

Background

- In 2015 an ETEAM study (BAuA, 2015) evaluated Tier 1 worker exposure models.
- Their database measurements and assumptions used to validate model estimates are now available.
- ECETOC took the opportunity to examine the ETEAM findings, assess the database, and identify possible areas of improvements to TRA worker exposure estimates.

Objectives

ECETOC investigated several questions:

- Can ETEAM data analysis be accurately re-constructed?
- Does the database contain sufficient contextual information for PROC choices?
- Do scenarios cover situations considered within the TRA domain?
- How were Use Descriptors applied to develop the TRA estimate? e.g. per Use Maps
- Was the method of validation analysis by ETEAM appropriate for the TRA?
- Are ETEAM estimates 'accurate'?
- What improvements might be considered for TRA?

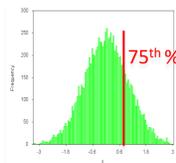
Method

1. ECETOC Scientific Committee endorsed re-analysis in March 2016; TRA working groups (WG) formed.

2. ETEAM access database converted into Excel to aid analysis and transparency.

Parameters included:

- scenario information
- sample information
- ETEAM TRA input variables and TRA exposure estimates
- 75th percentiles calculated for ETEAM scenarios with datasets and single data points to compare with TRA 75th percentile (P75) estimates
- sample data
- number of samples for each scenario (N)
- minimum (MIN), maximum (MAX), arithmetic mean (AM), geometric mean (GM), geometric standard deviation (GSD)



3. TRA WG preliminary analysis:

- Powder handling and metal abrasion scenario data limited
- Volatile substance data more extensive
- Focused on PROCs 4, 5, 7, 13, 14, and 19 due to ETEAM report of underestimation

4. Scenarios by PROC allocated to 3 teams of REACH worker exposure assessors

5. Judgments and comments of assessors recorded and consolidated

6. Comparisons to ETEAM decisions and TRA WG judgments analyzed

Findings

- ETEAM database contains 1673 sample data points
 - These derive from 337 scenarios total in database
 - 64 of the 337 scenarios have datasets with ≥ 6 data points
- Of the 337 scenarios, 282 relate to volatile substances, 30 powder handling, 25 were metal abrasion
- ETEAM database contains sufficient information to re-construct estimates
- ETEAM Methodology for TRA model validation found to be problematic:
 - ETEAM analysis compared single measurements to TRA estimates
 - 165 of the 337 scenarios (~50%) contained only a single measurement
 - TRA provides a P75 exposure prediction for a work group activity
 - ETEAM analysis should have compared the scenarios with datasets to TRA P75 estimates for relevant work group activities
 - ECETOC TRA WG aggregated the single measurements in same scenarios to determine P75 values. These were then compared to the TRA estimate.
 - For many scenarios, use and exposure descriptor choices were inaccurate
 - ETEAM assignments often did not match database contextual information
 - Particularly for PROCs, LEV assumptions, and duration
 - ECETOC TRA WG applied a Consensus-based approach for Use Descriptor decisions

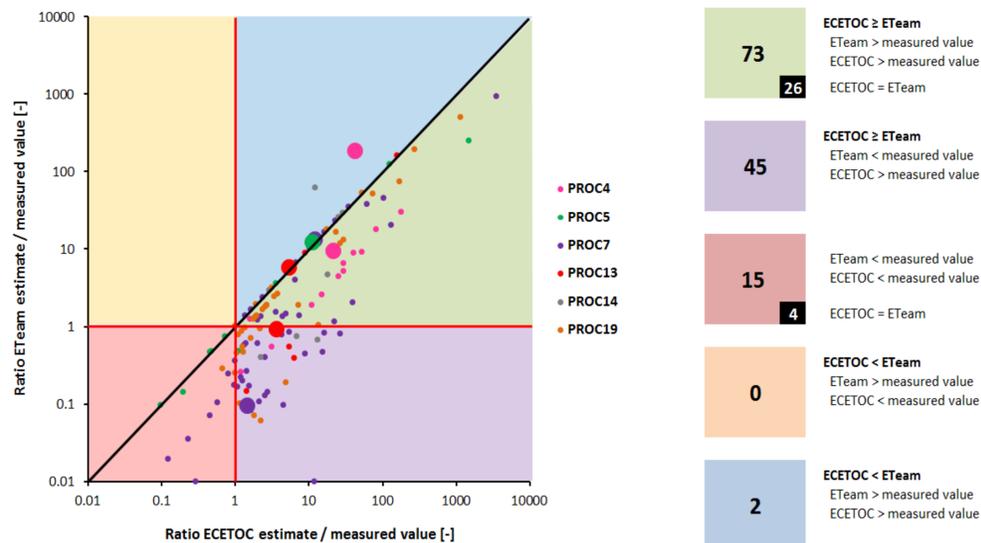


Category / Proc	Scenarios	Samples	TRA <p75	Team Assigned
Metal abrasion	25	82	15	
24 High (mechanical) energy work-up of substances bound in /on materials and/or articles	25	82	15	
Powder handling	30	248	16	
4 Chemical production where opportunity for exposure arises	1	1	0	
5 Mixing or blending in batch processes	6	63	3	
7 Industrial spraying	1	2	0	
9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	1	30	0	
14 Tableting, compression, extrusion, pelletisation, granulation	3	24	3	
08a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	12	74	7	
08b Transfer of substance or mixture (charging and discharging) at dedicated facilities	6	54	3	
Volatile Liquids	282	1343	124	
3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition	2	4	1	
4 Chemical production where opportunity for exposure arises	25	59	11	Team A
5 Mixing or blending in batch processes	13	56	9	Team B
7 Industrial spraying	61	195	37	Team C
9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	7	76	1	
10 Roller application or brushing	45	245	21	
11 Non industrial spraying	9	23	0	
13 Treatment of articles by dipping and pouring	35	130	16	Team A
14 Tableting, compression, extrusion, pelletisation, granulation	10	188	5	Team C
15 Use as laboratory reagent	1	1	1	
19 Manual activities involving hand contact	40	47	14	Team B
08a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	12	70	2	
08b Transfer of substance or mixture (charging and discharging) at dedicated facilities	22	249	6	
Grand Total	337	1673	155	

Re-Analysis Results

- 184 scenarios were re-analyzed by 3 teams of experienced REACH workplace exposure assessors
- 135 scenarios determined as inside domain of TRA (27% found outside TRA domain)
- 118 cases where TRA WG disagreed on ETEAM allocation of TRA input parameters
- 90 cases where comparisons to measured values by TRA WG and ETEAM agreed on the conclusion as either under or overestimate

Figure below compares ECETOC TRA WG estimates and ETEAM TRA estimates against measured values for 135 scenarios



- Large dots represent 6+ data points
- Dots on diagonal: 30 scenarios where ECETOC TRA WG and ETEAM estimates same
- Dots in red box: scenarios where TRA estimates not conservative (<measured values)
 - in the 15 scenarios where measured P75 > TRA P75; there were fewer than 6 data points
- Dots below diagonal represent scenarios where ECETOC TRA WG estimate was greater than ETEAM estimate (103 cases)
- 2 cases where TRA WG estimates were lower than original ETEAM predictions
- ETEAM errors tended to bias to lower estimate

Conclusions

- Many instances found where datasets have few samples and not sufficiently robust to draw critical conclusions.
 - A few datasets appear to heavily weigh on overall findings
 - No 'statistical test' applied to determine if the datasets can be considered representative
- The ETEAM database contains cases where REACH Use Descriptors were incorrectly applied.
 - This materially affects the nature of the associated ETEAM findings
 - Use map resources can aid ETEAM in assigning proper TRA parameters
- Based on the preliminary findings presented above suggest ETEAM results on TRA underestimation of some PROCs, is premature and less severe than reported by ETEAM
- Conclusions in ETEAM report need further examination

Next Steps

- ECETOC will continue to review new information that is relevant to ensuring the TRA remains accurate and fit-for-purpose for use under REACH
 - Discuss findings with ETEAM investigators
 - Explore options to gain additional measurement data
 - Develop 2017 plans for future TRA update

References

- BAuA, 2015, Evaluation of Tier 1 Exposure Assessment Models under REACH (eteam) Project (<http://www.baua.de/en/Publications/Expert-Papers/F2303-D26-D28.html>)
- European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), *Targeted Risk Assessment*. Technical Report number 93, European Centre for Ecotoxicology and Toxicology of Chemicals, Brussels, Belgium, 2004.
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- European Chemicals Agency (ECHA), 'Guidance on information requirements and chemical safety assessment Chapter R.12: Use Description' (v3, Dec 2015)
- European Chemicals Agency (ECHA), 'Guidance on information requirements and chemical safety assessment Chapter R.14: Occupational exposure estimation' (v3, Aug 2016)