



# **ECETOC TRA version 3 : What are Planned Changes?**

**Chris Money, ExxonMobil**

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# TRA Task Force Members

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- Chris Money, ExxonMobil
- Johannes Tolls, Henkel
- Carlos Rodriguez, P&G
- Sylvia Jacobi, Albemarle
- Frank Schnoeder, DuPont
- Tim Kedwards, SC Johnson
- Namali Corea, SC Johnson
- Jay Ingram, Unilever
- Dook Noij, Dow
- Oliver Price, Unilever
- Hsieng-Ye Chang, DuPont
- Carol Lee, ExxonMobil
- Joy Worden, Shell
- Rosemary Zaleski, ExxonMobil
- Detleff Keller, Henkel
- Violaine Verougstraete, Eurometaux
- Mike Penman, Penman Consulting
- Mike Comber, MCC
- Volker Koch, Clariant
- Geert Booije, P&G
- François Floc'h, Rhodia
- Christ de Rooij, Solvay
- Martin Holt, ECETOC
- Markus Ulrich, BASF
- Elliot Deag, Unilever
- Chris Stevens, Dow Corning
- Sylvia Gimeno, P&G
- Tom Feijtel, P&G
- Gauke Veenstra, Shell
- Pat Koundakjian, Eurofer

# Outline

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- **Background**
- **TRA v2 : REACH experiences from 2010**
- **ECETOC activities following Phase 1**
- **Chesar v2**
- **TRA v3 : Summary of the changes and their impacts**
- **Conclusions**

# Some Background

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- **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 for 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 basis for key Use Descriptors (PROCs, PCs, ACs, ERCs)
- **Integrated tool for worker, consumer and environmental assessment.**
  - /// Constructed to meet the expectations of the REACH Technical Guidance Documents (Chapters R12, R14, R15, R16) which is reflected in their inherent conservatism
  - /// Including batch mode for up to 60 worker and consumer scenarios and 24 env scenarios per substance for a total of 80 substances (via “datasheets”).

# Website and supporting TRA activities

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- **Around 9000 downloads of the TRA tool have been made from the TRA website since May 2009**
  - /// The website continues to receive around 1200 hits every month
- **Around 10 enquiries continue to be received via the help facility each month**
  - /// Now at a constant and manageable level
- **TRA website considered ‘future proof’ but will require routine review and maintenance**
- **TRAv2 used as the basis for a significant majority of 2010 Registrations**

# ECETOC Activities Post 2010

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- **Reconvened the TRA Task Force**
- **Contacted the registered users of the TRA to harvest their experiences in 2009/10**
- **Solicited detailed feedback from major users**
- **Engagement with ECHA re experiences of the TRA in Chesar v1**
  - /// With a view to help inform the future shape and form of Chesar v2

# TRA Experiences 'after REACH'

## Positive

- **TRA worker predictions 'about right'**
  - /// Solids 'validation' limited however
- **User friendly : degree of flexibility sufficient to cope with most substances**
- **Ability to generate exposure estimates, CSAs and ext-SDS Annexes from a single tool**
- **Does not require access to specialist technical support**
- **Applied in the majority of 2010 REACH Registrations**

## Potential Areas for Improvement

- **TRA consumer predictions too conservative to be routinely useful for many substance groups**
- **Insufficient flexibility for worker dermal exposure estimation**
- **Revising user guidance to reduce frequency of 'tool misuse'**
- **Domain of worker tool excludes some key exposure routes e.g. fume**
- **Environmental CSAs require access to skilled technical resource**
  - /// Numerical form of outputs not readily 'translatable'

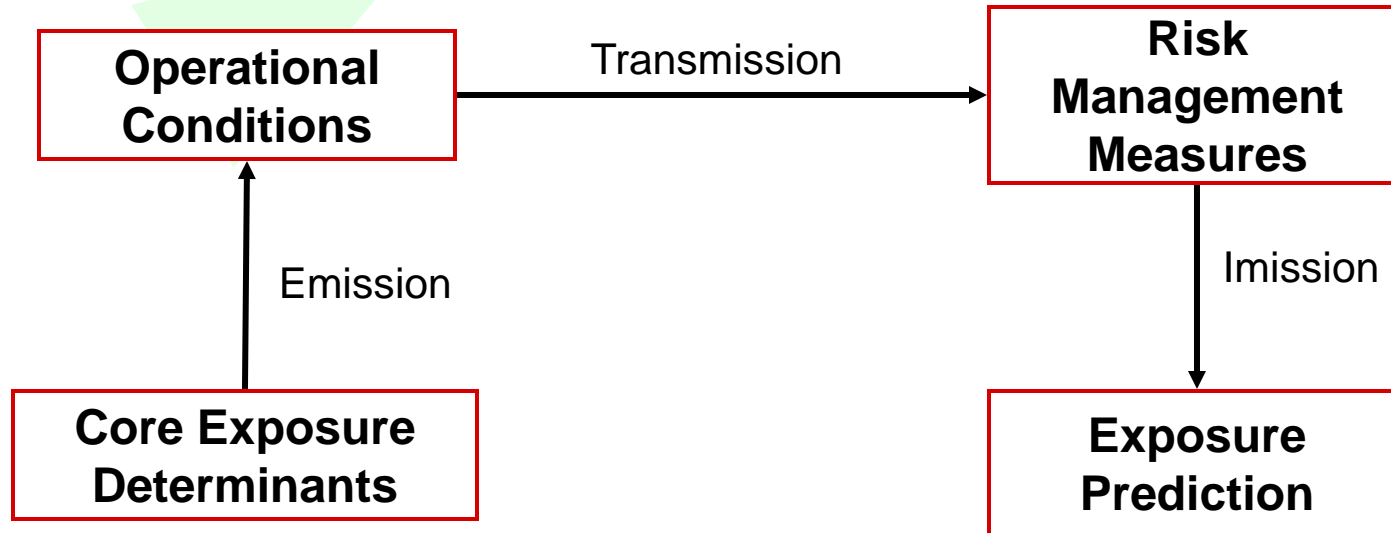


# Workers



# Application 'Beyond Version2'

## New Worker Determinants Suggested by Users



**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 working training; specific work procedures e.g. remote handling; specific work equipment e.g. drum pumps; enhanced RPE and extraction ventilation (beyond TRA)

# Workers : Scope of Changes

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## *Elimination of anomalies*

- **Correction of LEV anomalies affecting dermal exposure**
  - Will affect how dermal exposures are predicted in v3 (professional/industrial)
- **Consistency between nature of industrial/ professional inhalation predictions**
  - Will affect how dermal exposures are predicted in v3

## *Further flexibility and accuracy*

- **Concentration modifiers for dermal exposures**
- **Exposure modifiers for dermal protection (gloves)**
- **Rationale for predicting short term inhalation exposures**
- **Additional RMMs for inhalation exposures e.g. general ventilation**
- **Rationale for modifying dermal exposures by activity duration**
- **Refinement of dermal exposure estimates by substance property**

# Implications of the Changes (Workers)

## Obvious

- Increased flexibility to accommodate more exposure modifiers (RMMs)
- Improved sensitivity for dermal exposure predictions and controls
- More (Tier 1+) solutions to situations outside TRA domains e.g. mists

## More Complex

- Higher dermal exposures for professional uses (alignment of LEV reduction efficiencies)
- Changed (lower/higher) inhalation exposure predictions for defined PROCs
- Less flexibility for some uses of very low volatility substances
- Potentially more information contained in ESs (where  $RCR < 1$  challenging to achieve)



# Consumers

# TRAv2 Consumer Module

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- **The consumer part of the TRAv2 reflects the expectations of Chapter R15 of the REACH TGD**
  - /// It is not intended to accurately predict exposure, but rather to serve as a conservative screen to provide a high level of assurance
- **The TRA describes 16 scenarios covering the principle situations where consumer exposures to chemicals occur and which arise from their use in consumer products or articles.**
  - /// The scenarios relate to the Product and Article Categories (PCs and ACs) described in Ch R12.
- **Where a PC or AC covers multiple likely uses, then sub-categories have been developed in order to offer useful discrimination.**
  - /// Dependent on the scenario, both adult and child exposures are also addressed
- **TR107 Appendix F highlights how Tier 1 consumer estimates can be further refined based on reliable habits and practices information**
  - /// Links to related activities in some trade groups

# TRA v3 Consumer Module

- **The current v2 structure of PCs/ACs and PC/AC sub-categories will remain**
- **Version3 will include minor modifications in the underlying algorithms for inhalation, dermal and oral exposure**
- **Version3 will include a capability to generate/define further scenarios (PC/AC sub-categories) using a standard format**
  - /// Basic default is conservative but level of available iteration much higher in version3
- **Offers ability for exposure predictions to be less conservative if the user has available suitable H&P and other data for the substance/product combination**
- **Onus on identifying this information rests outside ECETOC e.g. with the sector associations**
  - ECETOC has developed guidance and templates for accomplishing this: the consumer equivalent of SpERCs => **SCEDs**

# Developing 'SCEDs'

- **Specific Consumer Exposure Determinants**
  - ❖ Can be seen as the consumer equivalent of SpERCs
- **Several sector associations known to have described/justified H&P information for relevant consumer uses**
  - /// AISE, ESIG, FEICA, CONCAWE, etc
- **ECETOC is now finalising a template to facilitate the efficient and consistent collection and display of relevant information across PCs/sectors**
  - /// Aligns with v3 algorithms (and TR107 Annex F)
  - /// Enables flexibility afforded by v3 to be efficiently realised
  - /// Vision is for managing and sharing/posting as part of CEFIC/DUCC ES libraries activities : starting Q1/12
  - /// Helps focus trade association activities on critical consumer determinants for their uses
  - /// Final vision is for incorporation of the library into the TRA (and Chesar) in a manner similar to the SpERCs

# Draft Outline of the SCED

Exposure Descriptor or Determinant	Value	Justification
Use description	Consumer re-fuelling of cars and similar vehicles	
Product/Article Use Category	PC13	
PC/AC Subcategory	None	Automobile refuelling
Product Ingredient Fraction	100%	
Frequency of Use	0.14	Once per week
Relevant Route(s) of Exposure	dermal / inhalation	Oral exposure not considered relevant for this use
<b>Dermal Specific Parameters</b>		
Skin Contact Area (cm <sup>2</sup> )	210	Palm of only one hand holds fuel nozzle
Skin Transfer Factor	0,05	Assumed value of no greater than 5% of material transferred from contaminated pump handle/item to skin. Long standing contamination eliminated through evaporation. Contact invariably is indirect with contaminated surfaces rather than virgin product.
<b>Inhalation Specific Parameters</b>		
Amount of Product used per application (g)	37500	Based on 50 litres and density of 750 g/l
Exposure Time (hr)	0.05	3 minutes. 97 <sup>th</sup> % value from Vainiotalo et al, 1999
Is product used outdoors ?	Outdoor use	
Room Volume (m <sup>3</sup> )	n/a	100m <sup>3</sup> used as default volume (consistent with Stoffenmanager)
Ventilation specified or likely due to properties	n/a	Outdoor air exchange rate considered to equivalent to value cited by RIVM for garages (0.6x)
Inhalation factor (fraction of total amount handles lost to air)	0.2% loss	Evaporative losses during refueling expected to be <<1% based on mass balances
<b>Oral Specific Parameters</b>		
Volume Ingested (cm <sup>3</sup> )	n/a	
Oral Transfer Factor	n/a	
Responsible organisation	CONCAWE	Arlean Rohde ( <a href="mailto:arlean.rohde@concauwe.be">arlean.rohde@concauwe.be</a> )



# Implications of the Changes (Consumers)

## Obvious

- Significantly improved exposure algorithms leads to lower predictions than v2
- Increased flexibility to accommodate PCs/ACs (and their sub-categories)
- Opportunity for substantial reductions but only if relevant H&P data available for the use

## More Complex

- Requires more effort and expertise to constructively apply than v2
- Flexibility afforded by v3 only open to sectors with suitable supporting H&P data
  - /// Rewards those with a knowledge of their products
- Some users will continue to need to refer to the TR Appendices to access information on possibilities for further refinement



# Environment

# Work Already Defined / Completed

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## Revision of documentation

- Updated User guide and Technical Report

## Improvement of the use of SPERCs

- Additional industry sectors covered; total number of SPERCs >175
- Selection of SPERCs via a code aligned with Cefic ES phrase list
- Cefic activity focused on improving the documentation of SPERCs also enables the efficient and reliable use of the TRA.
- Key SpERC RMM/OC assumptions described in phrases

## Transparency of TIER II release estimation

- Focus on two formats of release data:
  - /// release fraction (% of used amount)
  - /// release rate (as kg/day)
- Options to document the source/rationale/justification of TIER II refined release data

# Implications of the Changes (Environment)

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## Obvious

- More SPERCs are accessible via TRA v3
- Improved possibilities for documenting non-standard assessments.

## More Complex

- Redundancy in customised release estimation is eliminated.
- Improved documentation of SPERCs is available via improved factsheets (available via the sector organisation websites).

# Communication of Changes

Activity	Lead	Timing	Status
Chesar Consultation group	ECHA	Sept	Done
ECETOC/ECHA workshop with consumer exposure experts	ECHA	Sept/Oct	Planned
ECETOC to Industry ES stakeholders	ECHA	Sept / Oct	Done
ECETOC newsletter	ECETOC	Nov	Done
Cefic REACH Implementation Workshop	ECETOC	Dec	Today
TRA v3 with revised User Guide & change management document	ECETOC	End 2011	Planned
Publication of supplement to TR107	ECETOC	Q1 2012	
TRAv3 user workshop/webinar	ECETOC	Q1 2012	
Release of Chesar v2	ECHA	Q2 2012	

# Summary

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- **ECETOC has worked hard to define TRAv3 based on the experiences of the Phase 1 registrations**
- **Version3 will offer significantly increased flexibility and accuracy**
  - /// But is more complex and hence will require more ‘thought’
- **TRAv3 should become available shortly, well in time for 2013 Registration activities**
  - /// Supported by a new user guide and updated Technical Report
- **TRAv3 will be incorporated into Chesar v2 (for human health)**
- **TRAv3 is also available for 2010 dossier updates**
  - /// But it does not follow that 2010 registrations that have used v2 as the basis now need to be updated (Art 22 covers this obligation)



# Questions ?