



ECETOC TRA - Basics, application, performance – REACH & Control Banding perspectives

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Some Background

- **The ECETOC Targeted Risk Assessment (TRA) model was first launched in 2003**
 - /// And a significantly revised version of the TRA was made available in 2009.
- **The original aim of the TRA was to demonstrate the utility of tiered and targeted approaches to the risk assessment of chemicals**
 - /// Those that serve as a suitably conservative screen for identifying where (targeting) the application of more detailed (higher Tier) models is appropriate.
- **The concepts of tiering and targeting are now enshrined within REACH**
 - /// Together with the Exposure Scenario as the basis for any evaluation of use
 - /// And the basis for key Use Descriptors (PROCs, PCs, ACs)
- **For human health, the TRA addresses worker and consumer exposures separately.**
 - /// And have been constructed to meet the expectations of the REACH Technical Guidance Documents (Chapters R14, R15) which is reflected in their inherent conservatism.

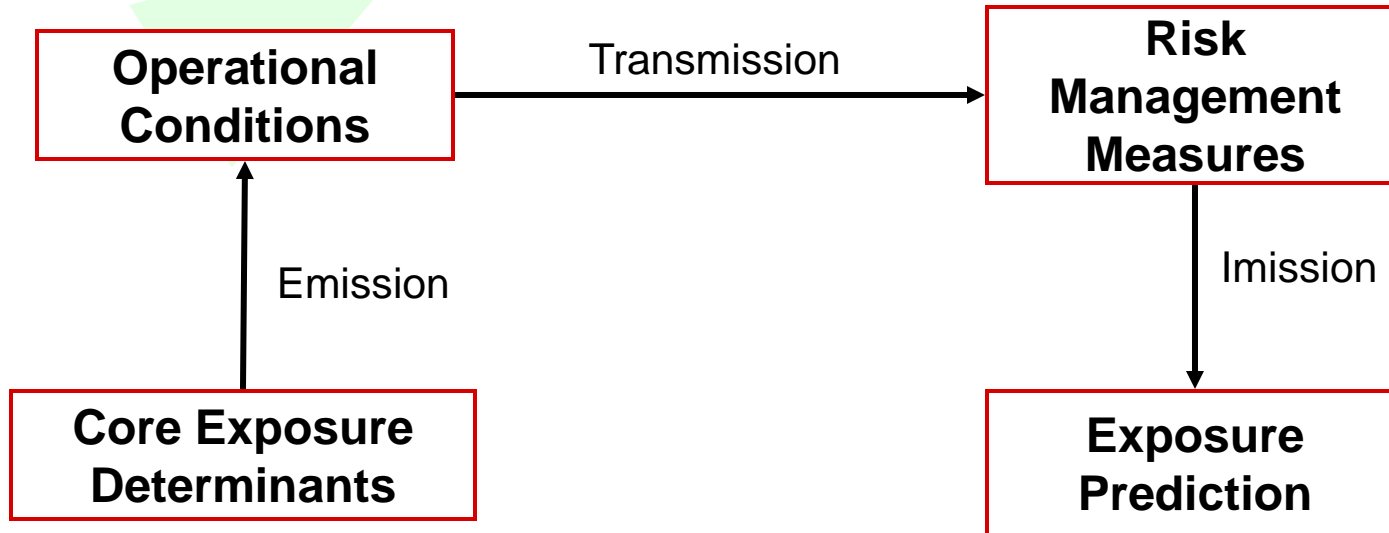
Outline

- **Focus on the TRA Worker Module**
- **Related tool developments**
- **Relationship between TRA and REACH**
- **Linkage with Control Banding**

TRA Worker Module

- **Worker exposures are determined using a source receptor model (emission, transmission and imission).**
 - /// Inhalation and dermal exposures are calculated using a refined version of the EASE model
- **The reliability and accuracy of the EASE predictions has been improved by bootstrapping against recent exposure measurement data for defined scenarios of use**
 - /// Exposure predictions using the TRA therefore relate to those obtained using the earlier EASE model.
- **By incorporating a range of exposure modifiers related to the transmission and imission pathways, the TRA is able to describe the impact resulting from alternative Risk Management Measures and non-standard Operating Conditions.**
- **Individual and cross route exposures are calculated per scenario but are not aggregated across scenarios.**

TRA Source Receptor Model



Core Determinants : vapour pressure at operating temperature; dustiness; circumstances of use; sector of use

Operating Conditions : exposure duration; percentage in a mixture

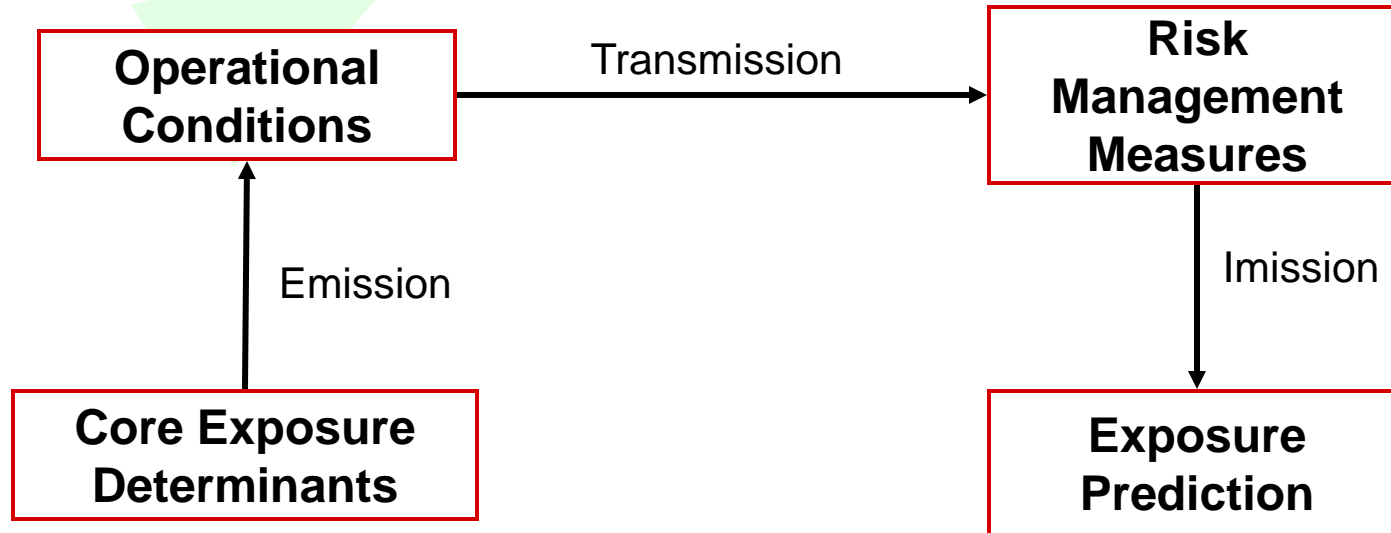
Risk Management Measures : extraction ventilation; respiratory protection

Workers

- **Validity of inhalation exposure estimates for volatiles gaining increased acceptance**
 - /// TNO-authored study demonstrates acceptable levels of accuracy and conservatism for Tier 1 purposes
 - /// Recent Nofer publication reinforced TNO assessment
 - /// Extent to which equivalent data on dusts/solids are available means parallel comparison is not yet possible
 - /// BAuA project now starting to address all Tier 1 REACH models
- **Increasing interest over the dermal exposure estimates**
 - /// How are dermal exposure predictions validated against a paucity of (reliable and consistent) dermal exposure measurements?
 - /// Role of gloves and other forms of dermal protection
 - /// Ability to include other exposure determinants e.g. Duration, concentration
 - /// Nature of LEV exposure reductions

Application Beyond Tier 1

New Determinants Suggested by External Groups



Core Determinants : Volatility/dustiness applied to dermal estimates; exposures from UVCBs; aerosols (mists); very low VP

Operating Conditions : Control of operating temperatures; duration and concentration applied to dermal exposure

Risk Management Measures : general ventilation; use outdoors; dermal protection (gloves); specific worker training; specific work procedures e.g. remote handling; specific work equipment e.g. drum pumps; enhanced RPE and extraction ventilation (beyond TRA)

Future ECETOC Plans

Short term

- /// Improving the user guidance
- /// Optimising the use of the TRA at the Tier 1, 1.5 and 2 levels
- /// Applying the TRA for aggregate exposure assessments
- /// XML transfer tool compatible with Chesar

Medium term

- /// Revising and extending the structure of the core model
- /// Development of a standalone environmental tool
- /// Further improving the user friendliness
- /// XML transfer compatibility with relevant Tier 2 models

Relationship between TRA and REACH

- **TRA v2 designed not only as a stand alone Exposure Assessment Tool**
 - /// Exposure estimates directly link PROC Codes (REACH worker Use Descriptor - tasks) with OC and RMM modifiers
 - /// Allows direct linkage to supply chain mapping of uses and associated typical OCs and RMMs, e.g. as described within the Generic Exposure Scenario (GES) approach*
 - GES grouped by Sector/Application area for substances with similar hazard and phys-chem profiles
 - Similar to the approaches adopted in several CB schemes
 - /// Supports an integrated solution for CSA development and communication within the chemicals supply chain

* (supported by Cefic and recognised within the REACH guidance)

Linkages with Control Banding (CB)

- TRAv2 provides a springboard for developing Control Banding centred solutions
- Relationship between TRA, Exposure Assessment and Generic Exposure Scenarios (with supply chain mapping grouped by Sector/Application) is a form of Control Banding
 - ❑ Descriptions of use determined through dialogue between suppliers and users of chemicals
 - ❑ Descriptions of use informed by/aligned with traditional CB approaches e.g. COSHH Essentials Control Guidance Sheets
 - ❑ GES-based information contained within ext-SDSs should therefore help to further reinforce the merits of CB-based schemes
- It is suggested that there is merit in reviewing the REACH/GES and CB approaches to explore how any similarities could be exploited and developed

Summary

- **The TRA has been applied in the vast majority of the 3400 Phase 1 (2010) REACH substance registrations where exposure assessments were required**
- **Experience indicates that the application of the tool is straightforward**
 - /// and offers significant time/resource efficiencies versus traditional 'bottoms up' approaches to risk assessment:
- **ECETOC has sought the views and experiences of stakeholders in order to better understand where improvement opportunities exist**
 - /// No fundamental issues with the core structure of the TRA have been identified
- **But it is clear that further improvements can be implemented to extend the domain of the tool**
 - /// the accuracy of exposure predictions; and its overall utility when viewed in the context of its workflows and industry IT platforms.
 - /// This highlights the importance of understanding, defining and refining applicability domains in order that tools such as the TRA can continue to be reliably and usefully applied in the process of chemicals risk assessment.
- **Allows integration with control banding solutions such as the GES approach**
 - /// Exploring similarities between the GES and Control Banding approaches for their mutual enhancement is suggested



Thank you for your attention