



Industry views on Tier 1 exposure assessment

ETEAM Conference
Challenges and Perspectives of Tier 1 Exposure Assessment
March 25-26, Dortmund



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(on behalf of Cefic)



Tier 1 worker exposure assessment tools



- **Application of exposure assessment in occupational hygiene**
 - Prioritization for regulatory compliance
 - Integrated in company-structured approaches for occupational risk assessment and risk management
 - Conservative prediction of workplace exposures after first (Tier 0) screening identifies scenarios of likely concern
 - Selection of situations that require more accurate predictions of workplace exposures using Tier 2 models, specific scenario models or measurements
- ***Application in risk assessment under REACH***
 - *Conservative exposure and risk assessment of worker exposure scenarios; demonstrating 'safe use' or targeting for use of higher Tier tools or measurements*
 - *Risk assessment of 'virtual' worker exposure situations*

Risk assessment under REACH: needs for industry



To meet the 2010 and 2013 REACH deadline, industry has registered approximately 2500 - 3000 classified substances (which require a risk assessment)

Assuming on average 10 uses/worker ES's per substance and 10 worker contributing scenarios per ES, this amounts to approximately **250,000 - 300,000** worker assessments

This would not have been possible without worker exposure assessment tools that:

- Are easy-to-use/user-friendly (without compromising a basic level of expert knowledge to utilize such tools)
- Applicable across a full range of industries, chemistries, exposure routes
- Can be integrated in sector approaches
- Facilitate mass processing of ES worker risk assessments with 'sufficient' conservatism and 'acceptable' uncertainty (capable of automation)
- Enable a tiered risk assessment approach

Key characteristics for Tier 1 REACH assessment

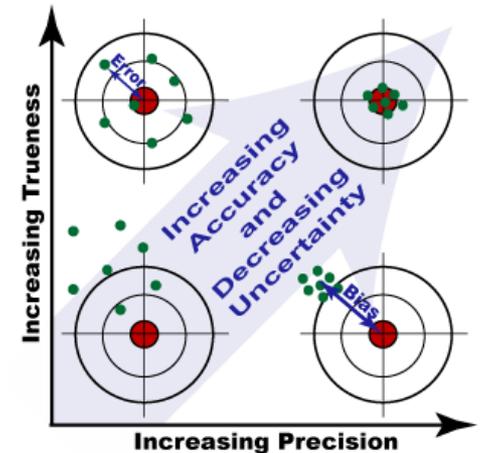


‘Sufficient’ conservatism:

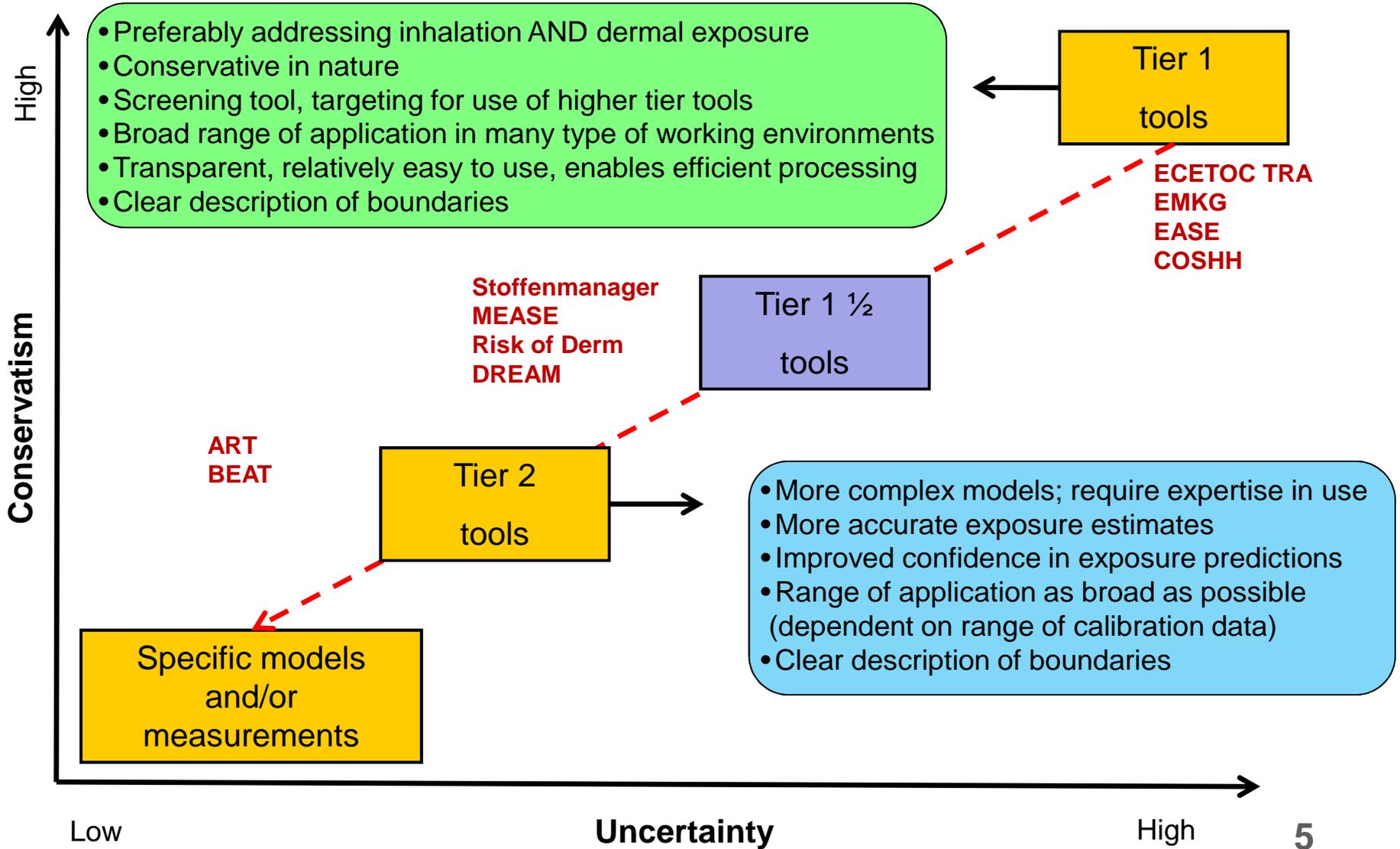
- Tier 1 tools should in general overestimate exposure, over a wide range of exposure situations , with clear statements on boundaries of the tool (e.g., what situations or type of substances, physical forms, etc. are out of the tool’s scope)
- The degree of overestimation should be limited (determined by the level of ‘uncertainty’ of the tool)

‘Acceptable’ uncertainty:

- Each tool has a certain level of uncertainty
- Difficult to measure, determined by many sources (inherent to the tool and the users)
- User sources of uncertainty (variation) can be controlled (reduced) to some extent:
 - Training, level of expertise
 - Enhancing consistency in application (e.g. sector specific approaches, GES development)



Use of Tier 1 tools in a tiered approach



ECHA Guidance on Tier 1 tools: IR&CSA: R14



“The currently available tools for first Tier 1 occupational exposure estimation have been developed to be at the same time *simple-to-use and inherently conservative*. They are therefore best used as initial screening tool i.e. they enable a defined range of OC’s and RMM’s to be identified and evaluated quickly.”

“The *preferred Tier 1 tool (ECETOC TRA)* is described in section R14.4.8. In section R.14.4.9 *another first Tier tool, the EMKG-Expo-Tool* is described. In section R1.14.5 higher level assessment tools are presented” (e.g.: *Stoffenmanager, Risk of Derm, ART*)

“Limited comparisons of the tool-predicted exposure with available measured data (independent data-sets) show a *reasonable correlation for all the tools*.... Nevertheless, there is *room for improvement*.”

“Registrants need to be aware that *exposure prediction based on the tools* described in this guidance *cannot be considered as finally ‘validated’* in a strict sense. Experience in using the tools and increased availability of more exposure information over the next few years will lead to further development of the tools and the related models.”

Objectives of the ETEAM study



Critical evaluation of Tier 1 models

- **Internal validation:** addresses the theoretical structure of the model under consideration and the corresponding uncertainties; questions of concern:
 - Are the underlying assumptions and model determinants plausible and consistent with established scientific theories?
 - How uncertain are the model assumptions?
- **External validation:** comparison of model outcome with independent measurement data; questions of concern:
 - Do the model estimates correspond to monitoring data?
 - What is the accuracy and precision of the predictions?
- **Operational analysis:** covering aspects of “between-user-variability” and “user friendliness/fitness for purpose”.

Operational analysis



- **Between-user-variability:**
 - The variability of exposure estimates caused by the application of the same electronic tool by different users with different expertise, experience and background
- **User friendliness/fitness for purpose:**
 - Is the electronic tool understandable and of practicable value for the target group?
 - Does the documentation meet the needs of the target group?
 - Are the electronic tools able to operate within the context of REACH?

NOTE:

Statistical accuracy and precision of model predictions shall not be regarded as single criteria for validity but also aspects of model uncertainty and operational behaviour. Scientific and operational aspects of the evaluation shall be balanced.

Cefic views on Tier 1 tool evaluation



Industry has been able to meet the tight REACH registration timelines, however, at the start of Phase 1 of REACH, no Tier 1 models were presented by ECHA/COM beyond those developed by industry.

Some of the applied tools had to be further developed during the registration period itself. Because of the timescales, it was not feasible to undertake comprehensive validation studies prior to application in Phase 1.

Cefic fully supports initiatives to evaluate and validate tools that have been and still are used for REACH registration purposes.

The general objective of this project is to achieve more confidence about the accuracy, precision and reliability of model predictions in order to enable industry to choose the best suited model for a given situation.

Cefic, however, would like to emphasize the outcomes of this study in terms of practical opportunities to improve the Tier 1 models, the guidance for use and the level of expertise of the users, in the light of effective and efficient processing of ES worker assessments for REACH registration.

Theoretical structure of the models



Should the underlying assumptions of a model and model determinants always be consistent with established scientific theories?

In the study reference is made to the concepts for exposure modelling by Cherrie (1996), Schneider et al. (1999) and Tielemans et al. (2006). Although these concepts in general are widely accepted, this does not imply that models that are structured on these principles are 'better' than models using a different justification basis. For example, this would exclude models that use empirical data as the basis for exposure prediction.

Models should have a logical and plausible structure, which is properly justified and documented in the accompanying documentation; models should preferably also have a structure which reflects the exposure determinants (OC and RMM) in concepts that a DU can understand.

In the end the value of a model is determined by its ability to predict exposure within an acceptable degree of accuracy and precision in combination with its operational characteristics (e.g. user friendliness, transparency, etc.) within a certain setting (e.g. REACH risk assessment).

Comparison with measurement data



Comparison of model predictions with independent measurement data ('true values') for exposure situations is the core of any validation exercise; particularly situations where a tool tends to underestimate exposure are of relevance.

However some points need to be taken into account.....

- To what extent are the independent data really independent (e.g., not used in building and calibrating some of the tools under study)?
- To what extent do the independent data represent REACH type of exposure scenario situations?
- Is it possible to 'convert' the information on the exposure scenario conditions into exposure tool parameter inputs in a correct and consistent way?

Provided these issues have been taken into account properly, the outcome of this comparison is leading for tool and tool parameter related improvements.

Between user variability

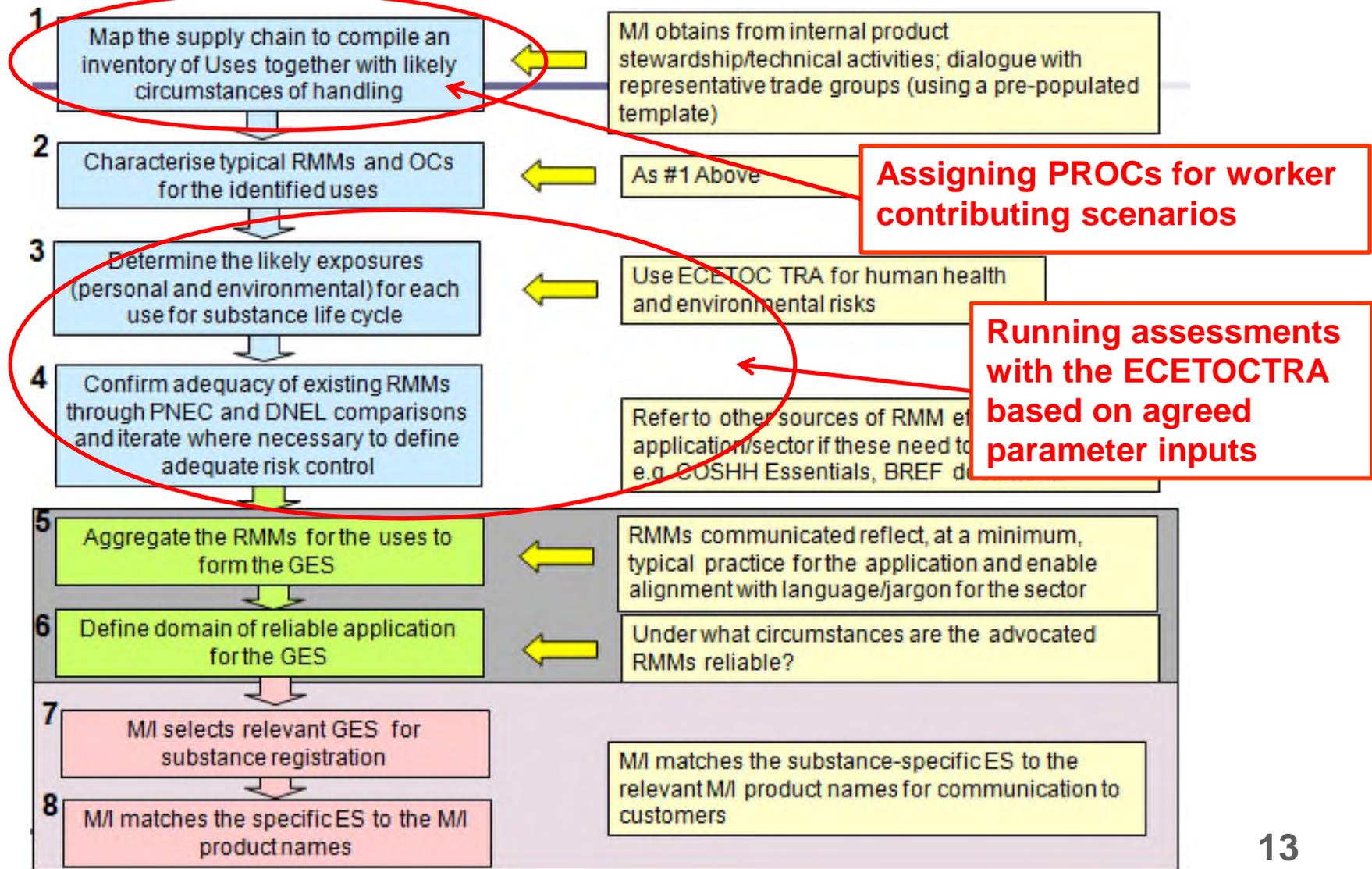


This addresses the variability of exposure estimates caused by the application of the same electronic tool by different users with different expertise, experience and background.

Some comments:

- Exposure scenarios used are selected from specific worker exposure situations, not necessarily reflecting the more generic REACH exposure scenarios that industry has to deal with.
- What would be the impact on between user variability, if the parameter inputs for the tool would be based on a discussion and agreement between worker risk assessors after consultation of product stewards on typical use conditions and measures in a sector?
- What would be the impact on between user variability, if the parameter inputs for the tool would already be available to a large extent in the form of a Generic Exposure Scenario?
- Models should not be seen in isolation but in the context of how they are expected to be used and applied => Industry Use Maps; Generic Exposure Scenarios

GES development



User friendliness/fitness for purpose



A tool should be user friendly and fit for purpose, however also users should meet certain requirements.

Some observations of the ECETOC TRA task force based on questions from tool users:

- A drawback of 'easy-to-use' tools is that everyone suddenly becomes an expert in using the tool; a certain basic level of expertise in occupational hygiene and risk assessment is required for selecting the correct inputs and determining the applicability of the model results to the scenario
- Tool users are not reading the tool documentation and are applying the tool outside of its applicability domain, despite the clear statements regarding limitations of the tool.

Expectations from industry



The outcome of the study should result in practical recommendations for tool developers and industry on:

- How to improve Tier 1 models (decrease inconsistencies in structure, minimize areas where a tool underpredicts exposure, improve user interface, etc)
- How to improve the guidance for users
- How to enhance the level of expertise of the users

These recommendations should take into account the need to maintain or improve the ability of a tool to effectively and efficiently process worker exposure assessments for REACH registration, for example:

- Linking to/integration in sector-developed supporting tools (e.g. Industry Use Maps, Generic Exposure Scenarios)
- Alignment with the Process Category as reflection of the worker contributing scenario

Scientific criteria alone should not be dominating the interpretation of the results; practical and operational aspects within the context of REACH registration are of equal importance.



Thank you for your attention!

