



Further Stratification of the ETEAM Study Results

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Abstract

The ETEAM study was an evaluation of several low-tier models commonly used in the estimation of exposure to chemical agents at the workplace. The aim of these low-tier models is to offer simple, but conservative estimates. Amongst others, the study included a validation of the models against measurement data in order to estimate the level of conservatism. The results were that the level of conservatism of the models is variable. The study also included a simple stratification by model parameters to gain a better understanding of non-conservative estimates.

This analysis extends this stratification into more combination of parameters and finer partitions. The main results are that the ECETOC TRAv3 model tends to underestimate exposure when local exhaust ventilation is present and that the Stoffenmanager includes a specific set of parameters responsible for most of the non-conservative estimates of that model. This analysis also provides information about the size of the underestimation of some models.

Key words:

REACH, ETEAM, exposure assessment, exposure modelling, evaluation, validity, stratification

Weitere Auswertungen der Ergebnisse der ETEAM-Studie

Kurzreferat

Die ETEAM-Studie war eine Untersuchung mehrerer einfacher Modelle zur Expositionsbestimmung gegenüber Chemikalien am Arbeitsplatz. Das Ziel dieser Modelle ist es, sowohl einfache, aber konservative Schätzungen der Exposition zu liefern. Die Studie bestand unter anderem aus einer Validation der Vorhersagen anhand Messdaten, um das Maß der Konservativität der Modelle zu bestimmen. Die Ergebnisse dieser Validation waren, dass dieses Maß sehr variabel ist. Die Studie enthielt auch eine einfache Stratifizierung anhand der Modellparameter, um die nicht-konservativen Vorhersagen besser zu verstehen.

Diese Analyse erweitert diese Stratifizierung mit weiteren Kombinationen von Parametern und feineren Aufteilungen. Die Hauptergebnisse sind, dass das ECETOC TRAv3 Modell zur Unterschätzung der Exposition tendiert wenn lokale Absaugung vorhanden ist und dass der Stoffenmanager eine spezifische Kodierung enthält, welche die meisten nicht-konservativen Vorhersagen verursacht. Weiterhin enthält diese Analyse auch Informationen über die Größe der Unterschätzung für manche Modelle.

Schlagwörter:

REACH, ETEAM, Expositionsabschätzung, Expositionsmodellierung, Evaluation, Validität, Statistik, Stratifizierung

1 Introduction

Model calculations of exposure to hazardous agents at the workplace play an important role in the risk assessment of these agents. For instance the guidance on occupational exposure assessment R14 (ECHA, 2010) in context of the REACH Regulation explicitly states that safe use can be proven by using an appropriate modelling of the exposure.

The modelling of occupational exposure is an intricate process involving many different variables, e.g. ventilation conditions, physical properties of the agent, activity carried out by the worker. In order to limit the information needed to carry out a simple assessment, most models were designed with a tiered approach: Initial assessments start with a simplified model which uses coarse information to generate a rough estimate of exposure. If this estimate does not prove safe use, either by a higher exposure estimate than the reference value or by the uncertainty of the simplified estimate, a higher tier model should be used. These models use finer information and thus calculate more precise exposure estimates. For this general strategy to work and to limit the impact of the uncertainty the lower tier models should be conservative meaning that they should tend to overestimate the exposure values. If such a conservative estimate is already sufficient for demonstration of safe use the more realistic, lower estimates can also be considered safe.

It is thus very important that the initial (or Tier 1) models are conservative and also show a good correlation with actual measured exposure for a given situation. This can be proven by validating the models against real data, e.g. coding the model for a well-documented measured scenario and comparing the estimate with the results of the measurement. The ETEAM (Evaluation of Tier 1 Exposure Assessment Models) project was a systematic in-depth analysis of several Tier 1 exposure models recommended by the REACH guidance on occupational exposure assessment (ECHA, 2010). Investigated models include ECETOC TRA (workplace version) versions 2 and 3 (ECETOC, 2012), MEASE (EBRC, 2010), Stoffenmanager (Tielemans et al., 2007) as well as the EMKG-Expo-Tool (BAuA, 2008). Besides an external validation against measured data, it also includes a conceptual evaluation, an estimation of between-user reliability and an uncertainty analysis for all above models.

The main results of the external validation were that the level of conservatism of the models is highly variable. Different models however are not conservative in some situations: The ECETOC TRA (v2 and v3) model proved to be conservative for some of the process categories (PROCs) from the descriptor system used in REACH (ECHA, 2015) but not for others. The specific PROCs mostly varied between different classes of agents: For example, in case of powder handling PROC 8a and 14 were not conservative while for volatile liquids it were PROCs 5, 7, 14 and 19 amongst others. For volatile liquids it showed lesser levels of conservatism if local exhaust ventilation (LEV) was present and if the activity took place in an industrial setting. In case of powder handling the results were reversed: here situations without LEV were much more often conservative while those without LEV were not. Further categories in the external validation included fugacity (dustiness for powders, vapour pressure for volatile liquids) obtained mixed results. The same categories were used for all other evaluated models as well whether they use such a parameter in their coding

(e.g. the PROC is directly used in the ECETOC TRA and MEASE models) or not (Stoffenmanager and the EMKG-Expo-Tool). Across all models no firm conclusions to single non-conservative parameters could be obtained in the original report (Lamb, Miller, MacCalman, Rashid, & van Tongeren, 2015).

Due to the limited size of the database not all combinations of parameters are present equally. Thus, certain combinations of codings might dominate a simple stratification (e.g. all data with PROC 7 might also have LEV present). If one of those parameter choices is causing the model estimate to be too low (e.g. LEV being present) it might appear that the other one is also modelled too low in comparison to other choices (PROC 7 in comparison with other PROCs in this example). These effects can be disentangled by further stratifying the data into multiple categories (simultaneously into PROC and LEV). In that case, if a single parameter setting is causing non-conservative behaviour it would show up only in these stratifications where that setting is present and not in the others.

The external validation of ETEAM contained a simple stratification into PROC and an additional parameter. The results suggest for example, that for volatile liquids the presence of LEV is more likely to cause the model estimates to be not conservative than the actual PROC (Lamb et al., 2015).

However the original analysis only considered PROCs where at least 50 measurements were present and where at least 20 % of the model estimates were higher than the result of the measurements. While this gives a good initial understanding of PROCs with many non-conservative estimates it omits a significant part of the database which might give further insights and stronger confidence in the conclusions. Also, by focusing mostly on the PROC even for tools which do not use it as a parameter some effects can be hidden (e.g. the Stoffenmanager activity classes will be split onto multiple PROCs). Additionally a further stratification into additional parameters than PROC + X will further improve the understanding of the model behaviour in multiple scenarios.

This analysis provides such a further stratification. Besides considering all scenarios where at least 20 measurement values are present it also stratifies until too few measurements are present in one category. It also includes stratification by actual tool parameter for the Stoffenmanager and for the EMKG-Expo-Tool. Finally, it also considers distributions of the ratio of model estimate and measurement result for a more specific understanding of the non-conservative behaviour of some stratifications.

2 Methodology

Part of the external validation results of the ETEAM project was a database containing information about the measurements as well as all of the coding information for the evaluated models. This database was used to gather all the data used in this analysis. The information in the database was used as provided by the ETEAM consortium in order to use exactly the same information as them. The data were exported to CSV (comma separated values) and further analysed using python with its numpy (<http://numpy.scipy.org>), and matplotlib (<http://matplotlib.org/>) extensions.

The external validation study estimated the level of conservatism of a model in the following way: For each measurement value, M , a tool estimate, E , for the respective tool was created. These values were used to calculate the ratio:

$$R = M/E$$

If this ratio is larger than one, i.e. the model prediction is lower than the measurements value, this indicates underestimation of the model. For each grouping of data (e.g. “volatile liquids”) the percentage of measurements with $R > 1$ was calculated. Further ratios were calculated when the data were also grouped by PROCs, volatility/dustiness of the substance, type of workplace (professional or industrial), ventilation or amount of substance in the preparation.

In this analysis the data were further stratified. This was done by analysing the level of conservatism of the data when more than one of these selections was performed simultaneously. One example for such a selection is all data for scenarios coded with PROC 14 and the presence of LEV.

In ETEAM, a model was deemed highly conservative for a selection, if equal or less than 10 % of the measurements had $R > 1$. If more than 10 %, but less than 25 % of the measurements had $R > 1$, the level of conservatism was “medium”, otherwise it was defined as “low”. For comparison reasons this analysis uses the same definition.

In a first step, the data were stratified into combinations of PROC and presence of LEV. For models, where the presence of LEV is not a direct parameter (e.g. ECETOC TRAv3 as opposed to the TRAv2 variant), the grouping was done by the parameter which describes ventilation situation the best (e.g. “Use of Ventilation” for ECETOC TRAv3). A manually assignment of these parameters to classes whether LEV was present or not was subsequently performed. The assignment for ECETOC TRAv3 is shown in Table 2.1.

Table 2.1 ECETOC TRAv3 „Use of ventilation" parameter options and assignments to LEV classes.

Parameter	Assignment
Outdoors	Not grouped
Indoors with basic ventilation	No LEV present
Indoors with good general ventilation	No LEV present
Indoors with enhanced general ventilation	No LEV present
Indoors with LEV and good general ventilation	LEV present
Indoors with LEV and enhanced general ventilation	LEV present
Indoors with basic ventilation LEV	LEV present

For combinations of PROC and LEV where at least 20 measurements were present of which at least 10 % of the predictions were not conservative the data were subsequently grouped by volatility (liquids) or dustiness (powders) and setting (professional vs. industrial).

If fewer measurements were present a subsequent division into further subclasses would unlikely yield significant results. Also, if fewer than 10 % of measurements in a category were not conservative it was unlikely to find a specific set of parameters where the model performs worse than on others.

Another step of analysis is the generation of distribution figures of the ratios. While two sets of data may give same results when only calculating the fraction where the tool estimates are not conservative, they may still differ significantly. A distribution, where the non-conservative fraction clusters are just slightly above the threshold is much less concerning than one where it is much larger than one. Also it may provide the basis for safety factor in situations where the model provides non-conservative estimates. For all aforementioned categories histograms of the ratios as well as the respective cumulative density functions were generated. An example can be found in Figure 2.1.

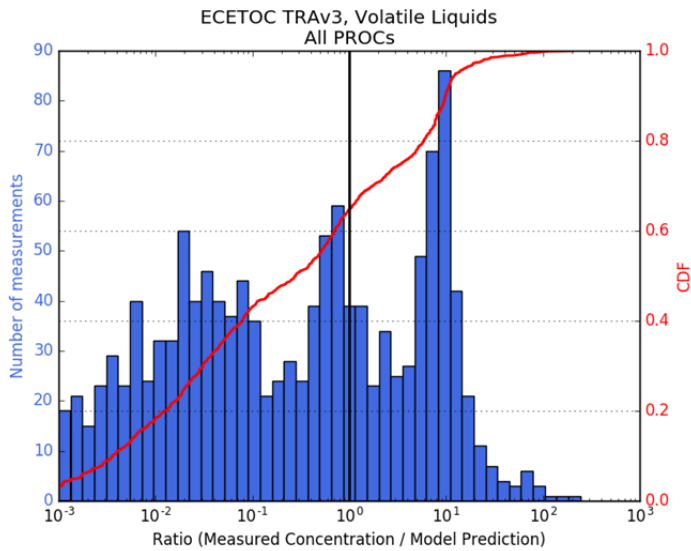


Figure 2.1 Distribution of ratios of model prediction and measurement results (blue) and cumulative density function (CDF) of ratios (red) for the ECETOC TRAv3 model. If the value is larger than one, the estimate is not conservative.

Whilst the ECETOC and MEASE models use the PROCs of the use descriptor system, this is not the case for the Stoffenmanager and EMKG-Expo-Tool models. If some parameter – or combination of parameters – are causing the predictions to be non-conservative splitting the measurements by PROCs might soften or even hide the effect as the affected measurements will be spread out over the various PROCs. To gain insight into such effects these models have also been stratified by their own set of parameters (e.g. “task description” of Stoffenmanager).

3 Results

3.1 General remarks about the data

For this analysis only individual (non-aggregated) measurements data was used, in accordance with Tables 3.32 and 3.48 of (Lamb et al., 2015). This allows an easy comparison with the results presented in the original study. Also, the aggregated data showed much worse correlation coefficients across all models (cp. Table 4.3 in (Lamb et al., 2015)). However, it should be noted that the combined data show better level of conservatism for most models in regards to the treatment of powders.

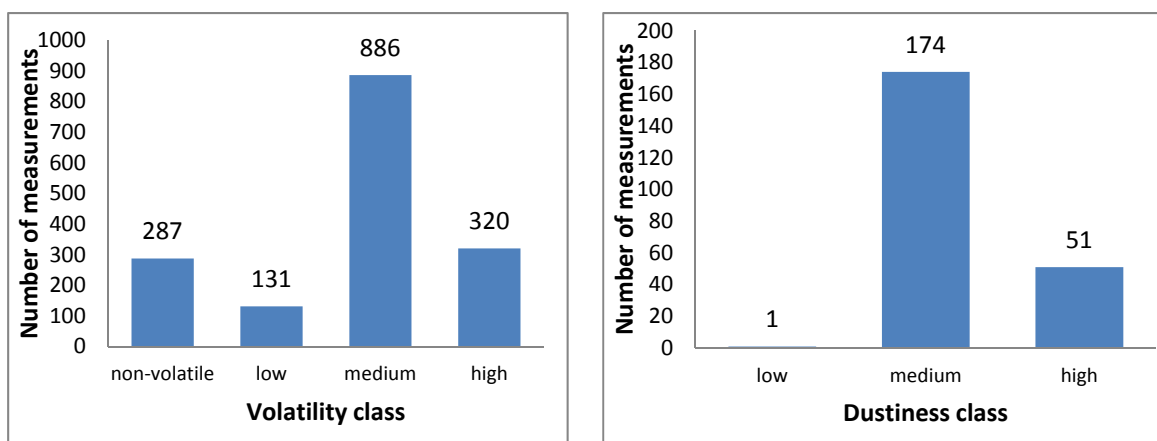


Figure 3.1 Number of measurement data, split into volatility classes for liquids (left) and dustiness classes (right).

In the ETEAM study, liquids were split into volatile liquids and non-volatile liquids. The classification depends on the vapour pressure of the substance; if it is larger than 10 Pa it is considered volatile and non-volatile otherwise. These two categories were treated differently in the analysis as some models are not applicable for substances with vapour pressure less than 10 Pa. Furthermore, the volatile liquids were split into three more categories (low, medium and high volatility). This was again dependent on the vapour pressure: If it is less than 500 Pa it is considered low, 500 – 10000 Pa is considered medium and > 10000 Pa is considered high volatility. Figure 3.1 (left) shows the number of measurements for each category. Most substances had a medium vapour pressure, with about a quarter of the volatile liquids having a high vapour pressure. The results might therefore be more accurate for these substances.

Similar to liquids also the solid substances were split into dustiness categories, also called low, medium and high. All models use (very similar) qualitative approaches depending on the physical appearance of the substance for categorization. Figure 3.1 (right) shows the number of measurements stratified in ECETOC TRAv3 dustiness classes. Basically all substances have a medium or high dustiness. Thus the behaviour of the models might be different for substances with low dustiness.

3.2 ECETOC TRAv3

The results for ECETOC TRAv3 stratified by PROC code and use of ventilation are shown in Table 3.1.

For some of the PROCs (7, 8a and 13) the level of conservatism is high for scenarios without LEV but low for those with. Similarly, for PROCs 10, 14 and 19 it is medium for scenarios with LEV respectively high for scenarios without. Only for PROC 5 there is no difference depending on the presence of LEV. This suggests that in all of these cases (except PROC 5) the reason for non-conservatism is more likely the ventilation modelling of ECETOC TRA and not the task description modelling for scenarios involving volatile liquids.

In Figure 3.2 the ratio distributions for PROC 10, depending on the presence of LEV is shown. Both Figures show a grouping of data slightly below a ratio of one which is expected for a realistic and conservative model. However most of the other data are either grouped much below one (in case of no LEV present) or much above it (in case of LEV present).

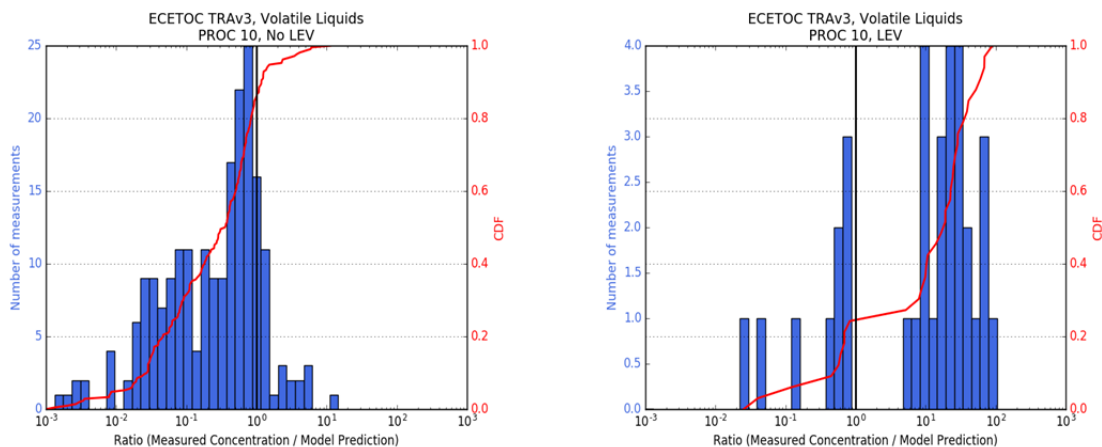


Figure 3.2 Ratio distributions for volatile liquids data, coded with ECETOC TRAv3 and PROC 10. Left: No LEV present, Right: LEV present.

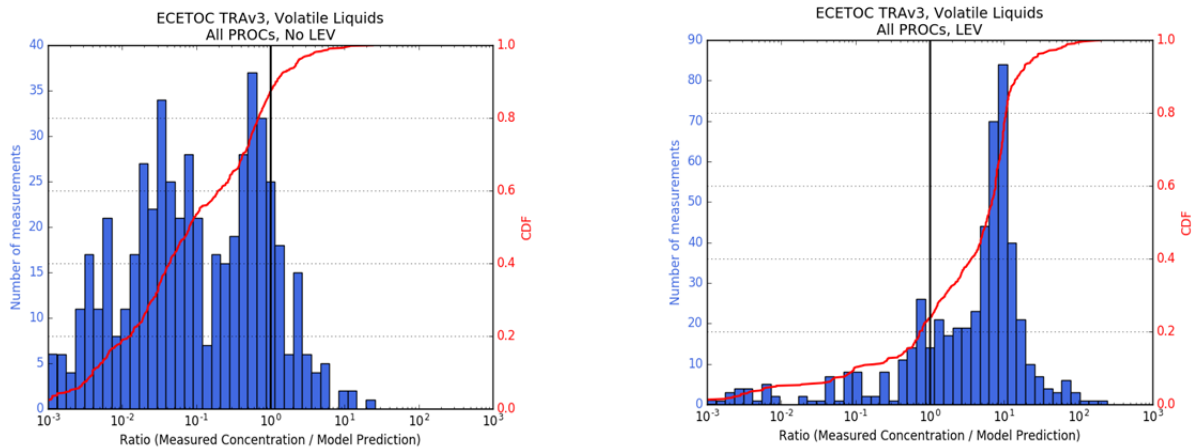


Figure 3.3 Ratio distributions for ECETOC TRAv3 for all PROCs. Left: No LEV present, Right: LEV present

A similar picture emerges when splitting all PROC data depending on whether LEV is present or not. The distributions are shown in Figure 3.3. The ratios of data without LEV present are either slightly or much below one. In case of LEV being present, there is a small grouping of data with ratios less than unity, but a much larger grouping with ratios much above unity.

In case of powder handling there is no clear structure with regards to the presence of LEV. In some stratifications the scenarios with LEV present are less conservative (PROC 5 or 8b) and in some others more (PROC 8a and 14). This indicates that some other effect is causing the predictions to be not conservative enough. It is noteworthy that for the powder handling scenarios basically all non-conservative estimates are clustered within two PROCs, 8a and 14, which suggests that their treatment within the model may be the cause for the non-conservative behaviour.

Another way of visualizing the distributions of conservative/non-conservative estimates is the usage of a tree structure. All data is presented in the top node and split into different categories downwards in the tree. A tree for ECETOC TRAv3 is shown in Figure 3.5, Figure 3.6 and Figure 3.7. In the first row, all volatile liquids data are shown: out of 1337 data 35 % have a model prediction lower than the measurement result. In the second row the data are split into some of the PROCs. If more than 10 measurements were present in that row, the data were split into the ventilation categories (neglecting outdoor scenarios) and finally into whether the scenario was industrial or professional. Each element describes the total number of measurements within it (in brackets) and the percentage of non-conservative estimates. A legend for reading the contents of each field is also shown in Figure 3.4.

Besides the already discussed stratification into PROC and LEV they also show a further stratification by setting. Stratification by fugacity class was also performed but has been omitted as the results it did not show a big dependence on it (see Annex 1 for details). This further stratification shows that basically all scenarios where LEV was present also took place in industrial settings; often the overlap is as big as 100 %. In the only exception (volatile liquids, PROC 13) both types of setting (industrial and professional) are not modelled conservative. The professional settings how-

ever show a smaller fraction of non-conservative estimates. In cases where no LEV was present (e.g. volatile liquids, PROC 10), the professional settings were also modelled more conservative than the industrial ones.

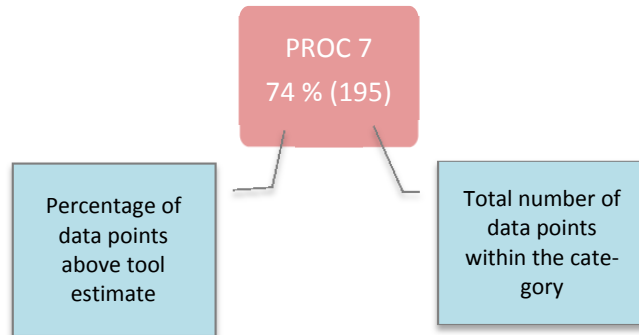


Figure 3.4 Legend for reading tree elements in visualisation of data in a tree structure.

Table 3.2 Example for further stratification by volatility and domain for ECETOC TRAv3 for volatile liquids situations and PROC 7. The data correspond to all data in the PROC 7 column Table 3.1. The first value denotes the amount of measurement results which exceeds the model predictions. The value in brackets is the total number of measurements in that category.

ECETOC TRAv3 - volatile liquids - PROC 7		Volatility class		
		High	Medium	Low
Domain	Industrial	88 % (9)	71 % (49)	86 % (114)
	Professional	- (-)	- (-)	- (-)

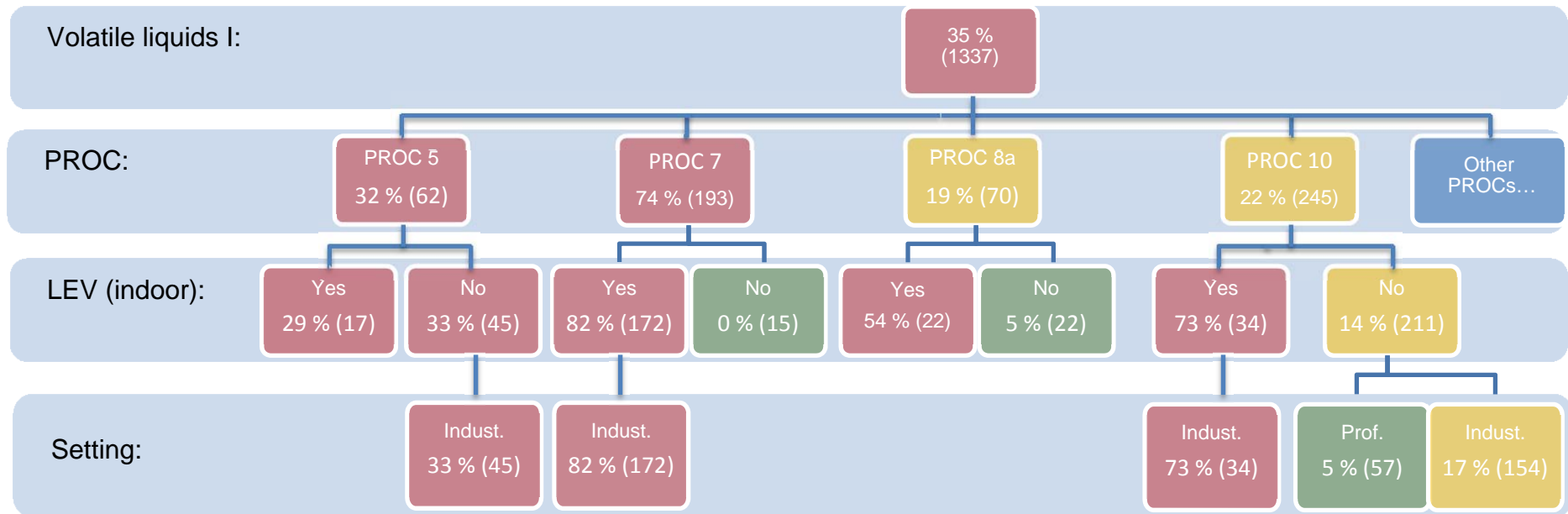


Figure 3.5 Tree describing the grouping of the various exposure measurements and codings by ECETOC TRAv3 for volatile liquid situations (part I). Each element describes the total number of measurements within it (in brackets) and the percentage of non-conservative estimates.

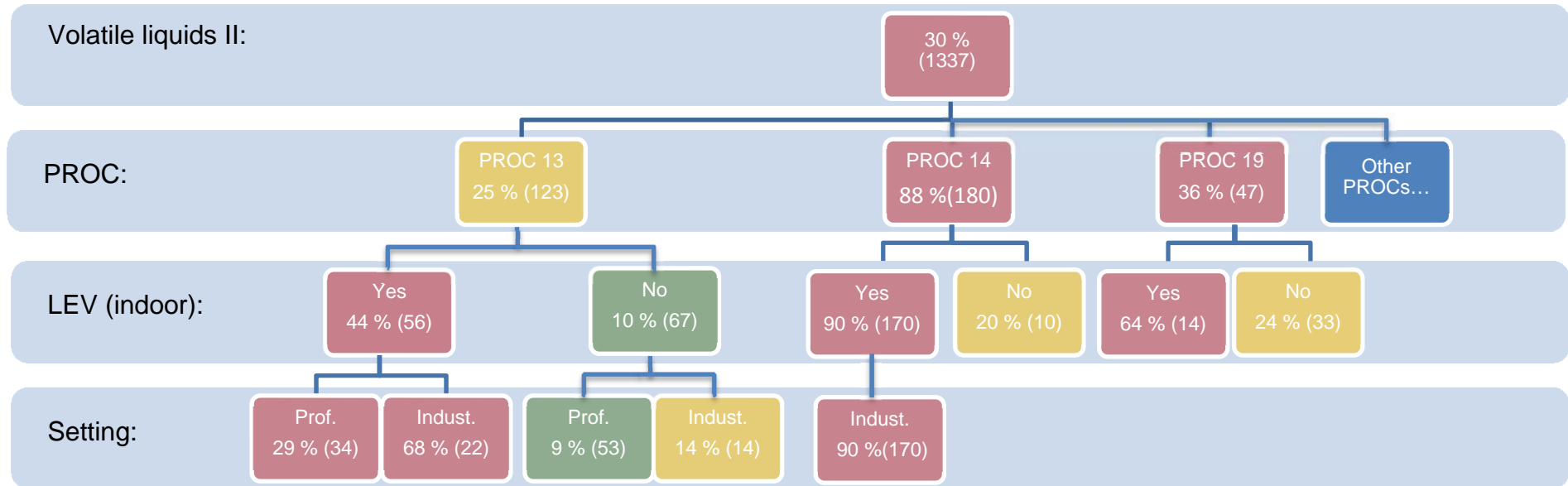


Figure 3.6 Tree describing the grouping of the various exposure measurements and codings by ECETOC TRAv3 for volatile liquid situations (part II). Each element describes the total number of measurements within it (in brackets) and the percentage of non-conservative estimates.

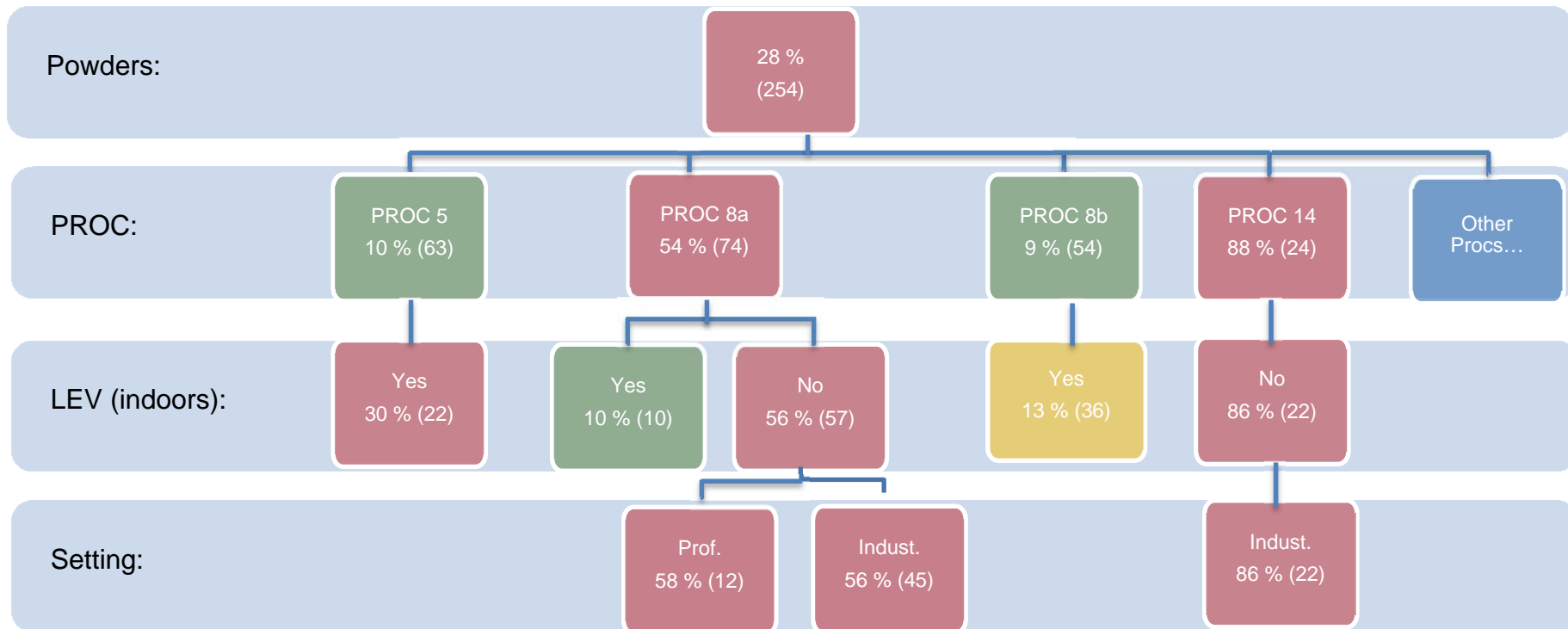


Figure 3.7 Tree describing the grouping of the various exposure measurements and codings by ECETOC TRAv3 for powder handling situations. Each element describes the total number of measurements within it (in brackets) and the percentage of non-conservative estimates.

3.3 Stoffenmanager

The results when splitting the volatile liquids data of Stoffenmanager by its parameters (“Task Description” and “Use of Ventilation”) are shown Table 3.3 and in Figure 3.9 (tree form). It is noticeable that almost all of the non-conservative estimates are attributed to a single combination of parameters, namely “Handling of liquids where only small amounts may be released” and “Containment of source with LEV”.

The ratio distributions for these data are also shown Figure 3.8. The split between non-conservative and conservative estimates depending on the “Use of Ventilation” parameter is clearly visible. However, the actual ratios of the non-conservative estimates are close to one, which gives only a small overestimation. A small change in the model may thus yield conservative estimates for that set of parameters as well.

Additionally Table 3.3 it can be concluded, that the task description “Handling of liquids where only small amounts may be released” (ID 3) performs very well when combined with other parameter choices of “Use of Ventilation”. This might suggest that the latter parameter plays a stronger role in the non-conservative behaviour. Only a limited amount of data is available for “Containment of source with LEV” and other task descriptions, but these also give much more conservative results which makes a definite conclusion difficult from these data.

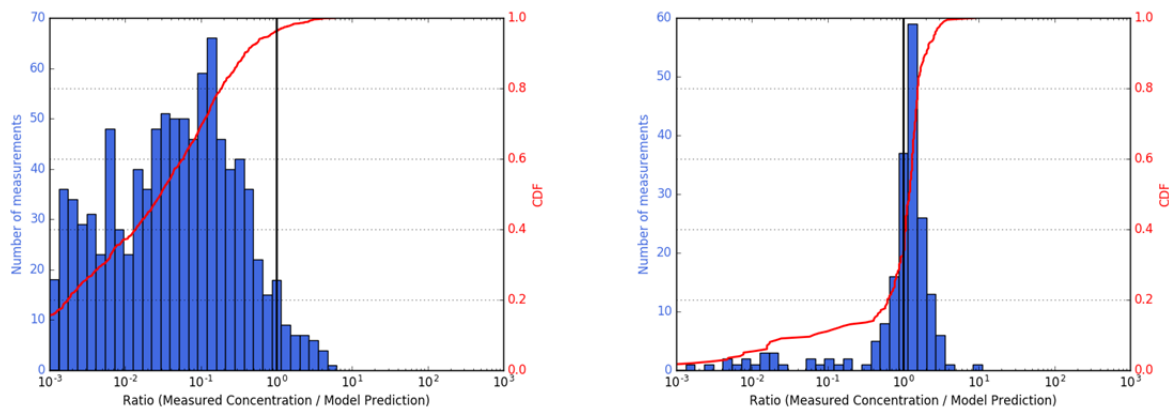


Figure 3.8 Stoffenmanger 90th percentile ratios for volatile liquids and "Handling of liquids where only small amounts may be released". Left: Only measurements where "Containment of source with LEV" has been coded, Right: All other measurements.

3.4 EMKG-Expo-Tool and MEASE

The EMKG-Expo-Tool shows less-conservative estimates for powders than for volatile liquids, which are handled quite well. These data were also further investigated and the results are shown as a tree in Figure 3.12. The non-conservative scenarios can be mainly attributed to four PROCs: 5, 8a, 8b and 14 which also contain the largest number of measurements. PROC 9 is another PROC containing a significant number of measurements, but all estimates are conservative. When further splitting the data into EMKG-Expo-Tools "Control Strategy" parameter, no single parameter is performing better or worse, with the exception of "containment" in combination with PROC 14 and "no LEV" in PROC 8b. This suggests that neither certain PROCs nor control strategies are handled better or worse than other ones. The same picture emerges when stratifying the data completely into the tools own parameter. The tree structure for this is shown in Figure 3.11. Neither control strategy nor amount of substance used show any clear structure with regard to the level of conservatism.

In the case of the MEASE model, there were too few data to gain further insights than the ETEAM study already did. In general, it seems that scenarios with the presence of LEV are handled worse (are less conservative) by the model than scenarios without, similar to the ECETOC TRA results. As these models have a similar model structure such behaviour is not surprising and the ECETOC TRA results may also apply here.

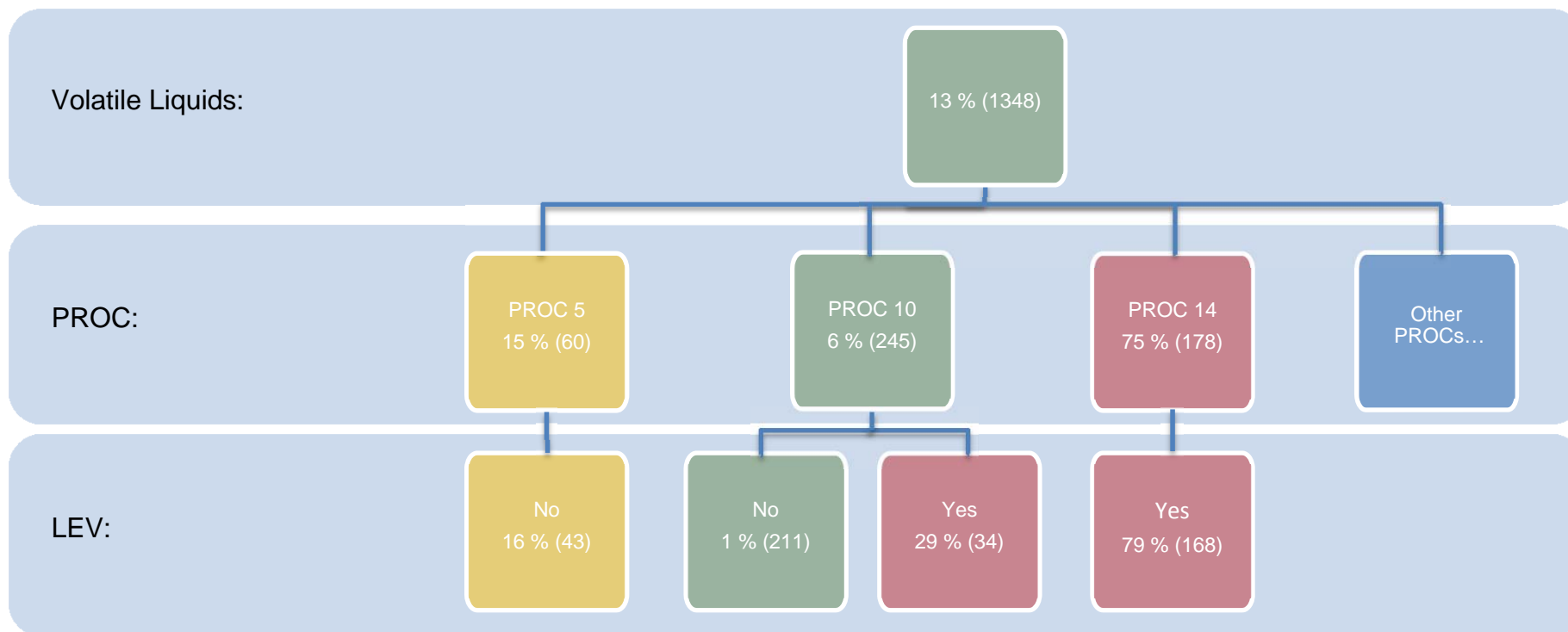


Figure 3.9 Tree describing the grouping of the various exposure measurements and codings by Stoffenmanager by PROC and presence of LEV. Each element describes the total number of measurements within it (in brackets) and the percentage of non-conservative estimates.



Figure 3.10 Tree describing the grouping of the various exposure measurements and codings by Stoffenmanager by the tools own parameters. Each element describes the total number of measurements within it (in brackets) and the percentage of non-conservative estimates. Task description 3 refers to “Handling of liquids where only small amounts may be released” and number 5 to “Handling of liquids using low pressure, low speed, or on medium sized surfaces”.

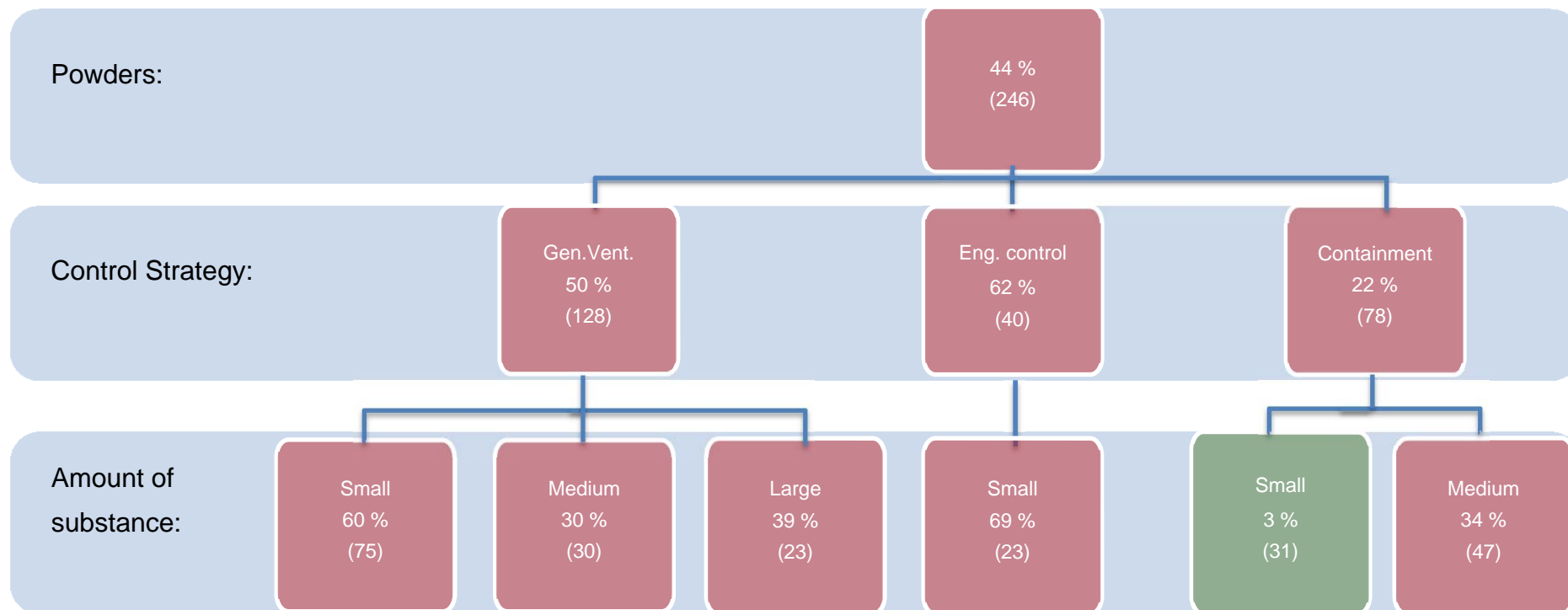


Figure 3.11 Tree describing the grouping of the various exposure measurements and codings by the EMKG-Expo-Tool using tool parameters as stratifications. Each element describes the total number of measurements within it (in brackets) and the percentage of non-conservative estimates.

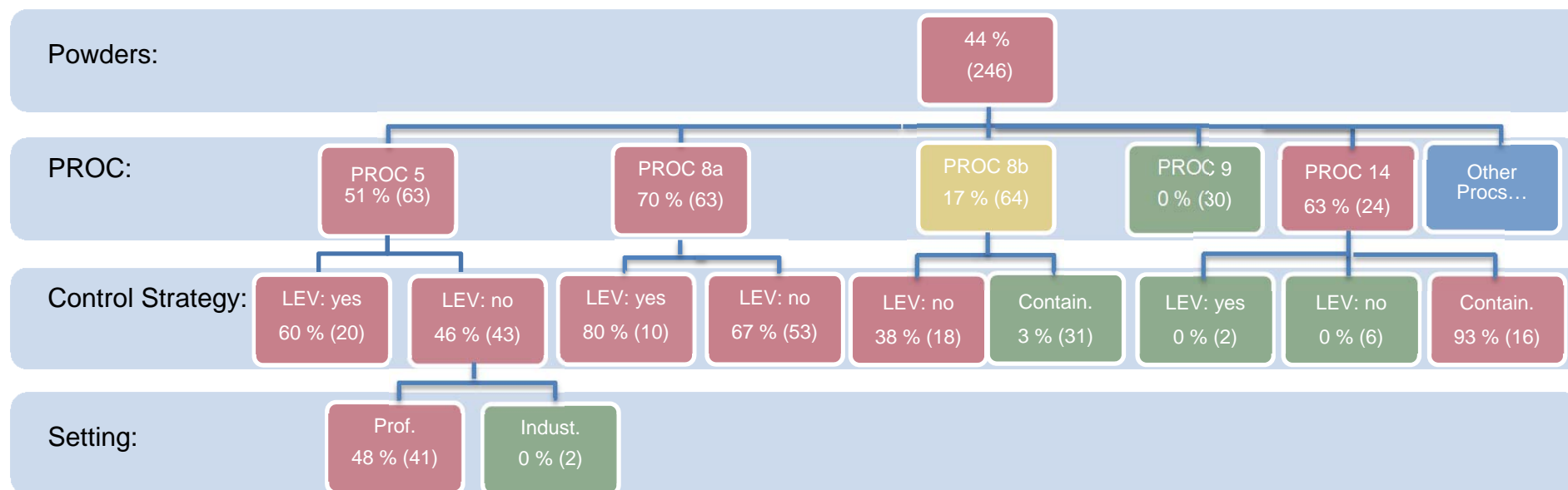


Figure 3.12 Tree describing the grouping of the various exposure measurements and codings by the EMKG-Expo-Tool. Each element describes the total number of measurements within it (in brackets) and the percentage of non-conservative estimates.

4 Summary

The results of the external validation performed as part of the ETEAM project were stratified to gain further insights into the performance of the analysed models under different scenarios. In general, the results of the external validation were underlined, but some behaviour could be stronger attributed to some choice of parameters: In the case of ECETOC TRAv3 for example, the presence of LEV seems to be playing a stronger role than the choice of process category. Similar effects may play a role for the MEASE model. For these models, a refinement in handling of local exhaust ventilation (e.g. choice of lower efficiencies for the LEV) might improve the level of conservatism. The values presented in this document might help in these efforts.

The EMKG-Expo-Tool shows worse levels of conservatism for powders. No single parameter performs better or worse than the others. Thus, it might need some general improvement when assigning exposure bands. Stoffenmanager is the only model, where most non-conservative scenarios can be clearly attributed to a single choice of codings. Also, that overestimation of exposure is rather low, a different handling of that specific coding would very likely result in a model with very good levels of conservatism overall.

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Annex 2, Table 3 Percentage of measurements above tool estimation and number of measurements stratified by PROC and “Use of Ventilation” (ECETOC TRAv3, metal abrasion)

ECETOC TRAv3 – metal abrasion		PROC 24
Use of Ventilation	Outdoors	- (-)
	Indoors	50 % (4)
	Indoors with good general ventilation	8 % (35)
	Indoors with enhanced general ventilation	62 % (8)
	Indoors with LEV and good general ventilation	73 % (23)
	Indoors with LEV and enhanced general ventilation	87 % (8)
	Indoors with LEV	50 % (4)

Annex 2, Table 7 Percentage of measurements above tool estimation and number of measurements stratified by PROC and “Use of Ventilation” (Stoffenmanager metal abrasion)

	Stoffenmanager - metal abrasion	PROC 21
Use of Ventilation	Containment of source with LEV	0 % (3)
	LEV	20 % (5)
	Use of product that reduces emissions	- (-)
	No control measures at source	0 % (6)
	Containment of source	- (-)

Annex 2, Table 10 Percentage of measurements above tool estimation and number of measurements stratified by PROC and “Use of Ventilation” (MEASE, metal processing and metal abrasion)

MEASE - metal processing and metal abrasion		PROC			
		22	23	24	25
Use of Ventilation	No RMMs	- (-)	- (-)	0 % (4)	- (-)
	Enclosure	0 % (7)	0 % (2)	- (-)	- (-)
	LEV (generic)	100 % (3)	- (-)	62 % (8)	100 % (4)
	--> Exterior LEV	0 % (2)	14 % (7)	41 % (24)	50 % (2)
	--> Integrated LEV	50 % (4)	- (-)	100 % (7)	- (-)
	General ventilation	- (-)	0 % (4)	14 % (41)	31 % (35)
	Suppression techniques (generic)	- (-)	- (-)	- (-)	- (-)
	--> Wet suppression	- (-)	- (-)	- (-)	- (-)
	--> Capture sprays	- (-)	- (-)	- (-)	- (-)
	Separation of workers	- (-)	0 % (1)	- (-)	- (-)

