ECETOC Response to Publication of E-Team Findings on the available REACH Tier 1 worker exposure models

A major study of the available REACH Tier 1 worker exposure models has recently been published (http://www.baua.de/en/Publications/Expert-Papers/F2303-D26-D28.html). The project, known as the ETEAM, was sponsored by the German Federal Institute for Worker Health and Safety (BAuA), with the intention of comparing measured exposure data against the modelled estimates from the commonly encountered REACH Tier 1 worker models (TRA, MEASE, Stoffenmanager and EMKG). ECETOC participated in the Advisory Board to the project. Although the project is the largest of its type, it has been hampered by its inability to identify large numbers of representative exposure measurements for the range of situations demanded by REACH: measured data have only been identified for 18 of the 29 PROCs described by REACH; only 11 PROCs have more than 20 data points associated with them; and of those, only 5 PROCs have associated data points of >150 samples. Because complex analyses require a lot of data (for example, covering the range of volatilities and use characteristics covered by the TRA), then this severely limits the extent to which any reliable conclusion can be drawn by the ETEAM and particularly so for those situations where fewer than 75-100 data points are available. A more extensive analysis of the ETEAM findings for the TRA can be found on the TRA webpage (www.ecetoc.org/tra).

Despite these limitations, it is ECETOC's opinion that the ETEAM report generally serves to confirm that the TRA is providing reliable estimates of worker exposures for use under REACH. Indeed, the E-Team analyses appear to indicate that the TRA is an inherently conservative model and hence eminently suitable for application at Tier 1 of REACH. However, the ETEAM analyses also identify that there are elements of the TRA that may benefit from review and possible revision (such as the TRA's ability to predict exposures to substances of very low volatility and the role that extract ventilation can have in reducing exposures). In these areas, ECETOC will be working with the other participants of the E-Team to better understand the characteristics of the database and the basis of the researcher's findings.

ECETOC will continue to review the performance of the TRA and to make revisions to the model where relevant. In this context, it will continue to work with and communicate the findings of the ETEAM project with the TRA community and to update the TRA and its supporting FAQs should reliable data becomes available that demonstrate serious shortcomings in the performance of the TRA.

Background

The ETEAM project, sponsored by the German Federal Institute for Worker Health and Safety (BAuA) aims to compare and contrast the different REACH Tier 1 worker exposure assessment models (the TRA, MEASE, Stoffenmanager and EMKG models) in terms of the nature of their predictions, scope of application, functionality and user-friendliness. The EU REACH Regulation covers all uses of all substances and applies the Use Descriptor (UD) as a mechanism for distinguishing the different exposures that are associated with different types of worker, consumer or environmental use. For workplace uses, REACH allocates different

Process categories (PROCs) to distinguish different use: a total of 29 PROCs have been described of which 26 are addressed by the TRA (ECETOC, 2009; ECHA, 2010)

To achieve the aims of the ETEAM, the researchers set out to create a database of measured data against which the predictions of the various models being evaluated could be compared. Clearly, in order that research objectives could be met, such a database must be able to cover the key uses of chemicals as described the available PROCs as well as a range of chemical types (solids, liquids and gases). In order to meet such an aim, data were submitted by 11 major institutions, including those from the US. Several thousand sets of measured data were offered by these institutions to the ETEAM researchers. In order to ensure that only data of a high quality were included in the database, the researchers developed quality criteria which the data were required to meet (and which relate both to the integrity of the measurements as well as supporting contextual data that enable such data to be interpreted). However, the consequence of applying the criteria to the data were that only a small fraction of the data submitted were deemed acceptable for inclusion in the database.

Table 3.8 below is taken from the ETEAM Substudy Report on the External Validation Exercise (BAuA, 2015) and summarises the distribution of the data that were accepted into the database versus their origin (task/activity/operation) in terms of how such data are likely to described under REACH (their PROCs).

Table 3.8: Individual measurement data by allocated PROC code (BAuA, 2015)

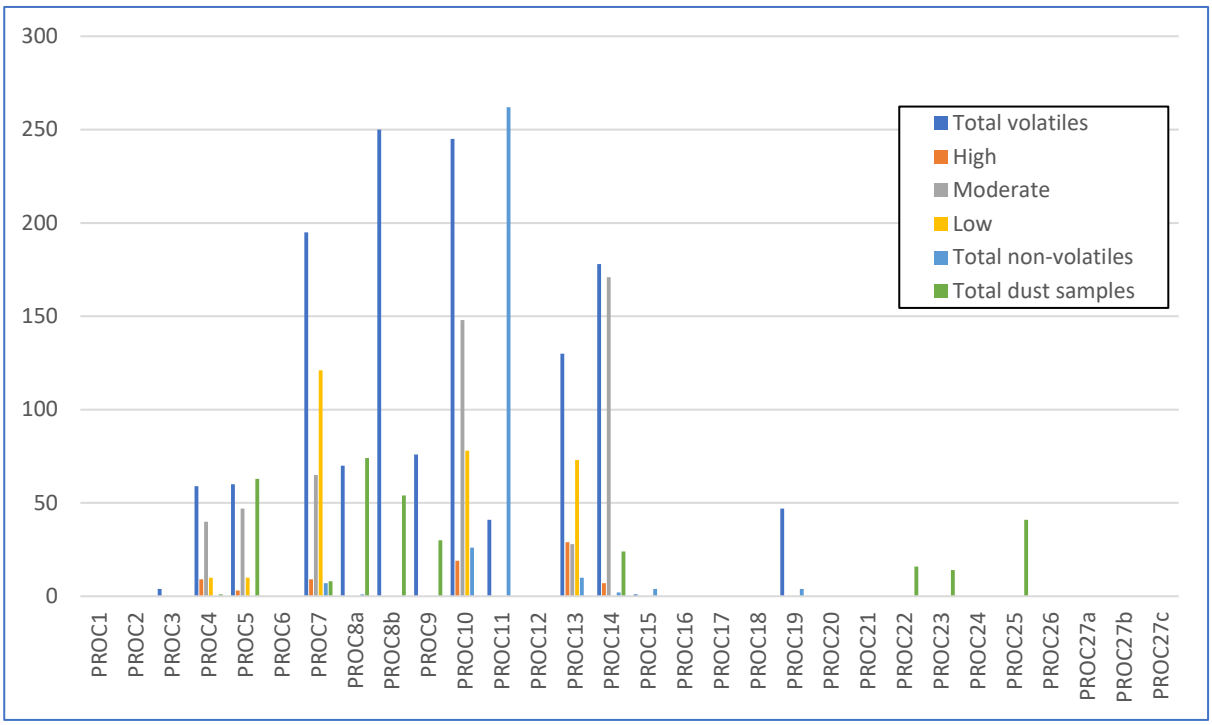
	PROC codes																		
Exposure category	3	4	5	7	8a	8b	9	10	11	13	14	15	19	21	22	23	24	25	Total
Non-volatile liquids[1)]	0	0	0	7	1	0	0	26	262	10	2	4	4	0	0	0	0	0	316
Volatile liquids[2)]	4	59	60	195	70	250	76	245	41	130	178	1	47	0	0	0	0	0	1356
Metal abrasion	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	87	0	87
Metal processing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	16	14	0	41	71
Powder handling	0	1	63	8	74	54	30	0	0	0	24	0	0	0	0	0	0	0	254
Wood processing	0	0	0	0	0	0	0	0	0	0	0	0	0	14	0	0	0	0	14
Total	4	60	123	210	145	304	106	271	303	140	204	5	51	14	16	14	87	41	2098

[1)] non-volatile liquids are defined as liquids with a vapour pressure (at room temperature) ≤10 Pa.
[2)] volatile liquids are defined as liquids with a vapour pressure (at room temperature) >10 Pa.

The expectations for any exposure model are that its predictions are reliable across a full range of substances types (i.e. different physico-chemical forms such as dusts, gases and vapours), as well as the routes and forms of exposure that the use of such substances can be expected to result in (for example, inhalation and dermal exposures and exposures to dusts, aerosols and vapours/gases). A further expectation is that the models might reasonably be expected to account for the commonly encountered OCs and RMMs, as well as whether the substance is encountered in the pure form or as part of a mixture. Table 3.8, however, clearly shows that not only are several of the key PROCs not represented in the database, but that the database is dominated by measurements of volatile liquids and that for many PROCs no or few data exist against which any comparison might be made. It is also to be noted that because of the shortcomings of how data have been recorded, the ETEAM has not been able to provide a breakdown of the different substance types within an exposure category for all substance types e.g. nature of dustiness.

Figure 1 below, which is based on the data contained in Appendix 4 of work package D15 (BAuA, 2015), further illustrates the lack of completeness of the database in terms of its ability to describe the distribution of exposure with industry (PROCs).

Figure 1: Representativeness of E-Team Database



When seen in the context of the need for data covering all uses and substance types, it can clearly be seen that the ETEAM database only addresses a small fraction of the need. Only 15 of the 25 PROCs have data associated with them and only 11 of these have more than 20 data points. Moreover, only 5 PROCs are associated with >150 samples with the vast majority of these being for volatile substances (but where no information is provided on the nature of these volatilities). However, for any one PROC, there are potentially well over 100 different estimates that can result from different combinations of volatility/dustiness, use type (industrial/ professional), presence/absence of exposure controls; handling pure/diluted substance; exposure duration; etc. Within this context, it can clearly be seen that the database is insufficient for drawing broad conclusions on the 29 PROCs described in ChR12 although it has the potential to provide a basis for a preliminary analysis for volatile substances for PROCs 7, 8b, 10, 11 and 14.

Despite these limitations, Table 3.48 of the D15 Report (reproduced below) provides an insight into the inherent conservatism of the TRA's base estimates. It shows that for (all) volatile substances, the TRA 'over predicts' in the c.9% of cases where 'no LEV' is encountered although the ETEAM analyses do not provide an analysis by volatility type so this value may not be uniform across volatility bands. This finding contrasts with an over-prediction rate of 67% where local exhaust ventilation (LEV) is encountered and has been applied to the base estimate. This contrast may be due to the actual effectiveness of LEV in the workplaces where the measurements were obtained being low and much less than the values assumed within the TRA and which accords with the findings of wider studies on the effectiveness of LEV (HSE, 2011; ECETOC, 2012). Another explanation could be that because of the nature of the contextual information supporting the data, the researchers' allocation of LEV as a control type was misplaced. Although Table 3.48 appears to indicate that the TRA may be insufficiently conservative with respect to exposures to dusts, the strength of the analysis is low (comparatively few samples available when compared to those required) and biased (the available

samples are clustered around just a few PROCs) but clearly warrants follow-up using a larger and more representative dataset.

Table 3.48: Percentage of (individual) measurements above the tool estimates (%M>T) by tool input parameter factors (BAuA, 2015)

	Factor															
	Dustiness			Vapour pressure			Domain		LEV				Concentration in mixture			
Exposure Category	High	Med	Low	High	Med	Low	Professional	Industrial	LEV	LEV/ out [1]	No LEV	No LEV/ out[1]	<1%	1-5%	6-25%	>25%
ECETOC TRAv2 (%M>T)/ (number of measurements)																
Volatile liquids	*	*	*	37 (n=320)	29 (n=886)	18 n=(131)	5 (n=374)	40 (n=963)	67 (n=542)	0 (n=15)	5 (n=772)	0 (n=8)	43 (n=7)	2 (n=296)	30 (n=364)	42 (n=670)
Metal abrasion	*	66 (n=41)	20 (n=41)	*	*	*	0 (n=4)	45 (n=78)	74 (n=35)	*	19 (n=47)	*	*	*	0 (n=7)	47 (n=75)
Powder handling	35 (n=51)	25 (n=194)	100 (n=1)	*	*	*	13 (n=92)	35 (n=162)	13 (n=107)	*	37 (n=147)	*	*	*	0 (n=8)	28 (n=246)
ECETOC TRAv3 (%M>T)/ (number of measurements)																
Volatile liquids	*	*	*	43 (n=320)	35 (n=886)	21 (n=131)	6 (n=374)	47 (n=963)	74 (n=542)	0 (n=15)	9 (n=772)	0 (n=8)	57 (n=7)	3 (n=296)	43 (n=364)	45 (n=670)
Metal abrasion	*	68 (n=41)	20 (n=41)	*	*	*	0 (n=4)	46 (n=78)	74 (n=35)	*	21 (n=47)	*	*	*	0 (n=7)	48 (n=75)
Powder handling	35 (n=51)	27 (n=194)	100 (n=1)	*	*	*	8 (n=92)	40 (n=162)	13 (n=107)	*	39 (n=147)	*	*	*	0 (n=8)	29 (n=246)

It is ECETOC's view, therefore, that while the ETEAM project set out to compare the performance of different REACH models, the nature of the ETEAM database is inadequate to draw categorical conclusions as it appears to lack data for some substance types and does not cover many of the major uses of key chemical types. Moreover as the ETEAM project only examined the models in isolation and not within the context of how the models are intended to be applied under REACH e.g. accounting for the impact that support structures such as Use Maps have on reducing the variability of predictions and improving consistency across users, then the ETEAM's analyses have not addressed key areas of interest for the users of such tools: for example, the relationship of the tools to the efficient (and consistent) development of Chemical Safety Assessments (CSAs) and Exposure Scenarios (ESs); the communication of ESs; and the ability to implement and scale the exposure control advice that they contain.

In summary, it is ECETOC's opinion that the ETEAM analyses are insufficiently reliable, powerful or detailed to enable developers of the various Tier 1 REACH models to identify where/how their models should be further improved e.g. any need to refine the estimates or assumptions underpinning how any OC and RMM may affect the predictions. The ETEAM has now made available its database and ECETOC will be examining it in more detail in order to determine the extent to ECETOC's concerns can be accounted for and meaningful conclusions drawn from it. In this respect ECETOC will continue to review the performance of the TRA and any new information that becomes available on it. It also remains ECETOC's intention to make further revisions to the TRA when substantive new knowledge becomes available on its performance under REACH.

References

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