

Reflections on a performance study of the ECETOC TRA worker exposure prediction tool

ECETOC exposure workshop Alicante
October 2023

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Content

- The Targeted Risk Assessment (TRA) tool
in a nutshell
- Why the performance study
- Some dilemma's

The TRA tool in a nutshell

- ECETOC created the TRA tool (2004-2009) to support REACH registrations
 - Modules for worker, consumer and environment exposure
 - Aligned with ECHA Use Descriptor system
 - Incorporated in ECHA's CHESAR tool/platform
 - Updated (v3.1, 2012) after REACH round 1, now v3.2 (2023)
- Screening tool
 - Requires few inputs – fast, but generic – widely used
 - Intended to be conservative
 - To avoid screening 'out' potentially problematic scenarios
- Tool governance: TRA steering team, task forces

Why the tool performance study

- Since 2010 several validation studies have been published on the performance of the ECETOC TRA-Worker module
- Studies reported mixed results
 - Over- and underestimations compared to ‘real-world’ measurement data
- Questions on validity of TRA tool as conservative screening tool for worker exposure scenarios
 - No study covered full domain of applicability of tool
- Request by ECHA to all tool owners to ‘maintain’ tools
 - ENES action 3.2 “Consolidate the different worker exposure tools into a common framework”

➡ 2019: ECETOC TRA Expert Task Force

Study approach

- Examined quality of published analyses in great detail
 - Retrieved and reviewed underlying data
 - Exposure measurements and workplace conditions; TRA application
 - ‘Curated’ in case of errors
- Constructed and analyzed 3 databases
 - ≥ 6 measurements/scenario (basis for distribution percentile)
 - Full-shift (‘long-term’) inhalation
 - Full-shift dermal
 - Peak inhalation (< 30 min.)
- Identified and implemented some changes
 - Full-shift inhalation analysis published in Annals WEH
 - New look-up tables V3.2 released (TR 141)

Users should read...

Annals of Work Exposures and Health, 2023, **XX**, 1–12

<https://doi.org/10.1093/annweh/wxad001>

Advance access publication 15 February 2023

Original Article



The Chartered
Society for Worker
Health Protection



ECETOCTRAv3: An In-depth Comparison of Publicly Available Measurement Data Sets With Modelled Estimates of Occupational Inhalation Exposure to Chemicals

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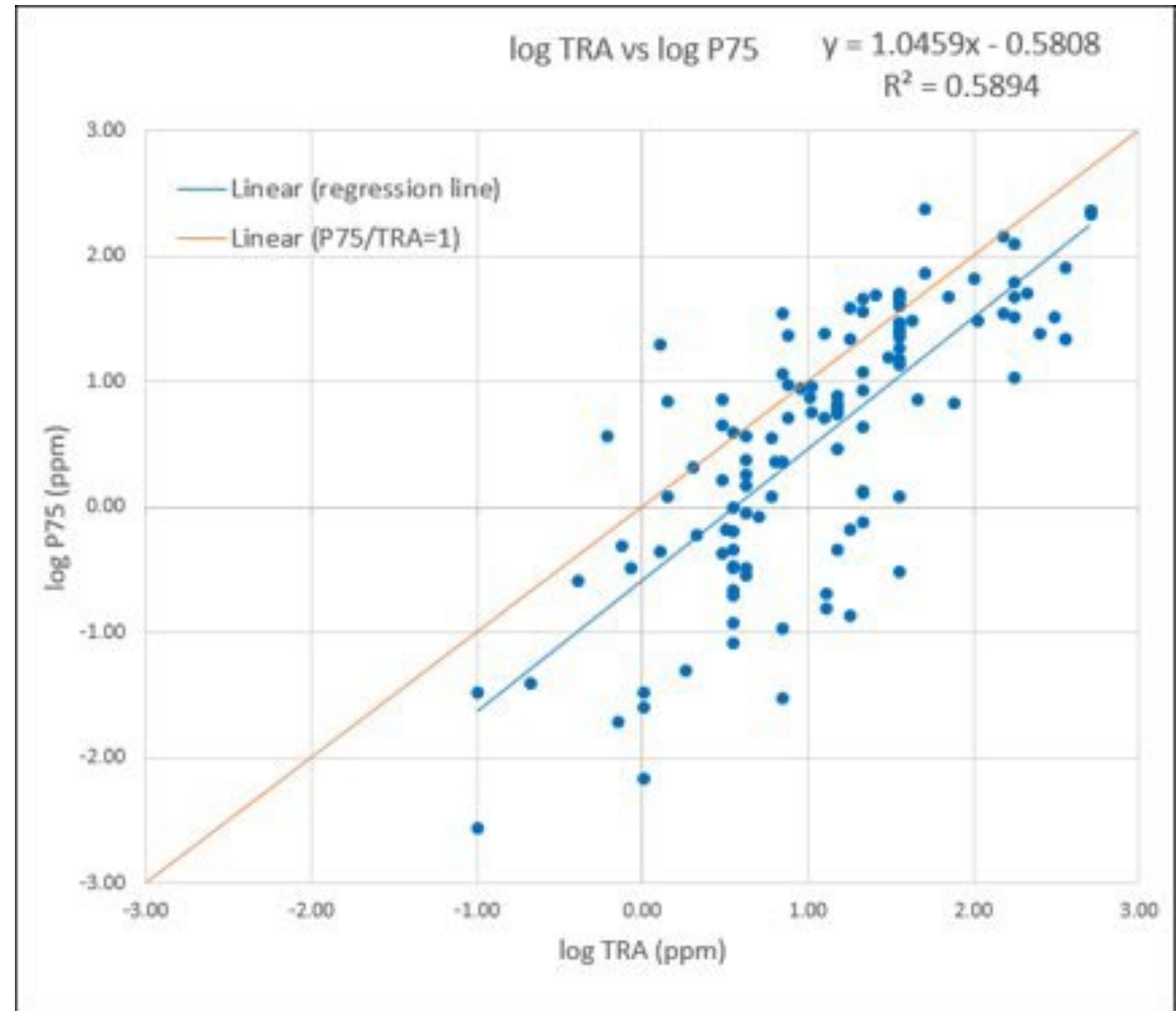
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Downloaded from <https://academic.oup.com/annweh/advance-article/doi/10.1093/annweh/wxad001/6888888>

Example finding of the study

Vapour exposures from handling liquid substances:

- On average overestimated by TRA
- Precision is low



Dilemma's in the course of the study

- No formal protocol for such studies
- Comparison material – what to use?
- Conservatism – what does it mean?
- Analytical strategy and interpretation of results
- The role of the model developer – objective?

Lack of a protocol

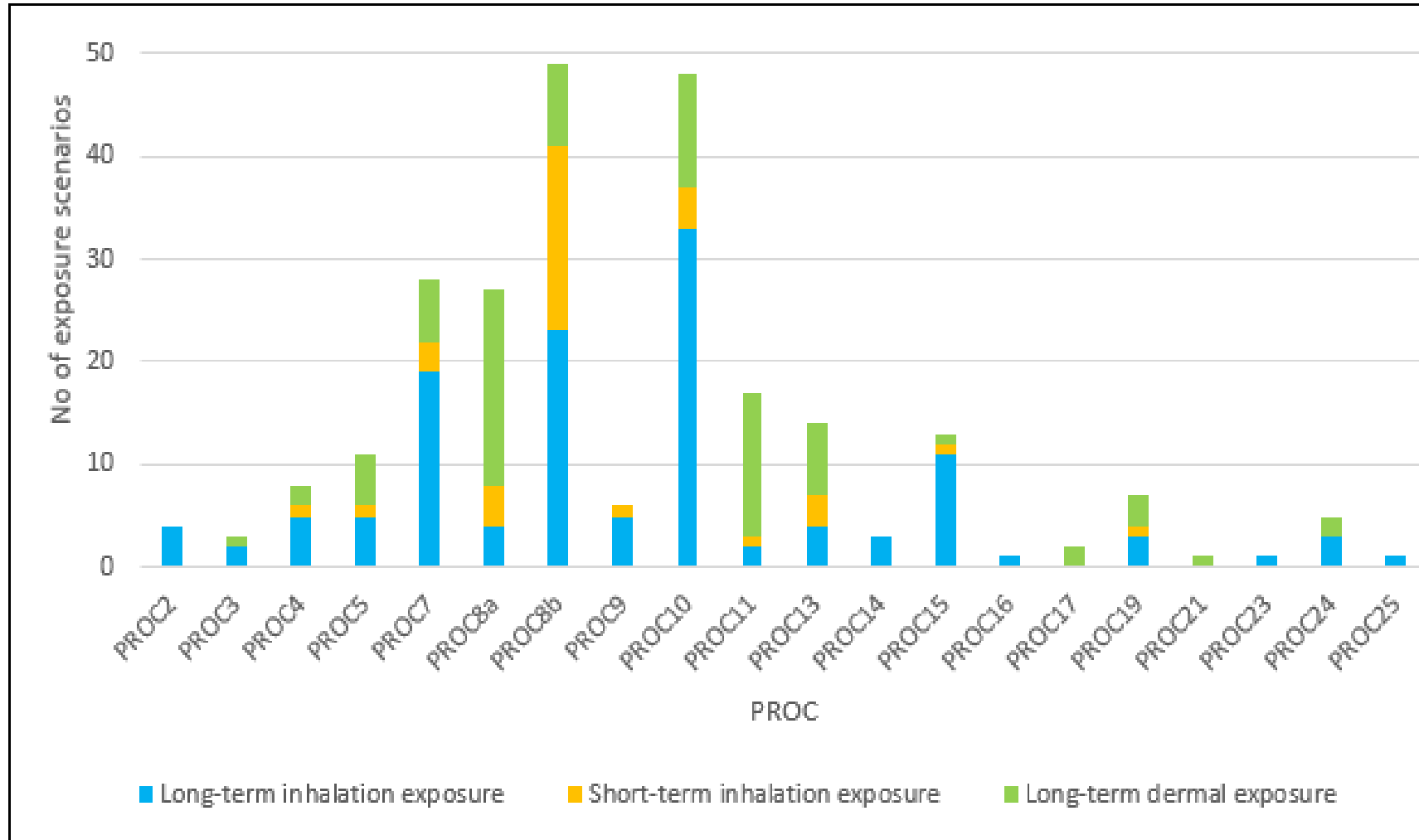
Solution:

- Apply 'good scientific practice'
 - Consult externally (advisory panel)
 - Transparent
 - Published all study materials ('Supplementary Information')

Comparison material for tool performance

- Existing exposure measurements
 - With adequate contextual data as tool inputs
 - Why was exposure measured?
 - Representative for 'normal' operations, sector?
 - Minimum quality requirements
 - How many data needed (power)?
- Ideally: dedicated campaigns
- Opportunistic: take what is available
 - Unbalanced

Uneven PROC coverage by number of data sets from all studies combined



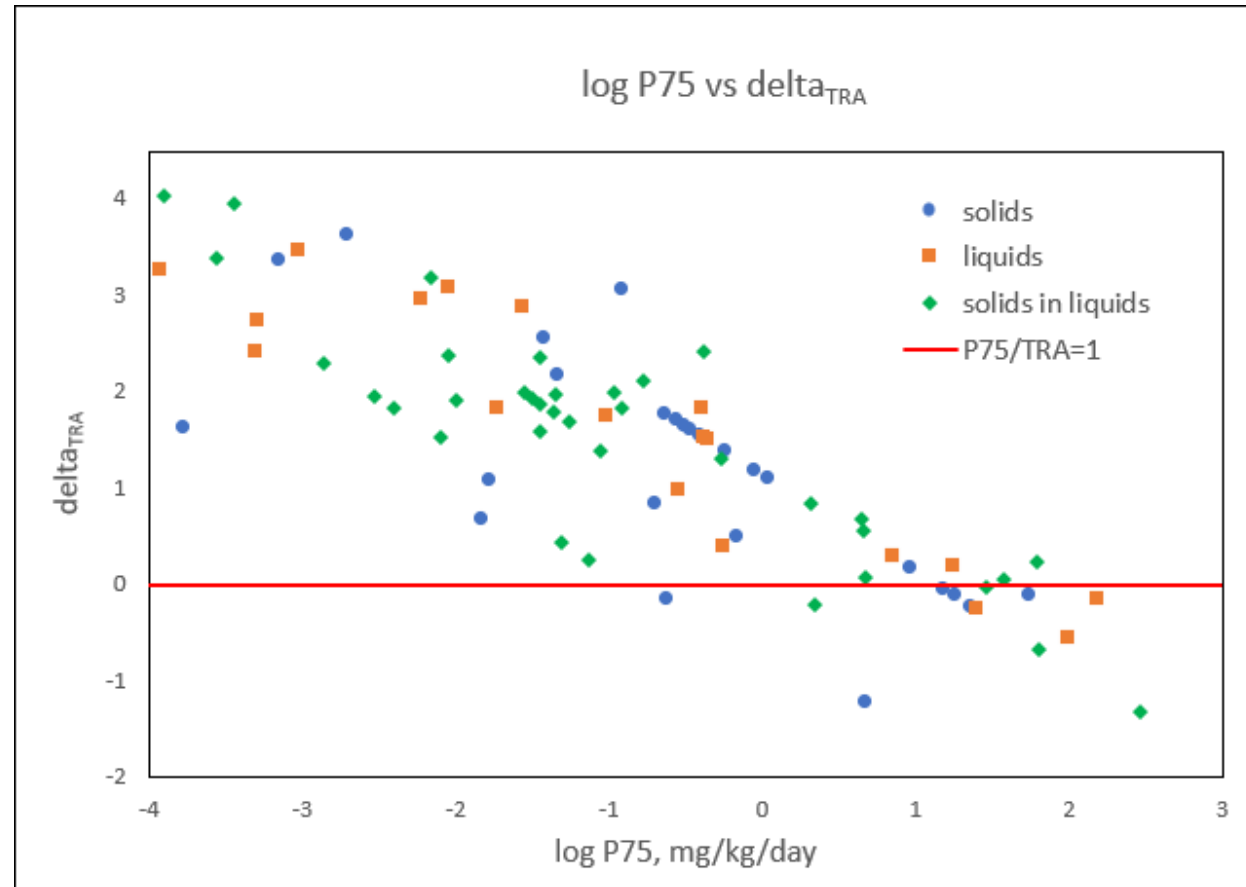
Analytical strategy and interpretation of results

- Simply counting # of underestimations
 - E.g., E-Team considered <10% underestimations as ‘highly conservative’
 - Does not recognise that some scenarios have more data points than others
- Our study used regression analysis
 - To counter uneven distribution of data across scenarios
 - Able to home in on some sub-scenarios associated with underestimations
- Extensive plotting of data comparisons
 - Visualisation to guide interpretation

Example of insightful plotting

(Δ_{TRA} = difference between $\log(\text{measured data})$ and $\log(\text{TRA prediction})$)

Example: dermal data, some under-estimations at high exposure levels



Some considerations on conservatism

- In screening assessment:
 - Tool overestimates actual exposure level
 - Avoids ‘false negative’ conclusions
 - But by how much to remain meaningful?
- In risk assessment:
 - Compare a high-end percentile from exposure level distribution with limit value
 - Even where average exposure most relevant to health risk
 - TRA-Worker provides 75th percentile
 - Derived from interquartile ranges in EASE
 - ECHA guidance prefers 90th
 - For multi-location (sector-level) assessments: choose conservative tool inputs

And finally, the role of the model developer

- Expectation to keep tool 'up-to-date'
 - Not rest on your laurels
- External evaluators
 - What if they use your tool wrongly?
- Model developer's pride ... Bias in self-evaluation?
 - Transparency, accountability ... Build trust

Acknowledgements

- Members of the **ECETOC TRA Expert Task Force** (see TR 140, TR 141)
- Members of the **External Advisory Panel** (see AWEH paper)
- Anonymous **peer-reviewers** of AWEH and other publications