

Proposals to develop exposure assessment input templates for workers – focus on Risk Management Measures

Jan Urbanus

ENES 7

18/19 November 2014



Contents

- Direction provided by ENES 6 in worker exposure area
- Who is ECETOC and why at ENES 7?
- Basic RMMs in the ECETOC Targeted Risk Assessment tool
- Extending RMM options for demonstration of safe use in a CSR
- Factors affecting Risk Management Measure efficiency
- How to develop the data to quantify efficiency of a specific worker RMM
- How to use a specific worker RMM in CSA for registration
- How to communicate a specific worker RMM in an extended SDS
- Proposal for an ENES work stream and envisaged timelines
- Suggested Process for Development
- Questions & Discussion



Direction provided by ENES 6 in worker area

- Priority on Exposure assessment inputs:
 - Action 2.3 – *Connecting existing RMM packages for worker exposure to REACH CSA*
 - Further fine tuning & align the understanding in respect of description of use, conditions of use, exposure assessment on industrial and professional use(s).
- Lower priority put on
 - Definition of closed systems or 'containment'
 - Use of measured data sets in chemical safety assessment



Who is ECETOC

- Not-for-profit European scientific organization, funded by chemical companies
- Observer status with number of international bodies dealing with scientific aspects chemical safety assessment for regulatory purposes
- Developed and published Targeted Risk Assessment tools (Worker, Consumer, Environment) for REACH



Why ECETOC at ENES 7

- ECETOC has been assisting ECHA to clarify the TRA decision logic for exposure estimation as basis for CHESAR
 - Technical Report 114 describes version 3 of the TRA
 - Some limited further discussion on closed systems for task-specific PROCs (e.g. PROC 13)
 - Option 1: account for exposure reduction
 - Option 2: adopt alternative PROC (1, 2 or 3)
 - Favour option1;
 - » Need to standardize information format ('RMM template')
- Opportunity to converge with ongoing ENES activity



Basic RMMs in the ECETOC Targeted Risk Assessment tool

- TRA v2:
 - Local Exhaust Ventilation (SU/PROC-specific % reduction)
 - Respiratory Protective Equipment
- TRA v3 extensions:
 - General ventilation
 - Dermal Protective Equipment



Extending RMM options for demonstration of safe use in a CSR

- Use different tools than TRA
- Use TRA/other tool with 'non-standard' RMM
 - Single RMM's
 - Generic ('horizontal') v sector-specific
 - RMM packages
 - Often typical for sectors
 - Need exposure reduction data (%): 'efficiency'

Factors affecting Risk Management Measure efficiency

- Operational conditions: quantity of product, scale of process, energy inputs, duration
- RMM design, maintenance, testing/adjustment, 'wear and tear'
- Human error

How to develop the data to quantify efficiency of a specific worker RMM

- Intervention studies in real workplaces: before/after installation of the RMM
- Comparison of similar workplaces: with/without the RMM
- Simulation studies in controlled environment
- Modelling studies
- Combination of some/all of the above



How to use a specific worker RMM in chemical safety assessment for registration

- Basic exposure level without RMM
- Import reduction percentage from reference library if available
- Provide direct evidence
- Account for limitations



How to communicate a specific worker RMM in an extended Safety Data Sheet

- Standard phrases (ESCOM) linking to libraries
- Applicability domain
- Scaling information, equivalency with other RMMs?



Proposal for an ENES work stream and envisaged timelines

- Based on prior experience with SPERCs and SCEDs
- Need time, discussion, pilots, and consensus building
- Need for documentation template, libraries, other references
 - CEFIC LRI project B15 revisiting IR & CSA Chapter R13
- ECETOC role: coordination, basic guidance, peer-review

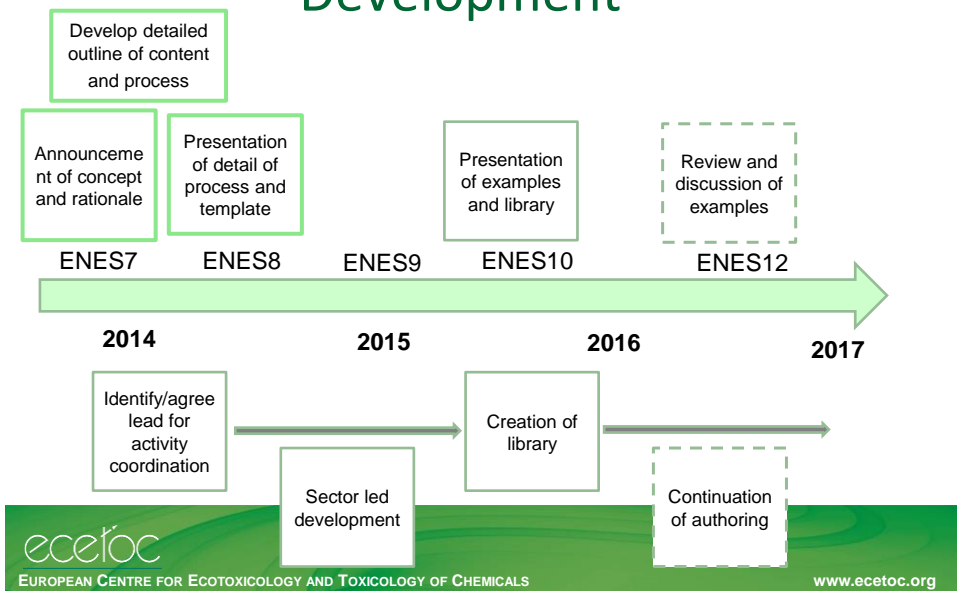


Key Considerations

- Standard template enabling all relevant data to be included
 - Full transparency of data used in substantiation of RMM (or OC) efficiency and application
- Applicability domain : which PROCs, which substance types; what limitations; etc.
- Quality criteria facilitating increased user confidence : reliable with/without restrictions
- Specific worker RMM documentations will be developed by 'affected' trade group(s) – and referenced in iUM's
- Leading to the development of a worker RMM library
- Becoming a resource beyond REACH e.g. EU-OSHA



Suggested Process for Development



Questions & Discussion

- Thank you!

