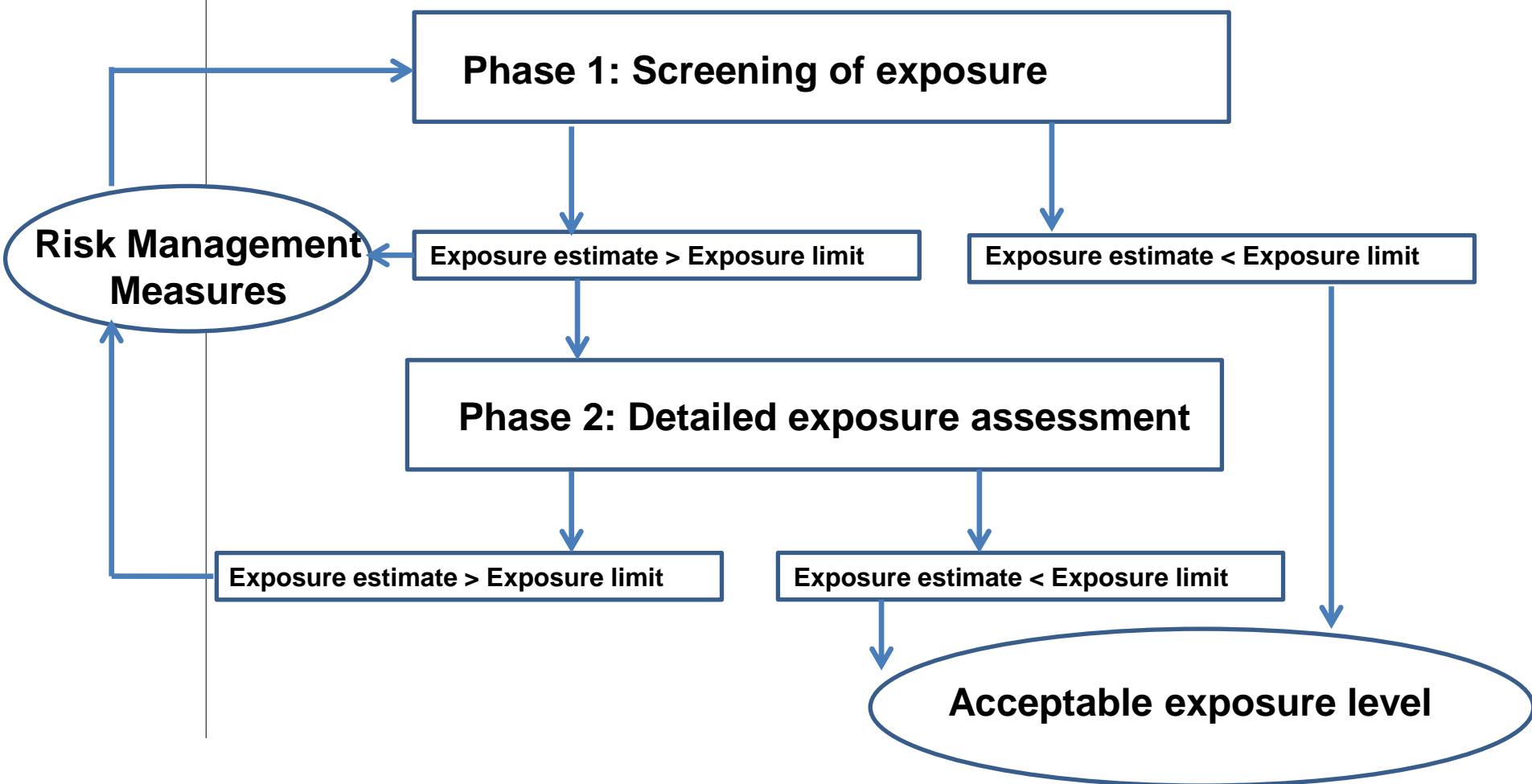


In the Netherlands: ‘Self inspection tool’

- 1: make an inventory of used chemicals and how they are used
 - 2: make an exposure assessment
 - 3: control the exposure
 - 4: take care of the results (borgen)
- REACH: Top down
 - Self inspection tool: Bottom up
 - Tier 1 (screening) models could be used in both approaches



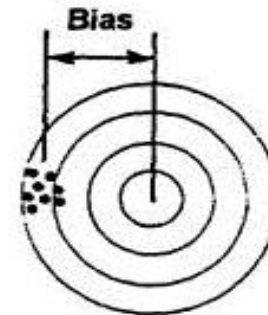
Control strategy for chemical exposure





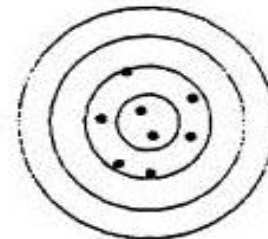
Model performance

- (External) Validation.
 - How does the model perform when it's used 'correctly'?
- Reliability or between user variability
 - How is the model used?



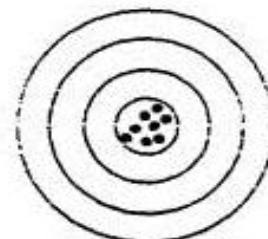
**Good Precision
Poor Accuracy
Biased**

Average off Center



**Poor Precision
Good Accuracy
Unbiased**

Average on Center



**Good Precision
Good Accuracy
Unbiased**

Average on Center



Performance of exposure models

The validity and reproducibility of the predictions of any model should be evaluated before results can be used safely and effectively in the risk assessment process.

However,

- Most of the generic exposure models have been validated only to some extent and often long after their introduction.
- In general validation studies do not cover the broad range of scenarios necessary to provide the complete picture of the validity domain.
- It is unclear whether different models provide comparable results for the same scenario.
- This lack of insight does not allow a sound weighting of available tools, which will be clearly needed in the scope of (regulatory) risk assessments.



E-TEAM project

- Project sponsored by the German Federal Institute for Occupational Safety and Health (BAuA)
- The project aims to compare and contrast the different REACH tier 1 exposure assessment models in terms of their determinants, scope of application, functionality and user-friendliness
- The evaluated models are: ECETOC TRA, Stoffenmanager, MEASE, EMKG-Expo-Tool and RISKOFDERM
- The project is carried out by the Institute of Occupational Medicine (IOM) from Scotland and Fraunhofer Institute of Toxicology (ITEM) from Germany.
- An international advisory board was appointed to provide objective scientific advice.