ECETOC Environmental Exposure Modelling Workshop 2017

Outcome and ECETOC TRA Task Force Reflections (on EUSES)

ECETOC, May 2018

ECETOC Environmental Exposure Modelling Workshop 2017

▶ Workshop: 'Advances in (Environmental) Exposure Modelling: Bridging the Gap between Research and Application'

▶ Held on 4-5 May 2017 in Brussels (Chair: Todd Gouin)

▶ Convened scientists from academia, regulatory agencies and industry

▶ Overview of current practices in <u>various industry sectors</u> (general chemicals/biocides; agrochemicals; pharmaceuticals; P/B assessment)

▶ Model fair with demos

▶ Report 35 published March 2018

▶ Produced two outcomes

  ▶ Set of recommendations

  ▶ Consensus on principles of good modelling practice and application to decision making

Workshop Objectives

- Timing!
  - Nearing end of REACH registrations 2010-2018
  - US National Research Council Reports: *'Exposure Science in the 21st century: a vision and a strategy'*, and *'Toxicity testing in the 21st century'*

- Bring together users and developers of environmental fate models used in assessing exposure, with an emphasis on the following key themes:
  - Review recent advances on tools that help to better quantify <u>uncertainties</u> associated with both information gaps and the variance in environmental properties
  - Identify and assess <u>harmonized approaches</u> for assessing exposure between the different industry sector groups
  - Address <u>applicability domain challenges</u>, including chemical, spatial, and temporal (e.g. handling of polar, ionized, and other chemicals with properties outside the applicability domain of existing exposure models)
  - Assess advances in tools aimed at <u>integrating environmental fate models with ecological and/or effects models (towards 'ecosystem models')</u>
  - Exposure assessment of <u>chemical mixtures</u> as well as tools capable of addressing the exposure of both the <u>parent chemical and transformation products</u>

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Workshop Recommendations: Objectives & Strategies and the ECETOC TRA TF Interpretation

(High Level) Objectives	Strategy	Relevance to EUSES Update
Promote fit-for-purpose modelling ('what questions can the model answer'?)	Develop sector-specific decision trees and heuristic techniques	EUSES exposure modeling clearly targets lower tier regulatory assessments How can EUSES co-exist with higher tier exposure models?
Ensure best current practice of the science of exposure assessment	Foster improved communication and coordination of the science underlying models used across the different industry sectors (e.g. within CEFIC-LRI projects)	Key is understanding & communicating the uncertainties of EUSES outcomes Develop case studies in support of model updates and revisions (e.g. sewer model)
Ensure best future development of the science of exposure assessment	Encourage involvement of and communication with all stakeholders (e.g. regulators, industry, NGOs, public) in model updates	Fully addressed by the stakeholder engagement in EUSES update process (e.g. multistakeholder workshop) Evolve to an update process with regular intervals

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Consensus on principles of good modelling practice and application to decision making – Fit for purpose modelling

Agreed consensus on best practice	Relevance for EUSES
1. A decision process must start with problem definition, followed by further scoping (prompted by specific questions regarding temporal/spatial scale, relevant compartments/receptors etc.), considerations of input data availability and, finally, model selection. Exposure models need to be fit for purpose, i.e. an appropriate tool to answer questions for a specific context	Problem definition and guidance documents are available: Regulatory assessment for industrial chemicals / biocides – usually at lower tier
6. Loss of parsimony in exposure modelling is a potential threat to acceptance of models and credibility in risk assessment	Model needs to be fit for purpose – but as simple as possible - see above
3. Guidance regarding applicability domain considerations is essential for good use of models. This should be provided alongside advice for/development of models for chemicals outside the applicability domain, e.g. ionics, hydrophobics etc	The substance applicability is one aspect of fitness for purpose. Clear(er) statements are needed for EUSES and expansion of range of equations

Consensus on principles of good modelling practice and application to decision making – Dealing with Uncertainty

Agreed consensus on best practice	Relevance for EUSES
2. Tiered assessments are key to ensuring models are fit for purpose. The most effective way of actualising tiered assessment is via a decision tree	Within EUSES different tiers of assessment are possible. However, the result does not show at which tier it was obtained/the related uncertainty
4. Improving the quality of input data is key for reducing uncertainty in exposure modelling. Sensitivity analysis can be used as a tool to identify which input data is critical with respect to uncertainty	Reduction of (and thus knowing) uncertainty is key. ECETOC plans to work on this
5. Modelling results must be communicated along with the associated level of uncertainty/confidence. Higher levels of uncertainty may be acceptable at lower tiers, or where results are used for screening purposes	There is a need to assess and communicate the degree of uncertainty of EUSES results (see above)

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Consensus on principles of good modelling practice and application to decision making - Other

Agreed consensus on best practice	Relevance for EUSES
7. Advice and model development for addressing chemical mixtures is needed. Non-chemical stressors in the environment is an important consideration in this regard	These are higher tier issues and thus not of particular relevance to EUSES update
8. Use of monitoring data, and research campaign data (e.g. sales or prescription/consumption data), for model design and refinement, and visa-versa, are areas that could be better exploited ('inverse modelling')	The use of monitoring data in EUSES is a recognised improvement need. Guidance on coverage needed.

Note: The feasibility of points 7 and 8 being taken forward as a research project (e.g. via Cefic LRI) will be considered by the WS organising committee

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Some Practical Recommendations for the EUSES Update

▶ General recommendation: Keep the fully flexibile research character of the model, but significantly improve the interface/'user experience'

▶ Update the model with validates science developments from last 2 decades

▶ A staged development process for EUSES will be necessary with clear priority setting

▶ ECETOC TRA TF revitalized to follow & support EUSES update within industry modelling expertise available: general chemicals, pharmaceuticals, agrochemicals, etc.