Berlin workshop ISES-Europe, 19-21 March 2024

The new ECETOC TRA worker tool 3.2

Utilizing workplace measurements to evaluate and improve exposure predictions of the screening tool

Joost G.M. van Rooij
on behalf of ECETOC

ecetoc

WE ARE THE CENTRE FOR CHEMICAL SAFETY ASSESSMENT

Members of the
ECETOC-TRA Expert Task Force

Gerald Bachler   (DuPont de Nemours Belgium BV)

Athanasios Gkrillas   (Dow Belgium BV)

Oliver Henschel   (BASF SE)

Qiang Li   (Clariant Produkte Deutschland GmbH)

<u>Joost G.M. van Rooij</u>   (Caesar Consult, Chemrade Software BV)

Jan Urbanus   (Consultant, formerly Belgian Shell NV)

Matthias Wormuth   (Syngenta International AG)

Contents

- What is the ECETOC TRA-tool?
- Why a revision?
- How was this done?
- Key findings
- What has changed?
- ECETOC Worker exposure tool version 3.2 at a glance
- Resumé
- Acknowledgments

ecetoc

WE ARE THE CENTRE FOR CHEMICAL SAFETY ASSESSMENT

Presenter

Joost G.M. Van Rooij (PhD)

Toxicologist (EuroTox) /
Occupational hygienist

Consultant at Caesar Consult &
advisor at Chemrade Software BV

Education
o PhD-Toxicology
o MSc –Toxicology and
 Environmental Science,
o BSc- Biology

Hobby
Tennis, volleyball, kick-boxing, piano

Professional affiliations

NVvA Netherlands Occupational Hygiene Society
 o President since March 2012
BOHS British Occupational Hygiene Society
ACGIH American Conference of Governmental
 Industrial Hygienists
DGAH German Occupational Hygiene
 Association
NVT Netherlands Toxicology Society
CGC Netherlands Contact Group on Chemicals
IIHA Indonesian Industrial Hygiene Association

What is the ECETOC-TRA Tool?

- ECETOC's Targeted Risk Assessment (TRA) tool estimates the risk from exposure to chemicals for workers, consumers and the environment

- Launched in 2004, it went through several updates

- Currently available in 3 applications:

  o Integrated tool: Worker, Consumer and Environmental module

  o Stand-alone tool: Consumer module

  o **Stand-alone tool: Worker module   ‼NEW‼**

- ECHA has implemented the ECETOC-TRA Consumer and Worker modules in Chesar to assess exposure and risk under REACH regulation

Worker exposure module

- Simple, easy to use, Tier 1 exposure tool.

- Provides conservative estimates of both inhalatory (8hr TWA, peak) and dermal exposure (8hr TWA).

- Use of PROCs (Process Categories), type of setting (industrial/professional) and fugacity for providing base estimates. Further refinement of prediction using modifiers: e.g. ventilation, LEV, duration, concentration.

- Widely used for REACH registrations but also for worker exposure assessments in the context of OSH.

Why a revision?

- A number of independent validation studies have been published on the performance of the ECETOC-TRA Worker exposure tool since its creation.

- Most comprehensive study: the E-Team study (2014).

- Validation studies show mixed results.

- Questions on validity of ECETOC-TRA Workers exposure tool as conservative screening tool.

→ ECETOC convened a group of experts via **ECETOC Expert Task Force** to critically review these studies.
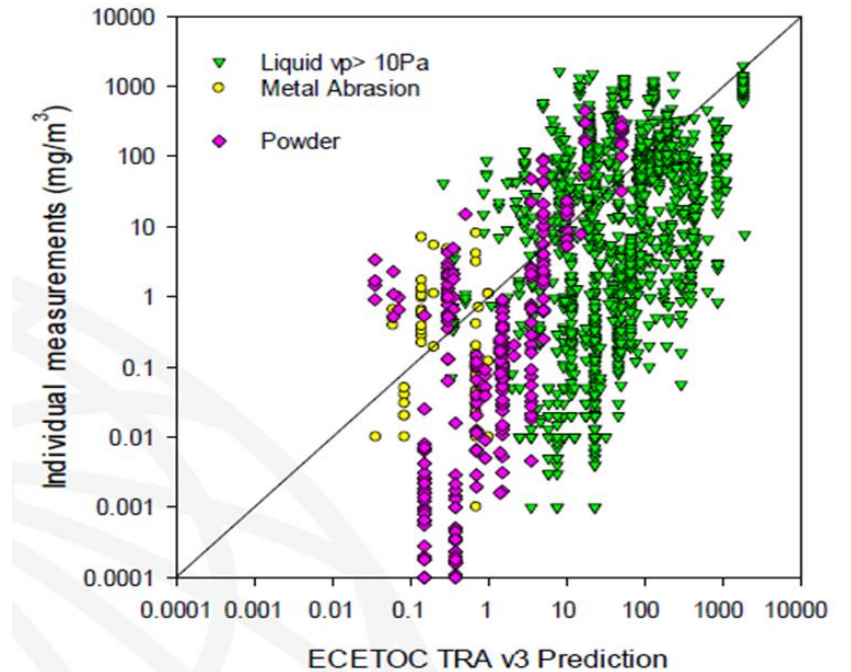
E-TEAM project (2014): **E**valuation of **T**iered **E**xposure **A**ssessment **M**odels under REACH (www.eteam-project.eu, includes ECETOC-TRA, Stoffenmanager, EMKG Expo tool)

How was this done?

- ECETOC experts reviewed the published validation studies, creating a curated database of workplace measurements.

- Using the ECETOC-TRA Worker exposure tool version 3.1, they generated estimates for each exposure scenario in the database.

- The ECETOC-TRA estmates were then compared with the measured exposure data.

- Based on this comparison, some parameters were subsequently adjusted to improve the performance of the ECETOC-TRA Worker exposure tool (→ version 3.2)

Curated database of workplace measurements [1]

Criteria for selecting valid (datasets in) studies, e.g.:

- at least 6 measurements per exposure scenario (N ≥ 6)
- quality of exposure data (rating scale 1-4)
- quality of information elements (rating scale 1-4)
- representativity of measurements (e.g. reflecting personal exposure)
- sufficient information available to calculate a 75th percentile
- sufficient contextual information to assign PROC, setting, volatility, etc.
- review process: lead reviewer, second reviewer, consensus

Number of exposure scenarios (ESs) and measurements in database

Databases	Liquid scenarios	Solid scenarios	Solids in liquids scenarios	Non valid scenarios
Long-term inhalation				
# ESs	119	10	n.a.	10
# measurements	2171	101	n.a.	60
Short-term inhalation				
# ESs	36	2	n.a.	3
# measurements	356	43	n.a.	29
Long-term dermal				
# ESs	21	25	36	1
# measurements	881	284	554	14

Curated database of workplace measurements [(2)]

Coverage of PROCs by exposure scenarios per database
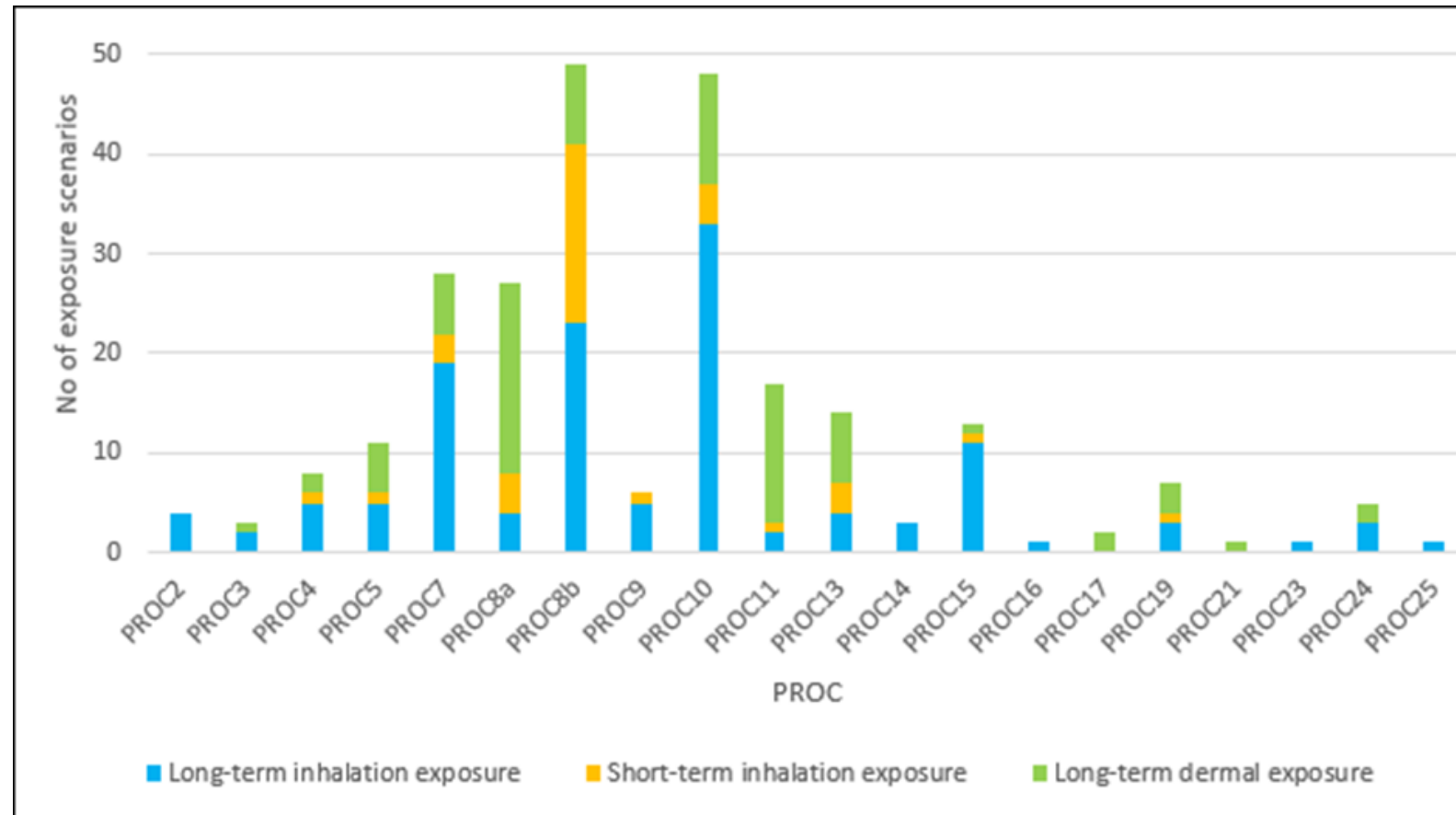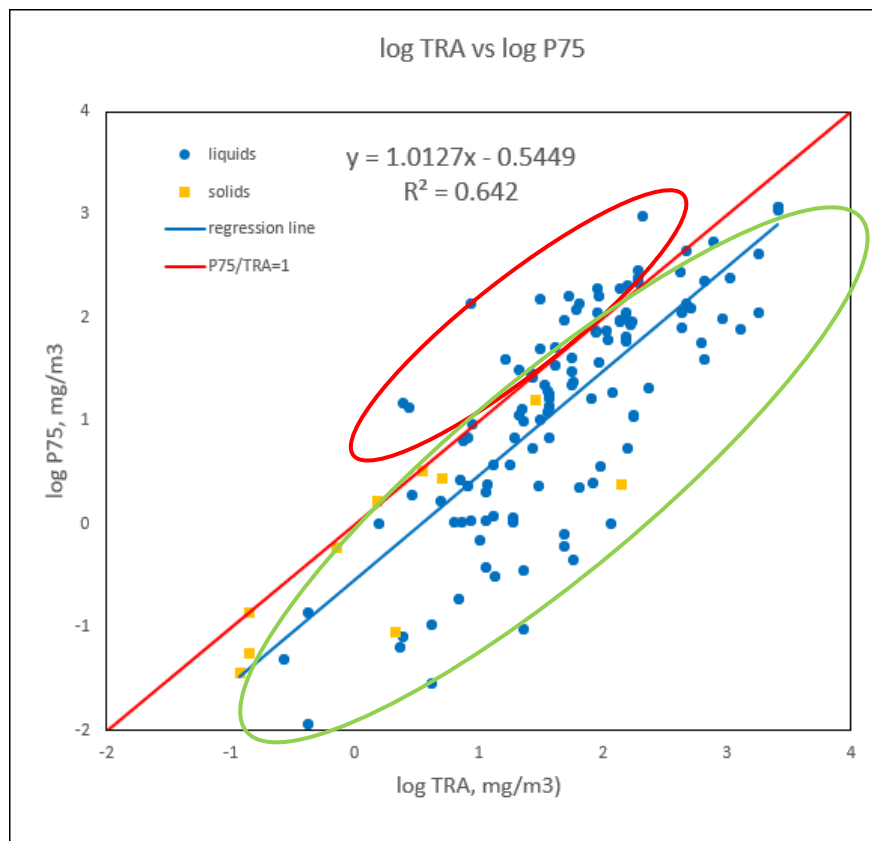
Construction ECETOC-TRA exposure estimates

- Based on available contextual information and complemented with generic industry knowledge.

- Highlight any disagreement with original publication; provide justification for alternative selection.

- If information on modifier was unclear, err on the side of conservatism, i.e., produce a lower TRA estimate, e.g.: product with ~5% of substance: modelled as 1-5%, not 5-25% (TRA estimate would be 3x higher)
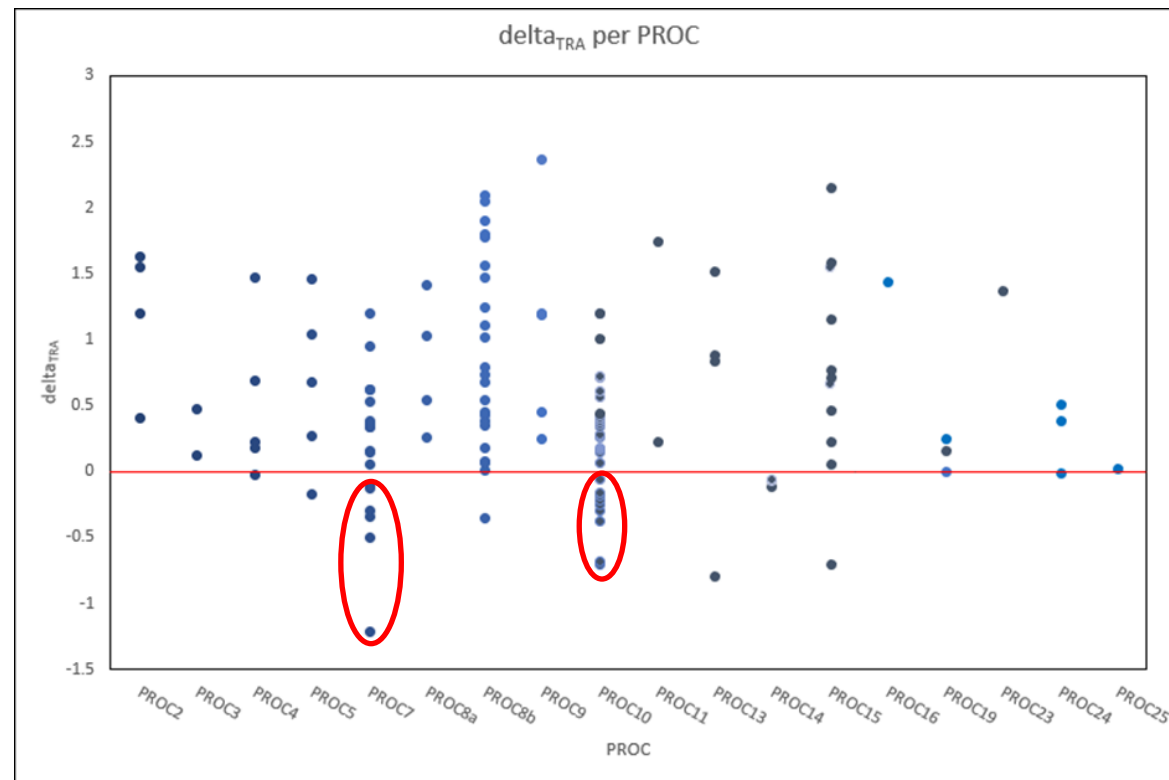
- Document all changes and decisions.

Comparison of TRA estimates with measurements [1]

log TRA vs log P75

$y = 1.0127x - 0.5449$
$R^2 = 0.642$

- liquids
- solids
- regression line
- P75/TRA=1

105 of 129 ESs with TRA > P75   (**81%**)
24 of 129 ESs with TRA < P75   (**19%**)

Long-term inhalation exposure

delta$_{TRA}$ per PROC

delta $_{TRA}$ = log (TRA) – log (P75)

Comparison of TRA estimates with measurements [(2)]

log TRA vs log P75

- liquids
- solids
- regression line
- P75/TRA=1

$y = 1.056x - 1.3415$
$R^2 = 0.3933$
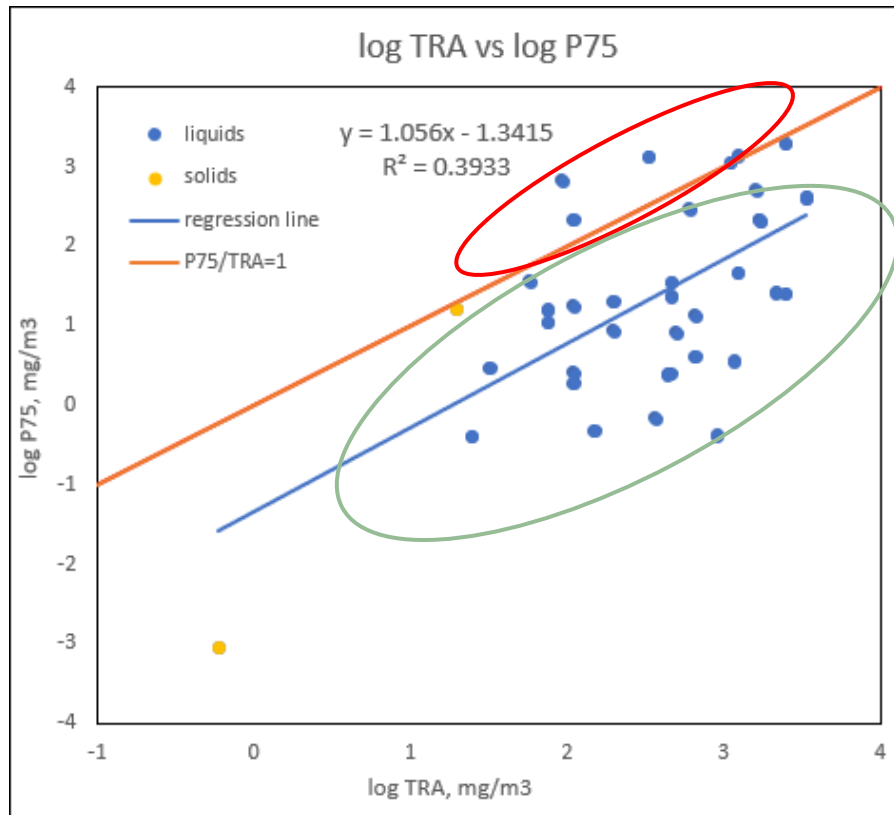
33 of 38 ESs with TRA > P75   (**87%**)
5 of 38 ESs with TRA < P75   (**13%**)

Short-term inhalation exposure

$delta_{TRA}$ per PROC

delta $_{TRA}$ = log (TRA) – log (P75)
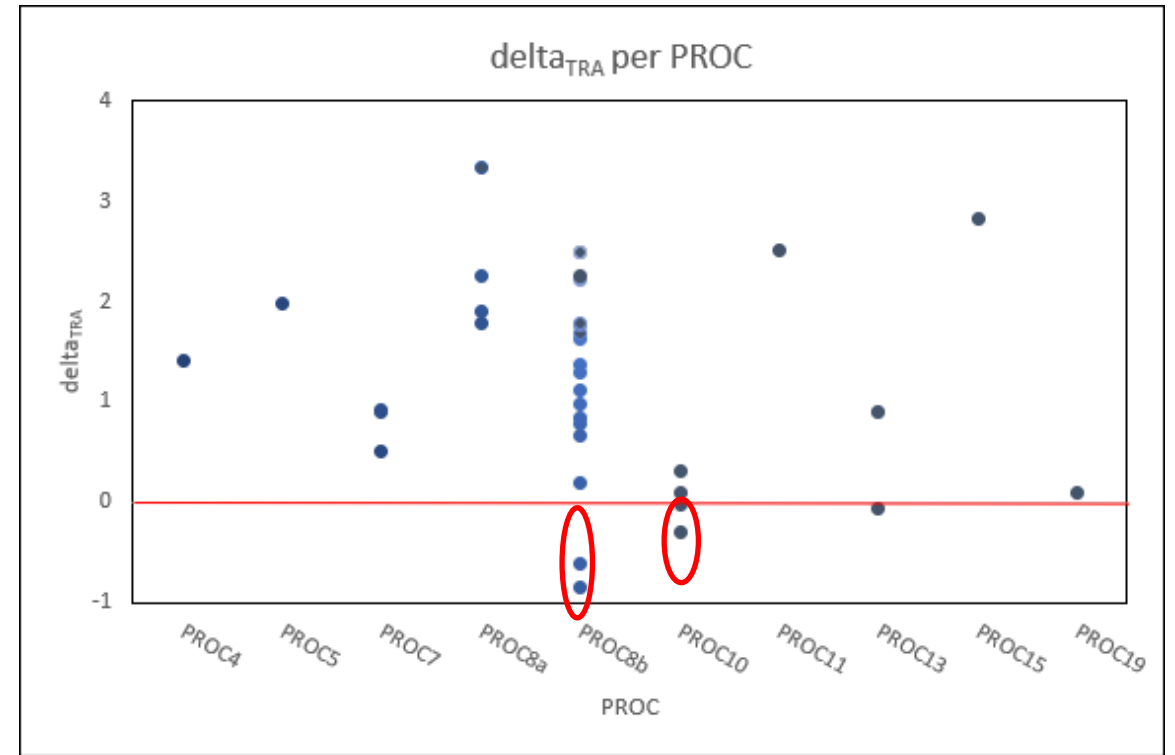
Comparison of TRA estimates with measurements [(3)]

Dermal exposure (long-term)

$$delta_{TRA} = log\ (TRA) - log\ (P75)$$
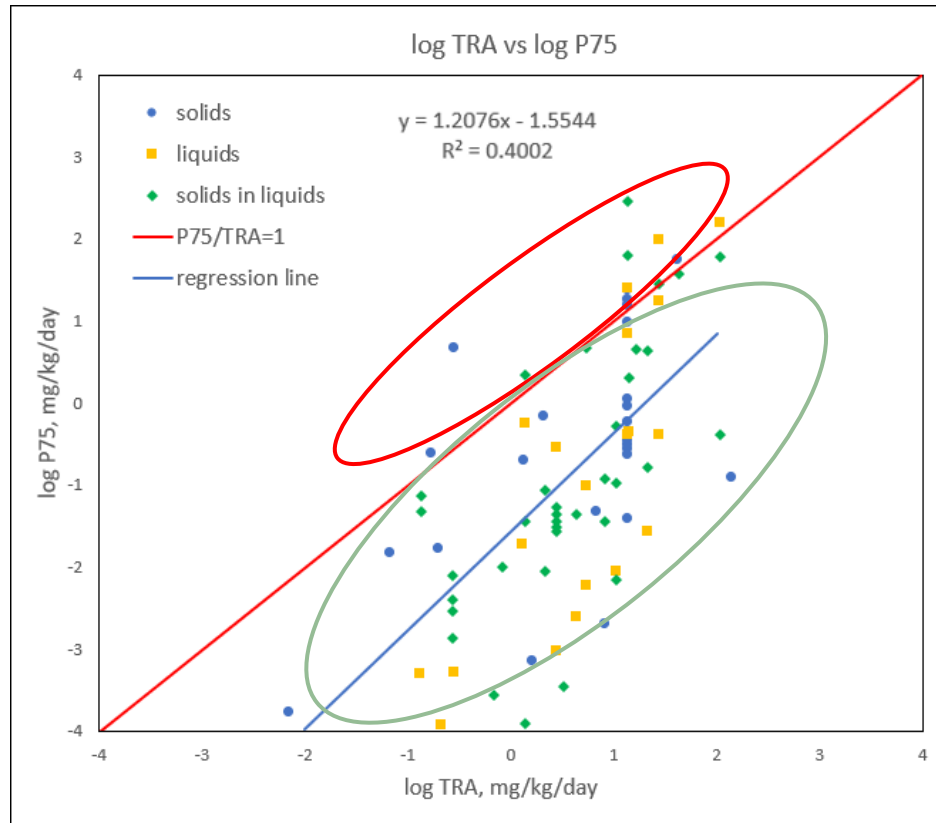
67 of 82 ESs with TRA > P75   (**82%**)
15 of 82 ESs with TRA < P75   (**18%**)
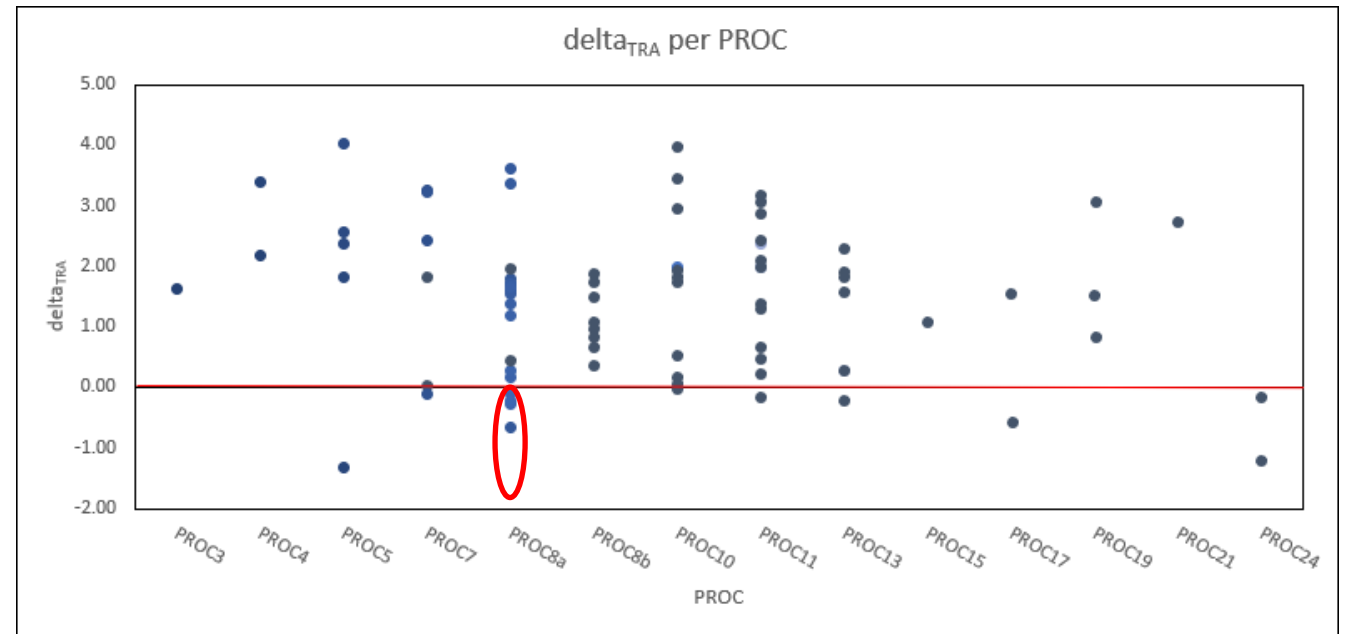
What has changed?

Modifications of ECETOC-TRA Worker exposure tool parameters in **version 3.2** to improve the performance of the tool:

- Increase of base estimates for PROC 10, medium volatility liquids for inhalation exposure (industrial: 50 => 100 ppm; professional: 100 => 200 ppm)

- Increase of base estimate for PROC 8a for dermal exposure (13.7 => 27.4 mg/kg/d)

- Reduction of effectiveness of Local Exhaust Ventilation for PROCs 7, 8b, 17, 18 (industrial: 95% => 90%; professional: 90% => 80%)

=> These changes reduce the number of underestimations of the ECETOC-TRA Worker tool

=> Percentage of 'false negatives' after implementation of the changes:

	Long-term inhalation	Short-term inhalation	Long-term dermal
# datasets	129	38	82
# datasets with DNEL or OEL	129	29	32
# datasets with $RCR_{TRA} < 1$ AND $RCR_{P75} \geq 1$	5	0	1
Percentage 'false negatives'	5/129 = 2.3 %	0/29 = 0 %	1/32 = 3.1 %

ECETOC Worker exposure tool 3.2 at a glance

NEW FORMAT

- Now also available as a new **stand-alone tool**, a more user-friendly, macro-free excel sheet

NEW RESULTS

- More conservatism
- Changes could shift RCR >1

Additional information:

Visit: www.ecetoc.org
download the ECETOC-TRA tool
obtain suplementary information
browse FAQ and access the user guides

ECETOC - TRA worker v3.2 dissemination video
ECETOC – TRA worker v3.2 Press release

Publications:

ECETOC TRA Worker tool v3.1: a review and update of the tool based on an extensive comparison of measured and modelled inhalation and dermal exposure data. Tijdschrift voor Toegepaste Arbowetenschap 2023; 26 (3), 61-77.

ECETOC TRAv3: An In-depth Comparison of Publicly Available Measurement Data Sets With Modelled Estimates of Occupational Inhalation Exposure to Chemicals. Annals of Work Exposures and Health, 2023, 67, 496–507

Systematic review of published studies of ECETOC TRA Worker exposure predictions . ECETOC Technical report No. 140, April 2022

ECETOC TRA v3 Worker module: Comparison of measured and modelled short-term inhalation and dermal exposure; Changes to tool settings. ECETOC Technical report No. 141, Sept 2023

ecetoc
WE ARE THE CENTRE FOR CHEMICAL SAFETY ASSESSMENT

Resumé

- Efforts to maintain/improve the ECETOC-TRA Worker exposure tool continue.

- Recent efforts have reviewed validation studies and resulted in revisions of the tool.

- The revised ECETOC-TRA Worker exposure tool v3.2 and background documents are freely available online.

- Chesar plans to integrate the updated ECETOC-TRA Worker exposure tool v3.2 in the Chesar Platform (planned for 2024)

- Further work is underway => More datasets of workplace exposure measurements would very much support the further efforts (especially for data-poor PROCs, such as PROC 6, 12, 18, 20)

- New Task Force members are welcome!

=> **If you are interested, please contact ECETOC:** sergio.perez@ECETOC.ORG

ecetoc
WE ARE THE CENTRE FOR CHEMICAL SAFETY ASSESSMENT

Acknowledgments

Former members of the ECETOC Expert Task Force, who contributed to this project:

Dave Marsh	ExxonMobil
Chris Money	Cynara Consulting
Dook Noij	consultant (formerly Dow)
Nenad Savic	University of Lausanne
Paul van de Sandt	consultant (formerly Shell)

And special thanks to Frank Schnoeder (Dupont) for assistance with programming the new stand-alone version and for updating the worker module within the integrated tool

More information?

Visit: https://www.ecetoc.org

or contact: sergio.perez@ECETOC.ORG

ecetoc
WE ARE THE CENTRE FOR CHEMICAL SAFETY ASSESSMENT