Evaluation of Tier 1 Exposure Assessment Models under REACH (eteam) Project

Substudy Report on Between-User Reliability Exercise (BURE) and Workshop

J. Lamb, K. S. Galea, B. G. Miller, S. Spankie, M. van Tongeren, G. Hazelwood

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Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Research
Project F 2303

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Dortmund/Berlin/Dresden 2015

This publication is a substudy report resulting from the work package D22 of the project “Evaluation of the Tier 1 Exposure Assessment Models used under REACH (eteam) Project” on behalf of the Federal Institute for Occupational Safety and Health.
The responsibility for the contents of this publication lies with the authors.

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Cover figure: ritajaco/JanPietruszka/MoreISO/Mikefahl/mediaphotos/
ImageegamI/FotoSpeedy
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Cover design: Susanne Graul
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Publisher: Federal Institute for Occupational Safety and Health
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www.baua.de/dok/6914126

ISBN 978-3-88261-156-4

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Abstract

When applying the Tier 1 assessment tools to an exposure situation, users must select options from several possible input parameters. Previous studies have suggested that results from exposure assessments using expert judgement can vary considerably between assessors. In addition, similar results were observed for use of exposure tools, where different users may obtain different results based on similar information. This study aimed to investigate the between-user reliability for the Tier 1 tools.
Two assessment methods were used to evaluate consistency between users in making these input choices. A remote-completion exercise and focus group were used to identify and evaluate tool parameters and other factors potentially associated with between-user variability, for example users' employment sector, experience level and English language ability.

In the remote-completion exercise, participants (N=146) generated dermal and inhalation exposure assessments (N=4066) from a defined set of exposure situation descriptions/Tier 1 tool combinations over a fixed time period. Qualitative information on decision-making processes associated with tool use was collected during the focus group. The interactions between users, tools and situations were analysed and described. Within user variation was minor compared with between-user variation. Significant variation was observed between users when selecting task/ activity, dustiness and risk management measures within the tools.

The results showed that considerable variability was observed in results obtained by different users of the tools. This variability did not seem to be determined by the characteristics of the user. The results are based on representative participants, many of whom use the tools routinely. Therefore, these results suggest that more needs to be done to ensure consistency between tool users.

Key words:
Exposure assessment; reliability; inter-assessor variability; exposure modelling; occupational exposure; REACH; risk assessment; exposure assessment tools

Teilbericht über die Zuverlässigkeit und Variabilität zwischen Anwendern mittels Übungsaufgaben und Workshop

Kurzreferat

Bei der Anwendung von Tier 1 Tools auf eine Expositionssituation, müssen die Anwender aus mehreren möglichen Eingabeparametern eine bestimmte Option auswählen. Vorhergehende Studien legen nahe, dass die Ergebnisse aus Expositionsberechnungen auf der Grundlage von Expertenentscheidungen („expert judgement“) je nach Gutachter deutlich variieren können. Für die Anwendung von Expositionstools, bei denen verschiedene Anwender verschiedene Ergebnisse auf Basis ähnlicher Information erhalten können, wurde ähnliche Variabilität beobachtet. Diese Studie zielt darauf ab, die Zuverlässigkeit der Ergebnisse von Tier 1 Tools bei Anwenderwechsel („between-user reliability“) zu untersuchen. Zwei Methoden wurden verwendet um die Konsistenz bei Anwenderwechsel in Bezug auf die Auswahl von Eingabeparametern zu evaluieren. Eine Übung via E-Mail Kontakt und ein Workshop mit einer Fokusgruppe wurden durchgeführt um Toolparameter und andere Faktoren, welche potenziell mit der Variabilität zwischen Anwendern verknüpft sein können, zu identifizieren und zu evaluieren, z.B. den Arbeitsbereich des Anwenders, Erfahrungshintergrund und Englischkenntnisse.
Im Verlauf der E-Mail Übung generierten die Teilnehmer (N=146) innerhalb eines festgelegten Zeitintervalls dermale und inhalative Expositionsabschätzungen (N=4066) aus einem definierten Set von Expositionssituationsbeschreibungen/Tier 1 Tool Kombinationen. Während des Workshops mit der Fokusgrupp wurden qualitative Informationen über den Prozess der Entscheidungsfindung in Verbindung mit der Toolverwendung gesammelt. Die Interaktionen zwischen Anwendern, Tools und Situationen wurden analysiert und beschrieben. Die Variation innerhalb der Ergebnisse eines Anwenders war minimal im Vergleich zur Variation zwischen verschiedenen Anwendern. Signifikante Variation wurde zwischen Anwendern bei der Auswahl der Aufgabe/des Prozesses, Staubigkeit und Risikominimierungsmaßnahmen innerhalb der Tools beobachtet.

Die Ergebnisse zeigten, dass beachtliche Variabilität in den Expositionsabschätzungen bei verschiedenen Toolanwendern beobachtet wurde. Diese Variabilität schien nicht von den Charakteristika der Anwender bestimmt zu werden. Die Ergebnisse basieren auf einer repräsentativen Auswahl von Teilnehmern, von denen viele die Tools regelmäßig anwenden. Die Resultate legen daher nahe, dass mehr getan werden muss, um die Konsistenz zwischen Toolanwendern sicher zu stellen.

Schlagwörter:
Expositionsabschätzung; Zuverlässigkeit; Variabilität zwischen Anwendern; Expositionsmodellierung; Exposition am Arbeitsplatz; REACH; Risikoabschätzung; Werkzeuge zur Expositionsabschätzung

1 Introduction

When applying Tier 1 exposure assessment tools, users are required to select options from a number of possible input parameters. Hence, results obtained with the tools could be affected by factors such as the professional experience and judgment of the tool user and access to an appropriate level of information. Studies of inter-rater reliability when grading subjects' occupational histories in epidemiological studies, and within other disciplines such as clinical medicine, have shown substantial variation between assessors (Friesen et al (2011); Kunac et al (2006)). High levels of variation between users of higher tier exposure assessment tools have also been identified (Schinkel et al, 2013). Some variation in Tier 1 tool estimates between different users when assessing exposure for the same situation could therefore be expected.

Work Package I.6 of the eteam Project aimed to assess the between-user reliability of the exposure assessment tools. In other words, how consistent tool users were in making choices in comparison with other users.

Participants in the Between-User Reliability Exercise (BURE) were asked to carry out inhalation and dermal exposure assessments for a given set of workplace situations using the Tier 1 tools. The variation between the exposure estimates generated by the different users from these situation-tool combinations was then determined and potential reasons for these differences identified. As part of the BURE, a workshop was also held to gather additional information on sources of variation in tool use and so complement the main exercise.

This report details the methods used in the BURE, the results obtained and their interpretation.

2 Methodology

2.1 Overview

The purpose of the BURE was to examine how consistent tool users are in making choices in comparison with other users when carrying out exposure assessments using the following tools:

- ECETOC TRA v2
- ECETOC TRA v3
- EMKG-EXPO TOOL
- MEASE v1.02.01
- RISKOFDERM
- STOFFENMANAGER® v4.5 (referred to as STOFFENMANAGER in this report)

Two complementary approaches were used in the study to evaluate tool user consistency.

In the first instance, a ‘remote-completion’ exercise was run whereby participants were asked to assess a variety of exposure situations using the Tier 1 tools within a defined timescale.

The participants were provided electronically with an introductory pack containing simple instructions for completing the exercise. A background questionnaire was also administered to collect key information on their previous experience of exposure assessment and use of the tools.

Participants were then forwarded a set number of exposure situation/tool combinations and supporting worksheets to complete. The distribution of the exposure situation/tool combinations was carefully structured to ensure both randomization and sufficient overlap of participants with each tool/ situation combination to allow analysis of variability of output between tool users. The distribution order was also varied to reduce the influence of learning effects for particular tools, i.e. participants becoming more familiar with a particular tool if they always used it first for the assessments.

On completion of the exercise, participants were asked to provide feedback on their experiences of using the tools for the given exposure situations via a final short questionnaire.

The second evaluation method used a workshop format to collect more detailed feedback from a selected group of participants on specific issues of importance identified from the main testing exercise. This workshop was held in Edinburgh over the 6th and 7th of February 2013 and has been described previously (Appendix 1). This report will focus on the remote-completion exercise, with information gathered via the workshop used to assist with interpretation of results.

2.2 Remote completion exercise

2.2.1 Recruitment of participants for the remote- completion exercise

The project team aimed to recruit and retain approximately 100 participants. Email invitations were issued to all individuals who had completed a previous on-line questionnaire within the eteam Project as part of an assessment of user-friendliness, and who had expressed an interest in attending a workshop/webinar.

The recruitment methods employed successfully in the previous on-line questionnaire survey were again used to attract additional participants; these included postings on professional organisations' message boards, personal contacts and communication via the tool developers' own networks.

2.2.1.1 Background questionnaire

All individuals who had expressed an interest in participating in the exercise were asked to complete a short background questionnaire (see Appendix 2).

The participants were requested to provide the following information:

- Employer type (e.g. industry/ regulator/ consultancy)
- Age
- Country of work (primary work location)
- Job title
- English language ability (reading/ written/ spoken)
- Years of experience in exposure assessment
- Main purpose for which exposure assessment is performed (e.g. REACH)
- Level of knowledge of the exposure assessment tools used in the BURE
- Frequency of tool use
- Last use of tool

Only those individuals who completed and returned the background questionnaire were eligible for inclusion in the study and were issued with the introductory pack and subsequent exercises for completion.

2.2.1.2 Introductory pack

The introductory pack included simple guides to installing and operating the Tier 1 tools for the purposes of the between-user reliability exercise. Guidance and screenshots detailing the required tool outputs were also included, to assist participants in identifying and recording the correct information.

For the purposes of this exercise, all participants were issued with an individual account for STOFFENMANAGER. These accounts were pre-populated by the project team with essential supplier and substance information, for example vapour pressures and molecular weights, to reduce the time required for completion of situation/tool combinations. These pre-populated inputs did not impact on the generation of exposure estimates, for example participants were still required to allocate dustiness for solid materials and choose the most appropriate activity descriptions.

2.2.1.3 Exposure Situations

A series of 20 exposure situation case studies were developed primarily using information collected during Work Package I4. Whilst it was not possible to cover the whole applicability range of the various tools, the exposure situations were structured to ensure sufficient coverage of several relevant factors including physical form, use category and quality of information. Where necessary to provide sufficient coverage, additional situations were gathered from IOM consultancy and research reports with the permission of the relevant clients.

Measurement data were not available for every situation, as some modifications had been made to the original descriptions of risk management measures and other parameters for clarity and variety. No measurement data were provided to the participants with the exposure situations.

A standardised single A4 page format was used for the situations to minimise participant uncertainty from differences in layout of the descriptive information. The information within the pre-populated STOFFENMANAGER accounts was also stated explicitly in the situation descriptions, for example the concentration of a substance in the product.

The development of the exposure situations has been detailed separately under project Deliverables D19 “Draft case descriptions” and D20 “Final case descriptions”. A list of the work activities and associated substances is given by situation in Table 2.1 below. The full situation descriptions provided to the participants are given in Appendix 3.

Table 2.1 Summary of exposure situations used in the BURE

Situation	Description	Substance
1	Use of Styrene-Resin in Fibre-Reinforced Plastics	Styrene
2	Cleaning of Floor Using Hand Brush	Magnesium stearate
3	Use of Toluene in Coatings- Spray painting in furniture manufacturing industry	Toluene
4	Use of Xylene in Formulations- Mixing of chemicals in an Open Vessel	Xylene
5	Use of Naphtha in Coatings- Solvent tank emptying and re-filling	Naphtha
6	Use of Toluene in Adhesives- Manufacture of Rubber Garments	Toluene
7	Use of N-methyl pyrrolidone in formulations- Changing of air filters in a vehicle paint spray booth	N-methyl pyrrolidone
8	Cleaning of Endoscopy Equipment in a Hospital	Glutaraldehyde
9	Packaging of Sodium Resinate Powder in a Factory	Sodium Resinate
10	Dipping of Metal Parts during Manufacture of Electrical Connectors	Isopropanol
11	Weighing of Powdered Pharmaceutical Products	Amoxicillin trihydrate
12	Re-filling of Dry Cleaning Equipment with 1-Bromopropane in Retail Premises	1-Bromopropane
13	Top loading of Tankers with Heavy Fuel Oil	Heavy fuel oil
14	Use of Phenol in Adhesives: Gluing of Rotors	Phenol
15	Packing of Nickel Metal Powder	Nickel
16	Filling of vessels with Isopropyl Benzene	Isopropyl benzene
17	Cleaning of Solder Dross during Manufacture of Electronic Components	Lead
18	Use of hexabromocyclododecane (HBCD) additive during production of Extruded Polystyrene	Hexabromo-cyclododecane
19	Casting of Aluminium into Blocks	Aluminium
20	Use of acetone in formulations- Batch Manufacture of Automotive Paints	Acetone

The tools used in the BURE generate the following types of exposure estimate:

- ECETOC TRA v2 - inhalation and dermal exposure estimate
- ECETOC TRA v3 - inhalation and dermal exposure estimate

- MEASE v1.02.01- inhalation and dermal exposure estimate
- EMKG-EXPO-TOOL - inhalation exposure estimate
- STOFFENMANAGER- inhalation exposure estimate
- RISKOFDERM - dermal exposure estimate

The situation descriptions were not tailored to a specific exposure route, however their content was such that either or both of the routes were applicable. Similarly, situations were not tailored to the applicability range of specific tools in terms of work activity or substance type. It is recognised that this will have led to situations being assessed by tools that were not applicable in terms of scope and/or exposure route.

For each exposure situation, participants were instructed to undertake both an inhalation and dermal exposure assessment using a specified tool, even where the situation was out of scope for that tool. As for “normal” tool users, the participants were required to determine applicability by consideration of the available tool guidance. Initial statistical analyses of between user variation were subsequently carried out with both non-applicable and applicable situations included. Further specific analyses were done with only those applicable to the individual tools included.

As some of the tools allow simultaneous assessment of both inhalation and dermal exposure whilst others cover only one exposure route, the following five tool combinations were applied to generate estimates of both routes for each situation:

1. ECETOC TRA v2 (inhalation and dermal)
2. ECETOC TRA v3 (inhalation and dermal)
3. MEASE (inhalation and dermal)
4. STOFFENMANAGER (inhalation) and RISKOFDERM (dermal)
5. EMKG-EXPO-TOOL (inhalation) and RISKOFDERM (dermal)

2.2.1.4 Study Design

Each participant was asked to complete a total of 20 exposure situation/tool combinations. Allocation of the 20 exposure situation/tool combinations to 20 participants was done using a 20*20 Latin square design, built using cyclic generation (John and Williams, 1995).

Each assessment was assigned to one of the five tool combinations. Table 2.2 shows the schema for the full design in a single 20-participant replication. Due to the cyclical Latin square design, the combinations were balanced by the end of a 20-participant replication. To minimise order effects, e.g. the results being affected by the participant always receiving/ operating a particular tool first in each batch, each 20-participant replication had a different randomisation of situation to Latin square letters A to T, and a different randomisation of toolsets to the letters {w,x,y,z}. The above design was scaled up for allocation of the situation/ tool combinations to the total number of participants.

Table 2.2 Design (before randomisation) for the BURE: 1st full replication

Parti-cipant	Factor	Batch 1					Batch 2					Batch 3					Batch 4				
1	**Situation**	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	W	x	y	z	w	x	y	z
2	**Situation**	T	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	W	x	y	z	w	x	y	z
3	**Situation**	S	T	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
4	**Situation**	R	S	T	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
5	**Situation**	Q	R	S	T	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
6	**Situation**	P	Q	R	S	T	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
7	**Situation**	O	P	Q	R	S	T	A	B	C	D	E	F	G	H	I	J	K	L	M	N
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
8	**Situation**	N	O	P	Q	R	S	T	A	B	C	D	E	F	G	H	I	J	K	L	M
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
9	**Situation**	M	N	O	P	Q	R	S	T	A	B	C	D	E	F	G	H	I	J	K	L
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
10	**Situation**	L	M	N	O	P	Q	R	S	T	A	B	C	D	E	F	G	H	I	J	K
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
11	**Situation**	K	L	M	N	O	P	Q	R	S	T	A	B	C	D	E	F	G	H	I	J
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
12	**Situation**	J	K	L	M	N	O	P	Q	R	S	T	A	B	C	D	E	F	G	H	I
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
13	**Situation**	I	J	K	L	M	N	O	P	Q	R	S	T	A	B	C	D	E	F	G	H
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
14	**Situation**	H	I	J	K	L	M	N	O	P	Q	R	S	T	A	B	C	D	E	F	G
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
15	**Situation**	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	A	B	C	D	E	F
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
16	**Situation**	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	A	B	C	D	E
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
17	**Situation**	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	A	B	C	D
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
18	**Situation**	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	A	B	C
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
19	**Situation**	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	A	B
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z
20	**Situation**	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	A
	Toolset	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z	w	x	y	z

2.2.1.5 Administration of the remote completion exercise

Over a four week period, participants were issued with five exposure situations/ tool combinations to complete on a weekly basis. For each combination, a separate email was issued which contained details of the allocated exposure situation, a worksheet to record their results and the Tier 1 tools to be used in the exercise. In the event of STOFFENMANAGER being allocated, this was highlighted in the accompanying worksheet.

For each exposure situation/tool combination issued, participants were required to document systematically the following contextual information on the worksheet (see Appendix 4):

- Previous experience of the given exposure situation.
- Instances where they found choice or description of parameter types difficult, i.e. the level of uncertainty in their choice for example when selecting substance characteristics or risk management measures.
- The outputs derived by the tool
- Their perception of the level of over/ under-estimation of the exposure estimate generated by the tool(s)

Participants were asked to complete the given exposure situation/tool combination and return the completed worksheet and tool files within one week. Upon receipt of these returns, the next batch of 5 exposure situation/tool combinations was issued. Two reminder emails were issued to participants who had not completed and returned the worksheets within the specified time.

2.2.1.6 Feedback questionnaire

On completion of their 20 allocated exposure situation/tool combinations, participants were asked to complete a final questionnaire to gather feedback on their experiences of using the tools for the assessing the exposure situations during the exercise (Appendix 5). At the end of the exercise, the feedback questionnaire was also distributed to those participants who had submitted some or no assessments to help identify reasons for non-completion.

Feedback was requested on the following topics:

- Whether the person had completed all 20 situations and where applicable their main reason for non-completion
- The helpfulness of the BURE instruction sheets
- Their ease of using the tools before and after the BURE
- The utility of user guidance documents provided with the tools
- Ease of translation of situation descriptions into tool input parameters
- Their perceived level of over-/ under-estimation of exposure by the tools
- Whether the participant intended to use the tools again

Participant opinions on the strengths, weaknesses and potential areas of improvement of the tools were also collected using free text responses.

2.3 Data preparation

On return from the participant, the emails and attachments were stored automatically by participant name for future reference. The exposure assessment outputs were harvested automatically from the returned worksheets and questionnaires using a data retrieval routine and tabulated for analysis in Microsoft Excel spreadsheets. This method minimised the risk of transcription errors by the project team.

Despite the robust measures taken to ensure that participants provided the assessment outputs for their allocated exposure situations in the required format, substantial cleaning and verification was needed to prepare the data file for analysis.

Crosschecking of the assessment results against the original tool Excel spreadsheet or STOFFENMANAGER account was carried out to verify outlying values. Simple typographical errors were corrected where obvious anomalies were identified; however other outlying values were included in the analysis as being valid participants' choices. These entries were examined to identify possible causes for the outlying result, for example the incorrect physical form being chosen.

Additional random checks were also carried out of the collected worksheet response against the original tool spreadsheet or STOFFENMANAGER account to validate the automatic data harvesting collection process.

The use of commas and decimal points between participants from different countries was standardised to eliminate errors associated with formatting of numerical values within Excel and the statistical analysis software.

Additional data preparation procedures carried out for the outputs from specific tools are detailed below. No additional data preparation was required for the MEASE tool estimates.

2.3.1 EMKG-EXPO-TOOL

The predicted exposure generated by this tool is given as a range of values, with the tool guidance recommending that the upper boundary of the range is used for comparison with limit values. The upper value of the range was therefore used for the between user comparison, for example in the range 1-10 mg m^{-3}, a value of 10 mg m^{-3} was used.

For exposure to solid material, the predicted ranges include the values "<0.001 mg m^{-3}" and ">10 mg m^{-3}", whilst for vapour exposures the possible values include ("<0.005 ppm", "<0.05 ppm", "<5 ppm" and ">500 ppm". To generate an estimate for comparison between users, these values were represented in the analyses by a single number as follows (Table 2.3).

Table 2.3 Single number values assigned for EMKG-EXPO-TOOL categories

EMKG-EXPO-TOOL value	Single value allocated for comparison
< 0.001 mg m^{-3}	0.001 mg m^{-3}
>10 mg m^{-3}	15 mg m^{-3}
< 0.005 ppm	0.005 ppm
< 0.05 ppm	0.05 ppm
< 5 ppm	5 ppm
> 500 ppm	750 ppm

To allow for a comparison of the estimates generated for each situation by the various tools, the values in parts per million (ppm) for vapour exposures were then converted to mg m^{-3} using:

$$C_{mg/m^3} = \frac{C_{ppm} \times M}{24.05526} \quad \textbf{2.1}$$

Where C_{mg/m^3} is the concentration in mg m^{-3}, C_{ppm} is the concentration in ppm and M is the molecular weight of the substance.

The conversion of the ppm estimates to mg m^{-3} does not introduce additional variation between users, as all estimates generated for a particular tool-situation combination are converted in an identical manner.

It should be noted during normal operation of the German EMKG-EXPO-TOOL, the use of estimates of > 10 mg m^{-3} or > 500 ppm are not recommended by the tool's developers. For both solids and liquids, a combination of the highest exposure potential group with the lowest control strategy is not considered to deliver adequate risk control. For solid materials, this combination predicts exposure greater than 10 mg m^{-3}, a concentration which is commonly used as an Occupational Exposure Limit for total inhalable dust. Similarly, for liquids, the exposure is considered to be too high to reflect adequate control if it is greater than 500 ppm, which is close to the highest German exposure limit for vapours (1000 ppm).

For the purposes of the BURE however, the actual value for the predicted exposure is of less importance than the degree of consistency of estimate-generation between tool users. The generation of high exposure estimates for particular situations was not therefore considered to be a source of potential error in the reliability study.

2.3.1.1 ECETOC TRAv2

The exposure estimates from this tool are provided as either ppm or mg m^{-3}. Prior to statistical analysis, those estimates given in ppm were converted to mg m^{-3} using Equation 2.1 as given above.

2.3.1.2 ECETOC TRAv3

This tool provides estimates in both ppm and mg m^{-3}. Although both outputs were collected, only the values in mg m^{-3} were used in the subsequent analysis.

During examination and preparation of the ECETOC TRAv3 data, it was noted that for a limited number of participants (n=6), the estimates generated by the tool were identical regardless of the input parameters.

This issue was discussed with the tool developers, and was attributed to errors in the cross-worksheet calculations caused by file compression during transfer and/or the participant reusing the tool without clearing the previous entries correctly. As the tool appeared to the user to be working correctly, and taking into consideration the time period of a week or so between different tool use sessions, these participants had not identified this problem. To ensure that the participants' intended assessment outputs were collected, the exact parameters chosen by each person were entered in clean copies of the tool by the project team, and the resultant estimates recorded and used in the analysis.

2.3.1.3 STOFFENMANAGER

To minimise the risk of results being entered incorrectly in the worksheet, participants were asked to record the 50^{th}, 75^{th} and 90^{th} percentiles of the distribution generated by STOFFENMANAGER. Only the 90^{th} percentile values were selected for the analysis to allow comparison with the estimates generated by the other tools, which are generally taken to represent a reasonable worst case exposure situation.

The estimates from STOFFENMANAGER are on a continuous scale, therefore outlying results were difficult to identify. It was not feasible to check every result obtained, therefore the highest and lowest estimates for each situation were verified, together with intermediate values.

2.3.1.4 RISKOFDERM

RISKOFDERM requires users to choose from one of six Dermal Exposure Operations (DEOs), from which the exposure estimate is generated as a rate or loading for the hands and/ or body. The possible estimates are shown below in Table 2.4, together with the relevant units.

Table 2.4 RISKOFDERM units by Dermal Exposure Operation

Dermal Exposure Operation (DEO)	**Estimate: Hands**		**Estimate: Body**	
	Rate	*Loading*	*Rate*	*Loading*
Filling/ mixing/ loading	µl min^{-1} or mg min^{-1}	µl or mg	not applicable	not applicable
Wiping	µl min^{-1}	mg	µl min^{-1}	mg
Dispersion Hand-held tools	µl min^{-1}	mg	µl min^{-1}	mg
Spraying	µl min^{-1} or mg min^{-1}	µl or mg	µl min^{-1} or mg min^{-1}	µl or mg
Immersion	µl min^{-1}	µl	µl min^{-1}	µl
Mechanical treatment	not applicable	not applicable	µl min^{-1} or mg min^{-1}	µl or mg

Participants were asked to record the 50th and 90th percentiles for hand and body loadings as generated by the relevant DEO. Only the 90^{th} percentile estimates were used in the analysis.

Within the underlying RISKOFDERM models, the density of liquid formulations is assumed to be 1 mg $µl^{-1}$, therefore the values in microlitres and milligrams were considered to be identical. The values recorded for all DEOs were therefore treated as being in mg during the analysis.

The highest, lowest and intermediate RISKOFDERM values were examined for each situation.

2.4 Data analysis

The analysis began by summarising the data collected and cross-tabulating the results by various factors.

The formal statistical analyses aimed to:

1. quantify the variation in results recorded for each tool applied to each situation assessed;

2. examine and quantify the components of that variation due to systematic differences between and within participants in carrying out their assessments;
3. examine systematic patterns within the components of variation relating to aspects of the situation assessed, the characteristics of the

participants, and their recorded opinions regarding familiarity with the specific situation and their perceived difficulty/ uncertainty in making the assessment.

As presented, the design was separable by toolset, and was balanced within each toolset separately. However, missing returns meant that the design was not complete, introducing some structural imbalance to the data sets. The extent of this was not expected to be serious, but meant that the analyses were not carried out using standard ANOVA routines.

Initial examination of the data revealed that, as expected, their standard deviations increased with mean levels, so analyses were carried out on the logarithms of the assessment results. Linear mixed models were fitted, with fixed effects for differences in level between situations, and a random distribution for differences between participants, assumed to follow the Normal distribution on the logarithmic scale. This resulted in the estimation of mean effects (corresponding to geometric means) for the situations, and a variance component (convertible to a geometric standard deviation) for the participants' distribution. The remaining variation not explained by either of those components estimated, on that scale, the random within-participant variance.

Additional analyses attempted to investigate systematic structure in the components estimated above. Terms representing differences between participants, e.g. country of origin, experience with tool or situation, etc., were added to the mixed models described above one at a time and the extent to which they explained structure in the relevant variance component was assessed for each.

Initial analyses were undertaken with applicable and non-applicable situations included. Further specific analyses were then carried out with only those situations which were within the stated range of applicability of each tool.
The fixed and random effects estimated were used to characterise the average differences in level in the assessed result, but could not highlight instances or characteristics that were associated with larger amounts of random variation. To investigate this, the standardised residuals from each analysis were extracted, and their variance cross-tabulated by situation and the factor(s) under investigation. The tabulated variances were reported as geometric standard deviations for ease of interpretation.

2.4.1 Impact of participant characteristics on variation

The impact of a number of participant characteristics on variation in response was investigated. These included: type of organisation/ sector of employment; English language ability; years of experience in exposure assessment; and main reason for carrying out exposure assessments.

Mixed statistical models were fitted, adding each of these factors, in turn to a base model containing factors for situation and participant, as described above. The variances of the standardised residuals were again tabulated, inspected and assessed as detailed previously.

2.4.1.1 Impact of situation-related factors on variation

Potential situation-related factors which may have influenced the degree of variation between participants assessing the same situation were investigated.

2.4.1.2 Influence of descriptive information provided for situation

The influence of the type of information provided in the situation description on variation was investigated using tabulation of key input parameters by situation number: task duration; local exhaust ventilation (LEV); general ventilation, respiratory protective equipment (RPE), gloves and overall level of contextual detail (high/ medium/ low). The physical form of the substance and applicability of each tool to the situation/ substance was also recorded.

2.4.1.3 Influence of familiarity of participant with situation

The level of previous experience of participants with each situation was tabulated by tool type to investigate whether increasing familiarity with the work activity/ workplace was linked to a decrease in variation.

2.4.1.4 Influence of level of uncertainty in choosing input parameters

The level of uncertainty assigned by participants in choosing input parameters was tabulated for each tool by individual situation to investigate whether increased uncertainty in choice of some or all parameters was linked to higher variation in estimates.

Mixed models were again fitted, adding each of these factors, in turn, to a base model containing factors for situation and participant, as above. Variances of standardised residuals and geometric standard deviations tabulated, inspected and assessed as described previously.

3 Results

3.1 Response Rate

The remote completion exercise was conducted over November and December 2012. From an initial pool of participants (n=148) who completed the background questionnaire, a total of 146 participants completed one or more assessments, with 70 participants completing all 20 situations. The participants returned 4066 tool-situation combinations in total. The number of completed documents (questionnaires and assessments) distributed to and returned by participants during each week of the BURE is shown below in Figure 3.1.

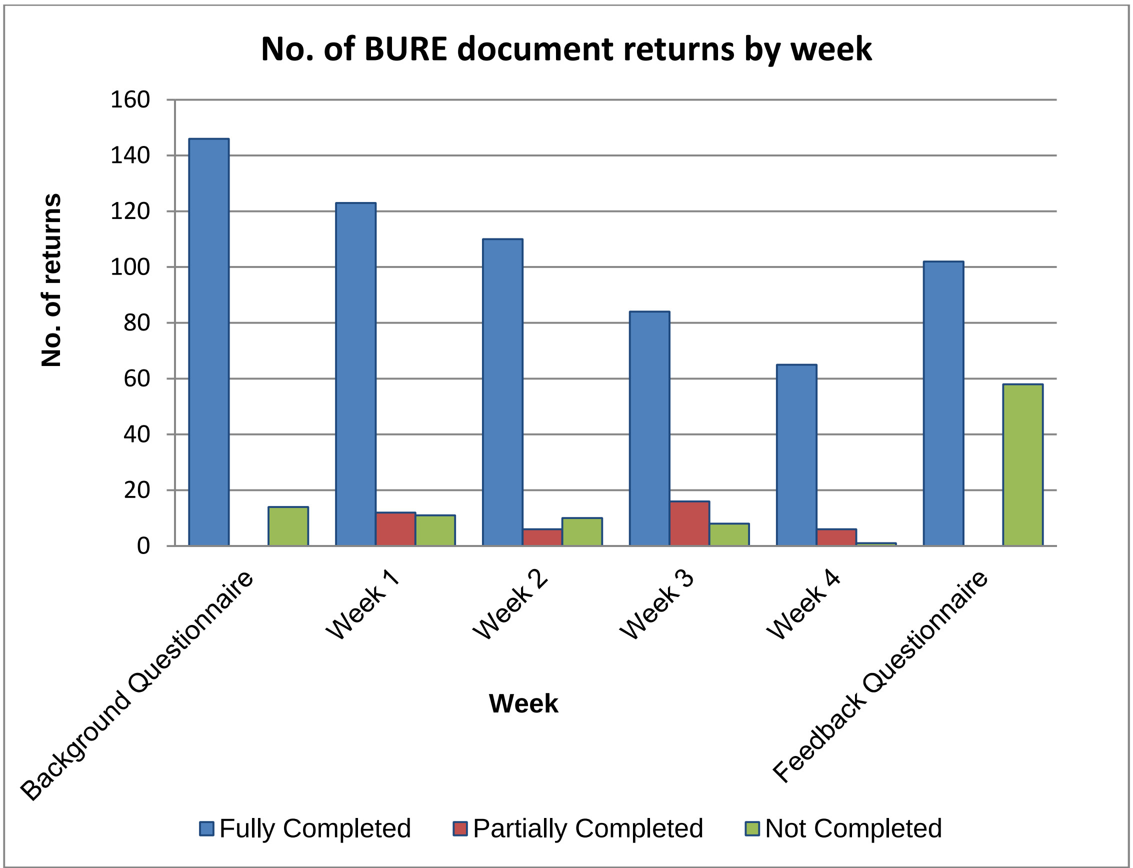

Figure 3.1 BURE document returns by week

As would be expected, the number of returns decreased over the period of the exercise, however as noted above, 70 participants completed a full set of assessment returns.

3.2 Participant demographics

Demographic information on the participants (n=146) is summarised in Figures 3.2-3.10. Additional information is tabulated in Appendix 6.

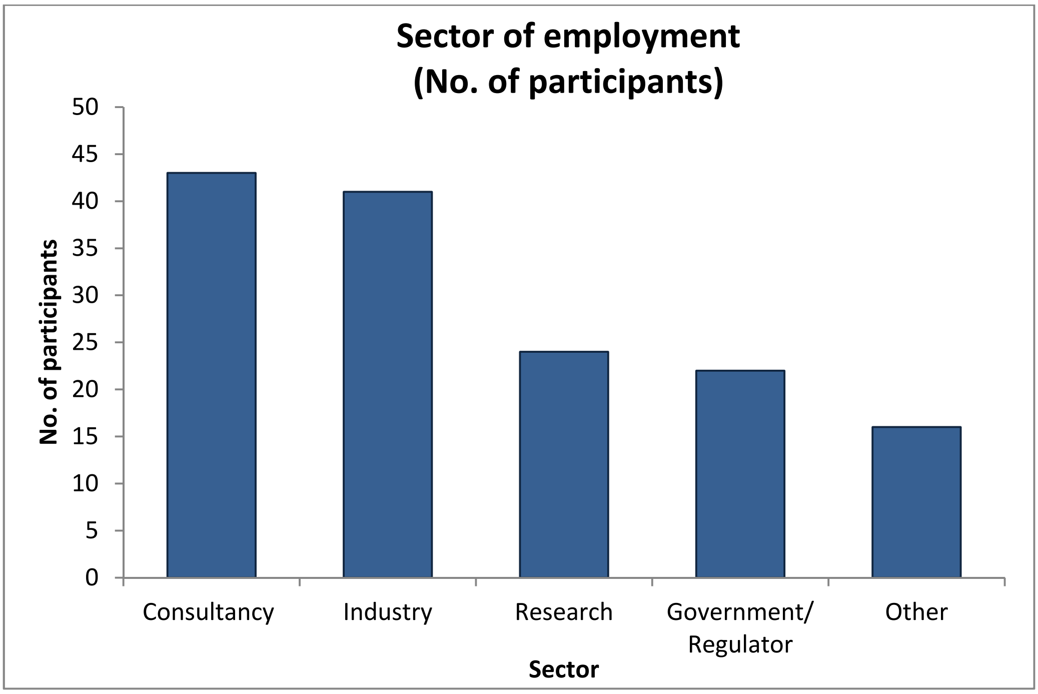

Figure 3.2 Participants' sector of employment

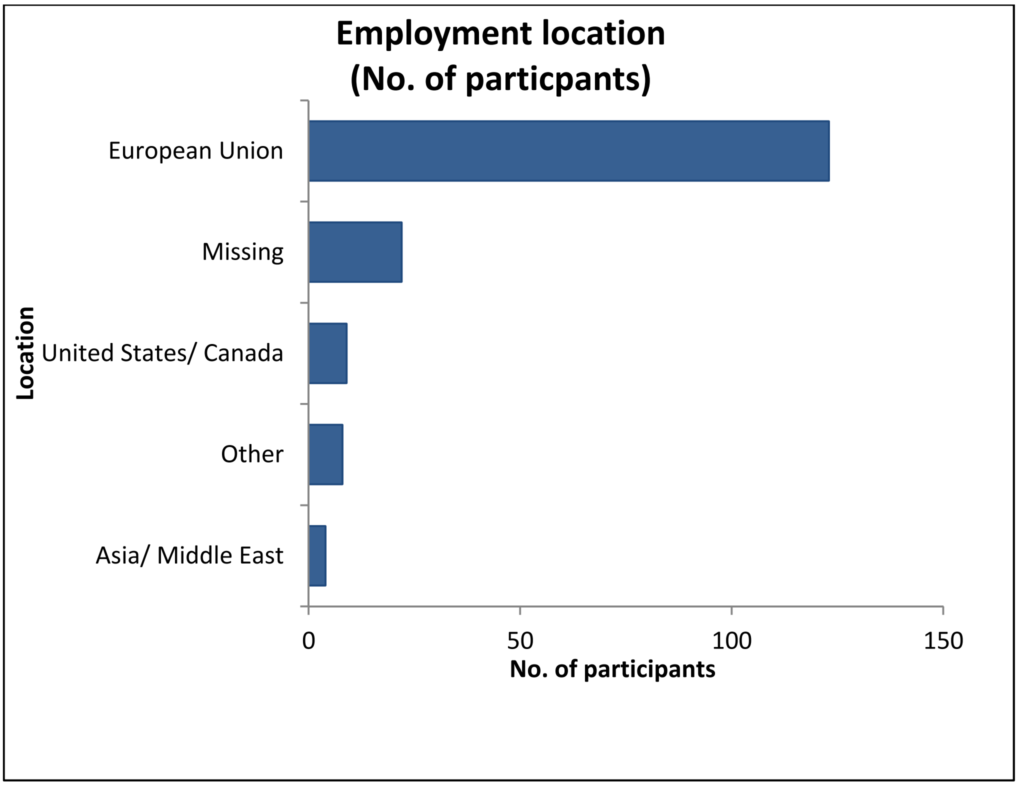

Figure 3.3 Participants' Employment location

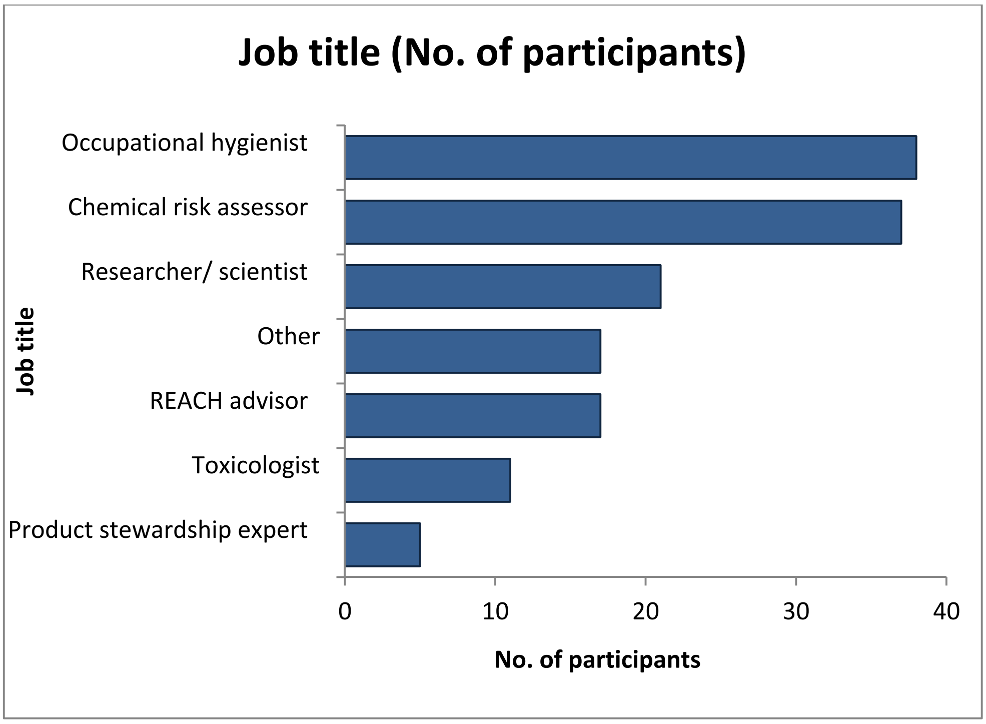

Figure 3.4 Participants' Job Title

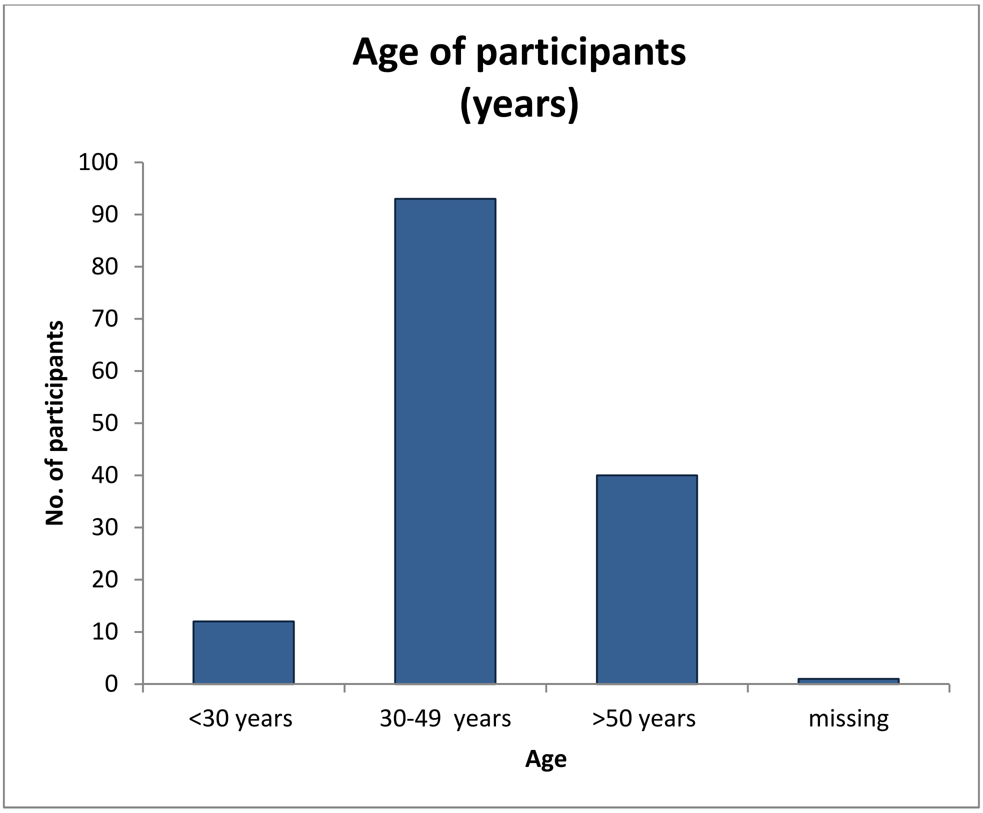

Figure 3.5 Age of participants

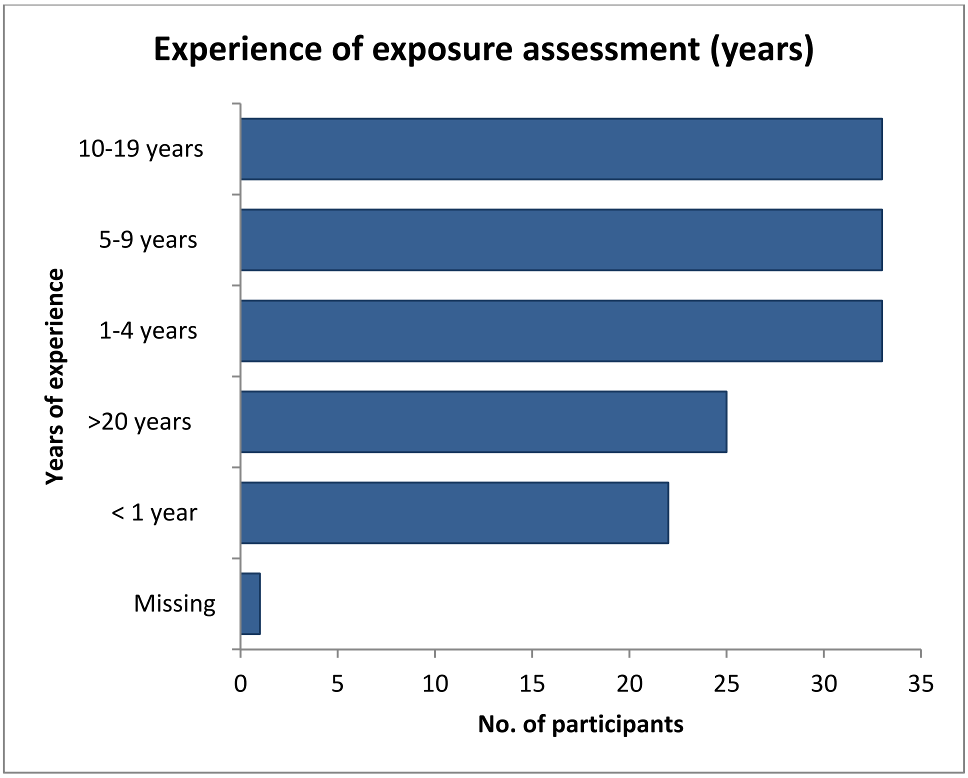

Figure 3.6 Participants' experience of exposure assessment

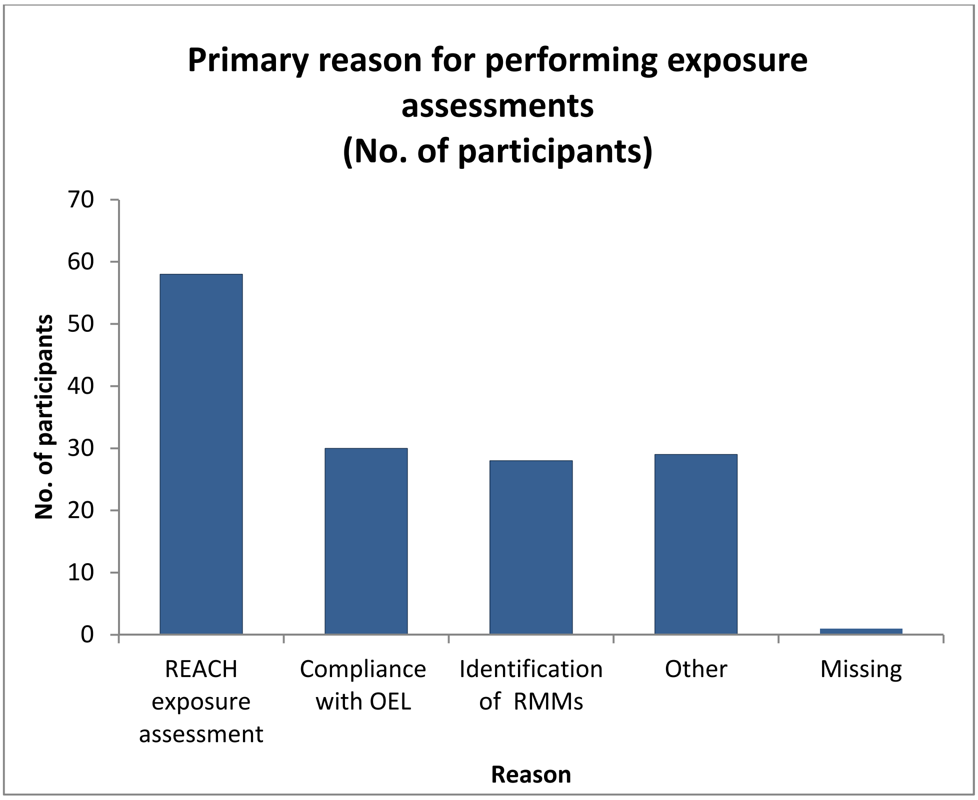

Figure 3.7 Primary reason for performing exposure assessment

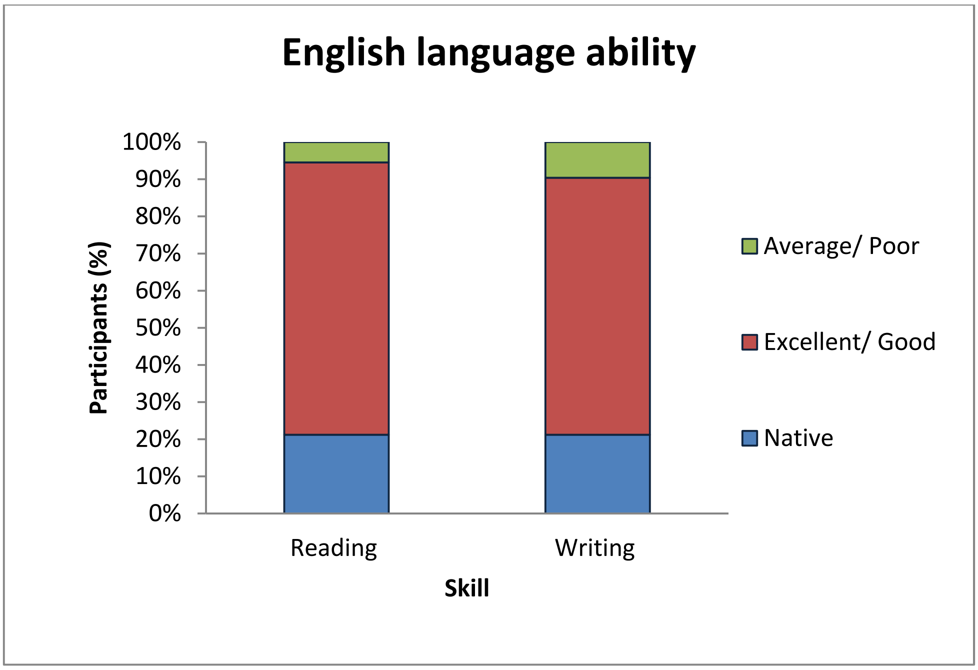

Figure 3.8 Participants' English language skill level

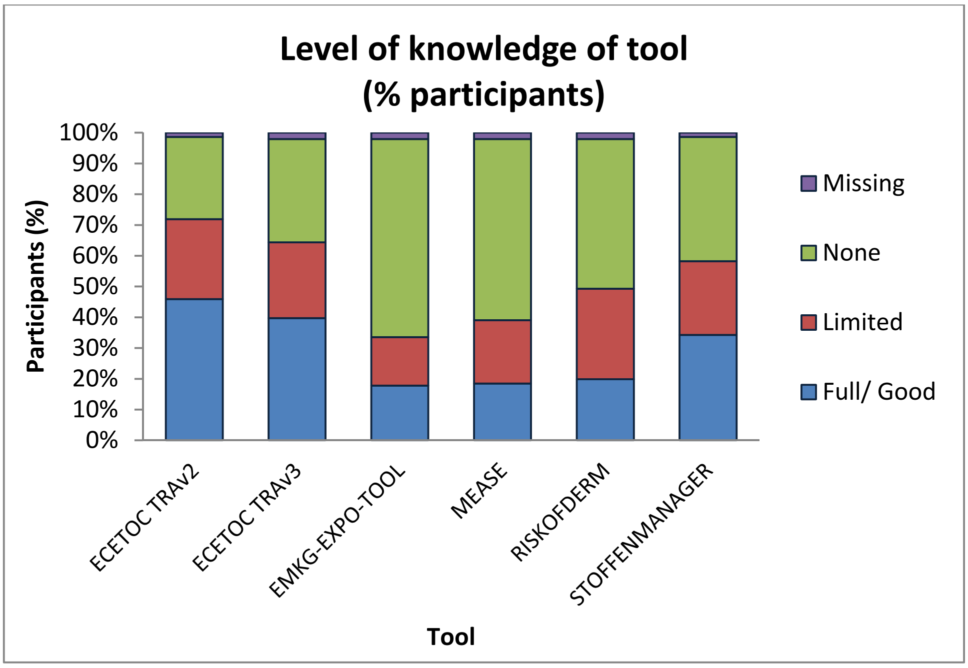

Figure 3.9 Participants' level of knowledge of tool

There were differences reported in the level of previous experience with the various tools amongst participants. Participants were most familiar with the ECETOC TRAv2 with 105 participants indicating some level of knowledge, compared with those with no knowledge (n=39) of the tool. Similar levels of previous knowledge were indicated for the ECETOC TRAv3, with 94 participants having knowledge of the tool compared with no previous experience (n=49). Slightly higher numbers of participants reported more previous knowledge of the older ECETOC TRAv2 than for version 3 tool.

Participants had comparable levels of experience with STOFFENMANAGER, with 85 indicating prior experience compared with 59 who had no experience.

Fewer participants had previous experience with the EMKG-EXPO-TOOL (49 participants with full/ good/ limited knowledge compared with 94 with no experience) and with MEASE (57 participants with some experience compared with those with 86 none experience). For RISKOFDERM, participants were evenly split between those who have full/ good or limited experience (n=72) compared with those who had no previous experience of the tool (n=71).

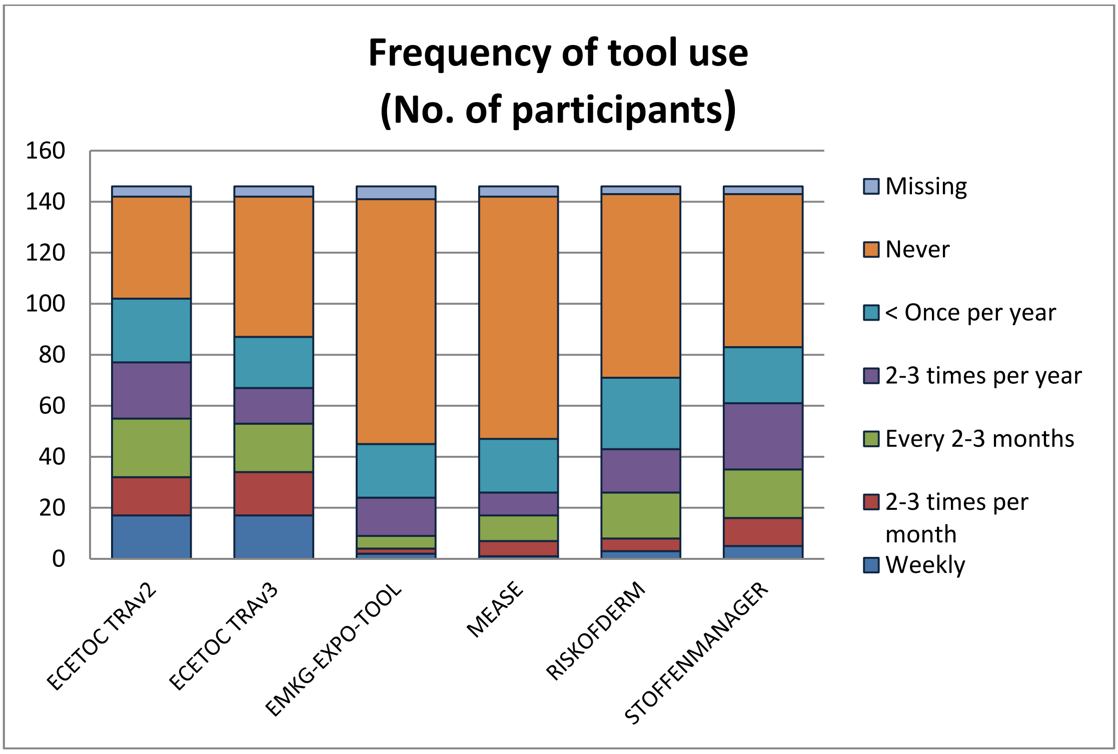

Figure 3.10 Participants' frequency of tool use

The ECETOC TRAv3 and ECETOC TRAv2 were the most frequently used tools, followed by STOFFENMANAGER. A relatively high proportion of the participants had never used the EMKG-EXPO-TOOL, MEASE and RISKOFDERM, which again may be associated with the more specialised nature of these three tools.

3.3 Number of returns by situation and tool

The number of worksheets returned by situation ranged from 95 to 107. This number includes those where there were complete, partially complete and empty worksheets.

The numbers of tool-situation assessments harvested from these returned worksheets were similar across the range of inhalation tools (Table 3.1). The numbers of returned dermal assessments were also balanced between the ECETOC TRAv3, ECETOC TRAv2 and MEASE, with more assessments being collected for RISKOFDERM as a result of its pairing with two different inhalation tools.

Table 3.1 Number of completed returns by tool

Tool	Inhalation returns	Dermal returns
ECETOC TRAv2	412	412
ECETOC TRAv3	400	400
EMKG-EXPO-TOOL	406	N/A
MEASE	411	411
RISKOFDERM	N/A	810
STOFFENMANAGER	404	N/A
TOTAL	2033	2033

A full description the returned assessments by situation and tool. The final numbers of exposure estimates generated and used in the analyses summarised in Figures 3.11 and 3.12 for the inhalation and dermal tools respectively.

The numbers of estimates used in the analyses were similar across the situations and tools for both inhalation and dermal exposures.

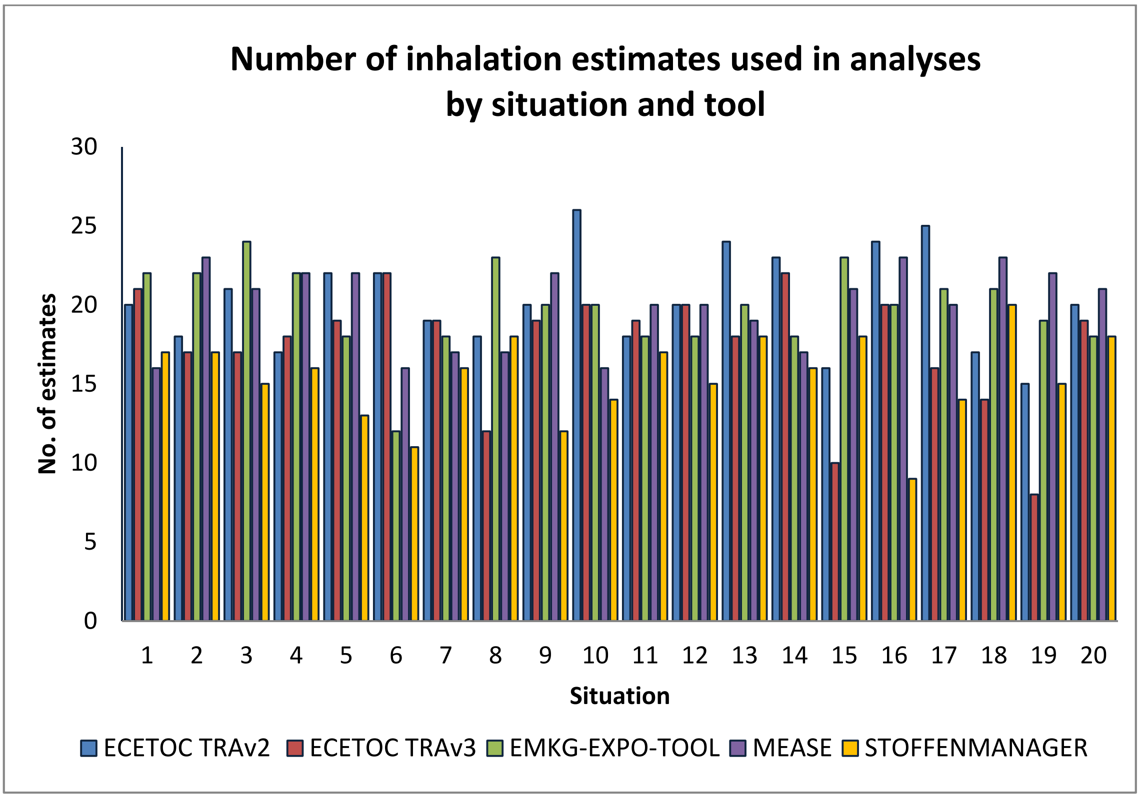

Figure 3.11 Inhalation estimates used in analyses

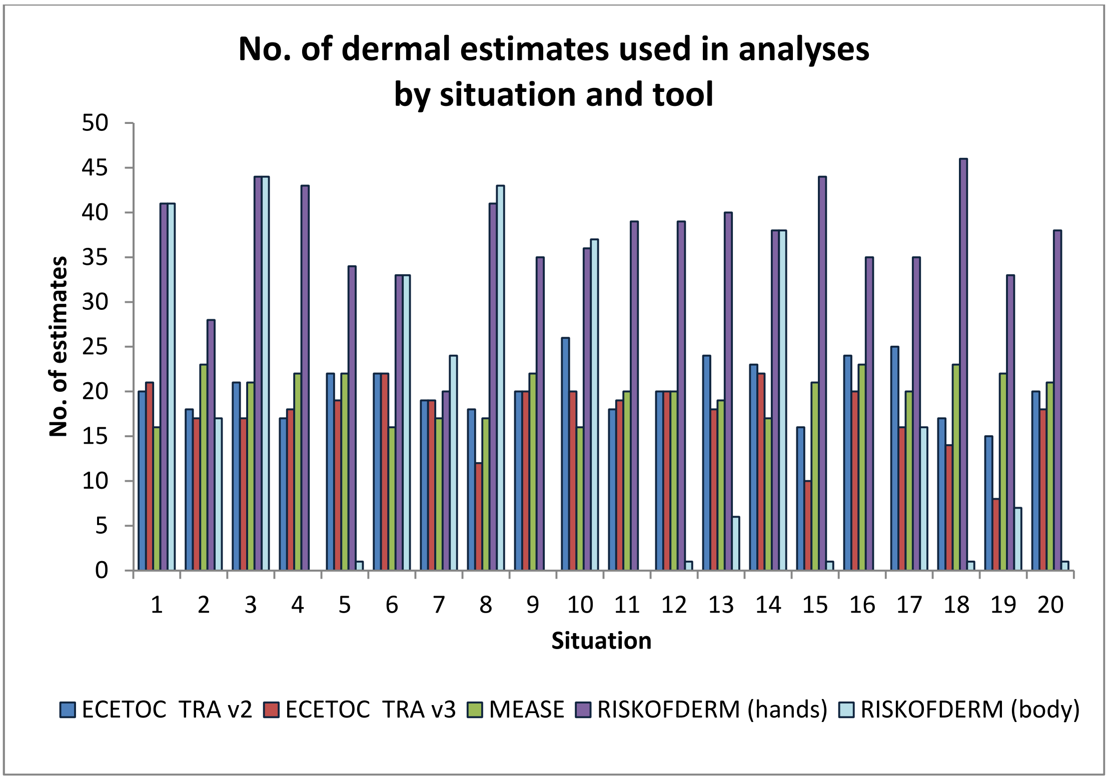

Figure 3.12 Dermal estimates used in analyses

3.4 Participants' prior experience of exposure situations

For each situation/ tool combination completed, participants were asked to indicate their previous experience of the situation described using the following categories.

- Extensive- participant had assessed exposure in this situation previously with the tools and have completed walk-through surveys
- Reasonable- participant had assessed exposure for a similar situation using measurements
- Limited- participant had read papers/ seen other information about the situation but had not actively carried out any exposure assessment
- None

The number (percentage) of participants who had limited or no experience of the situation being assessed is shown below in Tables 3.2 and 3.3.

For exposure to liquid substances via inhalation, participants had least experience of situation 7 for the ECETOC TRAv3 (95%), ECETOC TRAv2 (84%) and EMKG-EXPO-TOOL (89%)), situations 6 and 12 for MEASE (both 75%) and situation 8 for STOFFENMANAGER (94%). For solid substances, situation 19 (88%) was least familiar to assessors using the ECETOC TRAv3. Participants using MEASE (82%) and STOFFENMANAGER (87%) were similarly unfamiliar with situation 19. Situation 17 was also least familiar to participants using the ECETOC TRAv2 (76%). For the EMKG-EXPO-TOOL, participants had least experience of situation 18 (86%).

As can be seen in Table 3.3, the results for dermal exposure assessments were similar to those for the inhalation tools. For liquid substances, situation 7 was least familiar to assessors using the ECETOC TRAv3 (95%) and the ECETOC TRAv2 (84%). There were a number of situations which were assessed using RISKOFDERM (body) by only one participant, however for those situations where N>1, situation 7 was also least familiar to these participants (84%). Assessors using MEASE for liquid exposures had least experience of situations 12 and 6 (75%), whereas for assessment of liquid exposures via the hands using RISKOFDERM, situation 8 was least familiar (80%).

In relation to dermal exposures to solids, the participants using the ECETOC TRAV3 (88%), MEASE (82%) and RISKOFDERM (body) (86%) had least prior experience of situation 19, whilst for the ECETOC TRAv2, there was least familiarity with situation 17 (76%). For RISKOFDERM (hands), participants were least familiar with situation 18 (80%).

Table 3.2 Participants with limited or no previous experience of the situation by inhalation tool/ Number of participants (%)

Situation	Inhalation exposure									
	ECETOC TRAv3		ECETOC TRAv2		EMKG-EXPO TOOL		MEASE		STOFFENMANAGER	
	limited/none		limited/none		limited/none		limited/none		limited/none	
	liquids	solids	liquids	solids	liquids	solids	liquids	solids	liquids	solids
	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)
1	17(81)		13(65)	-	16(73)	-	7(44)	-	12(71)	-
2	-	11(65)	-	11(61)	-	18(82)	-	14(61)	-	11(65)
3	7(41)	-	8(38)	-	16(67)	-	14(67)	-	7(47)	-
4	9(50)	-	11(65)	-	11(50)	-	13(59)	-	11(69)	-
5	12(63)	-	13(59)	-	13(72)	-	16(73)	-	9(69)	-
6	15(68)	-	15(68)	-	8(67)	-	12(75)	-	9(82)	-
7	18(95)	-	16(84)	-	16(89)	-	12(71)	-	11(69)	-
8	5(42)	-	12(67)	-	17(74)	-	11(65)	-	17(94)	-
9	-	14(74)	-	9(45)	-	16(80)	-	15(68)	-	9(75)
10	12(60)	-	16(62)	-	13(65)	-	11(69)	-	11(79)	-
11	-	13(68)	-	12(67)	-	10(56)	-	15(75)	-	12(71)
12	15(80)	-	14(70)	-	10(56)	-	15(75)	-	10(67)	-
13	15(83)	-	19(79)	-	15(75)	-	13(68)	-	13(72)	-
14	16(73)	-	18(78)	-	11(61)	-	12(71)	-	12(75)	-
15	-	6(60)	-	12(75)	-	18(78)	-	16(76)	-	11(61)
16	13(65)	-	14(58)	-	12(60)	-	11(48)	-	5(56)	-
17	-	13(81)	-	16(76)	-	16(76)	-	16(80)	-	9(64)
18	-	7(50)	-	11(65)	-	18(86)	-	16(70)	-	14(70)
19	-	7(88)	-	10(67)	-	13(68)	-	18(82)	-	13(87)
20	14(74)	-	12(60)	-	11(61)	-	13(62)	-	12(67)	-

Table 3.3 Participants with limited or no previous experience of the situation by dermal tool/ Number of participants (%)

Situation	Dermal exposure									
	ECETOC TRAv3 limited/none		ECETOC TRAv2 limited/none		MEASE limited/none		RISKOFDERM (hands) limited/none		RISKOFDERM (body) limited/none	
	liquids	solids	liquids	solids	liquids	solids	liquids	solids	liquids	solids
	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)
1	17(81)	-	13(65)	-	7(44)	-	29(71)	-	29(71)	-
2	-	11(65)	-	11(61)	-	14(61)	-	21(75)	-	14(82)
3	7(41)	-	8(38)	-	14(67)	-	25(57)	-	25(57)	-
4	9(50)	-	11(65)	-	13(59)	-	27(63)	-	1(100)	-
5	12(63)	-	13(59)	-	16(73)	-	25(74)	-	22(67)	-
6	15(68)	-	15(68)	-	12(75)	-	22(67)	-	19(79)	-
7	18(95)	-	16(84)	-	12(71)	-	14(70)	-	36(84)	-
8	5(42)	-	12(67)	-	11(65)	-	33(80)	-	-	
9	-	15(75)	-	9(45)	-	15(68)	-	27(77)	-	-
10	12(60)	-	16(62)	-	11(69)	-	27(75)	-	28(76)	-
11	-	13(68)	-	12(67)	-	15(75)	-	24(62)	-	
12	16(80)	-	14(70)	-	15(75)	-	25(64)	-	1(100)	-
13	15(83)	-	19(79)	-	13(68)	-	29(73)	-	4(67)	-
14	16(73)	-	18(78)	-	12(71)	-	26(68)	-	26(68)	-
15	-	6(60)	-	12(75)	-	16(76)	-	31(70)	-	1(100)
16	13(65)	-	14(58)	-	11(48)		21(60)	-	-	-
17	-	13(81)	-	19(76)	-	16(80)	-	25(71)	-	11(69)
18	-	7(50)	-	11(65)	-	16(70)	-	37(80)	-	1(100)
19	-	7(88)	-	10(67)	-	18(82)	-	26(79)	-	6(86)
20	14(78)	-	12(60)	-	13(62)	-	24(63)	-	1(100)	-

3.5 Uncertainty in choice of tool input parameter

For each tool/ situation combination, participants were asked to record the level of uncertainty that they experienced when choosing parameters. To simplify completion of these questions and so maximise the number of responses returned, the tool input parameters were grouped into four categories:

- Substance characteristics- e.g. dustiness
- Operational Conditions- e.g. general work environment, process temperature
- Task/ activity description
- Risk management measures (RMMs)- e.g. local exhaust ventilation, personal protective equipment

The participants were asked to grade their level of uncertainty as follows

- No uncertainty - choice of correct parameter was clear
- Minor uncertainty - choice of parameter was reasonably clear
- Major uncertainty - choice of parameter was unclear

Tabulation of these returns was undertaken both across all tools and situations and by individual situation with the results given below.

3.5.1 Level of uncertainty experienced in parameter selection- all situations

The responses to these questions (across all situations) are shown for inhalation and dermal tools in Figures 3.13 and 3.14 respectively.

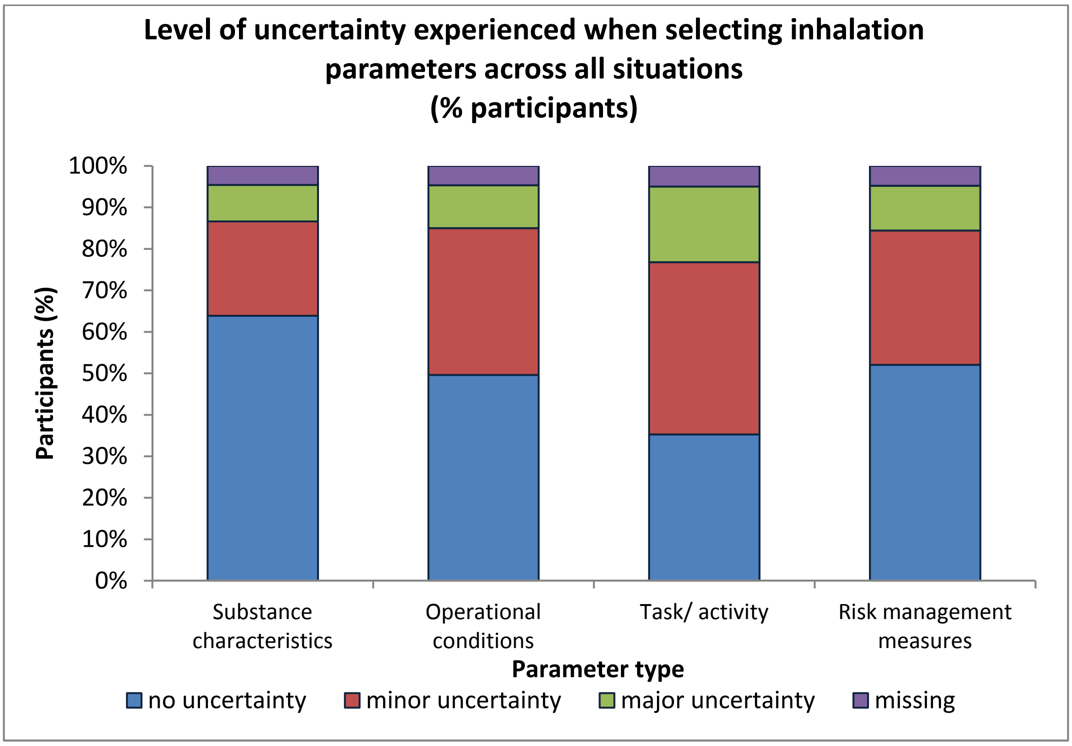

Figure 3.13 Percentage of participants experiencing inhalation parameter selection uncertainty

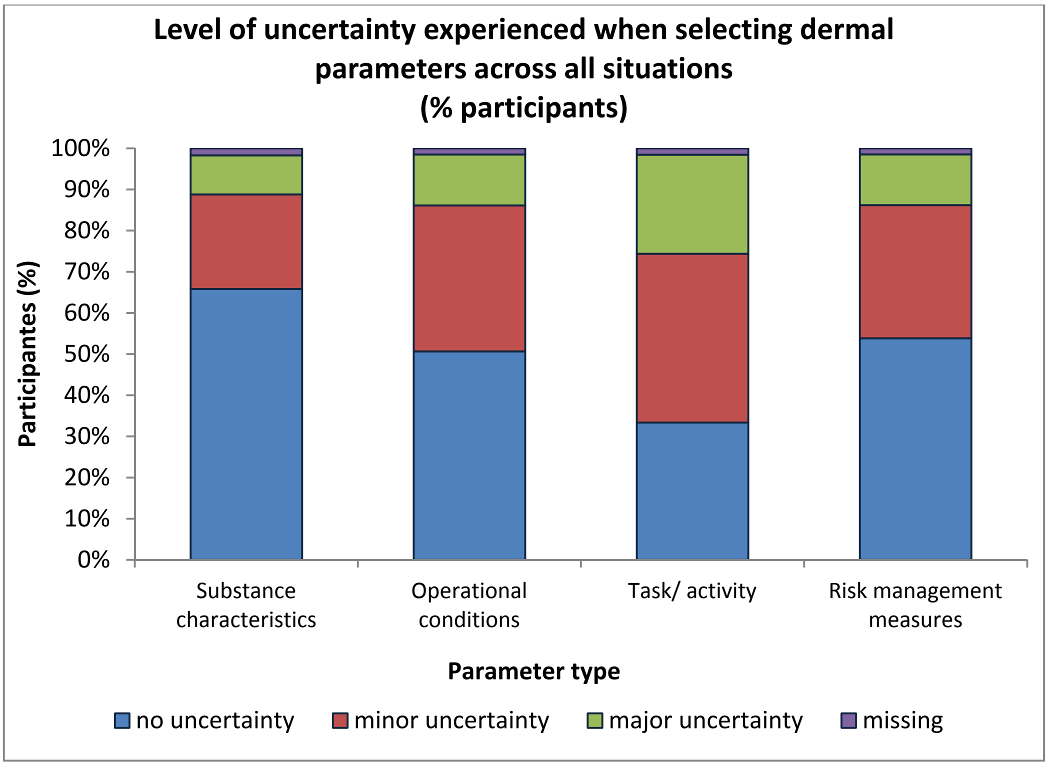

Figure 3.14 Percentage of participants experiencing dermal parameter selection uncertainty

Over all of the situations and tools, more participants reported major uncertainty in allocating inhalation parameters which describe the task/ activity being carried out, than for the other parameter groups. This group of parameter presents users with most input options within the tools (with the exception of EMKG-EXPO-TOOL).

Similarly, participants reported more major uncertainty in allocation of dermal task/activity than for other parameter types. The number of participants reporting major uncertainty in describing the dermal task/activity is greater than that for inhalation, which may be a reflection of lower general levels of experience in dermal exposure assessment.

The level of uncertainty in allocating the parameters for each situation is shown for the inhalation and dermal tools for liquid and solid substances in Tables 3.4- 21 and described in the following sections

3.5.2 Uncertainty in allocating inhalation tool parameters- liquids

Table 3.4 shows the reported uncertainty for the inhalation tools for situations with exposure to liquid substances.

3.5.2.1 <u>Substance characteristics</u>

There appeared to be little consistency in the level of uncertainty that participants experienced in assigning substance characteristics across tools and situations. For the ECETOC TRAv3, 23% of participants reported most uncertainty in assigning characteristics of the substance in situation 14 (phenol in adhesives), whilst for the

ECETOC TRAv2, situation 4 (use of xylene) was associated with most uncertainty (29%).

For the EMKG-EXPO-TOOL, allocating the characteristics associated with isopropanol in situation 10 caused most uncertainty (45%). In relation to MEASE, situation 1 (roller application of styrene resin) generated most uncertainty regarding the substance (56%). In case of STOFFENMANAGER most uncertainty (50%) was reported for allocating tool inputs for substance characteristics in situation 7 (handling materials contaminated with N-methyl pyrrolidone).

3.5.2.2 Operational conditions

For the ECETOC TRAv3, most uncertainty for assigning tool inputs related to operational conditions such as general work environment, was reported for situation 5 (63%), while for ECETOC TRAv2 most uncertainty this parameters was reported for situation 12 (55%). When using the EMKG-EXPO-TOOL, 72% of participants reported uncertainty in assigning operational conditions' parameters for situation 7. For MEASE the reported uncertainty was highest for situation 13 (68%). All participants (100%) assigning parameters related to operational conditions for STOFFENMANAGER experienced uncertainty for situation 16.

3.5.2.3 Task

For parameters associated with the task description highest uncertainty was reported for situation 7 for ECETOC TRAv3 (74%), MEASE (82%) and STOFFENMANAGER (100%). For the ECETOC TRAv2, most uncertainty was reported in allocation of task for situation 14 (83%). In relation to the EMKG-EXPO-TOOL, participants (85%) were most uncertain in their allocation of a task for situation 10. However, as task is not included as an explicit input parameter in this tool, this result should be considered in a different context to those from the other tools where a choice on the work activity is required. The EMKG-EXPO-TOOL directs the user to a set of Control Guidance Sheets, which outline work activities and control measures for a range of processes. As for other tool-specific guidance, participants were not explicitly informed of this information source or asked to use it.

3.5.2.4 Risk management measures

Allocation of RMMs for situation 7 caused most uncertainty for participants using the ECETOC TRAv3 (79%) and STOFFENMANAGER (88%) tools. Using ECETOC TRAv2, most uncertainty in assigning RMMs was reported for situation 4 (59%). Participants were most uncertain when choosing RMMs for the EMKG-EXPO-TOOL for situation 13 (55%). Assigning RMMs in MEASE for situation 5 resulted in uncertainty for 77% of participants.

3.5.2.5 Relative overall level of uncertainty for parameter groups

Across all of the inhalation tools, the highest level of uncertainty for liquid substances was reported for the "task" input parameter group, followed by similar levels of uncertainty in allocation of parameters for "operational conditions" and "risk management measures".

For all of the tools, participants reported least uncertainty when assigning “substance characteristics”. This is perhaps to be expected, as vapour pressures were supplied for all liquid substances in the exercise.

Table 3.4 Level of uncertainty in allocating inhalation tool parameters- liquids/ Number of participants (%)

Parameter Group	Situation	Inhalation tool (liquids)				
		ECETOC TRAv3	ECETOC TRAv2	EMKG-EXPO-TOOL	MEASE	STOFFEN-MANAGER
		Level of uncertainty				
		minor/ major	minor/ major	minor/ major	minor/ major	minor/ major
		N (%)	N (%)	N (%)	N (%)	N (%)
Substance characteristics	1	3(14)	1 (5)	6 (27)	9 (56)	6 (35)
	3	2 (12)	1 (5)	10 (42)	2 (10)	1 (7)
	4	0 (0)	5 (29)	7 (32)	3 (14)	4 (25)
	5	2 (11)	3 (14)	4 (22)	5 (23)	1 (8)
	6	1 (5)	3 (14)	3 (25)	1 (6)	4 (36)
	7	4 (21)	4 (21)	4 (22)	8 (47)	8 (50)
	8	1 (9)	0 (0)	5 (22)	6 (35)	4 (22)
	10	3 (15)	0 (0)	9 (45)	4 (25)	1 (7)
	12	4 (20)	3 (15)	4 (22)	3 (15)	4 (27)
	13	4 (22)	4 (17)	6 (30)	5 (26)	0 (0)
	14	5 (23)	5 (22)	5 (28)	3 (18)	7 (44)
	16	1 (5)	3 (13)	3 (15)	3 (13)	2 (22)
	20	1 (6)	1 (5)	3 (17)	1 (5)	1 (6)
	Total	**31 (13)**	**33 (12)**	**69 (27)**	**53 (22)**	**43 (22)**
Operational conditions	1	8 (38)	8 (40)	8 (36)	4 (25)	10 (59)
	3	3 (18)	6 (29)	11 (46)	8 (38)	10 (67)
	4	3 (17)	7 (41)	10 (45)	9 (41)	10 (63)
	5	12 (63)	11 (50)	9 (50)	10 (45)	10 (77)
	6	8 (36)	9 (41)	3 (25)	6 (38)	8 (73)
	7	11 (58)	9 (47)	13 (72)	8 (47)	12 (75)
	8	6 (55)	5 (28)	12 (52)	10 (59)	15 (83)
	10	5 (25)	4 (15)	12 (60)	4 (25)	9 (64)
	12	12 (60)	11 (55)	5 (28)	9 (45)	12 (80)
	13	9 (50)	11 (46)	8 (40)	13 (68)	10 (56)
	14	10 (45)	7 (30)	6 (33)	9 (53)	12 (75)
	16	5 (25)	6 (25)	8 (40)	9 (39)	9 (100)
	20	5 (28)	4 (20)	8 (44)	9 (43)	9 (50)
	Total	**97 (39)**	**98 (36)**	**113 (45)**	**108 (44)**	**136 (69)**
Task	1	11 (52)	11 (55)	9 (41)	5 (31)	9 (53)
	3	6 (35)	5 (24)	15 (63)	11 (52)	12 (80)
	4	6 (33)	10 (59)	11 (50)	14 (64)	12 (75)
	5	13 (69)	16 (73)	9 (50)	15 (68)	10 (77)
	6	9 (41)	9 (41)	4 (33)	9 (56)	7 (64)
	7	14 (74)	15 (79)	14 (78)	14 (82)	16 (100)
	8	8 (73)	12 (67)	13 (57)	8 (47)	15 (83)
	10	11 (55)	5 (19)	17 (85)	8 (50)	13 (93)
	12	12 (67)	13 (65)	8 (44)	13 (65)	12 (80)
	13	12 (67)	15 (63)	8 (40)	13 (68)	13 (72)
	14	12 (55)	19 (83)	10 (56)	12 (71)	12 (75)
	16	8 (40)	15 (63)	10 (50)	16 (70)	7 (78)
	20	11 (61)	12 (60)	12 (67)	11 (52)	15 (83)
	Total	**133 (54)**	**157 (57)**	**140 (55)**	**149 (60)**	**153 (78)**
Risk management measures	1	11 (58)	11 (55)	9 (41)	8 (50)	5 (29)
	3	7 (41)	5 (24)	9 (38)	15 (71)	6 (40)
	4	5 (28)	10 (59)	9 (41)	14 (64)	12 (75)
	5	11 (58)	11 (50)	5 (28)	17 (77)	10 (77)
	6	9 (41)	7 (32)	5 (42)	8 (50)	3 (27)

7	15 (79)	11 (58)	9 (50)	12 (71)	14 (88)
8	4 (36)	4 (22)	10 (43)	11 (65)	7 (39)
10	4 (20)	2 (8)	10 (50)	4 (25)	4 (29)
12	10 (50)	6 (30)	5 (28)	8 (40)	10 (67)
13	8 (44)	5 (21)	11 (55)	12 (63)	7 (39)
14	3 (14)	5 (22)	4 (22)	8 (47)	9 (56)
16	5 (25)	4 (17)	6 (30)	9 (39)	6 (67)
20	8 (44)	8 (40)	5 (28)	76 (33)	11 (61)
Total	**101 (41)**	**89 (32)**	**97 (38)**	**133 (54)**	**104 (53)**

3.5.3 Uncertainty in allocating inhalation tool parameters- solids

Table 3.5 presents the reported uncertainty for allocating parameters for the inhalation tools for situation with exposure to solid substances.

3.5.3.1 Substance characteristics

The levels of uncertainty reported in allocation of characteristics for solid substances are higher than those for liquids, perhaps because no information on dustiness was provided for any of the situations.

Participants assigning substance characteristics such as dustiness were most uncertain for situation 2 (weighing magnesium stearate) when using the ECETOC TRAv2 (67%) and MEASE (65%). The same percentage of participants using MEASE (65%) reported uncertainty in allocating substance characteristics for situation 11 (weighing of pharmaceuticals). For the ECETOC TRAv3, the choice of substance characteristics resulted in most uncertainty in situation 15 (70%), whilst for the EMKG-EXPO-TOOL, most uncertainty (81%) was associated with situation 17 (exposure to lead fume). This may be related to the tool's range of applicability of the tool- as hot processes are outside its scope and there are no obvious options to describe fumes. Similarly, STOFFENMANAGER does not include input parameters for hot processes. Therefore comparable levels of uncertainty to those for the EMKG-EXPO-TOOL for substance characteristics may have been expected. However, respondents using STOFFENMANAGER (92%) reported most uncertainty when assessing exposure for situation 9 (handling sodium resinate), which is within the range of the tool.

3.5.3.2 Operational Conditions

With the exception of MEASE, allocation of operational conditions for situation 19 caused the participants most uncertainty across all of the tools. The situation involves exposure to fume during aluminium processing and included very limited contextual information. The higher levels of uncertainty reported for this situation may therefore reflect the fact it is outside the scope of all of the tools except MEASE. It should be noted that although process-generated metal fumes are outside of the tools' scope, it is possible to select input parameters for hot processes within the ECETOC TRAv2 and ECETOC TRAv3. For the MEASE tool, situation 11 caused most uncertainty (65%) in relation to operational condition inputs.

3.5.3.3 Task/Activity

Participant using ECETOC TRAv3 (75%) and STOFFENMANAGER (100%) reported high levels of uncertainty in assigning task or activity parameters when estimating exposure for situation 19, which may also be partly related to the scope of the tools and the limited descriptive information provided. Participants using the ECETOC TRAv2 (94%) were most uncertain in allocating a task in situation 11. Users of the EMKG-EXPO-TOOL found most uncertainty with situation 17, which is out of scope of the tool. In addition, as noted previously, the EMKG-EXPO-TOOL does not include an explicit task-related parameter, but rather directs the user to external guidance on common work processes. The level of uncertainty associated with this parameter/tool should be considered accordingly, as if the guidance documents are not used, the task uncertainty relates only indirectly via the choices made for scale of use/ exposures of short duration. Allocation of the task to MEASE inputs gave rise to most uncertainty in situation 2, which relates to sweeping of spilt powder. This is a relatively common cleaning task, albeit representative of poor occupational hygiene practice, however it is not clear why participants seemed to have particular difficulty in deciding on task-related parameters in the tool.

3.5.3.4 Risk management measures

The highest levels of uncertainty for inputting RMM options were reported for all tools for situation 19. As noted previously, this situation contained limited descriptive information, therefore the level of uncertainty is likely to be higher than for situations with more contextual detail.

3.5.3.5 Relative overall level of uncertainty for parameter groups

As for situations involving exposure to liquids, highest uncertainty was reported for assigning inputs relating to “task” for situations with exposure to solid substances. In contrast with exposure to liquids, the allocation of tool input parameters describing “substance characteristics” was only slightly less challenging for participants. As noted above, the lack of provision of information about the dustiness of the substances in the situation descriptions may have increased uncertainty in allocation of tool inputs for this factor. Participants reported similar overall levels of uncertainty for allocation of parameters relating to “operational conditions” and “risk management measures”. The reported percentages of participants experiencing uncertainty in allocating tool inputs for operational conditions and risk management measures for solid substances are also similar to those for exposure to liquids.

Table 3.5 Level of uncertainty in allocating inhalation tool parameters- solids/ Number of participants (%)

Parameter Group	Situation	Inhalation tool (solids)				
		ECETOC TRAv3	ECETOC TRAv2	EMKG-EXPO-TOOL	MEASE	STOFFEN-MANAGER
		Level of uncertainty				
		minor/ major	minor/ major	minor/ major	minor/ major	minor/ major
		N (%)	N (%)	N (%)	N (%)	N (%)
Substance characteristics	2	8 (47)	12 (67)	9 (41)	15 (65)	10 (59)
	9	11 (58)	10 (50)	12 (60)	14 (64)	11 (92)
	11	12 (63)	9 (50)	11 (61)	13 (65)	10 (59)
	15	7 (70)	9 (56)	13 (57)	13 (62)	15 (83)
	17	6 (38)	16 (64)	17 (81)	12 (60)	9 (64)
	18	2 (14)	9 (53)	12 (57)	10 (43)	13 (65)
	19	5 (63)	9 (60)	11 (58)	9 (41)	9(60)
	Total	**51 (50)**	**74 (57)**	**85 (59)**	**86 (57)**	**77 (68)**
Operational conditions	2	5 (29)	7 (39)	5 (23)	7 (30)	11 (65)
	9	6 (32)	8 (40)	9 (45)	11 (50)	8 (67)
	11	9 (47)	8 (44)	7 (39)	13 (65)	14 (82)
	15	2 (20)	5 (31)	10 (43)	9 (43)	10 (56)
	17	9 (56)	14 (56)	13 (62)	9 (45)	8 (57)
	18	4 (29)	6 (35)	11 (52)	11 (48)	13 (65)
	19	6 (75)	11 (73)	16 (84)	11 (50)	14 (93)
	Total	**41 (40)**	**59 (46)**	**71 (49)**	**71 (47)**	**78 (69)**
Task	2	9 (53)	7 (39)	7 (32)	18 (78)	8 (47)
	9	10 (53)	10 (50)	8 (40)	16 (73)	8 (67)
	11	11 (58)	17 (94)	10 (56)	15 (75)	14 (82)
	15	7 (70)	11 (69)	12 (52)	8 (38)	13 (72)
	17	9 (56)	16 (64)	18 (86)	11 (55)	8 (57)
	18	9 (64)	11 (65)	17 (81)	15 (65)	17 (85)
	19	6 (75)	10 (67)	15 (79)	17 (77)	15 (100)
	Total	**61 (59)**	**82 (64)**	**87 (60)**	**100 (66)**	**83 (73)**
Risk management measures	2	2 (12)	1 (6)	8 (36)	6 (26)	3 (18)
	9	11 (58)	12 (60)	13 (65)	13 (59)	8 (67)
	11	5 (26)	8 (44)	8 (44)	10 (50)	11 (65)
	15	4 (40)	10 (63)	6 (26)	13 (62)	10 (56)
	17	6 (38)	6 (24)	13 (62)	11 (55)	9 (64)
	18	1 (8)	4 (24)	7 (33)	6 (26)	6 (30)
	19	7 (88)	13 (87)	17 (89)	17 (77)	15 (100)
	Total	**36 (35)**	**54 (42)**	**72 (50)**	**76 (50)**	**62 (55)**

3.5.4 Uncertainty in allocating dermal tool parameters- liquids

Table 3.06 presents the reported uncertainty for allocating parameters for the dermal exposure tools for situations with exposure to liquid substances.

Table 3.6 Level of uncertainty in allocating dermal tool parameters- liquids/ Number of participants (%)

Parameter Group	Situation	Dermal tool (liquids)				
		ECETOC TRAv3	ECETOC TRAv2	MEASE	RISKOF-DERM (hands)	RISKOF-DERM (body)
		Level of uncertainty				
		minor/ major	minor/ major	minor/ major	minor/ major	minor/ major
		N (%)	N (%)	N (%)	N (%)	N (%)
Substance characteristics	1	2 (10)	2 (10)	7 (44)	15 (37)	15 (37)
	3	3 (18)	1 (5)	3 (14)	17 (39)	17 (39)
	4	0 (0)	5 (29)	3 (14)	9 (21)	-
	5	2 (11)	3 (14)	5 (23)	6 (18)	1 (100)
	6	1 (5)	3 (14)	2 (13)	18 (55)	18 (55)
	7	5 (26)	5 (26)	8 (47)	9 (45)	15 (63)
	8	1 (8)	0 (0)	5 (29)	10 (24)	10 (23)
	10	3 (15)	0 (0)	3 (19)	4 (11)	4 (11)
	12	4 (20)	4 (20)	2 (10)	12 (31)	1 (100)
	13	4 (22)	5 (21)	6 (32)	4 (10)	0 (0)
	14	5 (23)	5 (22)	4 (24)	20 (53)	20 (53)
	16	1 (5)	2(8)	3 (13)	10 (29)	-
	20	1 (6)	1(5)	1 (5)	4 (11)	0 (0)
	Total	**32 (13)**	**36 (13)**	**52 (21)**	**138 (29)**	**101 (38)**
Operational conditions	1	10 (48)	9 (45)	5 (31)	17 (41)	17 (41)
	3	3 (18)	9 (43)	9 (43)	29 (66)	29 (66)
	4	2 (11)	7 (41)	10 (45)	25 (58)	-
	5	11 (58)	9 (41)	8 (36)	24 (71)	1 (100)
	6	8 (36)	7 (32)	7 (44)	16 (48)	16 (48)
	7	10 (53)	9 (47)	9 (53)	15 (75)	16 (67)
	8	5 (42)	4 (22)	10 (59)	23 (56)	24 (56)
	10	5 (25)	3 (12)	4 (25)	17 (47)	17 (46)
	12	12 (60)	9 (45)	10 (50)	22 (56)	1 (100)
	13	9 (50)	10 (42)	11 (58)	23 (58)	1 (17)
	14	9 (41)	6 (26)	10 (59)	25 (66)	25 (66)
	16	5 (25)	7 (29)	10 (43)	20 (57)	-
	20	3 (17)	4 (20)	9 (43)	24 (63)	1 (100)
	Total	**92 (37)**	**93 (34)**	**112 (45)**	**280 (58)**	**148 (55)**
Task	1	9 (43)	12 (60)	8 (50)	22 (54)	22 (54)
	3	5 (29)	6 (29)	11 (52)	35 (80)	35 (80)
	4	7 (39)	10 (59)	14 (64)	36 (84)	-
	5	12 (63)	15 (68)	15 (68)	26 (76)	0 (0)
	6	9 (41)	11 (50)	9 (56)	21 (64)	21 (64)
	7	13 (68)	15 (79)	12 (71)	18 (90)	22 (92)
	8	8 (67)	10 (56)	8 (47)	29 (71)	29 (67)
	10	11 (55)	6 (23)	9 (56)	30 (83)	30 (81)
	12	14 (70)	13 (65)	14 (70)	27 (69)	1 (100)
	13	11 (61)	14 (58)	12 (63)	25 (63)	5 (83)
	14	13 (59)	19 (83)	12 (71)	28 (74)	28 (74)
	16	8 (40)	16 (67)	16 (70)	25 (71)	-
	20	10 (56)	12 (60)	10 (48)	27 (71)	0(0)
	Total	**130 (53)**	**159 (58)**	**150 (61)**	**349 (72)**	**193(72)**
Risk management measures	1	12 (57)	12 (60)	6 (38)	14 (34)	14(34)
	3	6 (35)	4 (19)	12 (57)	22 (50)	22(50)
	4	9 (50)	8 (47)	14 (64)	25 (58)	-
	5	13 (68)	11 (50)	15 (68)	19 (56)	0(0)
	6	8 (36)	7 (32)	5 (31)	11 (33)	11 (33)
	7	13 (68)	10 (53)	11 (65)	9 (45)	16 (67)
	8	6 (50)	2 (11)	10 (59)	20 (49)	21 (49)
	10	1 (5)	2 (8)	4 (25)	8 (22)	8 (22)
	12	15 (75)	10 (50)	10 (50)	18 (46)	1 (100)
	13	10 (56)	13 (54)	14 (74)	18 (45)	3 (50)
	14	3 (14)	5 (22)	5 (29)	15 (39)	15 (39)
	16	11 (55)	7 (29)	9 (39)	14 (40)	-
	20	11 (61)	8 (40)	7 (33)	18 (47)	0 (0)
	Total	**118 (48)**	**99 (36)**	**122 (50)**	**211 (44)**	**111 (41)**

3.5.4.1 Substance characteristics

As for inhalation exposures, the participants reported relatively little uncertainty in allocating tool parameters related to the substances' characteristics, again perhaps because of the standardised vapour pressure data provided with each situation. For ECETOC TRAv3 (26%), MEASE (47%) and RISKOFDERM (body) (63%), situation 7 relating to exposure to N-methyl pyrrolidone during changing of paint-contaminated filters gave rise to most uncertainty in allocation of the substance characteristics.

For the ECETOC TRAv2, situation 4 caused most uncertainty (29%), whilst for exposure via the hands using RISKOFDERM, situation 6 was the source of most uncertainty (55%).

3.5.4.2 Operational Conditions

Situation 7 also caused most uncertainty for participants inputting parameters for operational conditions within the ECETOC TRAv2 (47%), RISKOFDERM (hands) (75%) and RISKOFDERM (body) (67%). Users of MEASE experienced most uncertainty (59%) in assigning operational conditions in situations 8 and 14, whilst those using the ECETOC TRAv3 experienced most uncertainty for situation 12 (60%).

3.5.4.3 Task/Activity

Allocation of task/ activity descriptors was again the cause of significant uncertainty for participants. There was some consistency across the tools regarding the situations which caused most uncertainty. For the ECETOC TRAv2, situation 14 led to most uncertainty (83%). Situation 14 and situation 7 (both 71%) also led to most uncertainty for MEASE users. Participants using RISKOFDERM for estimates of body exposure also found situation 7 gave rise to uncertainty (92%) in relation to task selection, whilst those estimating exposure for hands using the tool experienced most uncertainty for situation 4 (84%). Inputting task parameters in the ECETOC TRAv3 caused participants most uncertainty (70%) in situation 12.

3.5.4.4 Risk management measures

The level of uncertainty in allocation of RMMs was not consistent across situations for the various tools. For the ECETOC TRAv3, situation 12 caused most uncertainty (75%), whilst for the ECETOC TRAv2, it was situation 1 (60%). MEASE users experienced most uncertainty (74%) in situation 13. RISKOFDERM inputs for hand exposures were most uncertain in situation 4 (58%), whilst for body exposures inputting situation 7 into the tool caused most uncertainty (67%).

3.5.4.5 Relative overall level of uncertainty for parameter groups

As for situations involving inhalation exposures, the allocation of the task/ activity generated most overall uncertainty for the participants across all of the dermal tools. Uncertainty in the allocation of operational conditions and RMMs was however more evident for dermal exposures to liquids than for the inhalation tools.

3.5.5 Uncertainty in allocating dermal tool parameters- solids

Table 3.7 presents the reported uncertainty for allocating dermal tool parameters for situations with exposure to solid substances.

Table 3.7 Level of uncertainty in allocating dermal tool parameters- solids/Number of participants (%)

Parameter Group	Situation	Dermal tool (solids)				
		ECETOC TRAv3	ECETOC TRAv2	MEASE	RISKOF-DERM (hands)	RISKOF-DERM (body)
		Level of uncertainty				
		minor/ major	minor/ major	minor/ major	minor/ major	minor/ major
		N (%)	N (%)	N (%)	N (%)	N (%)
Substance characteristics	2	8 (47)	11 (61)	15 (65)	13 (46)	10 (59)
	9	10 (50)	11 (55)	14 (64)	24 (69)	-
	11	12 (63)	10 (56)	13 (65)	25 (64)	-
	15	7 (70)	7 (44)	11 (52)	31 (70)	0 (0)
	17	6 (38)	13 (52)	10 (50)	14 (40)	8 (50)
	18	2 (14)	8 (47)	11 (48)	24 (52)	1 (100)
	19	5 (63)	9 (60)	8 (36)	15 (45)	5 (71)
	Total	**50 (48)**	**69 (53)**	**82 (54)**	**146 (56)**	**24 (57)**
Operational conditions	2	4 (24)	8 (44)	8 (35)	9 (32)	9 (53)
	9	8 (40)	8 (40)	11 (50)	18 (51)	-
	11	8 (42)	8 (44)	13 (65)	27 (69)	-
	15	2 (20)	5 (31)	9 (43)	22 (50)	1 (100)
	17	7 (44)	14 (56)	11 (55)	19 (54)	8 (50)
	18	3 (21)	6 (35)	12 (52)	30 (65)	1 (100)
	19	5 (63)	11 (73)	12 (55)	23 (70)	6 (86)
	Total	**37 (36)**	**60 (47)**	**76 (50)**	**148 (57)**	**25 (60)**
Task	2	8 (47)	8 (44)	18 (78)	19 (68)	13 (76)
	9	11 (55)	10 (50)	17 (77)	20 (57)	-
	11	11 (58)	17 (94)	14 (70)	32 (82)	-
	15	7 (70)	10 (63)	8 (38)	33 (75)	0 (0)
	17	8 (50)	14 (56)	10 (50)	29 (83)	14 (88)
	18	9 (64)	11 (65)	17 (74)	43 (93)	1 (100)
	19	5 (63)	9 (60)	17 (77)	30 (91)	6 (86)
	Total	**59 (57)**	**79 (61)**	**101 (67)**	**205 (79)**	**34 (81)**
Risk management measures	2	3 (18)	1 (6)	8 (35)	11 (39)	7 (41)
	9	12 (60)	11 (55)	15 (68)	22 (63)	-
	11	7 (37)	8 (44)	10 (50)	13 (33)	-
	15	3 (30)	4 (25)	9 (43)	15 (34)	0 (0)
	17	9 (56)	6 (24)	7 (35)	17 (49)	10 (63)
	18	2 (14)	4 (24)	5 (22)	19 (41)	0 (0)
	19	7 (88)	13 (87)	18 (82)	31 (94)	7 (100)
	Total	**43 (41)**	**47 (36)**	**72 (48)**	**128 (49)**	**24 (57)**

3.5.4.6 Substance characteristics

The levels of uncertainty in allocation of solid substance characteristics in the dermal tools were similar to those for the inhalation tools, and it is suggested that the reason for this is also similar, i.e. the absence of supplied information on dustiness levels. Situation 2 gave rise to most uncertainty for users of the ECETOC TRAv2 (61%) and MEASE (65%). MEASE users also experienced similar uncertainty (65%) when allocating substance parameters in situation 11. Situation 15 resulted in most uncertainty for the ECETOC TRAv3 (70%) and RISKOFDERM (hands) (70%), whilst for RISKOFDERM (body) situation 19 caused most uncertainty (71%). As situation 19 is out of scope for the tool, with no obvious suitable options for fume exposures, this is not unexpected.

3.5.4.7 Operational conditions

There was some consistency in the level of reported uncertainty for the different situations between the tools. With exception of MEASE, the reported uncertainty for all of the tools was highest for situation 19: ECETOC TRAv3 users (63%), ECETOC TRAv2 (73%), RISKOFDERM (body) (86%) and RISKOFDERM (hands) (70%). Situation 11 caused most uncertainty for MEASE users (65%). Relatively low levels of uncertainty were reported for situation 15 for users of the ECETOC TRA v3 (20%) and ECETOC TRAv2 (31%) and situation 2 for MEASE (35%).

3.5.4.8 Task/ Activity

The levels of uncertainty experienced in describing tasks using the dermal tools were similar to those for the inhalation assessments for those tools which provide both types of estimate. The overall percentage of participants experiencing uncertainty in allocation of task, i.e. DEO in RISKOFDERM was slightly higher for both hands (79%) and body (81%) estimates than for the other tools (57-67%). Participants varied greatly in the situation which they found most uncertain for task, with situation 18 causing most uncertainty for those using the RISKOFDERM tool for exposure to the hands (93%), whilst situation 11 resulted in most uncertainty (94%) for users of the ECETOC TRAv2. Situation 15 gave rise to most uncertainty for ECETOC TRAv3 users (70%), whilst participants using MEASE experienced most uncertainty when allocating task parameters for situation 2 (78%). Users of the RISKOFDERM tool reported most uncertainty for situation 17 (88%) in allocation of task when estimating body exposures. Reported uncertainty for allocating task and activity related parameters was therefore considered to be high across all situations and tools, with no obvious situations that resulted in lower or higher reported uncertainties.

3.5.4.9 Risk management measures

Uncertainty to allocate tool parameters for RMMs was highest in situation 19 for all the tools, which is likely to reflect its limited contextual information, with relatively high uncertainties also reported for situation 9 across the tools.

3.5.4.10 Relative overall level of uncertainty for parameter groups

As for inhalation, task/ activity parameter allocation was again the source of most uncertainty for the participants when assessing dermal exposures to solids, followed by substance characteristics. Levels of uncertainty in allocation of the two other parameter types, operational conditions and risk management measures were similar for dermal exposures.

3.6 Ease of translation of situation into tool parameters

Participants were asked to indicate the overall ease of translation of the situation into the required inhalation and dermal tool input parameters. The results by inhalation and dermal tool type across all situations are shown below in Tables 3.8 and 3.9.

Table 3.8 Participants' ease of translation of situation into inhalation tool parameters (across all situations)/ Number of participants (%)

Tool	Ease of Translation into Inhalation Tool Parameters				
	Very easy/ easy	**Neither easy nor difficult**	**Difficult/ very difficult**	**Missing**	**Total**
ECETOC TRAv2	72 (49)	24 (16)	9 (6)	41 (28)	146
ECETOC TRAv3	53 (36)	34 (23)	15 (10)	44 (30)	146
EMKG-EXPO-TOOL	65 (45)	27 (18)	12 (8)	42 (29)	146
MEASE	62 (42)	30 (21)	13 (9)	41 (28)	146
STOFFENMANAGER	40 (27)	42 (29)	20 (14)	44 (30)	146

In general, participants did not report having a great deal of difficulty in translating the information in the situations into the required inhalation tool parameters, with the proportion choosing "difficult/ very difficult" relatively small compared with the categories "very easy/ easy" and "neither easy nor difficult". A slightly higher overall percentage of participants found translation of the situations into STOFFENMANAGER more difficult than for the other tools.

Table 3.9 Participants' ease of translation of situation into dermal tool parameters (across all situations)/ Number of participants (%)

Tool	Ease of Translation into Dermal Tool Parameters				
	Very easy/ easy	**Neither easy nor difficult**	**Difficult/ very difficult**	**Missing**	**Total**
ECETOC TRAv2	68 (47)	25 (17)	13 (9)	40 (27)	146
ECETOC TRAv3	51 (35)	32 (22)	20 (14)	43 (29)	146
MEASE	56 (38)	31 (21)	17 (12)	42 (29)	146
RISKOFDERM	34 (23)	41 (28)	30 (21)	41 (28)	146

Slightly higher numbers of participants chose "difficult/ very difficult" to describe how they found translation of situations into the dermal tools, compared with the inhalation tools. Participants reported more difficulty in translating the situations into RISKOFDERM (28%) compared with the other tools (9-14%). This is perhaps related to the requirement to make more explicit choices in the RISKOFDERM tool compared with the ECETOC TRAv2, ECETOC TRAv3 and MEASE. In the ECETOC tools, the inhalation and dermal parameters are in the main combined, whilst in MEASE the dermal inputs were perhaps not perceived by all participants as being different to those for inhalation.

The percentage of participants who found translation of the situation into tool input parameters difficult or very difficult is shown by situation, tool, exposure route and physical form in Tables 3.10-3.13.

Table 3.10 Participants reporting difficulty in translation into inhalation tool input parameters by situation and tool – liquids/Number of participants (%)

	Inhalation tool (liquids)				
	ECETOC TRAv3	**ECETOC TRAv2**	**EMKG-EXPO-TOOL**	**MEASE**	**STOFFEN-MANAGER**
Situation	**Ease of translation**				
	difficult/ very difficult	**difficult/ very difficult**	**difficult/ very difficult**	**difficult/ very difficult**	**difficult/ very difficult**
	N (%)	N (%)	N (%)	N (%)	N (%)
1	2 (10)	3 (15)	3 (14)	0 (0)	0 (0)
3	3 (18)	0 (0)	1 (4)	3 (14)	6 (40)
4	1 (6)	1 (6)	2 (9)	0 (0)	3 (19)
5	3 (16)	3 (14)	4 (22)	3 (14)	5 (38)
6	3 (14)	0 (0)	0 (0)	1 (6)	0 (0)
7	8 (42)	9 (47)	5 (28)	6 (35)	9 (56)
8	1 (8)	1 (6)	3 (13)	1 (6)	4 (22)
10	0 (0)	0 (0)	5 (25)	2 (13)	2 (14)
12	1 (5)	1 (5)	0 (0)	1 (5)	4 (27)
13	2 (11)	0 (0)	4 (20)	3 (16)	5 (28)
14	4 (18)	3 (13)	4 (22)	3 (18)	2 (13)
16	1 (5)	0 (0)	2 (10)	0 (0)	5 (56)
20	0 (0)	1 (5)	0 (0)	3 (14)	4 (22)

For all of the tools for situations involving inhalation exposure to liquid substances, participants reported most overall difficulty (i.e. ease of translation= “difficult + very difficult”) in translating the description given in situation 7 into the necessary input parameters. Participants using STOFFENMANAGER also reported relatively high levels of difficulty in translation for situations 16 (56%), 3 (40%) and 5 (38%).

Table 3.11 Participants reporting difficulty in translation into inhalation tool input parameters by situation and tool – solids/Number of participants (%)

	Inhalation tool (solids)				
	ECETOC TRAv3	**ECETOC TRAv2**	**EMKG-EXPO-TOOL**	**MEASE**	**STOFFEN-MANAGER**
			Ease of translation		
Situation	**difficult/ very difficult** N (%)	**difficult/ very difficult** N (%)	**difficult/ very difficult** N (%)	**difficult/ very difficult** N (%)	**difficult/ very difficult** N (%)
2	2 (12)	3 (17)	3 (14)	6 (26)	2 (12)
9	3 (16)	0 (0)	3 (15)	2 (9)	2 (17)
11	2 (11)	2 (11)	2 (11)	4 (20)	6 (35)
15	1 (10)	0 (0)	3 (13)	2 (10)	2 (11)
17	3 (19)	11 (44)	13 (62)	4 (20)	6 (43)
18	1 (7)	4 (24)	4 (19)	3 (13)	7 (35)
19	4 (50)	5 (33)	10 (53)	5 (23)	13 (87)

For situations involving inhalation exposure to solids, participants using the ECETOC TRAv3 (50%) and STOFFENMANAGER (87%) reported most difficulty in translating situation 19 into the tools, whilst users of the TRAv2 (44%) and EMKG-EXPO-TOOL (62%) found situation 17 most challenging. Those who used MEASE indicated most difficulty in translating situation 2 into the tool (26%).

Table 3.12 Participants reporting difficulty in translation into dermal tool input parameters by situation and tool – liquids/Number of participants (%)

	Dermal tool (liquids)				
	ECETOC TRAv3	**ECETOC TRAv2**	**MEASE**	**RISKOFDERM (hands)**	**RISKOFDERM (body)**
			Ease of translation		
Situation	**difficult/ very difficult**	**difficult/ very difficult**	**difficult/ very difficult**	**difficult/ very difficult**	**difficult/ very difficult**
1	2 (10)	7 (35)	1 (6)	3 (7)	3 (7)
3	3 (18)	1 (5)	3 (14)	11 (25)	11 (25)
4	0 (0)	2 (12)	2 (9)	18 (42)	0 (0)
5	2 (11)	3 (14)	2 (9)	13 (38)	0 (0)
6	1 (5)	1 (5)	1 (6)	5 (15)	5 (15)
7	5 (26)	11 (58)	5 (29)	9 (45)	16 (67)
8	1 (8)	0 (0)	1 (6)	11 (27)	12 (28)
10	3 (15)	0 (0)	2 (13)	6 (17)	6 (16)
12	4 (20)	1 (5)	1 (5)	6 (15)	0 (0)
13	4 (22)	0 (0)	3 (16)	19 (48)	3 (50)
14	5 (23)	3 (13)	3 (18)	14 (37)	14 (37)
16	1 (5)	0 (0)	1 (4)	12 (34)	0 (0)
20	1 (6)	1 (5)	1 (5)	8 (21)	0 (0)

For situations involving dermal exposure to liquids, participants using the ECETOC TRAv3 (26%), ECETOC TRAv2 (58%) and MEASE (29%) found most difficulty in translating situation 7 into the tool parameters. For RISKOFDERM hands (48%) and

RISKOFDERM body (67%), situation 13 and situation 7 respectively were most difficult to translate into the tool inputs.

Table 3.13 Participants reporting difficulty in translation into dermal tool input parameters by situation and tool – solids/Number of participants (%)

Situation	Dermal tool (solids)				
	ECETOC TRAv3	ECETOC TRAv2	MEASE	RISKOFDERM (hands)	RISKOFDERM (body)
	Ease of translation				
	difficult/ very difficult	difficult/ very difficult	difficult/ very difficult	difficult/ very difficult	difficult/ very difficult
2	2 (12)	2 (11)	6 (26)	12 (43)	12 (71)
9	4 (20)	1 (5)	2 (9)	8 (23)	0 (0)
11	2 (11)	2 (11)	5 (25)	13 (33)	0 (0)
15	1 (10)	2 (13)	3 (14)	11 (25)	0 (0)
17	4 (25)	10 (40)	3 (15)	15 (43)	9 (56)
18	1 (7)	4 (24)	3 (13)	16 (35)	0 (0)
19	4 (50)	4 (27)	6 (27)	25 (76)	4 (57)

For situations where there was dermal exposure to solids, participants using the ECETOC TRAv3 (50%), MEASE (27%) and RISKOFDERM hands (76%) found situation 19 most difficult to translate into tool inputs. Those using the ECETOC TRAv2 found situation 17 most difficult (40%), whilst translating situation 2 into the tool parameters for obtaining a body estimate using RISKOFDERM was most difficult for the relevant participants (71%).

The impact of level of uncertainty and ease of translation on the exposure estimates was also assessed using statistical modelling, with residual variation and associated geometric standard deviations (GSDs) calculated.

Tables 3.14 and 3.15 provide the geometric standard deviations for the residual variation by tool for the various uncertainty levels associated with different groups of input parameters. This was done to investigate if higher levels of uncertainty was associated with higher variation in the exposure estimates obtained using the tools. However, no consistent patterns could be observed which could suggest that this was the case. There was some spread in the reported GSDs, but these could easily have been caused by chance, rather than reflecting real differences in the observed GSDs. In addition, the highest GSDs were just as often observed for categories of low uncertainty as for categories of high uncertainty. Hence, there does not appear to be any evidence that the level of uncertainty is associated with a greater variability in exposure estimates obtained by the tools for both inhalation and dermal exposure.

The results in relation to ease of translation on the spread of inhalation and dermal estimates were similarly inconclusive, with high GSDs associated both with high and low ease of translation of situations into the tool inputs.

Table 3.14 Geometric standard deviations for the residual variation by tool, physical form and parameter type (inhalation)

	ECETOC TRAv3				**ECETOC TRAv2**				**MEASE**				**EMKG-EXPO-TOOL**				**STOFFENMANAGER**			
	Liquid		**Solid**		**Liquid**		**Solid**		**Liquid**		**Solid**		**Liquid**		**Solid**		**Liquid**		**Solid**	
	N	**GSD**	**N**	**GSD**	**N**	**GSD**	**N**	**GSD**	**N**	**GSD**	**N**	**GSD**	**N**	**GSD**	**N**	**GSD**	**N**	**GSD**	**N**	**GSD**
Uncertainty in allocation of parameters relating to Substance Characteristics (inhalation)																				
Missing	2	63	0	*	1	*	0	*	0	*	1	*	2	123	2	3.6	4	2.0	2	1.5
None	214	3.7	52	7.7	242	2.9	55	7.2	194	13	64	10	182	5.4	57	7.1	149	2.7	34	3.7
Minor	26	2.6	32	4.2	24	2.5	51	5.1	49	14	53	4.6	58	4.4	58	8.0	32	2.2	53	2.6
Major	5	6.0	19	9.7	9	2.3	23	3.2	4	41	33	5.4	11	8.0	27	10	11	2.8	24	7.8
Total	247	3.7	103	6.8	276	2.8	129	5.6	247	13	151	6.8	253	5.3	144	7.8	196	2.6	113	3.9
Uncertainty in allocation of parameters relating to Operational Conditions (inhalation)																				
Missing	2	62	0	*	2	1.6	0	*	0	*	1	*	2	121	2	3.6	4	2.1	2	1.6
None	148	4.0	62	6.8	176	3.1	70	6.5	139	11	79	5.1	138	5.6	71	7.4	56	2.5	33	2.9
Minor	84	3.0	31	7.4	83	2.1	51	3.9	92	17	60	8.0	92	4.6	46	8.8	100	2.7	49	2.8
Major	13	3.5	10	9.1	15	2.4	8	6.7	16	9.9	11	14	21	6.1	25	8.2	36	2.3	29	7.1
Total	247	3.7	103	7.1	276	2.7	129	5.3	247	13	151	6.8	253	5.3	144	7.8	196	2.5	113	3.8
Uncertainty in allocation of parameters relating to Task (inhalation)																				
Missing	2	63	0	*	1	*	0	*	3	2.8	1	*	4	24	4	2.7	4	2.0	2	1.6
None	111	2.9	42	6.6	118	3.0	47	6.5	95	9.6	50	6.7	109	5.9	53	6.6	39	4.0	28	2.2
Minor	102	4.1	40	8.4	118	2.2	61	5.4	120	15	72	6.2	103	5.0	48	5.2	103	2.2	50	3.0
Major	32	4.6	21	6.3	39	4.2	21	4.2	29	21	28	9.4	37	4.3	39	16	50	2.4	33	7.2
Total	247	3.7	103	7.1	276	2.8	129	5.5	247	13	151	6.8	253	5.4	144	7.9	196	2.6	113	3.9
Uncertainty in allocation of parameters relating to Risk Management Measures (inhalation)																				
Missing	2	63	0	*	2	3.0	0	*	1	*	1	*	3	30	2	3.8	4	2.1	2	1.6
None	144	3.8	67	6.5	185	3.0	75	6.0	113	12	74	7.0	153	5.9	70	7.8	88	3.0	49	2.9
Minor	89	3.3	23	7.8	74	2.4	39	5.3	108	14	54	6.8	72	4.3	46	7.8	77	2.2	45	2.4
Major	12	3.8	13	11	15	2.8	15	4.2	25	8.9	22	6.3	25	4.4	26	8.4	27	2.2	17	14
Total	247	3.7	103	7.2	276	2.8	129	5.5	247	13	151	6.9	253	5.3	144	7.8	196	2.6	113	3.9
Ease of Translation of situation into tool (inhalation)																				
Missing	2	64	1	*	2	120	0	*	0	*	1	*	5	19	5	11	10	2.2	4	1.4
Very Easy	32	2.6	12	5.5	53	1.9	12	5.3	28	8.5	11	17	41	4.5	21	4.6	5	2.3	4	5.5
Easy	119	3.5	41	8.7	137	2.6	57	6.8	120	12	57	5.0	89	4.9	52	4.8	56	2.5	27	2.5
Neither	65	2.9	33	7.1	62	2.7	35	5.7	73	14	56	7.5	85	6.0	28	11	76	2.8	40	2.9
Difficult	24	4.9	14	6.1	21	2.7	21	2.1	25	17	23	3.5	30	4.6	31	12	45	2.3	31	2.7
Very Diff	5	43	2	6.5	1	*	4	2.2	1	*	3	8.5	3	8.3	7	19	4	1.3	7	39
Total	247	3.7	103	7.1	276	2.6	129	5.3	247	13	151	6.4	253	5.3	144	7.6	196	2.5	113	3.7

Table 3.15 Geometric standard deviations for the residual variation by tool, physical form and parameter type (dermal)

	ECETOC TRAv3				ECETOC TRAv2				MEASE				RISKOFDERM (hands)				RISKOFDERM (body)			
	Liquid		Solid		Liquid		Solid		Liquid		Solid		Liquid		Solid		Liquid		Solid	
	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD
Uncertainty in allocation of parameters relating to Substance Characteristics																				
Missing	1	*	2	1.8	2	1.4	1	*	0	*	0	*	3	4.4	3	5.9	2	1.2	0	*
None	213	2.7	52	3.7	238	2.3	59	3.3	195	5.3	69	5.9	341	10	111	15	166	10	18	14
Minor	26	2.8	35	3.5	29	3.0	43	2.7	47	7.0	52	6.8	101	6.0	102	14	68	5.8	13	7.5
Major	6	3.9	15	4.7	7	2.1	26	3.8	5	5.5	30	5.3	37	11	44	14	33	9.4	11	4.7
Total	246	2.7	104	3.7	276	2.4	129	3.2	247	5.6	151	6.0	482	9.1	260	14	269	8.9	42	8.8
Uncertainty in allocation of parameters relating to Operational Conditions (dermal)																				
Missing	1	*	1	*	2	1.4	1	*	0	*	0	*	2	6.0	1	*	1	*	0	*
None	153	3.0	66	3.9	181	2.5	68	3.0	135	5.4	75	6.7	200	9.8	111	13	120	12	17	15
Minor	79	2.1	28	3.2	81	2.4	50	3.5	96	6.1	61	5.4	187	6.9	99	14	95	5.5	14	6.2
Major	13	3.8	9	5.9	12	2.8	10	3.5	16	4.5	15	6.1	93	13	49	16	53	10	11	5.7
Total	246	2.8	104	3.8	276	2.4	129	3.2	247	5.6	151	6.1	482	9.1	260	14	269	8.9	42	8.8
Uncertainty in allocation of parameters relating to Task (dermal)																				
Missing	1	*	0	*	1	*	1	*	1	*	0	*	1	*	3	4.1	0	*	0	*
None	115	2.5	45	4.0	116	2.4	49	3.0	96	5.0	50	6.1	132	8.9	51	10	76	12	8	12
Minor	95	3.0	39	4.0	118	2.3	57	3.6	118	6.3	69	6.8	203	6.9	100	13	115	9.0	16	14
Major	35	3.1	20	3.4	41	3.0	22	2.8	32	4.6	32	5.0	146	13	106	17	78	6.9	18	5.4
Total	246	2.7	104	3.9	276	2.4	129	3.1	247	5.5	151	6.1	482	9.1	260	14	269	9.1	42	8.9
Uncertainty in allocation of parameters relating to Risk Management Measures (dermal)																				
Missing	1	*	0	*	1	*	1	*	0	*	0	*	1	*	2	1.4	0	*	0	*
None	127	2.9.	61	3.9	176	2.3	81	2.6	125	5.4	79	6.3	270	9.4	130	12	158	10	18	16
Minor	91	2.8	27	4.0	74	2.9	28	3.3	99	6.3	54	5.6	158	9.0	87	15	77	8.7	16	4.9
Major	27	2.3	16	3. 5	25	2.0	19	4.8	23	3.8	18	7.0	53	8.5	41	18	34	5.0	8	6.3
Total	246	2.8	104	3.9	276	2.4	129	3.1	247	5.6	151	6.1	482	9.1	260	14	269	9.1	42	8.8
Ease of Translation of situation into tool (dermal)																				
Missing	1	*	1	*	2	2.3	0	*	0	*	0	*	6	3.0	2	240	1	*	0	*
Very Easy	31	2.1	13	5.2	50	2.1	10	3.1	30	5.7	11	12	19	18	8	7.5	13	22	1	*
Easy	115	2.8	42	3.7	127	2.3	52	3.3	116	5.4	53	5.4	153	9.3	64	9.6	89	5.9	6	4.9
Neither	67	2.53	30	4.4	67	2.7	42	3.4	75	5.9	59	5.5	169	7.7	86	12	96	10	10	6.7
Difficult	26	3.7	16	3.4	28	2.9	20	2.8	25	4.8	23	5.5	117	11	82	18	58	8.6	19	13
Very Diff	6	11	2	3.3	2	1.5	5	2.1	1	*	5	16	18	8.1	18	15	12	20	6	5.0
Total	246	2.8	104	4.0	276	2.4	129	3.2	247	5.5	151	6.0	482	9.1	260	14	269	8.9	42	8.8

3.7 Participants' perception of the level of over/underestimation of the exposure estimate

Following completion of each tool-situation combination, the participants were asked to give their opinion on the degree of over- or underestimation of exposure by the tool(s) used, i.e. the tools' level of conservatism. The responses to this question are shown in Table 3.16.

Table 3.16 Participants' perception of the level of conservatism in tool estimates (across all situations)/ Number of participants

Tool Type	Greatly over-estimated exposure	Appropriately over-estimated exposure	Appropriately Under-estimated exposure	Greatly under-estimated exposure	Don't know	Missing	Total
Inhalation	180	832	179	17	698	127	2033
Dermal	339	560	128	27	935	44	2033

The majority of participants felt that overall, the tools either greatly or appropriately overestimated exposures, however there were a significant number of participants who did not know whether the estimates generated were conservative. A difference in participant perceptions relating to the level of conservatism for dermal tools compared with inhalation tools was reported. Comparatively larger numbers of participants indicated that they felt that the tools greatly overestimated dermal exposure, with the number of participants who did not know whether or not the tools were conservative also higher for dermal estimates. Workshop delegates also reported difficulty in visualising/ perceiving the magnitude of dermal exposures. Dermal exposures are in general less frequently assessed than those via inhalation, with no standard measurement technique widely used. As a consequence, less emphasis is perhaps placed on this route in industrial hygiene training and practice, resulting in lower levels of knowledge and familiarity amongst practitioners.

3.8 Feedback questionnaire

Information collected from participants using the final feedback questionnaire is summarised below.

3.8.1 Completion of Exercise

All 20 tool/ situation combinations were completed by 70 participants. The reasons for partial/ non-completion given by those participants who did not assess all of their allocated combinations are shown in Figure 3.15.

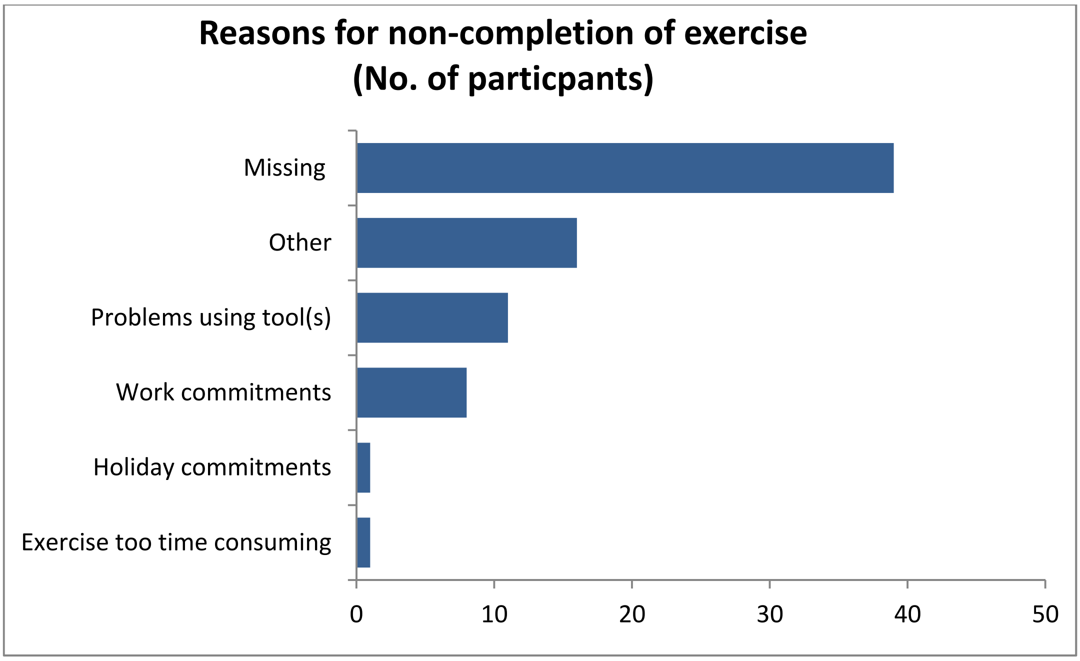

Figure 3.15 Participants' reasons for non-completion of exercise

3.8.2 Usefulness of BURE documentation

Participants were asked for their opinion on the usefulness of the documentation and guidance supplied by the project team to assistance them in completion of the exercise. The responses are illustrated in Figure 3.16.

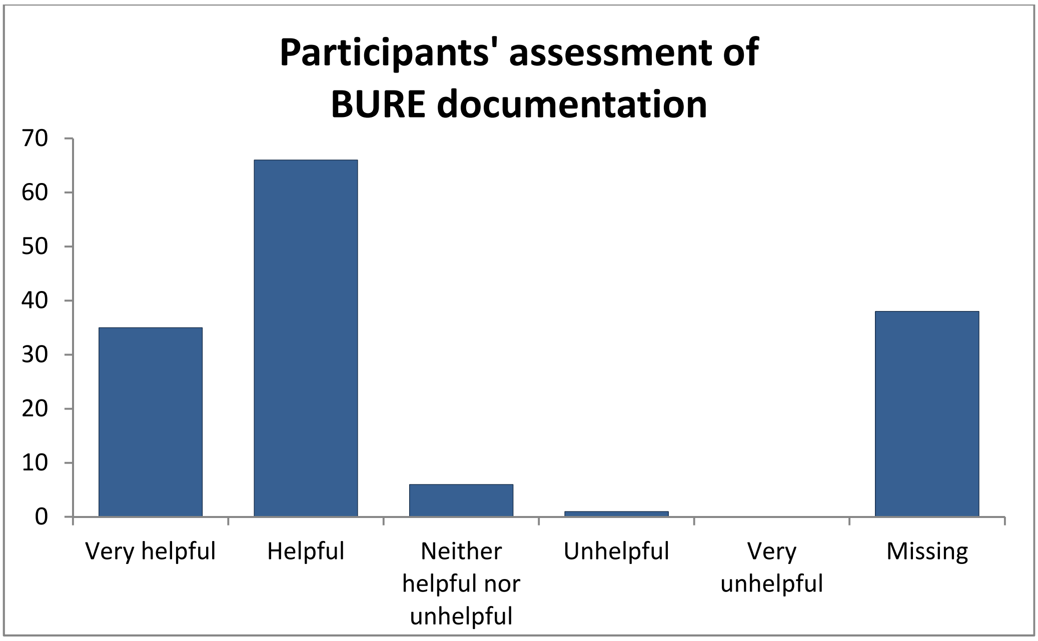

Figure 3.16 Participants' assessment of BURE documentation

The majority of participants found the worksheets, instructions and other documentation provided by the project team to be of assistance during the exercise.

3.8.3 Utility of help functions within tools

Participants were asked to grade the level of helpfulness of the guidance and help functions provided within the tools. The majority of participants found the information given in all of the tools useful. The results are shown in Figure 3.17 below.

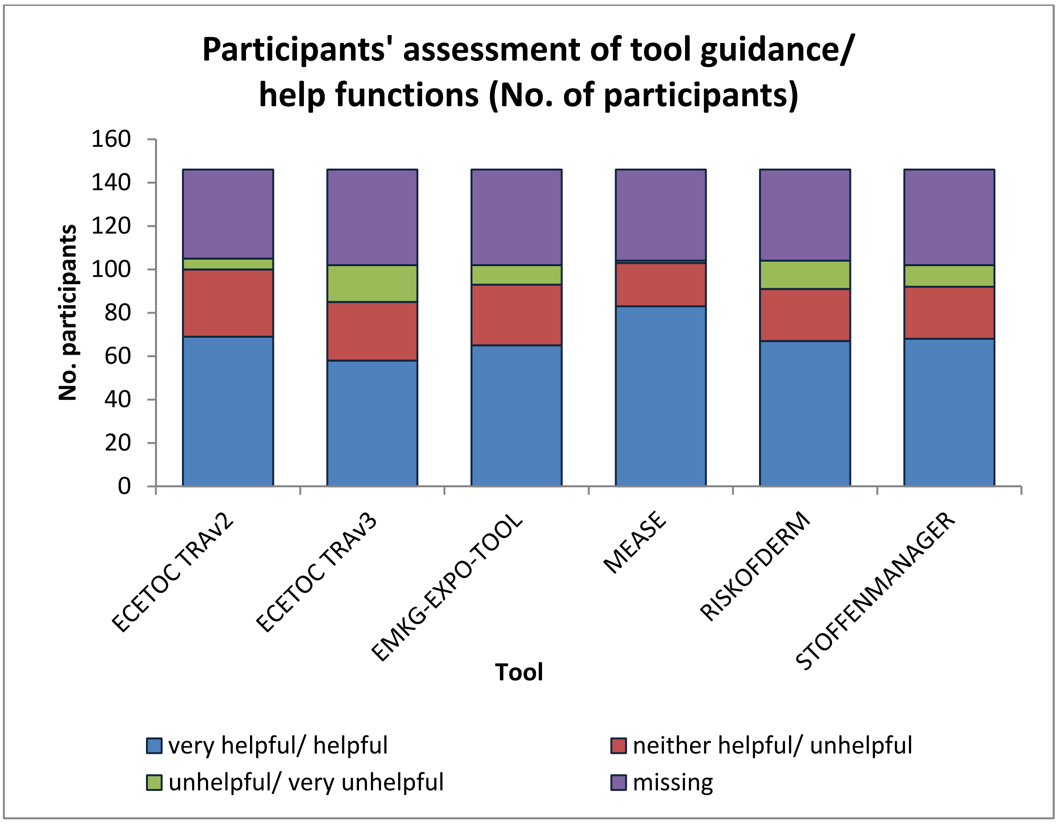

Figure 3.17 Participants' assessment of tool guidance and help functions

3.8.4 Level of over-/underestimation of exposure by tools

Participants were asked for their opinion on the degree of over or underestimation by the tools in general (i.e. not in relation to a specific exposure situation). The results across all situations are shown in Figures 3.18 and 3.19 for the inhalation and dermal tools respectively.

In general, the participants felt that the tools either greatly or appropriately overestimated inhalation exposure, however for all of the tools, around 25% of participants felt that the tool sometimes overestimated and sometimes underestimated exposures or underestimated exposure. The estimates provided by the dermal tools were also in general felt to either greatly or appropriately overestimate exposure. As for the inhalation tools, around a quarter of participants felt that the tools sometimes overestimated and sometimes underestimated exposure.

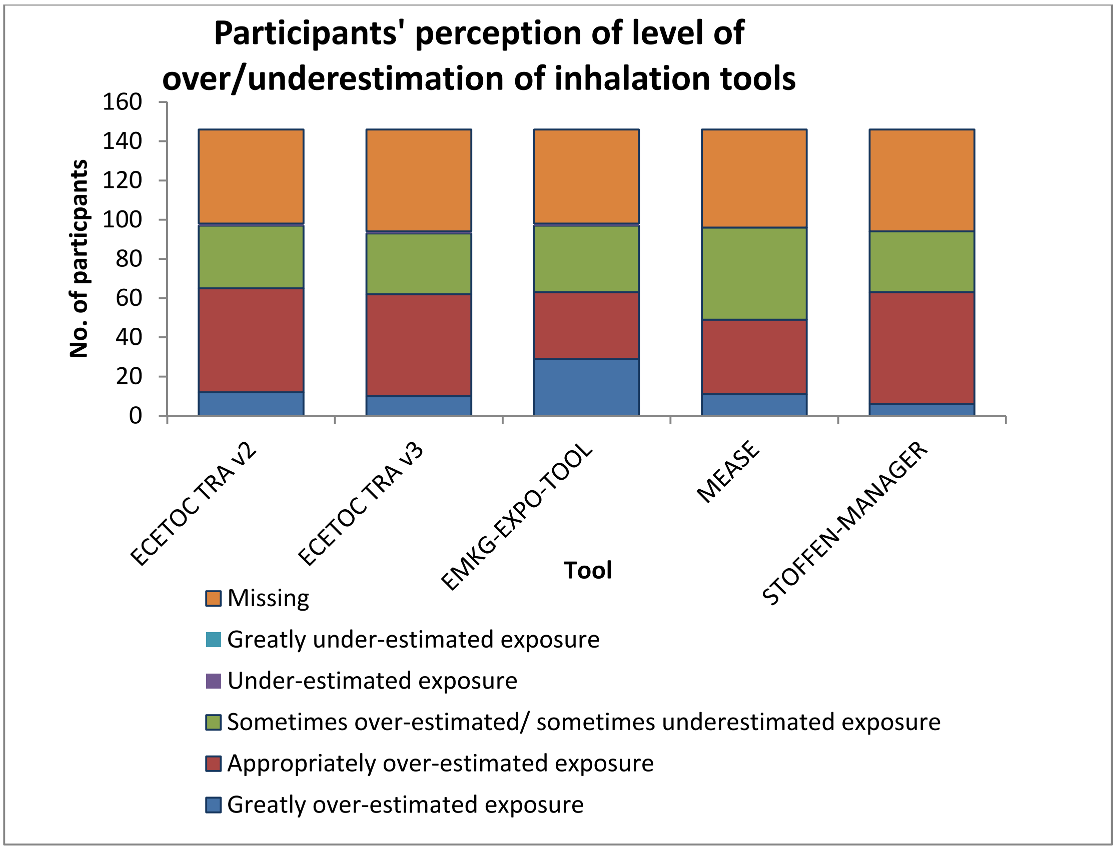

Figure 3.18 Participants' perception of level of inhalation tool over/ under estimation

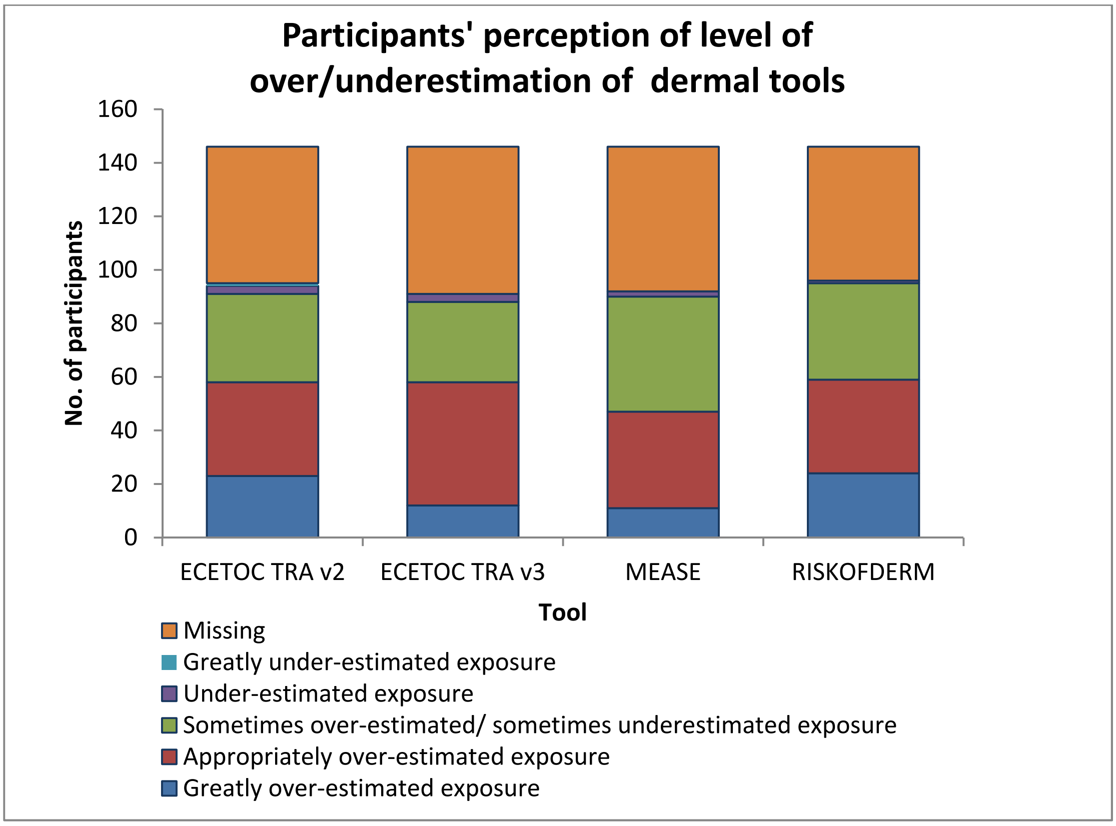

Figure 3.19 Participants' perception of level of dermal tool over/ under estimation

3.8.5 Participants' perception of ease of use of tools at start and end of the BURE

Participants were asked to grade their ease of use of the tools at the start and end of the BURE. The results are given in Table 3.17. For all of the tools, the participants reporting that they found using the tools "very easy" or "easy" increased during the exercise. The numbers of participants reporting that they found the tools "difficult" or very difficult" to use reduced similarly across all of the tools between the start and finish of the BURE.

Table 3.17 Participants' assessment of ease of use of tools at the start and after the BURE/ Number of participants

	Ease of use											
Tool	**very easy**		**easy**		**neither easy nor difficult**		**difficult**		**very difficult**		**missing**	
	start	after	start	after	start	after	start	after	start	after	start	after
ECETOC TRAv2	26	38	52	53	17	12	12	1	1	0	38	42
ECETOC TRAv3	14	18	31	48	26	29	23	6	12	2	40	43
EMKG-EXPO-TOOL	26	41	39	47	33	12	6	3	1	1	41	42
MEASE	16	35	53	57	26	9	9	2	1	1	41	42
RISKOFDERM	8	13	32	50	36	32	28	8	1	1	41	42
STOFFENMANAGER	4	9	30	52	40	30	25	9	5	1	42	45

3.8.6 Participants' intention to use tools in the future

Participants were asked if they intended to use the tools assessed in the BURE in the future, and their responses are shown in Figure 3.19.

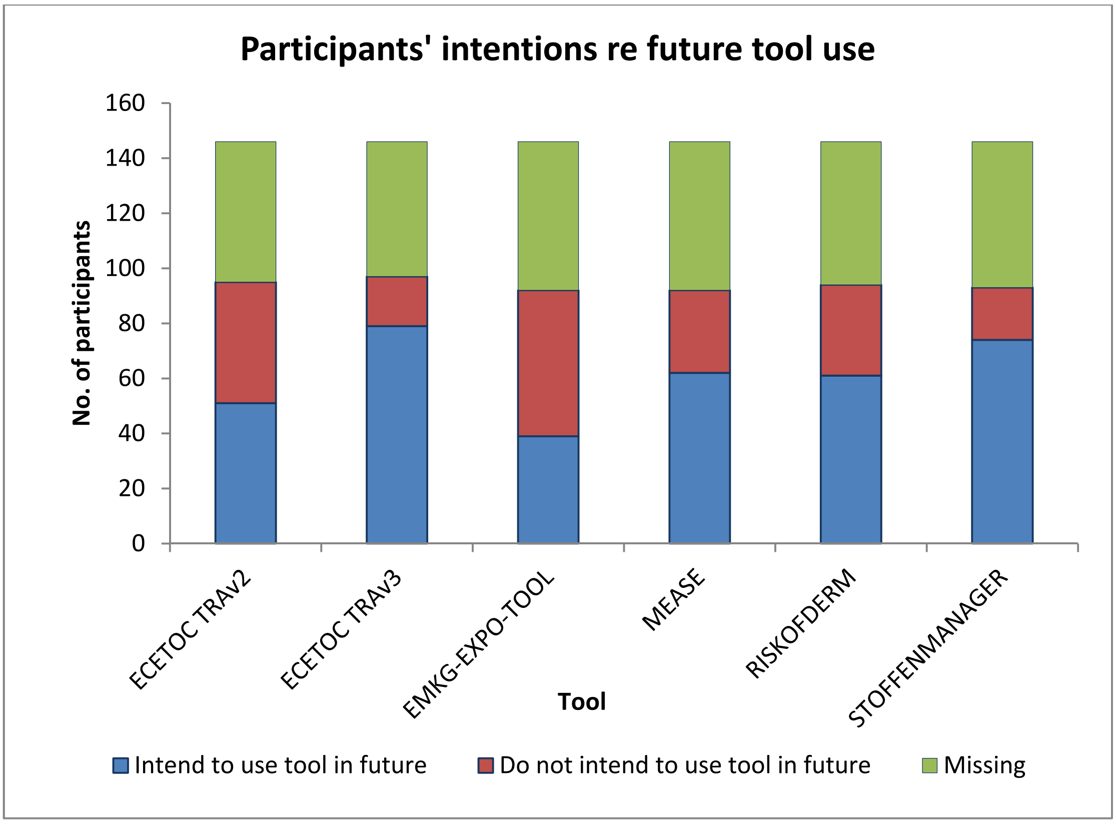

Figure 3.20 Participants' intentions re future tool use

3.9 Exposure Estimates- Statistical Analyses of Variation

3.9.1 Descriptive Statistics

Table 3.18 provides an overview of the results obtained by the tools during the BURE across situations with exposure to solids and situations resulting in exposure to vapours. Table 3.18 also provides estimates of geometric standard deviation (GSD), which express the total variation in exposure estimates obtained by the tools. These combine variation due to differences in exposure between situations and differences between assessments on the same situation. Analyses estimating these components separately are presented in later sections.

Table 3.18 Exposure estimates obtained by tools across all situations by exposure route (solid and vapour)/ (mg m^{-3})

	Solid						Vapour					
Tool Name	**N**	**min**	**AM**	**max**	**GM**	**GSD**	**N**	**min**	**AM**	**max**	**GM**	**GSD**
						Inhalation exposure						
ECETOC TRAv3 (mg/m^3)	103	7.0 $x10^{-4}$	2.6	21	0.3	12	247	1.0 $x10^{-4}$	1.3 $x10^2$	1.3 $x10^3$	21	17
ECETOC TRAv2 (mg/m^3)	129	1.0 $x10^{-4}$	2.9	32	0.3	14	276	8.2 x 10^{-3}	1.1 $x10^2$	1.1 $x10^3$	24	12
MEASE (mg/m^3)	151	5.0 $x10^{-4}$	1.9	41	0.3	12	247	5.0 $x10^{-4}$	1.2 $x10^2$	1.9 x 10^3	9.0	53
EMKG-EXPO-TOOL (mg/m^3)	144	1.0 $x10^{-3}$	107	4.3 $x10^3$ [2]	2.1	17	253	2.1 $x10^{-1}$	3.4 $x10^3$	9.3 $x10^4$	3.5 $x10^2$	14
STOFFEN-MANAGER (mg/m^3) [1]	113	1.5 $x10^{-5}$	34	4.7 $x10^2$	4.4	11	196	1.3 $x10^{-3}$	4.8 $x10^2$	7.2 $x10^3$	61	21
						Dermal exposure						
ECETOC TRAv3 (mg/ kg/ day)	104	2.8 $x10^{-3}$	6.2	43	1.5	9.7	246	1.4 $x10^{-3}$	11	1.1 $x10^2$	2.8	7.6
ECETOC TRAv2 (mg /kg/ day)	129	3.4 $x10^{-2}$	8.7	1.4 $x10^2$	1.5	7.2	276	3.4 $x10^{-2}$	11	1.4x 10^2	4.5	5.1
MEASE (mg/ day)	151	2.0 $x10^{-3}$	37	5.9 $x10^2$	1.8	18	247	5.0 $x10^{-4}$	30	2.4 $x10^2$	0.4	35
RISKOF-DERM hands (mg) [1]	260	2.0 $x10^{-3}$	3.1 $x10^4$	6.5 $x10^5$	2.0 $x10^2$	23	482	2.0	4.1 $x10^5$	8.7 $x10^7$	6.6 $x10^3$	24
RISKOF-DERM body (mg) [1]	42	2.0	3.8 $x10^4$	1.2 $x10^6$	1.2 x10^3	11	269	6.3 $x10^{-1}$	5.9 $x10^5$	7.4 $x10^7$	6.6 $x10^3$	2.6 $x10^2$

[1] tool-predicted 90th percentile exposure estimate

[2] Note: this value exceeds the upper limit for solids exposures in the tool (>10 mg m^{-3}). The participant had incorrectly assigned the physical form as liquid instead of solid, hence the converted value in mg m^{-3} is very high

N=number of assessments; AM=arithmetic mean; GM=geometric mean; GSD=geometric standard deviation

The mean inhalation exposure estimates for solids obtained by the tools range from 1.9 mg m^{-3} obtained with MEASE to 107 mg m^{-3} with the EMKG-EXPO-TOOL. The EMKG-EXPO-TOOL includes a scale of use factor, i.e. the amount handled in the task, but does not take into account the percentage of the agent within a mixture, so some of the difference between this and the other tools can be explained by these parameters. The mean estimate for solids obtained with the STOFFENMANAGER is 34 mg m^{-3}. The same pattern can be seen for exposure to vapours, with lowest estimates of exposure obtained with ECETOC TRAv2, ECETOC TRAv3 and MEASE, highest estimates using the EMKG-EXPO-TOOL and intermediate levels using STOFFENMANAGER.

Results for dermal exposure estimates cannot be compared directly, as the various tools express the results in different units. However, the estimates obtained using the RISKOFDERM tool appear to be much higher than those obtained by the other tools. After taking into account the default weight of an adult (70kg), it appears that the estimates from ECETOC TRAv2 and ECETOC TRAv3 are higher than those obtained by MEASE.

3.9.2 Variation related to participants and their characteristics

Variation between participants' responses was evaluated for each tool. Table 3.19 provides a summary of variance, on the natural log scale, associated with systematic differences between the levels of assessors' results ($Var_{assessor}$), the residual variance (Var_{res}), and the total variance (Var_{Total}), after taking into account the effect due to the difference in exposure level between exposure situations. The table combines assessments for exposure to volatiles and solids. The variances were calculated using a model where situation was included as a fixed effect and assessor included as a random effect.

Table 3.19 Variance in exposure estimates after taking account of exposure situation (all situations)

Tool Name	**N**	**$Var_{assessor}$**	**Var_{res}**	**Var_{Total}**
		Inhalation exposure		
ECETOC TRAv3 (mg m^{-3})	350	0.09	2.5	2.6
ECETOC TRAv2 (mg m^{-3})	405	0.28	1.9	2.2
MEASE (mg m^{-3})	398	0.35	6.1	6.4
EMKG-EXPO-TOOL (mg m^{-3})	397	0.28	3.7	4.0
STOFFENMANAGER (mg m^{-3}) (1)	309	0.61	1.6	2.2
		Dermal exposure		
ECETOC TRAv3 (mg/ kg/ day)	350	0.47	1.6	2.1
ECETOC TRAv2 (mg/ kg/ day)	405	0.18	1.1	1.3
MEASE (mg/ day)	398	0.78	3.7	4.5
RISKOFDERM (hands) (mg) (1)	742	0.55	6.1	6.7
RISKOFDERM (body) (mg) (1)	311	0.10	5.2	5.3

(1) tool-predicted 90^{th} percentile exposure estimate
N=number of assessments

It is clear from the table that even after taking into account the difference in exposure levels between exposure situations (and exposure types), there is still high or very high variation for all of the tools. In addition, systematic differences in level between assessors explains very little of this variation for any of the tools. In particular, for inhalation exposure, variance in the exposure estimates appears to be high for MEASE and the EMKG-EXPO-TOOL. For dermal exposure, the largest variance in estimated exposures was observed for RISKOFDERM, followed by MEASE.

We then carried out the same analyses on a data set restricted to those situations which were applicable to each of the tools. The results of these analyses are shown in Table 3.20.

Table 3.20 Variance in exposure estimates after taking account of exposure situation (applicable situations only)

Tool Name	**N**	**$Var_{assessor}$**	**Var_{res}**	**Var_{Total}**
Inhalation exposure				
ECETOC TRAv3 (mg m^{-3})	326	<0.01	2.6	2.6
ECETOC TRAv2 (mg m^{-3})	365	0.30	2.0	2.3
MEASE (mg m^{-3})	151	0.80	3.6	4.4
EMKG-EXPO-TOOL (mg m^{-3})	313	0.14	3.1	3.2
STOFFENMANAGER (mg m^{-3}) (1)	280	0.52	1.2	1.8
Dermal exposure				
ECETOC TRAv3 (mg/ kg/ day)	326	0.30	1.6	1.9
ECETOC TRAv2 (mg/ kg/ day)	365	0.32	1.0	1.3
MEASE (mg/ day)	151	0.68	4.0	4.7
RISKOFDERM (hands) (mg) (1)	674	0.58	5.8	6.4
RISKOFDERM (body) (mg) (1)	288	0.16	5.2	5.4

(1) tool-predicted 90^{th} percentile exposure estimate
N=number of assessments

We then carried out further analyses to determine if the background of the assessor, i.e. their characteristics such as employment sector, could explain some of the variance in the exposure estimates (Tables 3.21 and 3.22).

Table 3.21 Geometric Standard Deviations for standardised residuals of variation by tool and participant characteristics (inhalation tools)

	ECETOC TRAv3				ECETOC TRAv2				MEASE				EMKG-EXPO-TOOL				STOFFENMANAGER			
	Liquid		Solid		Liquid		Solid		Liquid		Solid		Liquid		Solid		Liquid		Solid	
	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD
English language writing ability																				
native	49	3.0	22	4.9	62	3.5	28	5.0	54	12	33	5.1	61	4.6	29	6.3	48	3.3	19	2.4
excellent	54	4.4	29	6.8	61	2.1	36	4.5	61	14	34	6.3	53	3.9	39	6.7	49	2.3	21	3.3
good	124	3.6	43	8.5	126	2.4	55	6.2	108	10	71	7.9	115	6.3	63	9.1	83	2.7	60	3.3
average	17	3.3	9	7.0	24	5.2	10	8.7	23	46	11	9.4	22	5.8	12	7.8	15	2.4	11	2.7
poor	3	2.1	0	*	3	7.2	0	*	1	*	2	21	2	1.2	1	*	1	*	2	1413
Total	247	3.6	103	6.8	276	2.8	129	5.6	247	13	151	6.97	253	5.3	144	7.8	196	2.8	113	3.8
Sector of employment																				
Consultancy	73	3.6	34	5.7	73	2.0	49	6.3	80	12	37	5.6	79	4.8	39	5.9	58	2.5	32	2.7
Government	30	9.8	12	3.7	45	3.6	14	3.8	35	8.2	29	6.7	36	5.0	25	15	36	2.3	13	2.3
Industry	71	3.1	33	7.5	82	2.6	31	5.9	67	11	42	7.1	68	3.9	43	5.7	57	2.8	27	3.8
Research	53	2.4	11	8.4	46	3.8	23	3.5	43	28	26	6.8	41	7.7	28	8.4	29	2.6	26	8.0
Other	20	2.1	13	9.7	30	2.5	12	7.5	22	12	17	11	29	7.7	9	11	16	2.6	15	2.2
Total	247	3.6	103	6.8	276	2.8	129	5.4	247	13	151	7.0	253	5.3	144	7.8	196	2.6	113	3.9
Main reason for carrying out exposure assessments																				
Compliance	36	3.5	19	5.2	46	2.6	21	4.8	41	9.5	26	7.1	42	5.3	24	6.9	31	2.4	18	2.5
RMM ID.	59	3.7	22	6.9	59	2.2	29	5.3	56	17	31	9.0	55	4.6	34	6.8	41	2.6	24	8.0
REACH	99	2.7	47	7.7	112	2.3	52	5.8	101	12	60	5.9	100	4.9	57	8.9	89	2.8	47	3.5
Other	53	5.8	15	7.7	58	4.7	27	5.8	49	16	33	6.4	56	7.4	29	8.6	35	2.2	24	2.2
Total	247	3.7	103	7.0	275	2.8	129	5.4	247	14	150	6.8	253	5.3	144	7.8	196	2.6	113	3.8
Years of experience in exposure assessment																				
0- 1	43	2.9	22	12	48	2.3	25	5.5	45	15	31	9.0	47	11	25	10	41	2.4	20	2.9
1- 4	73	2.9	22	5.7	67	2.4	33	5.3	58	16	39	6.0	58	4.6	42	9.9	53	3.3	25	3.2
5- 9	55	4.4	26	6.0	67	3.3	27	8.8	57	8.1	32	7.7	59	3.8	32	6.3	36	2.4	24	2.7
10-19	41	4.4	26	5.1	56	3.5	27	4.3	54	13	25	7.3	52	4.7	26	8.8	41	2.4	25	2.9
>20	35	4.3	7	9.7	38	2.1	17	2.8	33	16	24	4.7	37	4.6	19	5.3	25	2.1	19	10
Total	247	3.6	103	6.8	276	2.8	129	5.4	247	13	151	6.8	253	5.4	144	8.1	196	2.6	113	3.9

Table 3.22 Geometric Standard Deviations for standardised residuals of variation by tool and participant characteristics (dermal tools)

	ECETOC TRAv3				ECETOC TRAv2				MEASE				RISKOFDERM (hands)				RISKOFDERM (body)			
	Liquid		Solid		Liquid		Solid		Liquid		Solid		Liquid		Solid		Liquid		Solid	
	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD	N	GSD
English language writing ability																				
native	48	2.2	22	4.1	62	1.9	28	2.7	54	5.7	33	6.1	112	8.1	54	20	53	8.6	5	6.2
excellent	54	3.0	30	3.8	61	2.6	36	4.0	61	7.5	34	4.9	119	9.4	61	12	75	11	11	5.2
good	124	3.0	43	3.7	126	2.5	55	3.1	108	4.7	71	6.7	208	8.9	120	12	113	8.3	20	7.4
average	17	2.2	9	4.2	24	2.4	10	2.8	23	5.0	11	5.5	41	14	23	15	26	11	5	7.4
poor	3	1.2	0	*	3	4.7	0	*	1	*	2	3.8	2	1.0	2	1.3	2	2.7	1	*
Total	246	2.8	104	3.8	276	2.4	129	3.2	247	5.6	151	6.0	482	9.2	260	14	269	9.2	42	8.1
Sector of employment																				
Consultancy	73	2.9	34	2.9	73	2.7	49	3.0	80	5.7	37	5.6	147	10.7	75	26	75	9.2	14	9.4
Government	30	4.0	13	3.0	45	2.5	14	2.9	35	7.1	29	5.9	77	5.1	38	11	44	5.9	6	4.5
Industry	70	2.9	33	3.5	82	2.3	31	4.0	67	4.9	42	5.2	131	10.1	70	7.3	77	9.4	7	17
Research	53	2.3	11	6.3	46	2.1	23	2.9	43	5.6	26	7.2	78	10.4	50	16	49	13	10	3.7
Other	20	1.6	13	5.8	30	2.6	12	2.7	22	5.8	17	6.6	49	7.7	27	7	24	7.6	5	12
Total	246	2.8	104	3.7	276	2.4	129	3.2	247	5.7	151	5.9	482	9.2	260	14	269	9.0	42	8.3
Main reason for carrying out exposure assessments																				
Compliance	36	3.4	19	4.7	46	2.2	21	2.9	41	5.4	26	9.2	84	15	47	8.7	42	12	2	5.2
RMM ID.	59	2.6	22	5.4	59	3.1	29	3.6	56	4.8	31	5.9	97	7.7	53	14	60	6.0	14	11
REACH	99	2.5	47	2.9	112	2.3	52	3.2	101	6.4	60	4.7	198	8.1	102	12	103	9.5	16	11
Other	52	3.2	16	3.9	58	2.1	27	3.0	49	5.3	33	7.6	103	9.4	58	23	64	9.5	10	5.3
Total	246	2.8	104	3.8	275	2.4	129	3.2	247	5.6	150	6.1	482	9.3	260	14	269	8.9	42	8.6
Years of experience in exposure assessment																				
0- 1	43	2.4	23	3.8	48	3.1	25	3.3	45	7.0	31	7.1	93	10	44	13	60	8.5	10	5.1
1- 4	73	2.3	22	3.4	67	2.4	33	4.3	58	4.6	39	4.5	121	7.7	60	16	69	10	11	4.1
5- 9	55	3.1	26	3.9	67	2.3	27	2.9	57	5.6	32	7.0	110	9.6	64	9.3	60	9.4	9	14
10-19	40	3.0	26	4.0	56	2.3	27	2.8	54	7.3	25	7.4	97	11	53	13	49	10	9	19
>20	35	3.5	7	3.6	38	2.0	17	2.1	33	3.7	24	6.1	61	7.4	39	24	31	5.3	3	10
Total	246	2.7	104	3.7	276	2.4	129	3.1	247	5.6	151	6.2	482	9.1	260	14	269	9.0	42	8.5

From consideration of the GSDs for residual variation across all of the assessor characteristics in Tables 3.21 and 3.22, the following observations can be made.

3.9.2.1 Inhalation tools

With the exception of MEASE, there is in general more variation related to situations involving solids compared with those where the liquids-related exposures. For MEASE, there is more variation for situations involving exposure to liquids. This may be related to the range of applicability of the tool, whereby exposures to organic liquids are outside of its scope. The majority of the situations within the exercise related to exposure to organic liquids.

There appears to be least overall variation across the characteristics' groups for STOFFENMANAGER and the ECETOC TRAv2, with comparatively higher levels of variation for MEASE observed. There are no consistent patterns in respect of levels of variation for MEASE when considered across the different characteristic groups. For example it may be expected that more experienced participants would exhibit less variation in their assessments compared with participants with fewer years' experience. This does not seem to be the case, as in this example >20 years' experience in exposure assessment is associated with similar levels of variation to <1yrs' experience.

A similar observation can be made for the other inhalation tools and characteristics, for example it might be expected that those who carry out exposure assessments under REACH may be more familiar with the tools and processes, and therefore have less variation in their estimates. Again this does not seem to be the case: for example for STOFFENMANAGER, there is more variation amongst participants for whom REACH is the main reason for carrying out exposure assessments than for those who assess exposure to determine compliance with occupational exposure limit values.

Slightly higher levels of variation were associated with particular cases, for example participants with 0-1 yrs' experience of exposure assessment had slightly more variation in their estimates when using the EMKG-EXPO-TOOL compared with other categories of experience. The values of standardised residual variation obtained in these cases are not however outside of the range expected to occur randomly.

3.9.2.2 Dermal tools

Similar observations can be made for the variation associated with the use of the dermal tools by different types of assessor. Most overall variation was observed for the use of the RISKOFDERM tool for estimates of hand exposure, with more variability in estimates for solids compared with liquid exposures. There was also slightly more overall variation for the RISKOFDERM (body) and MEASE estimates compared with the ECETOC TRAv2 and ECETOC TRAv3.

As for the inhalation tools, there were no evident associations between assessor characteristics, for example years of experience or main reason for carrying out exposure assessments, and decreased levels of variation.

Overall, it is felt that there are no evident significant effects of the various participant characteristics on the variation in estimates obtained.

3.9.2.3 Impact of type and quality of descriptive information provided

The situations were ranked in order of decreasing variation between users, using the geometric standard deviation. The physical form of the substance, applicability of the tool, type and amount of descriptive information provided with each situation was then mapped to the rankings to allow visual comparison and identification of patterns.

The rankings and descriptions of situation information are shown in Tables 3.23-3.32.

In these tables, the level of detail provided in the descriptive information was graded as follows:

- High: Information provided on task duration and all RMMs;
- Medium: No information provided on task duration and/or information missing on 1-2 RMMs;
- Low: No information provided on task duration and information missing on >2 RMMs

Table 3.23 ECETOC TRAv3 (inhalation) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs	GM/ mg m^{-3}	GSD	min/ mg m^{-3}	max/ mg m^{-3}	Situation within range of tool applicability?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
8	12	2.7	21	4.0×10^{-4}	174	yes	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high
7	19	0.0	12	1.0×10^{-4}	0.8	yes	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
9	19	1.3	11	1.0×10^{-2}	21	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
18	14	0.1	11	8.4×10^{-3}	11	yes	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
15	10	0.1	10	1.0×10^{-3}	1.1	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high
11	19	0.2	8.9	7.0×10^{-3}	14	yes	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
17	16	0.1	7.0	7.0×10^{-4}	2.0	no	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
2	17	1.3	4.3	0.1	10	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
4	18	24	4.0	1.6	773	yes	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high
14	22	1.4	3.9	0.4	78	yes	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high

Table 3.23 ECETOC TRAv3 (inhalation) - Variation between users by situation, substance and amount of descriptive information (Continued)

Situation	No. of Obs	GM/ mg m^{-3}	GSD	min/ mg m^{-3}	max/ mg m^{-3}	Situation within range of tool applicability?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
5	19	5.5	3.8	0.3	123	yes	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
3	17	60	3.6	14	1339	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
19	8	5.1	3.6	0.4	10	no	aluminium	solid*	Ind.	no	no	no	no	no	low
6	22	11	3.4	0.4	161	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
16	20	35	3.3	5.2	523	yes	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high
20	19	70	3.0	5.1	508	yes	acetone	vapour	Ind.	yes	no	yes	yes	yes	med
13	18	245	1.9	87	523	yes	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
12	20	270	1.8	51	720	yes	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med
10	20	179	1.8	125	626	yes	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med
1	21	268	1.6	91	433	yes	styrene	vapour	Ind.	yes	yes	yes	no	no	med

* Exposure to metal fume. Use of tool for process generated fumes is not recommended, however inputs for hot metal processes are available to users

Table 3.24 ECETOC TRAv2 (inhalation) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs.	GM/ mgm^{-3}	GSD	min/ mgm^{-3}	max/ mgm^{-3}	Situation within range of tool applicability ?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
18	17	0.1	22	2.0×10^{-3}	32	yes	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
20	20	52	19	1.4×10^{-2}	361	yes	acetone	vapour	Ind.	yes	no	yes	yes	yes	med
9	20	1.3	11	1.0×10^{-3}	30	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
15	16	0.01	8.1	1.0×10^{-4}	0.6	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high
11	18	0.8	7.9	1.0×10^{-2}	25	yes	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
7	19	0.1	4.5	8.0×10^{-3}	2.0	yes	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
19	15	3.5	3.9	4.7×10^{-2}	10	no	aluminium	solid*	Ind.	no	no	no	no	no	low
13	24	130	3.1	1.7	523	yes	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
17	25	0.17	2.9	2.0×10^{-2}	3.5	no	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
6	22	24	2.8	4.6	230	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high

Table 3.24 ECETOC TRAv2 (inhalation) - Variation between users by situation, substance and amount of descriptive information (Continued)

Situation	No. of Obs.	GM/ mgm^{-3}	GSD	min/ mgm^{-3}	max/ mgm^{-3}	Situation within range of tool applicability ?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
14	23	0.8	2.8	3.9×10^{-2}	7.8	yes	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high
5	22	7.5	2.8	0.18	17	yes	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
2	18	1.2	2.7	0.10	5.0	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
8	18	2.3	2.7	0.50	12	yes	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high
3	21	49	2.4	3.8	953	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
12	20	262	2.4	20	513	yes	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med
4	17	21	2.0	6.6	221	yes	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high
16	24	90	1.7	50	150	yes	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high
1	20	287	1.6	216	1086	yes	styrene	vapour	Ind.	yes	yes	yes	no	no	med
10	26	125	1.0	125	125	yes	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med

* Exposure to metal fume. Use of tool for process-generated fumes is not recommended, however inputs for hot metal processes are available to users

Table 3.25 EMKG-EXPO-TOOL (inhalation) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs.	GM/ mg m^{-3}	GSD	min/ mg m^{-3}	max/ mg m^{-3}	Situation within range of tool applicability?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
17	21	16	47	1.0×10^{-2}	4316	no	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
19	19	20	16	0.1	846	no	aluminium	solid*	Ind.	no	no	no	no	no	low
8	23	25	13	0.2	2080	yes	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high
20	18	181	9.9	12	1808	yes	acetone	vapour	Ind.	yes	no	yes	yes	yes	med
11	18	0.1	8.7	1.0×10^{-3}	10	yes	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
7	18	5.7	8.3	0.2	206	yes	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
5	18	1188	7.1	2.9	2922	yes	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
14	18	106	7.0	1.9	2922	yes	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high
18	21	0.6	5.9	1.0×10^{-2}	10	yes	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
16	20	1012	5.8	25	3752	yes	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high
1	22	1556	5.7	22	3229	yes	styrene	vapour	Ind.	yes	yes	yes	no	no	med
3	24	773	5.4	19	2864	no	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
13	20	10509	5.4	624	93901	no**	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
10	20	459	5.0	12	1863	yes	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med
6	12	41	4.5	1.9	191	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
12	18	1572	4.5	26	3828	yes	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med
2	22	5.3	4.3	0.1	10	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
15	23	0.5	4.2	1.0×10^{-2}	10	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high

9	20	3.2	4.1	0.10	10	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
4	22	302	2.2	220	2208	yes	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high

*Exposure to metal fume ** Outdoor activity

Table 3.26 MEASE (inhalation) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs.	GM/ mg m^{-3}	GSD	min/ mg m^{-3}	max/ mg m^{-3}	Situation within range of tool applicability?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
10	16	6.0	94	6.0 x10^{-3}	123	no	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med
12	20	56	57	2.0 x10^{-3}	503	no	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med
20	21	26	50	5.0 x10^{-3}	354	no	acetone	vapour	Ind.	yes	no	yes	yes	yes	med
8	17	0.03	30	5.0 x10^{-4}	4.9	no	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high
11	20	0.8	21	1.0 x10^{-3}	20	no	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
7	17	0.03	20	5.0 x10^{-4}	4.1	no	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
14	17	0.4	19	1.0 x10^{-3}	7.7	no	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high
17	20	0.1	15	5.0 x10^{-4}	40	yes	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
5	22	0.7	12	5.0 x10^{-4}	28.5	no	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
4	22	29	9.0	4.0 x10^{-2}	217	no	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high

Table 3.26 MEASE (inhalation) - Variation between users by situation, substance and amount of descriptive information (Continued)

Situation	No. of Obs.	GM/ mg m^{-3}	GSD	min/ mg m^{-3}	max/ mg m^{-3}	Situation within range of tool applicability?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
18	23	0.03	8.1	5.0×10^{-4}	1.6	no	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
16	23	28	7.5	5.0×10^{-3}	123	no	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high
9	22	0.4	7.2	5.0×10^{-3}	10	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
15	21	0.07	6.3	4.0×10^{-3}	6.8	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high
19	22	1.0	5.5	1.0×10^{-2}	11	yes	aluminium	solid*	Ind.	no	no	no	no	no	low
13	19	94	5.1	0.2	735	no	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
2	23	1.8	2.7	0.1	10	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
3	21	334	2.4	47	1881	no	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
6	16	33	1.8	12	94	no	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
1	16	200	1.6	43	424	no	styrene	vapour	Ind.	yes	yes	yes	no	no	med

*Exposure to metal fume

Table 3.27 STOFFENMANAGER (inhalation) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs.	GM/ mg m^{-3}	GSD	min/ mg m^{-3}	max/ mg m^{-3}	Situation within range of tool applicability?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
19	15	1.9	31	$1.5x10^{-5}$	31	no	aluminium	solid*	Ind.	no	no	no	no	no	low
8	18	0.1	17	$1.3x10^{-3}$	118	yes	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high
18	20	1.5	7.7	0.02	43	yes	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
9	12	62	5.1	1.9	469	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
11	17	4.1	3.6	0.2	42	yes	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
7	16	1.8	3.3	0.4	13	yes	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
13	18	45	3.2	4.8	317	yes	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
15	18	1.2	3.1	0.2	13	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high
14	16	3.8	3.0	0.2	14	yes	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high
16	9	255	2.9	59	812	yes	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high

Table 3.27 STOFFENMANAGER (inhalation)- Variation between users by situation, substance and amount of descriptive information (continued)

Situation	No. of Obs.	GM/ mg m-3	GSD	min/ mg m-3	max/ mg m-3	Situation within range of tool applicability?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
20	18	721	2.7	240	7187	yes	acetone	vapour	Ind.	yes	no	yes	yes	yes	med
17	14	0.9	2.6	0.2	3.7	no	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
4	16	143	2.6	30	812	yes	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high
3	15	907	2.4	229	2807	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
2	17	75	2.4	19	221	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
12	15	1274	2.1	174	3714	yes	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med
6	11	58	2.0	24	219	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
10	14	821	2.0	255	4024	yes	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med
5	13	89	2.0	36	305	yes	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
1	17	211	1.7	88	707	yes	styrene	vapour	Ind.	yes	yes	yes	no	no	med

*Exposure to metal fume

Table 3.28 ECETOC TRAv3 (dermal) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs.	GM/ mg / kg/ day	GSD	min mg/ kg/ day	max mg/ kg/ day	Situation within range of tool applicability?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
7	19	0.7	9.8	1.4 x10^{-4}	28	yes	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
8	12	0.4	9.5	2.7 x10^{-3}	21	yes	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high
17	16	0.1	9.3	2.8 x10^{-3}	2.8	no	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
11	19	1.4	7.9	3.4 x10^{-2}	14	yes	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
20	18	0.4	7.5	2.1 x10^{-2}	26	yes	acetone	vapour	Ind.	yes	no	yes	yes	yes	med
9	20	1.3	6.6	1.4 x10^{-2}	43	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
18	14	1.5	4.2	8.2 x10^{-2}	8.2	yes	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
15	10	7.3	3.7	0.2	14	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high
3	17	28	3.2	2.1	107	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
5	19	0.5	3.2	2.1 x10^{-2}	6.7	yes	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
10	20	13	3.2	0.1	43	yes	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med
12	20	0.6	3.0	0.1	21	yes	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med
6	22	12	2.8	0.2	26	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
4	18	11	2.4	1.4	43	yes	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high
13	18	1.6	2.3	0.3	14	yes	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
2	17	13	2.2	2.7	27	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
14	22	5.1	2.2	0.7	28	yes	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high
16	20	0.8	2.1	0.3	5.2	yes	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high

19	8	1.4	2.0	0.3	2.8	no	aluminium	solid*	Ind.	no	no	no	no	no	low
1	21	23	1.7	2.7	27	yes	styrene	vapour	Ind.	yes	yes	yes	no	no	med

*Exposure to metal fume. Use of tool for process generated fumes is not recommended, however inputs for hot metal processes are available to users

Table 3.29 ECETOC TRAv2 (dermal) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs.	GM/ mg/ kg/ day	GSD	min mg/ kg/ day	max mg/ kg/ day	Situation within range of tool applicability ?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation ?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
20	20	1.4	8.5	0.03	14	yes	acetone	vapour	Ind.	yes	no	yes	yes	yes	med
9	20	3.8	6.9	0.1	141	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
8	18	2.8	6.2	0.1	141	yes	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high
11	18	0.6	5.6	0.03	6.9	yes	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
4	17	0.1	4.4	0.07	14	yes	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high
19	15	1.1	4.3	0.3	6.9	no	aluminium	solid*	Ind.	no	no	no	no	no	low
18	17	3.0	3.5	0.3	14	yes	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
7	19	16	3.1	1.4	141	yes	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
6	22	1.9	2.7	0.7	27	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
2	18	25	2.7	1.4	141	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
12	20	9.4	2.5	0.7	141	yes	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med
3	21	2.2	2.5	0.1	43	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
14	23	1.7	2.4	0.7	27	yes	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high
17	25	0.3	2.3	0.1	1.4	no	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
15	16	0.5	2.1	0.1	0.7	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high

5	22	9.0	1.9	0.7	14	yes	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
13	24	7.7	1.3	6.8	14	yes	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
16	24	7.5	1.3	6.8	14	yes	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high
1	20	27	1.2	14	43	yes	styrene	vapour	Ind.	yes	yes	yes	no	no	med
10	26	14	1.0	14	14	yes	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med

*Exposure to metal fume. Use of tool for process generated fumes is not recommended, however inputs for hot metal processes are available to users.

Table 3.30 MEASE (dermal) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs.	GM/ mg/day	GSD	min mg/ day	max mg/ day	Situation within range of tool applicability?	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
3	21	30	18	0.2	240	no	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
1	16	32	16	2.0×10^{-2}	240	no	styrene	vapour	Ind.	yes	yes	yes	no	no	med
9	22	1.6	15	5.0×10^{-3}	59	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
7	17	2.0×10^{-2}	14	5.0×10^{-4}	4.8	no	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
5	22	8.0×10^{-2}	13	5.0×10^{-3}	24	no	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
2	23	15	12	0.2	198	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
6	16	7.2	9.9	0.1	144	no	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
11	20	3.7	9.6	2.0×10^{-2}	240	no	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
15	21	26	9.5	0.2	596	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high
12	20	0.1	8.8	5.0×10^{-3}	48	no	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med

14	17	3.3	7.4	0.1	48	no	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high
19	22	1.2	7.0	0.1	99	yes	aluminium	solid*	Ind.	no	no	no	no	no	low
10	16	27	6.2	1.4	240	no	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med
18	23	0.4	5.6	3.0×10^{-2}	57	no	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
8	17	1.0×10^{-2}	4.8	1.0×10^{-3}	0.3	no	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high
16	23	5.0×10^{-2}	4.5	5.0×10^{-3}	1.4	no	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high
17	20	4.0×10^{-2}	4.4	2.0×10^{-3}	0.2	yes	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
13	19	3.0×10^{-2}	4.4	5.0×10^{-3}	1.4	no	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
4	22	0.7	4.1	0.1	24	no	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high
20	21	2.0×10^{-2}	3.5	7.0×10^{-3}	0.1	no	acetone	vapour	Ind.	yes	no	yes	yes	yes	med

*Exposure to metal fume

Table 3.31 RISKOFDERM-hands (dermal) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs.	GM/ mg	GSD	min/ mg	max/ mg	Situation within range of applicability of tool? **	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
4	43	2018	46	2.0	13660240	yes	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high
11	39	15	31	2.0×10^{-3}	144351	yes	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
19	33	380	30	1.0	6452641	no	aluminium	solid*	Ind.	no	no	no	no	no	low
15	44	176	20	1.0×10^{-2}	145801	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high
14	38	9136	17	9.4	1483627	yes	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high
6	33	1164	17	30	86876663	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
7	20	973	15	2.0	19341	yes	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
5	34	2465	14	13	1035091	yes	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
17	35	433	14	2.8	42193	no	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
18	46	74	13	2.0	21375	yes	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
13	40	6186	11	26	2730513	yes	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
9	35	863	11	4.0	384616	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
1	41	27447	11	639	15248627	yes	styrene	vapour	Ind.	yes	yes	yes	no	no	med
12	39	369	9.5	3.0	80017	yes	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med
20	38	626	9.4	4.0	145801	yes	acetone	vapour	Ind.	yes	no	yes	yes	yes	med
16	35	2416	8.2	39	1045494	yes	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high
8	41	82454	7.8	6.0	927270	yes	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high

2	28	1466	7.2	28	71682	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
3	44	65513	4.0	240	1014595	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
10	36	400312	2.8	33283	1155449	yes	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med

*Exposure to metal fume
** Refers to overall applicability range of tool. Individual Dermal Exposure Operations may not be applicable to/ generate an estimate for a particular situation, however may have been chosen by participants

Table 3.32 RISKOFDERM Body (dermal) - Variation between users by situation, substance and amount of descriptive information

Situation	No. of Obs.	GM/ mg	GSD	min/ mg	max/ mg	Situation within range of applicability of tool?**	Substance	Exposure type	Use type	Descriptive information provided on task duration?	Descriptive information provided on LEV?	Descriptive information provided on general ventilation?	Descriptive information provided on RPE?	Descriptive information provided on glove use?	Overall level of detail given in situation description
14	38	2322	27	1	1607193	yes	phenol	vapour	Ind.	yes	yes	yes	yes	yes	high
1	41	19536	21	21	74031408	yes	styrene	vapour	Ind.	yes	yes	yes	no	no	med
6	33	213	18	3	14650719	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
2	17	3678	16	34	1178791	yes	magnesium stearate	solid	Ind.	yes	yes	yes	yes	yes	high
7	24	556	8.2	17	79221	yes	N-methyl pyrrolidone	vapour	Ind.	yes	yes	no	yes	yes	med
19	7	1176	7.4	101	16647	no	aluminium	solid*	Ind.	no	no	no	no	no	low
17	16	407	6.7	2	6836	no	lead	solid*	Ind.	yes	yes	yes	yes	yes	high
13	6	2951	5.0	489	35954	yes	heavy fuel oil	vapour	Ind.	yes	no	yes	yes	yes	med
8	43	3294	4.5	17	23861	yes	glutaraldehyde	vapour	Prof.	yes	yes	yes	yes	yes	high
3	44	384616	3.6	3935	12115546	yes	toluene	vapour	Ind.	yes	yes	yes	yes	yes	high
10	37	11048	3.0	856	106938	yes	isopropanol	vapour	Ind.	yes	yes	no	yes	yes	med
4	0	-	-	-	-	yes	xylene	vapour	Ind.	yes	yes	yes	yes	yes	high

5	1	25084	-	25022	25084	yes	naphtha (heavy)	vapour	Ind.	yes	yes	yes	yes	yes	high
9	0	-	-	-	-	yes	sodium resinate	solid	Ind.	yes	no	yes	yes	yes	med
11	0	-	-	-	-	yes	amoxicillin trihydrate	solid	Ind.	no	yes	yes	yes	yes	med
12	1	404335	-	405307	404335	yes	1-bromopropane	vapour	Prof.	yes	no	yes	yes	yes	med
15	1	1224	-	1224	1224	yes	nickel	solid	Ind.	yes	yes	yes	yes	yes	high
16	0	-	-	-	-	yes	isopropyl benzene	vapour	Ind.	yes	yes	yes	yes	yes	high
18	1	550	-	551	550	yes	hexabromo-cyclododecane	solid	Ind.	yes	yes	yes	yes	yes	high
20	1	5219	-	5223	5219	yes	acetone	vapour	Ind.	yes	no	yes	yes	yes	med

*Exposure to metal fume ** Refers to overall applicability range of tool. Individual Dermal Exposure Operations may not be applicable to/ generate an estimate for a particular situation, however may have been chosen by participants

The amount of information provided in individual situations regarding tool input parameters could potentially affect the level of variation between users, with more detailed descriptions leading to less variation.

For each of the tools, the situations with most variation tended to be well described with information provided on the majority of tool inputs. From this simple tabulation exercise, additional contextual information does not appear to be linked to a decrease in variation between users.

3.9.3 Examination of participants' choice of tool input parameters

To further clarify the participant choice of tool parameters which resulted in the highest levels of variation, we examined the results and worksheets from a number of situations for each tool. For each tool, we chose representative situations with high levels of observed variation and compared the input parameters chosen by the participants. In general, only situations which were applicable for the tool in question were chosen. For those tools where simultaneous estimates of inhalation and dermal exposure are made, the situations chosen for both exposure routes were matched where possible.

3.9.3.1 ECETOC TRAv3

The following situations were chosen for more detailed analysis, as being representative of those with significant variation:

Situation 7: Use of N- methyl pyrrolidone in formulations (inhalation and dermal)
Situation 8: Cleaning of endoscopy equipment in a hospital (inhalation and dermal)
Situation 20: Use of acetone in formulations (dermal)
Situation 9: Packaging of sodium resinate powder (inhalation)
Situation 11: Weighing of amoxicillin trihydrate powder (inhalation)
Situation 15: Packing of nickel metal powder (inhalation)

The input parameters chosen for the selected assessments are shown in Table 3.33.

Table 3.33 ECETOC TRAv3- Input parameters for situations with high between user variability

Participant	Situation	Exposure route	PROC	Setting Prof/ Ind	Solid/ liquid	VP (Pa)/ dustiness	Task duration	Ventilation	RPE	Concentration in preparation	PPE	LEV for dermal	Inhalation estimate/ mg m^{-3}	Dermal estimate/ mg/ kg/ day
4180	7	inhalation/ dermal	7	Ind.	liquid	45	<15mins	indoors	90% effective	1-5%	APF5 gloves	no	0.8	1.7
4127	7	inhalation/ dermal	19	Prof.	liquid	45	<15 mins	indoors	90% effective	1-5%	APF10 gloves	no	0.2	2.8
4195	7	inhalation/ dermal	1	Prof.	liquid	45	<15 mins	indoors	90% effective	1-5%	APF5 gloves	no	8.2 x10^{-5}	1.4 x10^{-3}
4132	8	inhalation/ dermal	11	Prof.	liquid	1	1-4 hours	indoors plus good general ventilation	no RPE	not in preparation	APF5 gloves	no	175	21
4187	8	inhalation/ dermal	11	Prof.	liquid	1	1-4 hours	indoors plus enhanced general ventilation	no RPE	1-5%	APF10 gloves	no	15	2.1
4192	8	inhalation/ dermal	2	Prof.	liquid	1	1-4 hours	indoors plus good general ventilation	no RPE	1-5%	APF5 gloves	no	1.8	5.0 x10^{-2}
4240	9	inhalation	8a	Ind.	solid	high	1-4 hours	indoors plus good general ventilation	no RPE	not in prep	APF10 gloves	no	21	1.4
4141	9	inhalation	7	Ind.	solid	med	1-4 hours	indoors plus good general ventilation	no RPE	not in prep	APF5 gloves	no	8.4	8.6
4207	9	inhalation	8a	Ind.	solid	low	15mins-1hour	indoors plus LEV	no RPE	not in prep	APF10 gloves	no	0.01	0.3
4120	11	inhalation	9	Ind.	solid	high	>4 hours	indoors plus good general ventilation	no RPE	>25%	no gloves	no	14	6.9
4166	11	inhalation	5	Ind.	solid	med	>4 hours	indoors plus good general ventilation	no RPE	>25%	no gloves	no	3.5	14
4257	11	inhalation	9	Ind.	solid	low	<15 mins	indoors plus good general ventilation	no RPE	>25%	no gloves	no	7.0 x10^{-3}	0.7
4244	15	inhalation	8b	Ind.	solid	high	1-4 hours	indoors plus good general ventilation	90% effective	>25%	no gloves	yes	1.1	14
4200	15	inhalation	9	Ind.	solid	high	1-4 hours	indoors plus good general ventilation	95% effective	not in prep	no gloves	no	0.4	6.8
4163	15	inhalation	8b	Ind.	solid	med	1-4 hours	indoors+ LEV + good gen. ventilation	95% effective	>25%	no gloves	no	1.0 x10^{-3}	14
4228	20	dermal	7	Ind.	liquid	24000	1-4 hours	indoors plus good general ventilation	no RPE	>25%	no gloves	no	508	26

4166	20	dermal	5	Ind.	liquid	24000	1-4 hours	indoors plus good general ventilation	no RPE	>25%	no gloves	no	254	8.2
4233	20	dermal	3	Ind.	liquid	24000	1-4 hours	indoors plus good general ventilation	no RPE	>25%	no gloves	no	51	0.08

i) Situation 7: Use of N- methyl pyrrolidone in formulations

For situation 7, the estimates varied by a factor of 10000 between the highest and the lowest values. The main sources of estimate variation were the PROC code (PROC 7, PROC 1 and PROC 19) and the allocation of the type of use, i.e. professional rather than industrial. The variation in PROC code is perhaps caused by some confusion between whether the overall situation (i.e. work in an enclosed paint spray facility- PROC 7 or PROC 1) or the actual task should be assessed, which involved direct handling of a contaminated filter (PROC 19?). The choice of professional or industrial setting was also perhaps complicated as the situation involved a large scale, dedicated facility for spraying of an end-use product. Similar difficulties in allocating the type of use were identified by workshop participants, where scale of process, type of facility, reason for carrying out the activity and worker type were all considered to be relevant factors in defining the use category.

Although there were differences in the choice of gloves (APF5 and APF10), the differences in task and setting parameters are the main factors explaining the wide range in observed dermal exposure estimates for these participants, which ranged from 0.001- 2.8 mg/ kg/ day.

ii) Situation 8: Cleaning of endoscopy equipment in a hospital

For this situation, the main difference in exposure estimate can be attributed to the choice of industrial or professional setting and the use of a concentration reduction factor to account for the dilution of glutaraldehyde in an aqueous solution. The mid-range estimate also included enhanced ventilation as an option, which reduced the estimate further compared with the highest value. Participants chose either PROC 11 or PROC 2, which vary considerably in the estimate generated due to the dispersive nature of PROC 11, compared with the assumption of process enclosure in PROC 2.

The dermal estimates ranged from 0.05 to 21 mg/ kg/ day. In addition to the differences in choice of industrial or professional setting, the choice of glove protection also contributed to the difference in observed estimates.

iii) Situation 9- Packaging of sodium resinate

Participants picked either PROC 8a or PROC 7 for this situation. The rationale for choosing PROC 7 is unclear. The allocation of dustiness level covered all three categories, high, medium and low. The task duration specified in the description was 1 hour per shift, and participants had to choose between a task time of 1-4 hrs, or of 15 mins-1 hr. “Borderline” task durations may therefore be a source of discrepancy between tool users. Differences were also observed for ventilation, with one participant including LEV within the ventilation parameter.

iv) Situation 11: Weighing of amoxicillin trihydrate

Situation 11 described the weighing of small amounts of amoxicillin trihydrate in ventilated weighing enclosures. PROC codes used for this situation were PROC 9 and PROC 5. Dustiness was also assigned differently for all three estimates, with the highest, mid and lowest estimates from choices of high/ med/ low dustiness respectively.

There was no task duration given in the situation, therefore participants were given a free choice. The participants who generated the highest and mid-range estimates interpreted the task as lasting for > 4 hrs, i.e. for the whole shift duration, whilst another participant decided to use < 15 mins per shift, which resulted in a substantial reduction in the exposure estimate.

v) Situation 15: Packing of nickel metal powder

This situation describes the packing of nickel powder in drums at a filling station. PROC codes picked by the participants selected for this exercise were PROC 8b (transfer at dedicated facilities) and PROC 9 (filling of small containers). Either of these options appears valid for the given situation. Interestingly, the person who generated the lowest estimate included LEV, which was mentioned in the description, whilst the mid-range and highest estimates did not include this factor. As for the other situations involving solids, there were differences in the allocation of dustiness, with the participants choosing high, high and medium to generate the highest, middle and lowest estimates, respectively.

vi) Situation 20: Use of acetone in formulations

Situation 20 was chosen to illustrate variation in dermal estimates. The participants varied in their allocation of PROC code (5, 7 and 3), and in their allocation of glove type.

The variation in estimates from the lowest ($8.2x10^{-2}$ mg/ kg/ day) to the highest of 26 mg/ kg/ day for the lowest to is a factor of differences in these two input parameters: all other input choices were identical across the estimates studied in detail.

3.9.3.2 <u>ECETOC TRAv2</u>

The following situations were chosen for more detailed examination of input parameters for the ECETOC TRAv2 tool.

Situation 20: Use of acetone in formulations (inhalation and dermal)
Situation 7: Use of N-Methyl-pyrrolidone in formulations (inhalation and dermal)
Situation 13: Top loading of heavy fuel oil (inhalation and dermal)
Situation 9: Packaging of sodium resinate powder (inhalation and dermal)
Situation 18: Use of hexabromochlorododecane additive (inhalation and dermal)
Situation 11: Weighing of amoxicillin trihydrate powder (inhalation and dermal)
Situation 8: Cleaning of endoscopy equipment in hospitals
Situation 4: Use of xylene in formulations (dermal)

The input parameters chosen for the selected assessments are shown in Table 3.34.

Table 3.34 ECETOC TRAv2- Input parameters for situations with high between user variability

Participant	Situation	Exposure route	PROC	Setting Public/ Industrial	Solid/ liquid	VP (Pa)/ dustiness	Task duration	Indoors/ outdoors	LEV present	RPE	In preparation	Concentration	Inhalation estimate/ mg m^{-3}	Dermal estimate/ mg/ kg/ day
4168	20	inhalation/ dermal	8a	Ind.	liquid	24000	1-4 hrs	indoors	no LEV	no RPE	yes	>25%	362	14
4232	20	inhalation/ dermal	4	Ind.	liquid	24000	1-4 hrs	indoors	no LEV	no RPE	yes	>25%	145	6.9
4143	20	inhalation/ dermal	1	Ind.	liquid	24000	1-4 hrs	indoors	no LEV	no RPE	yes	>25%	0.01	0.3
4131	7	inhalation/ dermal	8a	Public	liquid	45	<15 mins	indoors	no LEV	no RPE	yes	1-5%	2.1	14
4242	7	inhalation/ dermal	7	Ind.	liquid	45	<15 mins	indoors	no LEV	RPE 90%	yes	1-5%	0.8	43
4257	7	inhalation/ dermal	2	Ind.	liquid	45	<15mins	indoors	no LEV	RPE 90%	yes	1-5%	0.01	1.4
4225	13	inhalation/ dermal	8b	Public	liquid	100	1-4 hrs	outdoors	n/a	no RPE	no	n/a	524	6.9
4240	13	inhalation/ dermal	8b	Ind.	liquid	100	1-4 hrs	outdoors	n/a	no RPE	no	n/a	262	6.9
4182	13	inhalation/ dermal	4	Ind.	liquid	0	15 mins-1hr	outdoors	n/a	no RPE	no	n/a	1.7	6.9
4242	9	inhalation/ dermal	8a	Ind.	solid	high	1-4 hrs	indoors	no LEV	no RPE	n/a	n/a	30	14
4154	9	inhalation/ dermal	8a	Ind.	solid	high	15mins-1 hr	indoors	no LEV	no RPE	n/a	n/a	10	14
4257	9	inhalation/ dermal	8b	Ind.	solid	low	15mins-1hr	indoors	LEV	no RPE	n/a	n/a	0.001	0.7
4142	18	inhalation/ dermal	8a	Ind.	liquid	1	15mins-1hr	indoors	no LEV	no RPE	yes	5-25%	32*	14
4147	18	inhalation/ dermal	4	Ind.	solid	low	15mins-1hr	indoors	no LEV	no RPE	n/a	n/a	0.1	6.9
4207	18	inhalation/ dermal	1	Ind.	solid	med	15mins-1hr	indoors	no LEV	no RPE	n/a	n/a	0.02	0.3
4244	11	inhalation/ dermal	8b	Ind.	solid	high	>4hrs	indoors	no LEV	no RPE	n/a	n/a	25	6.9
4227	11	inhalation/ dermal	9	Ind.	solid	med	>4hrs	indoors	no LEV	no RPE	n/a	n/a	5.0	6.9
4124	11	inhalation/ dermal	9	Ind.	solid	low	>4hrs	indoors	LEV	no RPE	n/a	n/a	0.01	0.7
4142	8	dermal	19	Public	liquid	1Pa	1-4hrs	indoors	No LEV	no RPE	yes	1-5%	12	141

4180	8	dermal	4	Public	liquid	1Pa	1-4hrs	indoors	LEV	no RPE	yes	1-5%	1.0	0.7
4219	8	dermal	2	Public	liquid	1Pa	1-4hrs	indoors	LEV	no RPE	yes	1-5%	0.5	0.1
4114	4	dermal	5	Ind.	liquid	1200Pa	>4hrs	indoors	no LEV	no RPE	yes	>25%	220	14
4215	4	dermal	4	Ind.	liquid	1200Pa	>4hrs	indoors	LEV	no RPE	yes	>25%	8.8	0.7
4162	4	dermal	5	Ind.	liquid	1200Pa	>4hrs	indoors	LEV	no RPE	yes	>25%	22	0.1

*Participant had chosen liquid/ vapour instead of solid for the substance form

i) Situation 18: Use of hexabromocyclododecane (HBCD) additive during production of extruded polystyrene

The selected assessments were based on three different PROCs, with PROC 8a associated with the highest estimate, PROC 4 with the mid-range estimate and PROC 1 with the lowest estimate. The assessor who provided the highest estimate had assumed that the substance was liquid, rather than a solid, and had allocated a concentration of 5-25% in preparation accordingly. The other assessors had allocated low and medium dustiness, which in combination with the difference in PROC code, contributed to a difference between the mid-range and lowest estimates of a factor of 5.

The allocation of an incorrect physical form/ concentration and different PROC codes also affected the dermal estimates, with the highest value of 14 mg/ kg/ day compared with the mid-range estimate for solids of 6.9 mg/ kg/ day and lowest estimate of 0.3 mg/ kg/ day.

ii) Situation 20: Use of acetone in formulations

In situation 20, the participants selected for this exercise varied in their choice of PROC code- PROCs 8a, 4 and 1. As the other parameters chosen were identical for the participants investigated, the difference in PROC code allocation contributed to a range of estimates from 0.01 - 362 mg m^{-3}. Interestingly, for this situation, the participants selected for review who used the ECETOC TRAv3 chose three different PROC codes (PROC 3, PROC 5 and PROC 7).

The differences in allocated PROC code also gave rise to significant variation in the dermal estimates of exposure, ranging from 0.03 - 14 mg/ kg/ day). This spread of values reflects the difference in predicted dermal exposure between a fully enclosed process (PROC 1), a process with limited exposure (PROC 4) and a less controlled open transfer process (PROC 8a).

iii) Situation 9: Packaging of Sodium Resinate Powder

In assessing situation 9, there was variation in PROC code allocated, with the lowest estimate based on the choice of PROC 8b (dedicated transfer facility), whilst the other assessors chose PROC 8a (non-dedicated facilities). For ECETOC TRA v3 the selected assessments used PROC 7 and PROC 8a.

The assessors also differed in their allocation of dustiness, and in the use of LEV, which was not included in the description. The activity described in the situation lasted for 1 hr, and again the assessors were split between choosing 1-4 hrs and 15 mins-1 hr. The difference in task duration did not affect the dermal estimates for these participants, which were identical for the highest and middle assessments (14 mg/kg/day), whilst the choice of PROC 8b code decreased the predicted dermal exposure in the lowest estimate to 0.7 mg/ kg/ day.

iv) Situation 7: Use of N-methyl-pyrrolidone in formulations

There were differences in the allocation of PROC code for this situation: PROCs 8a, 7 and 2. There was again a difference in the selection of PROC for this situation compared with those participants selected for review for ECETOC TRAv3, who picked PROC 7, PROC 19 and PROC 1.

As for the ECETOC TRAv3 tool, this difference in opinion may be related to the participants assessing the overall industrial setting (paint spraying in a booth) rather than the actual work activity described. Similar differences relating to the allocation of type of use, i.e. public or industrial may also have arisen for this reason: the process is an end-use of a product, but in a production setting. The highest estimate included "public", whilst the lower estimates reflected an "industrial" setting. This difference could be attributable to a lack of certainty about allocation of this parameter amongst participants. Although the description mentioned RPE being worn, the highest estimate did not include this factor.

v) Situation 13: Top loading of tankers with heavy fuel oil

For situation 13, the PROC codes used by the selected assessment were PROC 8b and PROC 4. The choice of setting was also variable, with the assessor who submitted the highest estimate choosing "public" rather than "industrial", which elevated the estimate. The lowest estimate included a vapour pressure of 0 Pa compared with 100 Pa, and shorter task duration of 15 mins -1 hrs. The situation described a task of 1 hr duration, with part of the variation in estimates arising from a choice of 1-4 hrs rather than 15 mins -1 hr option, with the latter generating the lowest estimate. The differences in PROC code, task duration and setting did not affect the dermal exposures in the same manner, with all of the estimates for these participants identical (6.9 mg/ kg/ day).

vi) Situation 11: Weighing of amoxicillin trihydrate powder

In situation 11, the assessors used PROC 8b (for the highest estimate) and PROC 9 (for the mid-range and lowest estimates). It is of interest by way of comparison that the selected assessments for this situation using the ECETOC TRA v3 incorporated PROC 5 and PROC 9.

Three different levels of dustiness were allocated by the three assessors- high, medium and low dustiness. The assessor submitting the lowest estimate also chose LEV, which was mentioned in the description, whilst the others did not. These differences in PROC code, dustiness and LEV gave rise to a range in the estimates from 0.01 mg m^{-3} to 25.0 mg m^{-3}.

The inclusion of LEV also reduced the dermal exposure between the mid-range estimate (6.9 mg/ kg/ day) and lowest estimate (0.7 mg/ kg/ day). Both PROC 8b (highest inhalation estimate) and PROC 9 (mid-range inhalation estimate) generate the same dermal exposure estimate (6.9 mg/ kg/ day).

vii) Situation 8: Cleaning of Endoscopy Equipment in a Hospital

The differences in dermal estimates for situation 8 were due to differences in PROC code, with PROC 19 resulting in the highest estimate, PROC 4 resulting in a mid-range estimate and PROC 2 resulting in the lowest estimate. These codes reflect a reduction in the level of estimated dermal exposure from the direct contact in PROC 19, through exposure in a batch process, to an enclosed process in PROC 2. The resultant wide range of estimates from 0.1 - 141 mg/ kg/ day illustrates this variation in control clearly. Assessments done with the ECETOC TRA v3 selected for review used PROC 2 and PROC 11.

viii) Situation 4: Use of Xylene in Formulations

Within situation 4, the allocation of PROC code impacted on the dermal estimates obtained, with the participants choosing either PROC 5 (resulting in the highest and lowest estimates) or PROC 4 resulting in the mid-range estimate. The allocation of LEV (as indicated in the situation) in the lowest estimate assessment reduced the predicted dermal exposure from 14 mg/ kg/ day to 0.07 mg/ kg/ day.

3.9.3.3 EMKG-EXPO-TOOL

The situations below generated inhalation estimates with large amounts of variation between participants and were examined in more detail to determine where differences in input parameters had occurred. Significant variation in exposure estimates for situations 17 and 19 was also noted. As these situations describe hot metal processes, which are outside of the EMKG-EXPO-TOOL's range of applicability, they were not examined in more detail.

Situation 8: Cleaning of endoscopy equipment in hospitals
Situation 20: Use of acetone in formulations
Situation 7: Use of N- methyl pyrrolidone in formulations
Situation 11: Weighing of powdered pharmaceutical products
Situation 18: Use of hexabromocyclododecane additive during production of extruded polystyrene

The input parameters chosen for the selected assessments are shown in Table 3.35.

Table 3.35 EMKG-EXPO-TOOL- Input parameters for situations with high between user variability

Participant	Situation	Physical form	Fugacity	Scale of use	Short term exposure	Application surfaces > $1m^2$	Control approach	Estimate/ ($mg\ m^{-3}$)
4176	8	liquid	medium volatility	medium	no	no	1	2079
4171	8	liquid	low volatility	small	no	no	1	21
4115	8	liquid	low volatility	small	no	no	3	0.2
4258	20	liquid	medium volatility	medium	no	yes	1	1808
4160	20	liquid	medium volatility	large	no	no	2	121
4129	20	liquid	medium volatility	large	no	no	3	12
4187	7	liquid	high volatility	medium	yes	no	1	206
4174	7	liquid	low volatility	small	yes	yes	1	21
4249	7	liquid	low volatility	small	yes	no	3	0.2
4256	*11	solid	high dustiness	medium	no	n/a	1	10
4112	11	solid	high dustiness	small	no	n/a	1	1.0
4145	11	solid	medium dustiness	medium	no	n/a	2	0.01
4193	*18	solid	medium dustiness	medium	no	n/a	1	10
4216	18	solid	low dustiness	large	no	n/a	1	1.0
4227	18	solid	low dustiness	medium	no	n/a	3	0.01

i) Situation 8: Cleaning of endoscopy equipment in hospitals

There were differences between participants in a number of input parameters, which led to estimates ranging from 0.2- 2079 mg m^{-3}. Although the vapour pressure of the substance was given, different volatility bands were chosen by the participants. The choice of scale of use parameter also varied between these participants, with the highest choosing "medium" and the others choosing "small". The level of control applied was also variable, ranging from general ventilation to containment between the highest and lowest estimates.

ii) Situation 20: Use of acetone in formulations

There were a number of differences in choice of parameters for this situation. The scale of use varied between medium (for the highest estimate) and large for the mid-range and lowest estimates. The participant who submitted the highest estimate included "application on surfaces > 1 m^2, which increased the estimate in comparison with the others. The choice for level of control also varied with the magnitude of the estimate, with the lowest level of control associated with the highest estimate and control option 3, containment, associated with the lowest estimate.

iii) Situation 7: Use of N- methyl pyrrolidone in formulations

For this situation, participants varied in their choice of volatility, scale of use and control approach. The corresponding estimates varied by a factor of 1000, ranging from 0.2 mg m^{-3} to 206 mg m^{-3}. The highest estimate resulted from a choice of high volatility, medium scale of use and the lowest control approach, general ventilation. The lowest estimate arose from the choice of low volatility, small scale use and containment control.

iv) Situation 11: Weighing of Powdered Pharmaceutical Products

In situation 11, the estimates ranged from 0.01 mg m^{-3} to 10 mg m^{-3}. There was some variation due to the allocation of dustiness (high and medium dustiness). There were also differences in the scale of use, and for the control approach (general ventilation and engineering control).

v) Situation 18: Use of hexabromocyclododecane additive during production of extruded polystyrene

There were differences in allocation of dustiness and scale of use between the estimates for situation 18. Differences in scale of use and in the level of control also contributed to a wide range in estimates, with an overall factor of 100 difference between the lowest and highest estimates.

3.9.4.4 <u>STOFFENMANAGER</u>

The STOFFENMANAGER tool requires a higher number of inputs to generate the exposure estimate than the other tools. For clarity only those parameters where there were differences noted between the participants are shown in Tables 3.36- 3.41. As for the EMKG-EXPO-TOOL, the situations chosen for more detailed analysis were within the range of applicability of the tool, i.e. hot metal processes were excluded.

The following situations were therefore selected.

Situation 8: Cleaning of endoscopy equipment in hospitals
Situation 7: Use of N- methyl pyrrolidone in formulations
Situation 13: Top loading of tankers with heavy fuel oil
Situation 18: Use of hexabromocyclododecane additive during production of extruded polystyrene
Situation 9: Packaging of sodium resinate powder in a factory
Situation 11: Weighing of powdered pharmaceutical products

i) Situation 8: Cleaning of endoscopy equipment in a hospital

Table 3.36 Situation 8- Cleaning of endoscopy equipment in a hospital

Substance		**Glutaraldehyde**	
Type of estimate	**Lowest**	**Mid-range**	**Highest**
Participant	4165	4124	4211
Worst case estimation/ (mg m^{-3})	0.002	0.8	118
Vapour pressure component/ (Pa)	1	1	14800
Dilution of the product (as % of product)	2	100	100
Vapour pressure of product	100	1	1
Activity	Handling of liquids where only small amounts of product may be released	Handling of liquids using low pressure, low speed or on medium-sized surfaces	Handling of liquids on small surfaces or incidental handling of liquids
Regular cleaning of work area	Yes	Yes	No
Regular inspection and maintenance	Yes	Yes	No
Evaporation, drying or curing after activity	No	Yes	Yes
Work area volume	100-1000 m^3	Under 100 m^3	Under 100 m^3
Control measures at the source	Containment of the source	No control measures at the source	Containment of the source

For situation 8, the main source of variation in the exposure estimates was the choice of vapour pressure. The highest exposure estimate for this situation was based on choice of vapour pressure of 14800 Pa. However; this participant made the assessment in error for a different product than the other participants. In addition, difference in the exposure estimates was also cause by choice of a dilution of 2% for the substance in the product, whilst the other assessors assumed no dilution. There was also a difference in allocation of handling activity, with three different options for low energy/ small scale processes being chosen by the participants. There were also differences in the allocation of exposure from drying/ evaporation of the liquids. A small room size (<100m^3) was chosen by two participants, whilst the other participant included a larger room size (100-1000m^3). Finally, different control options were made by different participants (no controls at source and containment of the source).

ii) Situation 7: Use of N-methyl pyrrolidone in formulations

Table 3.37 Situation 7- Use of N-methyl pyrrolidone in formulations

Substance	**N-methyl pyrrolidone**		
Type of estimate	**Lowest**	**Mid-range**	**Highest**
Participant	4114	4141	4237
Worst case estimation/ (mg m^{-3})	0.4	5.2	13
Dilution of the product (as % of product)*	2	100	100
Regular cleaning of work area	No	Yes	No
Regular inspection and maintenance	No	Yes	Yes
Work area volume	100-1000 m^3	Under 100 m^3	Under 100 m^3
Employee protection	Half mask respirator with filter/cartridge (gas cartridge)	Half mask respirator with filter/cartridge (gas cartridge)	No protection

For this situation, the main variation in estimates was due to the dilution of product (2% in the lowest estimate vs no dilution in the midrange and highest estimates). There were also differences in input with regard of cleaning and maintenance across all of the estimates, as well as for room volume. The lower and mid-range estimates also assigned respiratory protective equipment, which had been described in the situation, whilst the highest estimate assessor did not include this option.

iii) Situation 13: Top loading of tankers with heavy fuel oil

Table 3.38 Situation 13- Top loading of tankers with heavy fuel oil

Substance		**Heavy fuel oil**	
Type of estimate	**Lowest**	**Mid-range**	**Highest**
Participant	4249	4146	4212
Worst case estimation/ (mgm^{-3})	4.8	84	318
Activity	Handling of liquids on small surfaces or incidental handling of liquids	Handling of liquids (using low pressure, but high speed) without creating a mist or spray/haze	Handling of liquids at high pressure resulting in substantial generation of mist or spray/haze
Regular cleaning of work area	No	Yes	Yes
Activity in breathing zone	No	Yes	Yes
Multiple employees	No	Yes	Yes
Control measures at the source	No control measures at the source	Containment of the source	No control measures at the source
Segregation of employee	The employee is situated in an open or closed cabin without specific ventilation system	The employee does not work in a cabin	The employee does not work in a cabin

The estimates for situation 13 varied by a factor of 80, ranging from 4.8 mg m^{-3} to 318 mg m^{-3}. There were significant differences in the activity description choices which contributed to this variation, with the highest estimate associated with high pressure handling and significant mist generation compared with a much less energetic handling option “handling of liquids on small surfaces/ incidental handling” for the lowest estimate. Regular cleaning was assumed to take place by the participants who submitted the two higher estimates examined. There were also differences in the allocation of proximity to the source, with the assessor who provided the lowest estimate assuming that the employee worked in a cabin, therefore exposure had not occurred in their breathing zone. Secondary worker-related sources were included in the mid-range and highest estimates, but not in the lowest estimate. Containment of source was chosen for the mid-range estimate whilst the highest and lowest estimates did not include any control measures at source.

iv) Situation 18: Use of hexabromocyclododecane additive during production of extruded polystyrene

Table 3.39 Situation 18- Use of hexabromocyclododecane additive during production of extruded polystyrene

Substance	**Hexabromocyclododecane**		
Type of estimate	**Lowest**	**Mid-range**	**Highest**
Participant	4182	4252	4242
Worst case estimation/ (mgm^{-3})	8.8	19	42
Dustiness of product	Granules/grains/ flakes	Granules/flakes/ grains	Solid granules/grains/ flakes
Activity	Handling of product in small amounts or in situations where only low quantities of products are likely to be released	Handling of products with a relatively high speed/force which may lead to some dispersion of dust	Handling of very large amounts of the product
Work area ventilation	No general ventilation	General ventilation (open windows and doors)	General ventilation (open windows and doors)

In situation 18, the main variation in estimates relate to the choice of handling activity, ranging from handling of small amounts with low force, through handling materials with increased force, to handling of large amounts of product. The allocation of dustiness was also variable (granules/ flakes/ grains and solid granules/ grains/ flakes). The only other difference in inputs related to the choice of area ventilation (general ventilation and no general ventilation). However, for this situation, difference in the choice of handling activity appears to have had most influence on the estimate.

v) Situation 9: Packaging of sodium resinate powder in a factory

Table 3.40 Situation 9- Packaging of sodium resinate powder in a factory

Substance	Sodium resinate		
Type of estimate	**Lowest**	**Mid-range**	**Highest**
Participant	4126	4201	4131
Worst case estimation/ (mg m^{-3})	1.9	40	469
Dustiness of product	Granules/grains/ flakes	Fine dust	Extremely dusty products
Activity	Handling of product with low speed or with little force in medium quantities	Handling of products with a relatively high speed/force which may lead to some dispersion of dust	Handling of products, where due to high pressure, speed or force large quantities of dust are generated and dispersed
Work area ventilation	No general ventilation	General ventilation (mechanical)	General ventilation (mechanical)
Control measures at the source	Containment of the source with local exhaust ventilation	Local exhaust ventilation	No control measures at the source

In situation 9, the participants varied in their allocation of dustiness, choosing “granules/ grains/ flakes” for the lowest estimate, “fine dust” for the mid-range value and “extremely dusty products” for the highest estimate.

There was a similar variation in the activity description allocated, with low energy, medium energy and high pressure/speed choices being included in the lowest, medium and highest estimates, respectively. There were also differences in the level of control assigned between the three estimates (containment with LEV, LEV only, and no control measures at source).

The combination of high dustiness and highly energetic processes, and an absence of control measures allocated in the highest estimate compared with lower fugacity/ energy processes for the others resulted in the estimates spanning a range of almost 500 mg m^{-3}.

vi) Situation 11: Weighing of powdered pharmaceutical products

Table 3.41 Situation 11- Weighing of powdered pharmaceutical products

Substance		**Amoxicillin trihydrate**	
Type of estimate	**Lowest**	**Mid-range**	**Highest**
Participant	4147	4132	4253
Worst case estimation /(mg m^{-3})	0.18	19	42
Dustiness of product	Coarse dust	Extremely dusty products	Extremely dusty products
Activity	Handling of products in very small amounts or in situations where release is highly unlikely	Handling of product in small amounts or in situations where only low quantities of products are likely to be released	Handling of product in small amounts or in situations where only low quantities of products are likely to be released
Duration	1 to 30 minutes a day	1 to 30 minutes a day	4 to 8 hours a day
Work area volume	100 - 1000 m^3	Under 100 m^3	Under 100 m^3
Control measures at the source	Containment of the source with local exhaust ventilation	Containment of the source	No control measures at the source

In assessing situation 11, participants chose a variety of dustiness options, with the lowest estimate based on “coarse dust” and the mid-range and highest estimates based on a choice of “extremely dusty”.

The assessors who submitted the mid-range and highest estimates both chose the same activity description, however differed in the level of control, with the highest value associated with the choice “no control measures at source” compared with “containment of source”. The lowest estimate arose from a less energetic activity description, combined with “containment of source with LEV”. This assessor also chose a larger room volume compared with the higher estimates.

3.9.4.5 <u>MEASE</u>

The developers of the MEASE tool state that it is not applicable to organic substances, for example petroleum based solvents or organic powders. It is possible to choose input options for volatile liquids and organic powders in the tool; it was therefore considered appropriate and useful to investigate potential sources of variation for these substance types. We thus included one situation involving inhalation exposure to amoxicillin trihydrate powder to illustrate the different choices made by the participants, who were asked to complete all given tool-situation combinations regardless of applicability.

The participants’ inputs for the following situations were therefore considered in detail for MEASE.

Situation 11: Weighing of powdered pharmaceutical products (inhalation and dermal)

Situation 17: Cleaning of Solder Dross during Manufacture of Electronic Components (inhalation and dermal)
Situation 9: Packaging of Sodium Resinate Powder (dermal)

Table 3.42 MEASE- Input parameters for situations with high between user variability

Participant	Situation	Exposure route	Physical form/ %content in prep.	PROC	Scale of operation	Process temp./ °C	Duration of exposure	Pattern of use	Pattern of exposure control	Contact level	Implemented RMMs	RMM efficiency based on	RPE	Gloves	Inhalation estimate/ mg m^{-3}	Dermal estimate/ mg/ day
4114	11	inhalation/ dermal	solid high dustiness />25%	26	Prof.	-	> 240 mins	non-dispersive	direct handling	intermittent	general ventilation	LCL	no RPE	no gloves	20	10
4131	11	inhalation/ dermal	solid high dustiness />25%	26	Ind.	-	> 240 mins	non-dispersive	direct handling	extensive	enclosure	LCL	no RPE	no gloves	9.6	99
4202	11	inhalation/ dermal	solid low dustiness/ >25%	1	Ind.	-	> 240 mins	closed system no breaches	direct handling	none	enclosure	median estimate	no RPE	no gloves	0.01	0.1
4253	17	inhalation	liquid	8b	Ind.	-	15-60 mins	non-dispersive	direct handling	intermittent	integrated LEV	LCL	no RPE	proper gloves	41	0.05
4104	17	inhalation	liquid/ >25%	4	Ind.	-	15-60 mins	non-dispersive	non-direct handling	none	general ventilation	LCL	no RPE	proper gloves	7.0	0.005
4228	17	inhalation	massive object/ >25%	8b	Ind.	-	15-60 mins	non-dispersive	direct handling	none	LEV generic	LCL	no RPE	proper gloves	<0.001	0.005
4161	9	dermal	solid high dustiness/ >25%	26	Ind.	-	60-240 mins	wide dispersive	direct handling	extensive	general ventilation	LCL	no RPE	proper gloves	-	59.0
4125	9	dermal	solid high dustiness/ >25%	8a	Prof.	-	15-60 mins	wide dispersive	direct handling	extensive	general ventilation	LCL	no RPE	proper gloves	-	9.6
4258	9	dermal	solid low dustiness/ >25%	8b	Ind.	-	15-60 mins	non-dispersive	non-direct	incidental	exterior LEV	LCL	no RPE	proper glover	-	0.005

i) Situation 11: Weighing of powdered pharmaceutical products

In discussing this situation, as indicated above, it should be noted that the MEASE tool is designed to be used for inorganic solids' handling activities, rather than those which are organic. The available tool options for inputting powdered pharmaceutical products are identical to those required for inorganic dusty materials. Detailed examination of these inputs was therefore carried out for comparison with variation in the corresponding parameters of the other tools.

The participants varied in their choice of physical form, with the high and mid-range inhalation estimates incorporating "solid high dustiness" and the lowest estimate "solid low dustiness". The choice of PROC code also varied, with the highest and mid-range inhalation estimate being based on PROC 26, whilst the lowest estimate was based on PROC 1. (For ECETOC TRA vs 2 and 3 the assessments selected for review were based on PROC 5, PROC 8b and PROC 9). The highest estimate also chose a "professional" setting rather than the "industrial" option chosen by the assessors who submitted the mid-range and lowest estimates.

There was also variation between participants when assigning dermal exposure inputs. The pattern of use varied between participants ("non-dispersive" and "closed system no breaches"), as did the contact level ("intermittent", "extensive" and "none"). There was variation in both the choice of RMMs implemented ("general ventilation" and "enclosure") and in the assignment of RMM efficiency. For RMM efficiency, "lower confidence limit" was assigned in some estimates and "median estimate" allocated in the other case.

ii) Situation 17: Cleaning of Solder Dross during Manufacture of Electronic Components

As a hot metal process, this situation was clearly within the range of applicability of the MEASE tool. However, although the tool includes both appropriate input parameter options and clear guidance on suggested choices for hot metal processes, there was still significant variation between users. The participants who generated the highest estimate (41 mg m^{-3}) and the mid-range estimate (7.0 mg m^{-3}) both assessed the substance as though it was liquid. The participant who submitted the lowest estimate (<0.001 mg m^{-3}) had chosen "massive object" for the physical form.

In addition, different PROC codes were chosen by these participants (PROC 8b and PROC 4). Interestingly, none of these participants had chosen any of the metal-specific PROC codes available in the tool.

The participants chose identical task durations, however varied in their choice of RMMs. The highest estimate included "integrated LEV", whilst the others chose "general ventilation" and "LEV-generic". All of the participants had chosen the "lower confidence limit" for the RMM efficiency.

In relation to dermal exposure, these participants chose the same option for the pattern of use: "non-dispersive use". The participants varied in their choice of pattern of exposure control, selecting "direct handling" and "non-direct handling". The options for contact level were also different between users- "intermittent" and "none".

iii) Situation 9: Packaging of Sodium Resinate Powder

This situation was selected for more detailed examination of dermal input parameters, as it was within the range of applicability, but had a noticeable amount of variation in dermal estimates (0.005- 59 mg/ day). The participants who submitted the highest and mid-range estimates selected "solid high dustiness" compared with "solid low dustiness" for the lowest estimate. The highest estimate was based on PROC 26, which is specific to metal/ inorganic substances, whilst the mid-range and lowest estimates was based on the more general materials transfer PROCs 8a and 8b respectively. (For the ECETOC TRA versions 2 and 3, the selected assessments were based on PROC 7, PROC 8a and PROC 8b).

The choice of setting also varied, with the mid-range estimate arising from a "professional" input option, whilst the others chose "industrial". As for assessors using other tools, the stated task duration of one hour gave rise to variation in the participants using the MEASE tool. The highest estimate assumed a task duration of "60-240mins" within the shift, with the other participants choosing "15-60mins". The pattern of use parameter varied between "wide dispersive use" and non-dispersive use.

There was similar variation in the pattern of exposure control selected- direct handling vs non-direct handling (for the lowest estimate), and for the frequency of contact ("extensive" for the highest/mid-range estimate and "incidental" for the lowest estimate). The assessor who submitted the lowest estimate had assigned "exterior LEV", whereas the other participants selected only "general ventilation" for the implemented RMMs. The participants did not vary in their allocation of RMM efficiency, RPE and gloves (Lower confidence limit; "no RPE" and "properly designed/selected gloves")

3.9.4.6 ISKOFDERM (hands 90th percentile)

The following situations were examined in more detail to identify differences between participants in input parameters for the hand exposures estimated using the RISKOFDERM tool.

Situation 4: Use of xylene in formulations
Situation 14: Use of phenol in adhesives
Situation 11: Weighing of pharmaceutical products
Situation 15: Packaging of nickel metal powder

i) Situation 4: Use of xylene in formulations

Within this situation, the participants all chose the same DEO- fill/mix/load, same quality of ventilation, product type and level of automation. Their inputs varied in respect of the other parameters, with "more than rare" chosen for frequency of contact in the highest estimate, compared with "rare" for the mid-range and lowest estimate.

The kind of skin contact chosen also varied, with the highest estimate including “more than light” compared with “light” for the mid-range and lower ones. The application rates chosen varied from 0.17 l/ min for the lowest estimate to 257 l/ min for the highest value. The cumulative duration of the task within the shift also varied significantly, ranging from 1 min/ shift for the lowest estimate to 300 min/ shift for the mid-range and highest estimates. Differences in application rate and task duration have a significant effect on the overall estimate. Comparison of the mid-range and lowest estimates, where the other inputs for the DEO are identical would suggest that the application rate and cumulative duration are the main sources of variation between users for this situation.

Table 3.43 RISKOFDERM- Input parameters for Situation 4: Use of xylene in formulations

Participant	DEO chosen	Quality of ventilation	Freq. of contact	Kind of skin contact	Type of product	Significant aerosols? yes/no	Level of automation	Application rate (l/min or kg/min)	Cumulative duration of scenario in shift/ (min)	Estimate (µl or mg)	Comments/ notes from tool	Warnings from tool in results section
4242	Fill/ mix /load	Normal/ good	More than rare	More than light	Liquid	Yes	Manual task	257 l/min	300	1.4×10^7	Model based on values up to 125 mins for liquids	May be unrealistic
4124	Fill/ mix/ load	Normal/ good	Rare	Light	Liquid	No	Manual task	10l/min	300	2.2×10^4	Model based on values up to 125 mins for liquids	May be unrealistic
4105	Fill/ mix/ load	Normal/ good	Rare	Light	Liquid	yes	Manual task	0.17l/min	1	5	-	-

ii) Situation 14: Use of phenol in adhesives

Participants assessing situation 14 varied in their choice of DEO, with the participant who generated the highest estimate opting for “Wiping”, whilst the mid-range and lowest estimates arose from the “Dispersion with hand-held tools” DEO. A comparison between the mid-range and lowest estimates shows that identical inputs were made for the direction of application, viscosity, tool type and cumulative duration of the scenario. The difference in estimates can therefore be attributed to variation in the application rate, which differed by a factor of 10 between the mid-range and lowest values.

Table 3.44 RISKOFDERM- Input parameters for Situation 14: Use of phenol in adhesives

Participant	DEO chosen	Extensive body contact with freshly wiped surfaces?	Direction of application	Viscosity	Application rate (l/ min)	Kind of tools	Cumulative duration of scenario in shift / (min)	Estimate (mg)	Comments/ notes from tool	Warnings from tool in results section
4190	Wiping	No	-	-	0.7	-	420	1.4 x10^6	Model was based on values up to 35 mins	May be unrealistic
4141	Dispersion with hand-held tools	-	Downward	Like syrup or honey	0.01	Tools with handles < 30cm	420	2201	-	-
4126	Dispersion with hand-held tools	-	Downward	Like syrup/ honey	0.001	Tools with handles <3 0cm	420	9.0	-	-

iii) Situation 11: Weighing of powdered pharmaceutical products

The same DEO (fill/mix/load), quality of ventilation and level of automation was chosen in the three assessments examined. The assessments varied in all other parameters. The frequency of contact was allocated as “more than rare” in the highest and mid-range estimates, compared with “rare” for the lowest one.

The kind of skin contact also differed, with the highest estimate including “more than light” contact, whilst the others incorporated “light” contact. As for other tools, the choice of dustiness varied between participants: “highly dusty solid” for the high and mid-range estimates compared with “low or moderately dusty solid” for the lowest one.

Significant aerosol generation was included by the mid-range assessor, but was not considered to be relevant by the others.

The assessors again varied significantly in their choice of application rate: 0.001, 0.05 and 42.5 kg/ min for the low, mid, and highest estimates, respectively. A wide range of cumulative durations were also chosen, from 5 min/ shift in the lowest estimate, 20 min/ shift for the highest estimate and 360 min/ shift for the mid-range estimate.

Table 3.45 RISKOFDERM- Input parameters for Situation 11- Weighing of powdered pharmaceutical products

Participant	DEO chosen	Quality of ventilation	Freq. of contact	Kind of skin contact	Type of product	Significant aerosols? yes/no	Level of automation	Application rate (l/min or kg/min)	Cumulative duration of scenario in shift (mins)	Estimate (µl or mg)	Comments/ notes from tool	Warnings from tool in results section
4106	Fill /mix/ load	Normal/ good	More than rare	More than light	Highly dusty solid	No	Manual task	42.5	20	1.4×10^4	-	May be unrealistic
4112	Fill/ mix/ load	Normal/ good	More than rare	Light	Highly dusty solid	yes	Manual task	0.05	360	550	Model was based on values up to 20 mins for powders	-
4122	Fill /mix/ load	Normal/ good	Rare	Light	Low or moderately dusty solid	No	Manual task	0.001	5	0.002	-	-

iv) Situation 15: Packaging of nickel metal powder

In this situation, the participants chose the same DEO (fill/mix/load), quality of ventilation, frequency of contact, kind of skin contact, type of product and level of automation.

There was some variation in allocating the significance of aerosols, with the mid-range estimate indicating significant aerosol generation, whilst the others did not.

The main variation in the estimates for this situation arose from differences in application rate (0.001-42.5 kg/ min) and in the cumulative task duration within the shift (1- 180 min).

Table 3.46 RISKOFDERM- Input parameters for Situation 15- Packaging of nickel metal powder

Participant	DEO chosen	Quality of ventilation	Freq. of contact	Kind of skin contact	Type of product	Significant aerosols? yes/no	Level of automation	Application rate (l/min or kg/min)	Cumulative duration of scenario in shift (min)	Estimate (µl or mg)	Comments/ notes from tool	Warnings from tool in results section
4195	Fill/mix/load	Normal/good	More than rare	Light contact	Highly dusty solid	yes	Manual task	42.5	180	$1.4x10^5$	Model was based on values up to 20 mins for powders	May be unrealistic
4162	Fill/mix/load	Normal/good	More than rare	More than light	Highly dusty solid	yes	Manual task	0.5	180	6500	Model was based on values up to 20 mins for powders	-
4106	Fill/mix/load	Normal/good	More than rare	Light contact	Highly dusty solid	No	Manual task	0.001	1	0.01	-	-

4 Discussion

4.1 Overall

The results of the between-user reliability exercise suggest that when confronted with brief descriptions of exposure situations, very different results can be obtained by different users of the Tier 1 exposure assessment tools regularly used for REACH. There did not appear to be any systematic differences between users with different backgrounds and level of knowledge. For example, it did not appear to be the case that users working for different types of organisations consistently rated the situations higher or lower than those from other sectors. During the workshop, there was some suggestion that users who worked for national regulatory authorities may be more conservative in applying the tools than those working as consultants or for industry. However, this was not observed in the large remote-completion exercise.

In addition, there were no obvious differences in the variation in results obtained by participants who considered themselves experienced in exposure assessment compared to relatively inexperienced personnel. Likewise, the results generated by participants with less experience of using the tools were as variable as those submitted by assessors who were more familiar with tool operation. Thus there does not appear to be a higher level of consistency in results obtained by more experienced exposure assessors or tool users, compared to less experienced assessors or users.

The level of uncertainty reported by participants when choosing input parameters varied significantly by tool and situation. Allocating task/ activity descriptors and solid substance characteristics' parameters caused most uncertainty but did not appear to consistently affect the overall level of variation in estimates between users. For example, participants reported relatively high levels of certainty in their choice of parameter for situations where there were high levels of between-user variation. Difficulty in allocation of the most appropriate task / activity was also reported by the workshop participants.

Ease of translation of the situations into the tool inputs was also highly variable across tools and situations. There was no clear relationship between ease of translation and between-user variation, i.e. the choices made for situation descriptions which participants perceived as being easy to translate into the tools were no more consistent than those which were considered more challenging to input.

The parameters that appear to be leading to most variation in the results included the PROC code (for ECETOC TRAv2, ECETOC TRAv3 and MEASE) and other activity-related parameters, for example the task characterisation input in STOFFENMANAGER and the DEOs in RISKOFDERM. However; other input parameters also contributed significantly to the observed variation in results. For example, differences in exposure estimates were also obtained due to variation in the choice of input parameters associated with substance characteristics (dustiness and % in preparation) and ventilation. The choice of activity setting, i.e. professional or industrial also led to observable variation between user estimates from the ECETOC

TRAv2, ECETOC TRAv3 and MEASE. Differences in choice of vapour pressure were also observed, even though this was provided in the description of the exposure situation. Within the RISKOFDERM tool, there were also substantial differences in the free text inputs for the application rate and cumulative duration of exposure parameters, which contributed to large variation between the users' final estimates.

In the remainder of this section, we provide a more detailed discussion on the various aspects of the BURE and results of particular interest.

4.2 Participant population

In general, the study population is considered to be representative of a normal range of tool users in terms of frequency and purpose of tool use, familiarity with tools and level of experience of exposure assessment. Further detail on relevant participant characteristics is discussed below.

4.2.1 Number and employment sector of participants

The original project specification for evaluation of between-user reliability of the tools required a one-day in person workshop for 10-20 participants. Following discussion with the Advisory Board, a revised proposal to significantly increase the population size by carrying out a remote completion exercise was agreed. The project team forecast a maximum of 100 participants for the remote completion exercise, however the final number (n=146) far exceeded this expectation. The participants completed 4066 assessments in total.

There were balanced numbers of participants across the sectors, with the similar numbers coming from consultancy and industry backgrounds, followed by research, regulatory bodies and other (for example occupational/ primary health professionals and university academic staff). The composition of the group was therefore considered representative of normal tool users in the context of REACH, where the majority of exposure assessments are likely to be carried out by industry or consultancy staff. The workshop participants came from a similar range of backgrounds, again reflecting a standard tool user population.

4.2.2 Participants' country of employment

Recruitment to the study was undertaken using a number of methods, including tool-user and global and country-specific professional occupational hygiene forums, via the project Advisory Board and through personal contacts of the project team. The majority of the respondents were based within the European Union (n=123), which is perhaps expected given the REACH-focus of the tools and overall eteam Project. The primary work location of participants is therefore felt to reflect the normal range of REACH actors.

4.2.3 Participants' English language ability

The BURE, in common with REACH processes, was conducted in English. Participants' comprehension of the descriptive information and instructions could therefore have had an impact on the amount of between-user variation observed.

A significant majority of participants in general classed their English language reading ability as either "native", "excellent or good", compared with "average/ poor". Written English ability was also generally of a high standard, with the majority of participants (90%) reporting that their ability was "native", "excellent or good".

There may be a certain degree of natural, subconscious overestimation of personal ability by participants in relation to their English language ability. Indeed a certain amount of self-selection for the BURE on this basis may also have occurred, however cannot be quantified.

4.2.4 Participants' reasons for carrying out exposure assessments

The majority of participants carried out exposure assessments primarily under REACH, with other reasons for assessing exposure chosen by similar numbers of participants- determining compliance with an exposure limit, identification of risk management measures or other reasons, including epidemiological studies and biocides registrations. It is therefore felt that the study participants were representative of normal tool users in the context of REACH.

4.2.5 Participants' level of experience in exposure assessment

Participants' years of exposure assessment experience were evenly split across a number of categories: "<1 year" (n=22), "1-4 years"/ "5-9 years"/ "10-19 years" (all n=33), and ">20 years" (n=25). The participants are therefore considered to be representative of a normal population of tool users in terms of length of experience.

4.2.6 Participants' level of knowledge of the tools

Overall the participants' prior level of knowledge of the tools appears to match the prevalence of the individual tools, with the participants being more familiar with the ECETOC TRAv2 and ECETOC TRAv3, which have been used for the majority of exposure assessments carried out to date under REACH, compared with STOFFENMANAGER, MEASE, EMKG-EXPO-TOOL and RISKOFDERM.

The STOFFENMANAGER tool is used in various language versions within a number of countries, as a chemical risk management tool. It is therefore possible that the familiarity of the participants with STOFFENMANAGER relates to this type of tool use, rather than as a REACH-related assessment method.

The lower levels of knowledge with MEASE and EMKG-EXPO-TOOL may reflect the more specialised use of MEASE for metal and inorganic substances and a lack of familiarity with the EMKG-EXPO-TOOL outside of Germany.

4.2.7 Participants' frequency of use of the tools

The most commonly used tools were the ECETOC TRAv3, ECETOC TRAv2 and STOFFENMANAGER, which is consistent with the predominantly REACH-related exposure assessments and Europe-based locations reported by participants. The use of STOFFENMANAGER as a risk management tool in a number of countries is likely to be reflected in its comparatively high reported frequency of use. A relatively high proportion of the participants had never used the EMKG-EXPO-TOOL, MEASE and RISKOFDERM, which again may be associated with the more specialised nature of these tools.

4.3 Coverage of tools and situations

4.3.1 Number of returns by situation

The numbers of returned assessments carried out were similar across the situations suggesting that there was sufficient and balanced coverage between situations to proceed with the analysis. The main reasons given from the feedback questionnaire for non-completion or partial completion of the full set of situation were problems with running the tools and other commitments. As the exercise required participant commitment for 1-2 hours per week over 4-5 weeks, these reasons are not unexpected.

4.3.2 Number of returns by tool

The numbers of returns by tool were balanced across the inhalation tools. The number of dermal assessments returned for RISKOFDERM is around twice that of the other dermal tools, because of its pairing with two different inhalation-only tools. This approach was taken to maximise the number of assessments collected by standardising and simplifying the completion and process for the participants. This imbalance is not considered to be a cause of concern in the analysis.

4.3.3 Numbers of exposure estimates used in data analysis

In general, the numbers of data points used in the analysis were consistent across the tools, with the exception of STOFFENMANAGER. There were more missing returns noted than for the web-based STOFFENMANAGER software than for the other Microsoft Excel format tools. This may perhaps be due to reluctance on the part of participants to complete the additional log in and parameter input steps required for use of STOFFENMANAGER. It is also possible that the absence of an obvious Excel tool worksheet requiring completion and return may have led some participants to simply forget to carry out some of the STOFFENMANAGER assessments.

4.4 Participants' experience of situations

4.4.1 Inhalation tools

4.4.1.1 Liquids

Overall, participants seemed least familiar with situations 7 (for the ECETOC TRAv3, ECETOC TRAv2 and EMKG-EXPO-TOOL), situation 8 for STOFFENMANAGER and situation 12 for MEASE. It is interesting that situation 8 (cleaning of endoscopy equipment in hospitals) and situation 12 (re-filling of retail dry-cleaning machines) relate to professional uses of substances in end-use products. These are the only situations in the set which we categorised as "professional" uses. Situation 7 relates to the changing of spray booth filters contaminated with an end-use formulation.

The lack of familiarity of the participants with these situations may indicate a general lack of experience amongst the group in relation to professional/ end uses of products compared with industrial settings and/or manufacturing processes.

4.4.1.2 Solids

For solid substances, the participants using the ECETOC TRAv2, ECETOC TRAv3, MEASE and STOFFENMANAGER were most unfamiliar with situations 17 and 19. For the EMKG-EXPO-TOOL, participants were least familiar with situation 18. Situations 17 and 19 relate to hot metal processes. These processes are perhaps less common, and so less frequently encountered by occupational hygienists and other health and safety professionals, than work tasks involving exposure to organic liquids.

4.4.2 Dermal tools

4.4.2.1 Liquids

The levels of familiarity for participants using the dermal tools were almost identical to those for inhalation. As the ECETOC TRAv3, ECETOC TRAv2 and MEASE require input of both inhalation and dermal parameters within the same assessment, this was expected. Situation 7 was again least familiar to participants using the ECETOC TRAv3, ECETOC TRAv2 and RISKOFDERM, whilst for MEASE, participants had least knowledge of situations 12 and 6. It is considered likely that the reasons for this lack of experience are the same as those for inhalation tools, i.e. more limited experience of non-industrial uses of substances.

4.4.2.2 Solids

As for the inhalation tools, the participants had lower levels of familiarity for situations 17, 18 and 19 when carrying out dermal assessments. Again, this is perhaps attributable to a more limited experience of metal and solid handling processes compared with exposures to liquid organic substances such as solvents.

4.5 Participants' level of uncertainty in assigning inputs

4.5.1 Uncertainty in allocation of tool parameters by situation

4.5.1.1 Substance characteristics

In general, participants did not report high levels of uncertainty in the allocation of substance characteristics for inhalation assessments involving liquids. As noted previously, the provision of standardised vapour pressures for all of the substances is likely to have reduced uncertainty across all of the situations. The situations which gave rise to most uncertainty included situation 7 (describing handling of filters contaminated with paint), situation 14 (involving application of adhesives), situation 10 (dipping of metal parts in an isopropanol/water solution), and situation 1, describing manual application of styrene resin to a substrate.

These situations may have led to uncertainty in a number of ways- the correct substance or object to input (e.g. the solid filter or the liquid paint in situation 7/ substrate or resin in situation 1), the physical form of the product (e.g. gel-like adhesives in situation 14), or whether or not to include dilution in water for aqueous solutions, for example in situation 10.

Allocation of parameters for dermal exposures to liquids showed similar patterns, with situation 7 causing greatest uncertainty, most likely for the reasons given above regarding physical form.

There was more reported uncertainty in allocation of characteristics for solid substances for both inhalation and dermal exposures. We have attributed this to the absence of explicit dustiness or other substance-related information in the descriptions, requiring participants to decide on the best fit option.

4.5.1.2 Operational Conditions

The situations with associated with most uncertainty in relation to assigning operational conditions' parameters for inhalation and dermal parameters included situation 5 (tank filling with heavy naphtha), situation 12 (filling of retail dry-cleaning machines with solvent), situation 13 (tank loading of heavy fuel oil) and situation 16 (filling of vessels with isopropyl benzene). There is limited information given in any of the situations regarding factors such as room size, and situation 13 takes place outside.

It is therefore perhaps the case that assigning parameters in these circumstances is more difficult across all of the tools. For example, the EMKG-EXPO-TOOL only allows for the input of operational conditions such as process temperature in the context of determining volatility and does not include a room size option. Some of the reported uncertainty for this tool may be related to the range of available parameters. Similarly, the ECETOC TRAv2 and MEASE do not allow for the separate allocation of general area ventilation in addition to risk management measures such as LEV, for example, therefore participants may have experienced uncertainty in describing the situations using the inputs available to them.

4.5.1.3 Task/activity

The participants experienced most uncertainty in matching the work activity within the situations with the most appropriate tool input, in comparison with the level of uncertainty they reported in allocating the other types of required parameter. It is noted that situation 7 gave rise to most uncertainty across three of the tools. As noted previously, it is likely that the level of uncertainty may reflect some difficulty on the part of the assessors in deciding which task should be evaluated: the overall work activity (spraying in a booth), or the handling of contaminated filters.

Situation 14 led to most uncertainty for users of the ECETOC TRAv2, perhaps because of a lack of detail on the adhesive application method, e.g. spray or roller. Workshop delegates also mentioned difficulty in assessing ancillary tasks such as sampling, which for the ECETOC TRAv2 and ECETOC TRAv3 tools and MEASE are included within certain PROC codes relating to closed systems, but can also be assessed separately. This may also therefore lead to some variation in user input choice, depending on the individual's familiarity with the REACH descriptor systems.

For exposures to solid substances, situations 17 and 19 gave rise to most uncertainty in allocation of task, for the ECETOC TRAv2, ECETOC TRAv3 and STOFFENMANAGER. This is not unexpected, as although there are possible options for coding hot processes with the ECETOC tools, the situation is formally outwith the scope of all three of these tools. Situation 19 was in addition described in more limited detail compared with other situations.

4.5.1.4 RMMs

Assigning RMMs resulted in similar levels of uncertainty to those for allocating operational conditions. Situation 7 gave rise to high levels of uncertainty for users of the ECETOC TRAv3 and STOFFENMANAGER. Although it is stated clearly that LEV is not used during the activity, there may still have been uncertainty associated with its location in a spray booth, where LEV was present but not functioning during the task.

Again this potential source of uncertainty may be related to participants' difficulty in deciding which task (or subtask of an overall process) should be assessed. Uncertainty in allocation of RMMs in situation 19 was high across the majority of the tools, which can be attributed to the very brief description provided.

4.5.2 Overall level of uncertainty

It is clear that participants experienced most uncertainty in choosing the most suitable tool input to describe the task being carried out by the worker. This difficulty arose for both the inhalation and dermal tools, however was more noticeable for dermal assessments. Increased levels of uncertainty in allocation of tool parameters for dermal exposures were also reported by participants at the workshop. The workshop participants indicated that in general they found dermal exposures more difficult to visualise than those for inhalation exposures, and this may also have been an issue for the BURE participants.

In interpreting these results, it is obviously prudent to note that whilst participants may have been very certain about their chosen input, they may nevertheless have entered erroneous or unusual options into the tools. This point is illustrated by consideration of the geometric standard deviations for the residual variances by tool for the various uncertainty levels associated with different groups of input parameters. There were no consistent patterns observed, and indeed the highest GSDs were noted with similar frequencies for categories of low and high levels of reported uncertainty. It is therefore felt that the level of uncertainty in allocating tool inputs is not obviously associated with variability in estimates of inhalation and dermal exposure.

Identification of potential causes of input parameter uncertainty is however helpful in highlighting possible areas of improvement in tool user guidance documentation, for example clarity of definition of the different tool options within a parameter such as dustiness.

4.6 Ease of translation of situations into tool parameters

4.6.1 Inhalation tools

4.6.1.1 Liquids

Situation 7 proved most difficult for participants to translate into input parameters across all of the tools. From consideration of the other data gathered, the reasons for this are likely to be its relative unfamiliarity to the participants, uncertainty about the process to be assessed, uncertainty about the use of RMMs and uncertainty about the physical form of the substance to be used. STOFFENMANAGER users found equal difficulty in translating situation 16 into the tool parameters, though there are no obvious reasons for this difficulty, as it contains a high level of contextual information and is within the scope of the tool.

4.6.1.2 Solids

Inputting parameters relating to solids in situation 19 was most difficult for users of the ECETOC TRAv3 and STOFFENMANAGER. The process relates to fume exposure during the processing of molten aluminium, which is not applicable under either of these tools. For STOFFENMANAGER, there are no obvious input parameters for fume generation processes, which may have given rise to the reported difficulty in translation of the given description into the tool.

The context of this finding is slightly different for the ECETOC TRAv3. Although hot metal processes can be entered in the ECETOC TRAv3, using PROC 25, its use is not recommended by the tool developers. This finding should therefore be considered in relation to both the tool's stated range of applicability and the potential for a user to utilise the available tool options to assess processes of this type deliberately or in ignorance of the developer's advice.

With the exception of MEASE, for situations within the range of applicability of the tools, situation 18 was considered relatively difficult to translate into input parameters. Although referring to nickel metal powder, the situation covers a common type of solids packing process. The comparatively high percentage of participants who were reported that they were unfamiliar with the activity may have contributed to this higher level of perceived difficulty.

4.6.1.3 Overall perception of ease of translation

In general the participants appeared to have most difficulty in translation of processes which were "unusual" in some way, either because they were end-use product tasks, as in the case of situation 7 which also referred to a low volatility substance, or related to processes which were perhaps outside of the normal range of industrial hygiene practice, e.g. handling of powders, as opposed to assessment of mechanically-generated dusts. The difficulties in assessing fume generation processes were also perhaps related to a lack of participant familiarity with hot metal processes.

4.6.2 Dermal tools

4.6.2.1 Liquids

Situation 7, as mentioned above, clearly relates to a situation where dermal contact with the object is likely to be the main exposure route. The situation was not considered easy to translate into the majority of the tools, possibly because of the participants' difficulties mentioned previously in deciding on tasks, setting and RMMs. Situation 13, top loading of heavy fuel oil, also caused some difficulty for participants using RISKOFDERM, and again, it can be postulated that this may be related to problems in deciding on the task, substance characteristics and RMMs.

4.6.2.2 Solids

Difficulty in translating situation 19 (involving exposure during aluminium processing) was noted by participants for the majority of tools. As for the uncertainty in allocation of parameters, this is considered likely to relate to the lack of detail in the situation and perhaps to a lack of familiarity of the participants with this type of process. In addition, there is likely to be some uncertainty about how to translate activities involving high temperature molten metals into dermal exposure tools, as direct physical contact with the substance is not likely unless by accident. Although MEASE allows specific parameters for dermal exposure to be entered, including no contact, the participants reported similar levels of difficulty for this tool as for the others when assessing situation 19.

4.6.2.3 Overall ease of translation

The overall ease of translation of the situations into the various input parameters was similar across the inhalation tools, for example situation 7 was considered most difficult to translate into tool parameters. The impact of ease of translation on the level of variation amongst users was not consistent, with higher variance associated both with difficulty in translation of the situation, and for cases where the participants found translation very easy. As for the level of uncertainty experienced, participants' reported perception of ease in translation did not always result in the choice of appropriate or consistent input parameters.

4.7 Impact of participant characteristics

In general, there appears to be little impact on the amount of between-user variation in estimates associated with the participants themselves, for example their sector of employment, or previous experience of assessment. The exposure estimates generated were not systematically higher or lower between different categories of user.

Specific cases where there was some small but observable impact of characteristics on the amount of variation or estimate values are discussed below.

4.7.1 English language ability

English language ability had a small effect on the level of variation for the MEASE tool, with respondents with average or poor language ability exhibiting more variation than those in other categories. It could be postulated that the observed limited use of the metal/ inorganic PROC codes within MEASE for relevant situations may have been related to difficulty in comprehension of the English language in-tool glossary. However, as relatively few participants were familiar with this tool, identification of the most likely cause is difficult.

4.7.2 Exposure assessment experience

With the exception of the EMKG-EXPO-TOOL, the level of exposure assessment experience of the participant did not greatly affect the variation between users for the majority of tools, with no systematic increase in variation for participants with fewer years' experience observed as might be expected.

For the EMKG-EXPO-TOOL, a small but statistically significant increase in variation was noted for participants with less than 1 years' experience of exposure assessment, compared with the other categories. This result is interesting in light of the tool's control banding origins, where users would be expected to be non–professional exposure assessors with lower knowledge and experience levels.

Overall however, there seemed to be no consistent pattern to the variation between users, when the assessor's experience was taken into account. This is in accordance with previous research looking at inter-rater reliability, which found no association between assessor experience and the degree of agreement (Steinsvag et al, 2007).

Statistical analyses across all situations did not indicate any systematic differences associated with years of experience, e.g. those with most experience did not always generate higher or lower estimates.

4.7.3 Normal purpose for carrying out exposure assessments

The purpose of the eteam Project as a whole is to evaluate the performance of the Tier 1 tools in the context of their use in REACH. The effect of the participants' normal reason for carrying out exposure assessments on their tool-generated estimate was therefore evaluated, i.e. whether they generally carried out assessments under REACH or for other purposes, such as assessing compliance with limit values.

Although it might be predicted that participants who carried out assessments under REACH might show more consistency in their estimates than other assessors because of more knowledge of the tools and process, this did not seem to be the case for any of the tools.

There are a number of factors which may be relevant to this finding.

The usual use of the tools for REACH assessments involves iteration of the input parameters to achieve an acceptable description of safe use, i.e. where the ratio of the predicted exposure to the Derived No Effect Level is < 1, which can then be disseminated accordingly through the supply chain. The desired output of the assessment process therefore comprises the input parameters from the tool together with the associated estimate.

The BURE involved translating a written description of a process into the relevant tool parameters, to calculate an exposure estimate. This reversal of the normal process may therefore not have resulted in any natural reduction in variation between participants who are more familiar with REACH.

The statistical analyses did not identify systematic differences in the exposure estimates generated by those assessors who carried out assessments for REACH purposes compared with those who assessed exposure for other reasons.

4.7.4 Previous experience of tools

The level of familiarity with and knowledge of the operation and limitations of the exposure assessment tools was also considered. When considering prior knowledge of the tools, it could perhaps be expected that variation would decrease with increasing familiarity with the operation of the tools.

As for the other participant characteristics, the prior knowledge of the assessors did not impact consistently on the amount of variation. In some cases, increased levels of knowledge reduced variation, whilst in others, between-user variation fell with lower levels of prior experience of using the tools. A lack of prior knowledge of the tools may have encouraged some users to assess the situations more carefully than more experienced participants, who may have made quicker but less valid decisions on tool parameters.

Systematic differences in the exposure estimates generated by participants with different levels of prior knowledge of the tools were not observed, i.e. their assessments were not consistently higher or lower than those with less or more prior experience.

4.8 Impact of Situation-related factors

Analyses of variation in exposure estimates were undertaken separately for situations involving exposure to solid and volatile substances. For the purposes of the analyses, fumes from hot metal processes were categorised as solids.

There was in general more variation associated with situations involving solids than those for liquids, perhaps because of the requirement for participants to choose dustiness categories. Lower general levels of experience of solids' handling activities and metals' processes amongst industrial hygiene professionals may also be relevant. These factors may however be counteracted by participants finding dusty processes easier to visualise, and therefore assess, than those involving exposure to vapours. This tendency has been noted previously in other studies. (Mannetje et al, 2003); Friesen et al (2011).

The participants' previous experience of the situations was variable, with less experience of end-use/ professional situations being reported than those describing industrial/ manufacturing type processes. Participants had relatively lower levels of experience of situations 7 and 8 involving use of liquids in end-use and non-professional settings and situations 17 and 19, relating to hot metal processes. Higher levels of uncertainty in allocation of task input parameters for situations 7 and 19 were also reported by participants, again suggesting a level of unfamiliarity with the activity being undertaken.

The ease of translation of each situation varied across the tools, with decreased ease of translation not consistently associated with increased variation between assessor estimates.

No patterns in the amount of information provided within a situation and the degree of variation between user estimates were evident. Situations which had higher levels of between-user variation were in general well described, with information on the majority of parameters provided. The provision of additional information does not therefore appear to result in improved levels of reliability between assessors. This is consistent with other related research, where additional information increased the validity of exposure estimates compared with a measured or identified concentration, but did not improve the reliability amongst assessors (Friesen et al, (2011); Stewart et al (2000)). De Cock et al (1996)) also found that the provision of additional detail on work situations, including written background information on tasks, had little effect on the level of agreement between assessors of pesticide exposure. The workshop delegates differed in their opinion of the type and amount of information provided in the situations when compared with that normally available for assessments under REACH. Some delegates suggested that the detail provided was in excess of that generally provided (which may on occasion only be a PROC code), whilst others indicated that it was representative.

Within the BURE, some, albeit limited, variation in descriptive detail was introduced, to reflect the normal range of detail available to tool users. However; the type of information provided appeared to have little effect on the variation between users.

4.9 Specific parameters causing variation by tool

Parameters which were identified as sources of variation between users are discussed more fully by tool below. Some aspects of the discussion are common to more than one tool, for example choice of PROC code, and should be considered in this context. Input parameters for tools which influence both inhalation and dermal simultaneously are considered jointly, with exposure route specific parameters discussed separately. Relevant findings from the one-day workshop are also incorporated to assist in interpretation of the results.

4.9.1 ECETOC TRAv3

4.9.1.1 Selection of PROC code

Differences in the allocation of PROC codes led to wide ranges of estimates being generated by participants, for example for situation 7, where the choices included PROCs 1, 7 and 19 for an activity involving handling of contaminated objects. There appeared to be some confusion on the part of participants regarding whether the PROC should apply to the overall process, e.g. spraying or only the part where exposure actually happened, i.e. the handling task. This may be related to a lack of experience and understanding on the part of some BURE participants regarding exposure assessment techniques rather than the tool use. However; the issue was also raised by workshop delegates, who mentioned difficulty in splitting and describing subsidiary tasks from main activities, for example wiping down of equipment after filling of tanks, or cleaning of equipment during normal operation. As the delegates represented a range of experience levels, this is perhaps a parameter which requires additional guidance and relevant examples.

Workshop delegates also mentioned frequent difficulties in selecting PROC codes within the relevant tools. The lack of availability of exemplar activities covered by each of the codes was also discussed. Workshop delegates reported some uncertainty when assigning the more general “handling” and “transfer” PROC codes, for example PROCs 8a, 8b and 9. The interpretation of dedicated/ non-dedicated facilities and scale of process indicated by the descriptors “large” and “small” was not consistent across the workshop delegates. This is also illustrated by situation 15, where some participants allocated PROC 8b, whilst another chose PROC 9.

Such difficulties are not directly related to the tools, but rather to the REACH processes and documentation themselves

Within a REACH-context, the impact of difficulty in choice of PROC could be manifested in a number of ways. For example, a PROC code will have to be decided on for a particular activity by the manufacturer/ supplier or in some cases by a consultant working on their behalf. At a downstream user level, a decision must be made on whether a particular work activity is covered by the PROC defined in a safe use description.

In both of these cases, between user variation in assignation of the PROC may lead to a non-valid exposure estimate being used for the assessment. In turn, ineffective or unnecessary risk controls may then be implemented, resulting in associated health and/ or financial risks to the organisation.

Interestingly, allocation of task/ activity was identified as the parameter causing most uncertainty for all of the tools, regardless of whether they incorporate PROC code, which is consistent with the differences observed in interpretation of this determinant in the situations noted above.

4.9.1.2 Type of Setting

The decision on whether situations took place in professional/ public or industrial settings was made solely by participants, as no explicit information was included for this parameter in the descriptions provided. Variation in the choice of setting resulted in significant variation for some situations. Using situation 7 again as an example, the choice of professional or industrial was unclear to the participants, with some choosing professional and some industrial.

The workshop delegates also reported difficulty in deciding whether or not a particular situation was professional or industrial. A number of factors were mentioned as being relevant, for example process size, level of worker expertise, implemented control measures and purpose of activity. No consistent decision-making method for this parameter was identified. As the tools generally assume that professional settings are less well controlled than industrial situations, this is a potential source of both over- and underestimation of exposure.

For REACH purposes, limited regulatory guidance exists regarding allocation of setting. It is expected that tool users carrying out exposure assessments under REACH would be more certain of the type of setting, therefore the impact of this factor in a REACH context is likely to be limited.

Tool estimates generated for other purposes, for example general risk management of hazardous substances or in assessing compliance with limit values may however be more influenced by this parameter.

4.9.1.3 Dustiness

Differences in allocation of dustiness levels and the associated estimates were evident in a number of situations, for example situation 9, where each of the assessments studied included different dustiness categories (high, medium and low). A lack of available information on dustiness and of a simple way to estimate this parameter were also discussed at the workshop, where a number of factors including density, moisture content and particle size were considered relevant. The workshop delegates noted that whilst access to a sample of the material was very helpful in categorising dustiness, this was seldom possible for many of substances and assessments carried out, which were on occasion done using very limited textual information only.

Unlike other exposure determinants, such as risk management measures, a substance's physical form/ intrinsic dustiness is not likely to be variable for a particular set of process requirements.

It is therefore considered possible that this parameter may lead to considerable variation in estimates between users of all of the tools, whether they are being used for REACH or for other purposes.

4.9.1.4 Task duration

As the task duration options within the tool are not mutually exclusive, some variation was noted for tasks which fell on the boundary between categories. For example in situation 9, participants were split between choosing 1-4 hours and 15 mins-1 hr for the stated task duration of 1 hour. Workshop delegates were also divided between whether or not a realistic or conservative option should be chosen in such circumstances, with a general consensus that using a realistic duration was more appropriate for already conservative tools. Differences in allocation of borderline task durations whilst using the tool in a REACH context to identify safe uses are considered unlikely to be a cause of significant variation

4.9.1.5 LEV/ general ventilation

There was some variation amongst participants however this was generally associated with some assessors missing/ adding in LEV systems that had not been mentioned in the description. This is illustrated in situation 9, where the lowest estimate included LEV, although it was not stated as being present, and in situation 15 where LEV was present, but not included in the higher estimates examined. The erroneous attribution of local and secondary control measures because of errors in interpretation of workplace situation information was also noted by Schinkel et al (2013). The study, looking at the reliability of the ART tool, found extreme deviations from their gold standard estimate could be caused by allocation of LEV when none was present, and vice versa, i.e. assessors failing to include relevant exposure controls.

Although the parameter has a significant effect on the estimate obtained, and is a source of variation, it is not therefore considered a factor of importance in general use of the tool, where the assessor could be assumed to know if LEV was present, either through thorough reading of written information or visual inspection of the workplace.

In relation to general ventilation options, some variation was noted between participants. For example in situation 8, one participant assigned enhanced general ventilation, perhaps because the situation included reference to the presence of mechanical ventilation, whilst others chose good general ventilation. Workshop delegates also discussed the usefulness of the increased number of options for ventilation +/- LEV in version 3 of the ECETOC TRA, compared with the yes/no LEV choice in version 2 of the tool. The difficulty of deciding subjectively on workplace ventilation rates in the absence of measurements was also reported by delegates, therefore allocation of the most appropriate ventilation option is still likely to be a source of variation between users.

For the majority of the situations, participants had opted for the conservative option of not including LEV when estimating dermal exposure. In situation 15, one participant had chosen to include LEV to reduce dermal exposure, perhaps because the workstation was described as having LEV directly at the point of filling. The workshop delegates were not clear about the effectiveness of LEV on controlling dermal exposures. In general, they felt that the effect of LEV on dermal exposure was likely to be limited where splashes or direct deposition occurs, but was more effective in controlling exposure from vapour deposition. This may explain the general tendency for BURE participants to default to "no LEV" in generating dermal exposure estimates.

More obvious tool guidance on this respect would be helpful in assisting users to decide on the most appropriate choice for their particular requirements.

4.9.1.6 RPE

For some situations, participants were provided with detailed information on the type of RPE worn, for example situation 15 describes an air filtering respirator with P3 filters. In this situation, the participant who generated the highest estimate assumed a 90% effectiveness of the RPE, compared with 95% effectiveness assigned by the other participants. In other situations, non-specified RPE was described, which required participants to allocate the level of effectiveness. For example in situation 7, in the absence of a specification, the participants assigned the lower level of effectiveness. The presence/ choice of RPE is an important factor in determining the overall estimate. Some workshop delegates indicated that they would on occasion run the tools without RPE to generate an initial estimate, which they subsequently adjusted for RPE, either within the tool or manually. This was generally done in situations where the use of RPE was unavoidable.

As the use of the tool in REACH allows the inclusion of RPE, which can then be specified subsequently by the user, these differences in allocation of type of RPE were not considered to be a significant issue.

4.9.1.7 Concentration

There was limited variation noted amongst participants in relation to their choice of substance concentration. This finding is not unexpected as the concentration was given in the majority of situations. It is assumed that concentration information would generally be available to assessors using the tool under REACH. Therefore this parameter is not felt likely to contribute greatly to between-user variation.

4.9.1.8 Gloves

Varying levels of information were provided to participants within the situations on the use and type of gloves. No detailed information was given on glove specification or training, only simple descriptions such as "cotton gloves" or "rubber gauntlets", leaving the participants to decide on the level of effectiveness. For situations where gloves were worn, there was little consistency amongst users in their choice of effectiveness, for example in situation 7 where cotton gloves were worn, the participants were split between APF10 and APF 5. In situation 8 (nitrile gloves) and situation 9 (disposable latex gloves), there were also differences in the allocation of effectiveness for the worn. Workshop delegates did not generally feel that the reduction in exposure allocated in the tool was always achieved in practice, and acknowledged difficulties in determining whether or not appropriate selection and training procedures were actually in place.

In general, more variation was noted within the dermal estimates generated by the ECETOC TRAv3, compared with the same situations when assessed using the ECETOC TRAv2. This may be related to the additional options of including gloves, (and LEV) within the newer version of the tool.

As for RPE, the use of the tool in a REACH context allows the user to specify glove type and associated risk management measures such as training. The observed variation in glove choice is therefore likely to have a negligible impact.

To summarise, whilst there was observed variation between choices made for the majority of parameters, in the context of REACH, it appears that the greatest impact on the resultant estimates could arise from differences in choice of PROC code and of the dustiness level. More comprehensive guidance incorporating additional descriptive examples within the relevant REACH documentation and within the tool itself could perhaps help users in their choices for these particular parameters.

4.9.2 ECETOC TRAv2

Many of the sources of variation between users of the ECETOC TRAv2 are similar to those identified for version 3 of this tool, for example in relation to allocation of PROC code, dustiness and task duration. It is considered likely that many of the reasons and implications proposed above for the variation between users of the version 3 tool are very similar to those for the ECETOC TRAv2, therefore are not repeated in detail in the discussion below. Specific points of interest in relation to particular parameters are highlighted.

4.9.2.1 Selection of PROC code

As for the ECETOC TRAv3, differences in allocation of PROC code resulted in wide variation in exposure estimates between participants. This is illustrated very clearly in situation 20 where the PROC code was the only parameter that differed between the three assessments examined. The resulting inhalation estimates ranged from 0.01 - 362 mg m^{-3}, whilst the corresponding dermal estimates covered a range of 0.03 - 14 mg/ kg/ day. All of the PROC options chosen for the task (PROCs 1, 4 and 8a) seem potentially valid for the process, which involved a transfer of a liquid to a closed mixing vessel using a pump. This type of transfer/ filling process is common in many industrial settings, with 40% of the participants having some previous experience of the situation. Participants did not report any particular difficulty in translating the situation into the tool parameters, and 12 participants out of 20 indicated uncertainty in allocation of task (major uncertainty (n=3) and minor uncertainty (n=6)).

As in the case of the ECETOC TRAv3, significant potential for generation of incorrect exposure estimates and the allocation of inappropriate risk management measures therefore exists for this tool

4.9.2.2 Dustiness

In each of the situations involving exposure to solids, differences were observed between participants in their allocation of dustiness levels. For situation 11 which involves careful small scale handling of pharmaceuticals however generates visible dust emissions, the three participants all chose different dustiness levels. It is perhaps the case that to some degree participants may make choices based on the amount of dust generated because of the nature of the work activity (i.e. energetic handling processes would result in a high dustiness rating), rather than the intrinsic dustiness of the material. A similar thought process was reported during the workshop by delegates in relation to choosing contact level within the MEASE tool. Delegates associated extensive contact with highly dusty substances and intermittent/ incidental contact with medium dustiness, i.e. they were assessing likelihood of contact rather than its actual frequency. Conflation of two or more input parameters is likely to both increase between-user variation and impact on the estimated exposure.

More generally, as for all of the tools, inconsistency in choice of dustiness may result in incorrect exposure estimates being generated or in the case of downstream users, inappropriate risk controls being used.

4.9.2.3 Type of setting

The differences in allocation of setting noted within the ECETOC TRAv3 were also observed version 2 of the tool, in particular for situation 7. This may be due partly to the difficulty in separating task from overall activity, but also because of an absence of clear guidance on what constitutes each type of setting within the tool and REACH documentation.

4.9.2.4 Task duration

Choosing between borderline task durations within the ECETOC TRAv2 gave rise to differences in estimates. For example within situation 9, some participants chose the shorter duration of 15mins-1 hr, compared with the more conservative option of 1-4 hours. Workshop delegates reported that they would generally opt for the best-fit option rather than the more conservative option, however recognised that tasks sometimes run over their allotted time. As for the ECETOC TRAv3 and MEASE, significant between-user variation in exposure estimates could result from choice of different task duration, although this is perhaps less likely in a REACH-context than in risk management applications of the tools.

4.9.2.5 LEV

The LEV choices within the ECETOC TRAv2 tool are clear, with a simple yes/no decision required. Between participant variation for this tool parameter was therefore attributed to differences in interpretation of the situation descriptions, rather than the choices within the tool itself.

In summary, similar inconsistency was observed between users of the ECETOC TRAv2 tool as for the more recent version. As the ECETOC TRA v2 was used for many of the REACH assessments prior to 2012, there may be some variation between users who generated exposure estimates as part of this process. However, as the tool is no longer used for this purpose, the provision of extra information within the tool is unnecessary.

4.9.3 EMKG-EXPO-TOOL

The EMKG-EXPO-TOOL has fewer input parameters than the other tools and may therefore have been expected to show lower levels of variation between users. This prediction was not borne out by the results however, with high levels of variation noted between users for many of the situations. These are discussed below by physical form- specific parameters and by parameters common to both liquids and solids.

4.9.3.1 Liquids

i) Volatility bands

Although the participants were supplied with standard vapour pressures for each situation, there was some variation in the allocation of volatility bands in situation 8 (glutaraldehyde: vapour pressure 1Pa) and situation 20 (acetone, vapour pressure 24000Pa). There is no obvious reason for these differences, however it can perhaps be speculated that they arose from the participant mis-reading either the vapour pressure given in the description, or mis-interpreting/ mis-reading the definition of the bands in the tool input sheet. The high number of participants reporting no previous knowledge of the tool suggests that the latter reason may be more likely.

Participants using the EMKG-EXPO-TOOL experienced more uncertainty in the allocation of liquid substance characteristics than those of the other tools. Situation 10 generated most uncertainty for this parameter. This suggests that the difficulty may be related to the absence of concentration/ dilution factors in the tool, illustrated in this situation where there is exposure to an aqueous solution of isopropanol.

In general, providing that reputable sources of vapour pressure are chosen, and the tool guidance on band selection is followed, it is felt that this parameter would not be a significant source of between user variability. Workshop delegates reported using a range of sources to identify vapour pressures, including manufacturers’ safety data sheets, IARC monographs and chemical safety handbooks. The delegates felt that the web-based ECHA database would become a preferred information source as it becomes more fully populated with substance data. Standardisation of source data will help to reduce between-user variation.

ii) Application on surfaces > 1 m^2

A choice of application on surfaces > 1 m^2 of quantities more than 1 l results in a 10 fold increase in the exposure estimate. This option was chosen by participants in two of the situations examined- situation 20 and situation 7. It is not clear why the participant assessing situation 20 chose this option, as the process described a pumped-transfer of acetone into a closed mixing vessel, therefore this may have been a simple error. In situation 7, involving manual changing of spray-booth filters, the participant who chose this option may have done so to reflect exposure from paint spread over the filter surface, thus increasing exposure from evaporation. This seems feasible, depending on the filter size.

iii) Control approach

The control approach selected by the participants varied for all of the situations examined in detail. For example, in situation 20, involving addition of acetone to a closed vessel using a pump (with LEV), all three participants chose different control approaches. Within situation 7, although the process involved direct handling of filters, one participant chose control approach 3 (containment). It has been noted for other tools that there may be some confusion amongst participants regarding separation of the task involving exposure from the overall work process. Within EMKG-EXPO-TOOL, there is no task/activity specific parameter within the tool, only reference to external control guidance sheets. In this particular case, it could be postulated that the participant has allocated containment control, because the task occurs in an enclosed paint spray booth. Similar difficulties in delineation of task and sub-task therefore seem possible for this tool.

4.9.3.2 Solids

i) Dustiness

There was variation between the participants' choice of dustiness level for both of the situations examined. In this tool, differences in dustiness may not affect the estimate obtained, depending on the other chosen parameters such as quantity used, however is still a potential source of significant between- user variability. As for allocation of parameters for liquids, this may be at least partly related to unfamiliarity with the tool itself, which contains slightly different dustiness definitions than the more commonly-used ECETOC tools and more limited example substances than for instance the STOFFENMANAGER tool.

It is however assumed that most of the variation for this parameter in the EMKG-EXPO-TOOL arose for the same reasons as noted previously, i.e. a lack of availability of standardised dustiness data and difficulty in estimating dustiness without visual examination of the material. Within a REACH-context, similar problems relating to the validity of the estimates could therefore be foreseen.

4.9.3.3 Liquids and solids

i) Scale of use

Variation in the allocation of scale of use, i.e. the quantity of materials involved in the activities was observed in all of the situations studied in detail. There was limited information on quantity provided in the descriptions, requiring participants to choose the most appropriate scale of use. The variation in allocation of scale of use is consistent with the findings of Schinkel et al (2013), which noted low levels of agreement between ART users for subjective parameters such as amounts used.

The EMKG-EXPO-TOOL is the only inhalation tool which explicitly includes an input for the amount used, which, in combination with the absence of a concentration-related reduction factor, may account for the higher overall estimates generated by this tool in comparison with the others.

ii) Short term exposure

The tool includes an option to reduce exposure significantly by applying a correction factor for exposures which last for less than 15 minutes within the 8 hours shift. There was no observed variation in choice of this parameter in the situations examined in more detail, suggesting that the participants did not experience much uncertainty in its allocation.

In summary, whilst the EMKG-EXPO-TOOL may be perceived by users to be a simple and easy to use tool, our results suggest that there is a similar level of variation in the choice of parameters, and thus estimates, as for more complicated tools. The exercise was undertaken by participants with a degree of, (albeit in some cases limited), experience of exposure assessment. As the tool was designed originally to be used by lay persons as part of a risk management strategy, it is possible that the levels of variation between non-experienced users may be higher.

4.9.4 MEASE

There are a number of similarities between the parameters in the MEASE tool and those within the two ECETOC TRA tools, for example the requirement to enter a PROC code to describe the task undertaken, and the task duration options. The reasons for variation in relation to these parameters could therefore reasonably be expected to be similar to those for v2 and v3 of the ECETOC TRA, and it is assumed that this is the case.

There are however substantial differences for a number of parameters, particularly in relation to physical form, dermal exposure determinants, choice of implemented RMMs and their efficiency. These are discussed below as possible sources of between user variation.

4.9.4.1 Physical form

There are a relatively high number of options for physical form within the tool: including solids of varying dustiness, massive objects, volatile liquids, gases and aqueous solutions. The majority of the situations within the exercise do not fall within the range of applicability of the tool, which excludes organic powders and volatile organic liquids. We recognise that use of the tool outside of its correct domain should not occur within a REACH context, as a user would be expected to carry out assessments only with an appropriate tool. However, it is interesting to consider on a purely hypothetical basis which inputs might be a source of variation in the event that an inexperienced user employed the inputs available in the tool for volatile organic liquids.

Using situation 10 as an example: this involved an aqueous solution of isopropanol. Some participants interpreted this as an aqueous solution, which within the tool refers to solids in solution, whilst others interpreted it as a (volatile) liquid. As the aqueous solution option results in an exposure estimate for a solid substance, rather than a volatile liquid, these incorrect choices increased the relative amount of variation between users for MEASE. The option of dilution in water is also available in STOFFENMANAGER for liquids, which still generates an estimate based on evaporation of volatile. The effect on the estimate generated by STOFFENMANAGER is therefore not as noticeable as for the MEASE tool.

It is also notable that in situation 17, where exposure is to lead fume, and so is clearly within the scope of MEASE, participants were split between choosing liquid or massive object. This was assumed to be because the participants assumed that metal was molten, or allocated its original solid form prior to melting. As noted above, choosing “liquid” generates an estimate of exposure to vapours from volatile liquids, rather than for metal fume from liquid lead. The erroneous choice of liquid was likely to have been made by participants who had not referred to the tool help functions/ glossary, which contain guidance on choosing the most appropriate physical form. This assumption was supported by workshop delegates reports of using the very limited introductory documents supplied for the exercise rather than the detailed information within the individual tools.

Although the participant population as a whole appeared less familiar with solids and in particular metal processes, identification of the correct physical form of a substance is a routine and elementary aspect of occupational hygiene assessments. As such, the findings in relation to both applicable and non-applicable situations are of some concern. The lack of user clarity about this aspect of the tool led to significant inconsistency in their final estimates.

4.9.4.2 PROC code

In addition to the variation in choice of PROC discussed above, MEASE- specific causes of variation were also identified. The MEASE glossary includes suggested PROC codes for a range of processes involving metal and inorganic substances. It is therefore interesting that in situation 17, which related to cleaning of solder dross, none of the assessments studied in detail included choice of metal-specific PROCs which are the distinguishing feature of the MEASE tool. This may have resulted from failure of participants to consult the within-tool guidance. One workshop delegate suggested that users may not scroll down the full list of PROC codes, but perhaps settle on the first likely-sounding option. This approach may also have precluded some participants from selecting any of the higher numbered metal-specific codes. This incorrect approach is not considered to be a major source of error in exposure estimation under REACH, where tool users might be expected to have fully utilised the input options available.

Similarly, in situation 9, it was noted that participants also tended to choose general handling/ transfer PROC codes, 8a/ 8b in preference to PROC code 26 which is specific to metals/ inorganic substances. As PROC 26 is not available in the more commonly used ECETOC tools, this may be related to a lack of familiarity, and so awareness of, more appropriate tool options within MEASE.

4.9.4.3 Implemented RMMs

The tool guidance recommends a conservative choice of the lower confidence limit for the efficiency of the chosen RMMs, and the participants in the main chose this option, with a limited number choosing the median value. As for the other tools, there were differences between participants in their interpretation of the descriptive information provided, with RMMs being assigned when not actually present, as in situation 17, and not being selected when they were included. For situation 10, it was noted that one participant chose “general ventilation” whilst others chose no RMMs. It is therefore possible that, in the absence of any obvious additional control measures such as LEV or enclosure, these two options could be confused by users who do not recognise that general ventilation is available as a specific RMM.

4.9.4.4 Dermal exposure determinants

The MEASE glossary includes definitions and guidance on dermal parameters to assist users with the most appropriate choice, for example in relation to the frequency and degree of contact with the substance. The participants using MEASE did not however apply this guidance consistently, with much variation between user choices noted in these parts of the tool. This was likely to be partly related to the absence of this type of information within the situation descriptions, with participants being required to enter appropriate parameters. As noted previously, workshop delegates reported difficulty in separating out frequency of contact with a substance with its intrinsic properties that may make contact more likely, such as high levels of dustiness.

The pattern of exposure control chosen by participants also varied, and it was not clear if the definitions for this parameter are fully understood. For example in situation 9 which described a manual scooping activity, one participant chose non-direct handling, suggesting that they had not consulted the tool guidance.

In summary, much of the variation between users seemed to be related to a lack of awareness of how to use the MEASE tool in the most effective and appropriate way. As for all of the other tools, there were also between user differences noted in the allocation of task and dustiness information for MEASE.

4.9.5 STOFFENMANAGER

The STOFFENMANAGER tool includes most input parameters per assessment of all of the tools evaluated, and might therefore be expected to show most variation. More choice in input parameters did not however seem to increase between-user variability however, as the levels of variation between STOFFENMANAGER users were similar to those for the other tools. Many of the areas of uncertainty and difficulty reported by participants for this tool are identical to those identified for the other tools- allocation of task; dustiness of solid substances; risk management measures and general environmental conditions. These potential sources of between user variation are discussed below.

4.9.5.1 Task characterisation

STOFFENMANAGER includes a range of task descriptions for both solids and liquids, all of which include a small set of specimen activities to assist the user in their choice. In theory, provision of illustrated examples might be expected to simplify allocation of the category and so promote consistency between users. There was still significant variation in the task choices by participants, for example in situation 8, where three different options were chosen for the same activity. The scale of the three options was similar however, i.e. they were all small quantity/ low handling energy processes. This situation had the highest percentage of participants with no related experience (94%), therefore difficulty in assigning parameters is not unexpected. The choice of task description also varied in situation 13, with more diverse options chosen in terms of scale of process and its “energy”, e.g. small scale low energy handling/ low pressure activity/ no mist vs high pressure/ substantial mist.

Allocation of task is therefore considered a potential source of considerable variation between users of this tool. Communications with the tool developer suggest that, in line with its control banding origins, the STOFFENMANAGER is more often used as a risk management tool within enterprises than for REACH assessments. However, for use of STOFFENMANAGER in either of these contexts, as for the other tools which use PROC codes as a proxy handling parameter, inappropriate choice of task description could lead to incorrect exposure estimates, and/or inappropriate or unnecessary implementation of risk controls.

4.9.5.2 Vapour pressure/ dustiness

As for the other tools, the potential for variation caused by choice of vapour pressure was minimised by the inclusion of standard values for the individual situations. Some of the variation in situation 8 can however be attributed to the inclusion of the wrong product and associated vapour pressure for the assessment by one participant, resulting in a higher exposure estimate.

There were many observed differences in how participants assigned dustiness within each situation, for example in situation 9, when the options chosen ranged from relatively low dust “granules/flakes/grains”, “fine dust” and “extremely dusty”. The difficulties in assigning dustiness in STOFFENMANAGER were assumed to be similar to those for the other tools, i.e. caused by a lack of standard information for substances and no visual/ physical examination of the substance being possible during the exercise.

There are more categories of dustiness available to users of STOFFENMANAGER than for the other tools. This might have been expected to increase variation between users relative to the tools with fewer options. However; the inclusion of examples for each of the options may also have helped to reduce such variation. The amount of observed variation in choice did not suggest an obvious impact of either increased categories or increased guidance. The workshop delegates indicated that the inclusion of these exemplar descriptions was a helpful feature of the STOFFENMANAGER tool. The provision of examples with which the tool users can compare their substance may therefore be of some benefit.

4.9.5.3 Period of evaporation/ curing/ presence of other workers

Parameter choices relating to the presence/ absence of secondary sources of exposure, for example evaporation from curing paint, or other workers, varied in situations 8 and 13 respectively, but were not observed in the other situations examined. It is felt that these parameters are unlikely to result in significant variation between users in a REACH context, where the nature of the activity itself and follow-up processes such as drying/ curing are perhaps better described.

4.9.5.4 Breathing zone exposure

In theory, whether or not the substance is released into the worker’s breathing zone should be easy to predict using the information in the descriptions. Some variation was noted in situation 13, which related to top loading of tankers, where one participant chose working in a cabin for the task, whilst others indicated that the task took place in the employee’s breathing zone. Again, it is felt that this parameter is unlikely to be a cause of variation in normal tool use, either under REACH or in workplaces, where information on control measures/ route of exposure would be known.

4.9.5.5 Control measures

Variation in the allocation of control measures at source for the tasks was noted in many of situations examined. For example in situation 9, three different control options were chosen, covering the full range of control from “no control measures at source", "local exhaust ventilation" and "containment of the source with LEV". There was no clear reason for the differences in allocation, although it was possible that some resulted from mis-interpretation or simple mis-reading of the description. It was not possible to quantify the degree to which this factor contributed to variation.

4.9.5.6 Cleaning/ maintenance schedules

Feedback from the workshop delegates indicated that it was generally assumed in a REACH context, and recommended in the supply chain information, that good industrial hygiene practice should be followed in respect of cleaning schedules and maintenance of equipment and RMMs. These options would therefore be chosen when using STOFFENMANAGER for these purposes. The participants in the exercise were however variable in their inclusion or omission of parameters relating to cleaning and maintenance, perhaps because this type of information was not provided in the situation. These parameters are therefore a potential source of slight variation in the use of STOFFENMANAGER for non-REACH purposes.

4.9.5.7 Volume of work area

The majority of the situations did not include information on the size of the location where the exposure took place. As such, participants were left to choose the most relevant size. For example, the assessors for situation 8 were split between a choice of <100m^3, and 100- 1000m^3, which makes a noticeable difference to the final exposure estimate. Within the REACH context, it is not clear whether or not assessors using the tool would have access to accurate, or indeed any, information on the room size for any end/ intermediate use of the substance, therefore this parameter could be a source of significant variation between user assessments carried out for this purpose.

To summarise, for the STOFFENMANAGER tool, the main sources of between user variation appeared to be the allocation of task and dustiness. Differences in allocation of risk management measures were also noted. The tool already includes limited descriptive information on these parameters to assist the user in their choice of input. The interpretation of this information was observed to be different between users considering the same workplace activity. The use of the STOFFENMANAGER as a risk assessment tool is perhaps more akin to the format of the exercise than its use under REACH. The results suggest that expert and non-expert users may benefit from more descriptive information and detailed examples for each of the parameters where subjective assessment is required, e.g. the handling description and the dustiness.

4.9.6 RISKOFDERM

A number of parameters were noted as potentially leading to very large variation in exposure estimates when using the RISKOFDERM tool. The most significant of these are discussed below.

4.9.6.1 Choice of Dermal Exposure Operation

Within RISKOFDERM, the task is defined by choosing one of six DEOs, each of which covers a group of tasks. The DEOs are by definition significantly different to each other. It might therefore be expected that tool users should find little difficulty assigning a task to one of the categories. The majority of the situations described were covered by the fill/mix/load DEO. From closer examination of a number of situations, participants appeared to choose appropriately and consistently. A minor difference was noted situation 14, where one participant chose “Wiping” whilst the others chose “Dispersion with hand-held tools”. In the context of the situation which involved adhesive application, the validity of both options could perhaps be argued. The DEO is therefore considered to be a more limited source of between-user variation than the task-related parameters in the other tools. This is consistent with previous studies which found that differentiating between fewer, well-defined categories results in lower between-user variation compared with more and/or less distinguishable categories (Kunac et al (2006), Friesen et al (2011)).

4.9.6.2 Application rate

Very large between-participant differences in the assumed application rate were observed (for example in one situation varying from 0.001- 42.5 l min^{-1}). This is most likely because no descriptive information on this parameter was included. Workshop delegates had suggested that when they were unsure about rate, they had opted for the highest option given in the suggested applicability range of the tool. This approach does not however seem to have been taken by all participants. Workshop delegates also discussed difficulties in assigning a constant rate for manual processes, where exposures tend to be more sporadic over a shift. The general availability of detailed information on this parameter to tool users is not known. The tool flags up results which are outside of its range of modelled values and where the estimate is unrealistic, thus users have some indication of problems. However, the observed differences between participants suggest that this parameter is a potential source of very large variation between tool users. The importance of obtaining realistic contextual information on application rate prior to carrying out the assessment should be stressed to tool users.

4.9.6.3 Cumulative duration

Although the time of the task within the shift was provided in many of the situations, there was noticeable variation in how this was interpreted. For example in one situation, where the stated duration was 3 hours out of the shift, some participants chose 180 min, whilst another chose only 1 minute. In situation 11, where no task duration was given, participants were split between assuming that the task took only 5/ 20 min out of the entire shift, or that it was carried out for most of the work period (300 min). The relative duration of exposure to the shift time is in any assessment difficult to determine. The time taken for the exposure-prone activity is often shorter than workers self-reported durations, which can erroneously include ancillary tasks such as preparation of work area or equipment where no substances are used. In a workplace situation, this inaccuracy in assumed time will also lead to variation in the RISKOFDERM estimate.

The tool estimate combines application/ use rate and duration of exposure within the shift. Differences between users as noted in the BURE in assigning either or both of these parameters, combined with over-estimation of the actual time of exposure can therefore lead to very large ranges of estimates being generated for the same task.

4.9.6.4 Definition of contact levels

Participant choices for both frequency and type of contact were variable. The level of contact, i.e. light/ more than light varied in the situations observed. Similarly, participants also varied in their interpretation of the frequency of exposure, with more than rare/ rare splits observed in two of the situations considered in detail. As for the MEASE tool it is considered possible that the participants are finding it difficult to separate out the frequency of contact with the substance from the likelihood associated with its intrinsic properties, for example dustiness. This could again lead to both variation between users and estimates which do not reflect the exposure appropriately.

In summary of the main sources of variation between users of RISKOFDERM, the free choice of values for application rate and task duration lead to very large differences in exposure estimate. The importance of collecting and using accurate information on these parameters before generating and using an estimate from

RISKOFDERM should be emphasised to users. The tool highlights exposure estimates and inputs which are outside of its recommended range, however even when these guidelines are adhered to, small differences in choice can lead to significant differences in tool output.

4.9.7 Other identified sources of between-user variation

In addition to the factors discussed above, a number of non-tool-related causes of significant observed variation between assessors were identified as follows.

4.9.7.1 Transcription and typographical errors

A number of transcription errors were noted in the returned worksheets, where the participant had either misread/not inputted the required entry in the tool worksheet. For example, some participants entered a dermal rate instead of loading, or a body estimate instead of hands' estimate for RISKOFDERM, whilst others recorded the wrong percentile in STOFFENMANAGER and RISKOFDERM. On some occasions, participants entered an inhalation estimate instead of the required dermal result. There were also simple typographical errors made between generating an estimate in the tool and entering this value in the worksheet, including inconsistency in the use of commas/ decimal points and simple mis-typing of entries. As many of the tools can generate a wide range of possible estimates, erroneous values were not always easily identifiable. Where identified though random and systematic data checks, transcription and typographical errors were corrected before the reported analysis was undertaken. However; the size of the dataset and timescales of the project precluded checking of each of the ~4100 individual results against the relevant tool spreadsheet or STOFFENMANAGER account. Although several random and systematic quality control checks of the data were carried out, there may be a small number of residual errors of this type which increased the amount of between-user variation for a particular tool/ situation combination.

4.9.7.2 Physical form

Erroneous choices in relation to physical form contributed to significant between-user variation in a number of situations, in particular those relating to molten metals (e.g. situation 17), and where dermal exposure was perhaps the most important route via contact with contaminated solid objects (e.g. situation 7). We have included all of these values in the analyses, as representing valid, albeit incorrect, input choices made by the participants.

i) Differences in interpretation/ mis-reading of the situation description.

For a number of tools and situations, we noted a tendency of participants to omit RMMs which were mentioned in the situation description or to include ones which were not present. In some cases, participants also appeared to mis-read and then entered information incorrectly, for example vapour pressures or concentrations. These errors have been described where identified, however there are likely to be other similar cases. In general it is not possible to identify if these inputs are a valid reflection of the participant's interpretation of the actual situation, or were caused by participants' inattention to details within the description. We therefore feel that is best to consider all of these choices and results as being valid, if in some cases rather unusual, to avoid artificial reduction in between-user variation.

5 Conclusions

5.1 Overall conclusions

The BURE aimed to identify, and if possible quantify, sources of variation between tool estimates of exposure generated by different users. It is felt that, in terms of recruitment of a representative participant population, number of assessments by tool/ situation and overall numbers of results generated this aim has been achieved. Positive feedback on the organisation of the exercise and its associated documentation was obtained from remote-completion exercise participants and workshop delegates, with significant interest in the results also being expressed.

We have reported an assessment of the user-friendliness of the tools previously (Crawford et al, 2014). In this exercise, telephone interviews and an online questionnaire survey were used to collect users' perceptions of the usability (for example ease of availability and software quality) and user-friendliness of the tools. As a whole the interviewees and survey respondents were positive about these aspects of the tools, and were happy with the guidance and help functions provided. The respondents and participants also reported that they generally found the tools easy to learn, and in particular EMKG-EXPO-TOOL and MEASE. Many of the BURE participants were recruited via their involvement in the user-friendliness survey, therefore there was an overlap between the two populations.

It is clear from the results of the BURE that there is a mis-match between the participants' perceptions of learning and using the tools and the consistency of the estimates generated. In particular, tool guidance does not seem to be consistently applied by users, and more consistent estimates are not generated by those tools which are perceived to be simpler to learn and use.

There can be significant between-user variation in the Tier 1 tool estimates generated for the same workplace situation, which does not appear to be associated with characteristics of the assessor themselves. This is consistent with previous inter-rater reliability studies within a range of fields, where wide variation in response has been observed between users of different assessment tools.

Within the BURE, the differences in estimates can be attributed predominantly to variation in user choices for a limited number of input parameters, including task descriptors, fugacity, (in particular dustiness) and the allocation of RMMs. Whilst these parameters are characterised differently in the tools, a common pattern of variation was observed for their input regardless of the tool being used.

It must be remembered that the use of the tools in a REACH context has occurred over the last 5 years, to meet an immediate need for large numbers of exposure assessments within a short time period. It is therefore to be expected that the tools and user support systems will continue to develop.

In section 6 below, we offer some suggestions for future developments that may be of assistance in achieving and maintaining consistent and valid exposure assessments using the tools.

6 Recommendations

In modelling exposure for a particular work activity, an assessor has to interpret and translate what they know about the situation into the required tool parameters. To describe the exposure effectively, the same range of determinants has to be considered, whether this done explicitly within a tool by the inclusion of more parameters and/ or more options within each of these parameters, or less obviously by the user mentally “filling in the blanks” where only a limited number of input choices are available.

A degree of subjectivity will always therefore be present in any assessment process, thus the identification of potential methods of minimising the impact of this subjectivity are of interest and importance.

A number of approaches could be of assistance in standardising the use of tools within REACH and other contexts. These can be split into those which relate to the purpose for which the tool is used, those which relate to the tool itself and those which are user-specific. Some possible approaches are detailed below.

6.1 Tool use Purpose-Related approaches

As noted previously, the tools may be used for different purposes, including REACH exposure assessment, general chemical risk management and to determine compliance with occupational exposure limits. These different uses are considered below with suggestions made for increasing tool user consistency.

6.1.1 Use of tools within a REACH context

6.1.1.1 <u>REACH guidance information: general</u>

The REACH document “Guidance on information requirements and chemical safety assessment Chapter R.14: Occupational exposure (2012)” gives an overview of the methods that can be used for exposure assessment, for example the use of measurement data or exposure modelling. Guidance is also given on describing uses of substances, with reference to the use of PROC codes within document “Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system (2010)”.

Feedback from some workshop and BURE participants indicated that they did not find the level of detail currently available regarding choice of PROC to be adequate, for example in relation to ancillary activities such as maintenance, sampling and cleaning.

From observation of the guidance in Chapter R12, there is more detail supplied on non-occupational exposure use descriptors, for example Environmental Release Categories. Whilst it is appreciated that the provision of such specific examples might be challenging in terms of describing occupational exposures in a relevant manner across all industry sectors, the supply of more detail on common processes may be very beneficial to exposure assessors.

The results from the BURE suggest that tool users may find differentiation between similar PROCs challenging, for example between PROCs 8a, 8b and 9. The provision of additional detail may assist in deciding on the best option.

At present there is a basic list of PROCs provided, which are roughly grouped into activity types, for example manufacture/ formulation type processes, transfer processes and spraying processes. Providing a more defined hierarchy of PROC codes may assist tool users in selecting a more or less conservative option to suit their purpose, and also help reduce between user variation.

The allocation of a professional or industrial domain to a situation was problematic for some participants, and the workshop delegates also reported a lack of clarity about the decision process for this parameter. We could not find detailed systematic information on how the domain should be allocated. However; the guidance suggests that where there is uncertainty about the domain, a conservative approach is to assume a professional, and therefore less well controlled, setting. Additional REACH guidance on a systematic method of allocating domain would perhaps be helpful in avoiding both overly conservative and under-estimation of exposure.

6.1.1.2 REACH guidance information: tool-specific

We have emphasised the importance of tools being used for their designed purpose, i.e. within their range of applicability, to allow users to generate the best estimate possible. Clarity and consistency about the domain of applicability of the tools within the REACH documentation is therefore essential. Such clarity was not always observed.

For example within Chapter R14, the non-applicability of the ECETOC TRAv2 to molten non-mineral solids is highlighted in one section, whilst in another the fugacity categories (taken from the tool) for PROCs 23-25 are given for metals. Also, Chapter R12 states that “with two exceptions only, all process categories listed in Appendix R.12-3 can be used as an input parameter to the ECETOC TRA tool to derive a Tier 1 exposure estimation for workers”, suggesting that the tool can be used for any of the non-excepted activity types. The exceptions are assumed to be PROCs 26 and 27a/b, which are noted within Chapter R12 to have no corresponding entry in the ECETOC TRA. Within the ECETOC TRav2 and v3 tools, the fugacity tables suggest that metal processes with temperature greater than the substance’s melting point may be assessed, however from direct communications with its developers, the non-applicability of the tool to hot metal processes has been confirmed.

A similar issue was identified for the MEASE tool. The tool developers have confirmed that the tool should not be used for assessing exposure to volatile organic liquids. The tool is described in Chapter R14 in the context of assessment of exposure to metals and inorganic substances, however there is nothing to indicate that it is unsuitable for vapour exposure estimation. Within the tool itself, it is possible to select parameters and generate exposure estimates for volatiles without triggering an error message, and the initial estimate look-up table provided in the MEASE documentation gives values for vapour exposure taken from the original TRA tool (EBRC, 2014). The possibility of combining volatile organic materials with range of PROC codes is also given in the MEASE documentation, again perhaps suggesting to the user that this is an appropriate use of the tool.

The EMKG-EXPO-TOOL is available via a link from Chapter R14, and the tool homepage includes information on its applicability domain, for example non-applicability to open spray processes. Chapter R14 also directs the reader to a table of Control Guidance Sheets from the UK Health and Safety Executive (HSE) COSHH Essentials tool for further information on the work activities and risk management measures. The table includes, for example, spray processes, which have been confirmed by the developer to be outside of the tool's scope. Following the link in Chapter R14 to the German language version of the control guidance sheets takes the user to a list of available information, which does not include spray processes. It is therefore possible that the tool could be used for a non-applicable process and that users in different countries are operating the tool differently for the same activity. Both of these will increase variation between users.

Using these three tools as examples, it is felt that a consistency review of the relevant REACH, and related tool, guidance to remove contradictory information and improve clarity about the ranges of applicability would help prevent accidental mis-use of the tools and associated between user variation.

6.1.1.3 REACH compliance framework

Within the context of REACH, communications from Advisory Board colleagues have indicated that within industry, the tools are used in a support framework including Use Maps and generic exposure scenarios. These management systems allow an assessor to contextualise, synchronise and standardise their estimate within their industry sector and so should reduce between user variation. However, we do not have information on how widespread this approach is amongst REACH actors within smaller industry sectors and in particular amongst downstream users.

For all of the tools, it would seem prudent to replicate and extend this approach, for example by developing sector specific guidance to support users in carrying out assessments. This would be of particular benefit to smaller organisations where assessments may be less frequently carried out, by less experienced personnel and in isolation from other exposure assessors with which to compare their estimates. It would also benefit consultancy organisations working on behalf of smaller enterprises, who may be working in unfamiliar sectors.

Once submitted to ECHA under REACH, there is a legal requirement for at least 5% of substance dossiers to be checked either on a random or targeted basis (ECHA, 2014). This check may result in no action being taken; follow up with a quality observation letter or a request for further information. The choice of approach will depend on the issues identified. It is not known to how many assessments have been checked in more detail previously or whether between and within assessor consistency has been evaluated. This stage of the REACH process would seem to provide a convenient opportunity to assess consistency of the application and outputs of the exposure assessment tools used for estimation within the Chemical Safety Report.

6.1.1.4 Non-REACH tool use

Some of the approaches suggested above may also help to reduce between user variation for exposure assessment outside of the REACH context.

In particular, two of the tools, STOFFENMANAGER and EMKG-EXPO-TOOL were developed from control banding systems, designed to help small and medium enterprises in particular to assess and manage risks from hazardous substances. Discussions with the Advisory Board suggest that these tools may still be more commonly used for this purpose rather than for REACH.

The BURE participants and workshop delegates all possessed some knowledge of exposure assessment principles. It could be postulated that non-expert assessors using the tool for risk management purposes without the support of occupational hygiene professionals might exhibit more between user variation than observed here.

Some of this user-support network may already be in place via other chemical risk management initiatives, however the further development of additional sector-specific guidance and support for tool users may help to minimise between user variation.

6.2 Tool- related approaches

Our analysis of the BURE results suggests that updating the presentation and content of tool guidance may help users in achieving more valid and consistent results. In this section we suggest generic improvements that may help users of all of the tools, combined with specific issues by tool where appropriate. There is some overlap between these suggestions and the findings of eteam Project Work Package II 2: Uncertainty analysis of the tier 1 exposure assessment tools (Hesse et al, 2014), and we would refer the reader to the relevant report for additional information.

6.2.1 Access to information

It is helpful for users if all of the relevant documentation is available either within the tool itself or via accessible links within the tool to supplementary information. It is also suggested that information should be clearly signposted and provided in summarised and user-friendly manner, for example with essential information collated within one document, rather than split between sources. This is particularly important for information relating to the applicability of the tool to the process and/ or physical form.

During the exercise, we received positive feedback on the simple installation guidelines that we distributed for each of the tools, and workshop delegates suggested that participants may have been using these in preference to the in-tool help functions. Our instructions were not designed to help the participants carry out assessments, but rather to guide them in how to run the tools.

With the exception of the User Guide for the ECETOC TRAv3, which covers installation and inputting of parameters, we did not identify any readily accessible comparable step-by-step guides for carrying out assessments using the tools within the tool guidance. It is felt that the preparation of simple guides to tool use, which could be based on the existing and helpful pop-ups, comments and information boxes within the input screens, would assist users to operate tools effectively. These could incorporate information on applicability and parameter choice guidance together with information on the basic software operation of the tool. At present, the requirement for users to intentionally click on an information tag or comment box within the tools or to access separate external reports to get essential guidance increases the likelihood that important material might be missed.

Presentation of all of the relevant essential information in a clear format would facilitate user comparison of all of the different input options available and so their potential impact on the estimate. The inclusion of example assessments for a representative number of process types would also be of benefit in clarifying the process and reinforcing the range of applicability of the tools.

Where possible, it would also help users if input parameters which are not within the applicability range of the tool were removed, disabled or in some way flagged up as inappropriate.

6.2.2 Level of detail

We recognise that the tools are by nature generic and thus must cover a wide range of potential exposure situations. However, BURE participants and workshop delegates reported that additional detail on the options for more subjective parameters would be of great assistance. For example the inclusion of exemplar tasks to illustrate a PROC code, or providing a suitable range of comparator substances to help assign dustiness.

It is therefore recommended that additional descriptive information is included in the tools and/ or their guidance materials to help users assign parameters.

6.3 Tool-user related approaches

Generating valid and consistent estimates of exposure relies not only on the tools themselves, but also on the manner in which they are used.

REACH document Chapter R12 notes that a sufficient level of occupational hygiene expertise is required for the identification of the most suitable PROC for a particular application. There is therefore a responsibility on tool users to make sure that they are competent and able for this task.

A number of steps could be taken to increase the confidence that users have in relation to their own and others' exposure estimates.

6.3.1 Training of tool users

When carrying out measurements of exposure in workplaces, great emphasis is placed on the competence of the person doing the task, with basic training in occupational hygiene generally being a pre-requisite. At present there is no similar requirement for users to undertake formal training in the operation of the assessment tools or interpretation of the resultant estimates. As these modelled estimates are then used in place of workplace measurements, this approach seems somewhat contradictory.

With the exception of STOFFENMANAGER which requires user registration, the tools are freely available to download as Microsoft Excel files either directly, or in the case of the ECETOC TRAv2 and ECETOC TRAv3, by following a link sent by the tool developer.

The tools are then ready to operate, without any formal online or in person training being provided. Whilst they are based on Excel, we have shown that simple knowledge of the mechanics of operating the software is not enough to ensure consistency between users. For inexperienced exposure assessors in particular, who may have no mental benchmark about the veracity of their estimate, the current approach makes it difficult to gauge how competent their assessments are.

It would therefore seem prudent to ensure that new users have at least a brief training session before using the tool. This could be in the form of an online tutorial, covering the basics of tool applicability and operation and/ or in-person training courses. Users could be asked to confirm that they have read and understood the guidelines prior to being able to use the tool. This approach, in conjunction with the simple guide to tool use, may help to reduce variation caused by unfamiliarity with the tools and their full range of capabilities.

6.3.2 Collection of contextual information

To enable optimum use of the tools for REACH and other purposes, collation of a minimum amount of contextual information about a process is essential. Chapter R12 states that for transparency, assessors should describe the situation in sector specific terms prior to assigning use descriptors.

REACH document Chapter R14 also details the information needed to carry out a suitable assessment, for example a description of the activity, substance characteristics, risk management measures and general environment. It also notes that for Tier 1 assessments, this information can be limited but should include as a minimum the parameters for the correct operation of the Tier 1 tools.

During the workshop, it was noted that on occasion, assessors are supplied with very limited information on the work task, for example only a PROC code, from which to generate the exposure assessment. As noted previously, assignation of PROC codes can be difficult, therefore gathering detail about the task carried out will help identify erroneous choices.

It is therefore recommended that tool users collate the required information before using the tools, to maximise the robustness of the exposure assessment.

6.3.3 Usage of correct tool

It is essential that the tools are only used within their correct range of applicability. Tool users must therefore consult the tool guidance documents to determine which tool is appropriate for their requirements. The updated and clarified REACH and tool guidance recommended previously will assist users in making the correct choice.

6.3.4 Parallel use of tools and measurement data

In the absence of a completed validation process for the existing exposure assessment tools, REACH document Chapter 14 recommends that users compare the results of modelled estimates from one tool with other applicable tools and/ or measurement data. The document notes that this will reduce the uncertainty in the risk assessment process.

It is not known how often measurement data have been used in preference or conjunction with modelled estimates for previous REACH exposure assessments. The use of even limited amounts of data as a comparator, i.e. where numbers are not sufficient to utilise on a standalone basis, may help users to determine the legitimacy of their modelled assessments.

6.3.5 Team assessment

During the BURE, subjective assessment of situations was required, with each participant using their own knowledge of exposure and skill level in operating the tool to generate an estimate. For some of the parameters, there may be more than one possible option, and it has been shown that the participants varied significantly in their opinion as to which was the best fit.

Previous studies have noted that the use of more than one assessor can increase the validity of subjective assessments compared with an identified standard. As noted by others (Schinkel et al (2013), Semple et al (2001), Kunac et al (2006), it is felt that the use of a consensus/ team approach may be helpful. Tool input parameters could be generated separately by a small team of assessors and any discrepancies discussed. This process need not take place for every assessment, however might be done as a regular in-house or sector-driven quality control check on assessor performance and development.

In addition to genuine variation caused by differences between users in their choice parameters for particular exposure determinants, a proportion of the variability observed related to simple errors in interpretation of the descriptive information supplied, for example the inclusion of LEV when none was present. Errors of this type would also be minimised by the use of a team approach.

6.3.6 Quality control of the exposure modelling process

The generated tool estimates are used for assessment of exposure, often in the absence of comparable measurement data. The quality control systems implemented routinely for other methods of chemical risk evaluation, for example the use of calibrated sampling equipment and laboratory accreditation for chemical analyses, are not presently applied to the analogous process of assessment tool operation. From the results of the BURE and discussions with workshop participants, the tools are routinely applied in very different ways by different users for the same purpose.

The processes for collecting and using the required information are common to many of the Tier 1 and higher Tier tools. Whilst there is guidance in Chapter R14 regarding the exposure assessment process under REACH, there is no generalised procedure for carrying out assessments using tools for REACH or other purposes. The development of a standard operating method for tool operation would be of benefit in reducing between and within user variation. This document could cover in general terms the essential steps of carrying out an exposure assessment using tools, as is currently done for the use of sampling equipment. The combination of a standard method, tool guidance and where available, sector-specific information would form a comprehensive user support framework.

This framework could form the basis for implementation of a quality control scheme, whereby tool users would participate in regular assessments of different types of exposure situations. This system could be similar to existing “round-robin” exchange schemes for fibre counting and chemical analyses. Over time, the feedback that participants receive would allow them to improve and standardise their assessment performance, thus minimising between user variation.

7 Limitations of the BURE

In interpreting and contextualising the results of the study, it is helpful to consider some of the potential limitations of the exercise.

The project team recruited participants using a number of different routes, including tool developers' and professional occupational hygiene bodies' online discussion groups, personal contacts and presentations at conferences. These methods may not have reached tool users who are not actively involved in these activities, for example small manufacturing company and end-user personnel, who may have more limited experience of exposure assessment and in interpreting tool estimates. There may also be a degree of self-selection to the exercise, for example in relation to English language ability. The above factors may have affected the participant population, meaning that the results do not reflect the real-life variation amongst the full spectrum of tool users.

Within the exercise, the between-user reliability of the tools was carried out by requiring participants to enter inputs describing a given workplace situation, thus generating an exposure estimate for a defined task. This method is akin to using the tools for general exposure assessment and hazardous substances' risk management within workplaces. From discussions with workshop delegates and the project Advisory Board, it would appear that in a REACH- context, the tools are generally used in reverse. The assessor would use the tool to identify safe conditions of use, i.e. by amending/ choosing the available parameters to reduce the predicted exposure estimate to a value where the Risk Characterisation Ratio (RCR) is less than 1. The choice of parameters would then be noted and disseminated via the supply chain to inform substance users about the required health protection measures.

It could therefore be argued that the format of the BURE was not representative of normal REACH-related tool use. However; within the eteam Project, it was not possible to replicate this type of tool use, i.e. where participants would be given a very brief situation description and a free choice of parameters to include to achieve an RCR <1. It is felt that this approach would not have been as effective in identifying the main sources of variation between users. The iterative approach may also have led to an increased number of inappropriate responses, particularly amongst less experienced exposure assessors, which would be neither practicable nor effective in controlling real workplace exposures. The chosen BURE method is therefore considered more appropriate for the purpose of evaluating between-user variation.

The overall findings, conclusions and recommendations of the study are therefore considered to be valid and of benefit to the exposure modelling community in the further development of the tools and their user support framework.

8 Acknowledgements

We would like to thank all of the participants who took part in the BURE remote completion exercise and workshop, for their time, contributions and assistance. The help given by Aldo Quispel and colleagues at Ernst and Young, Netherlands with the organisation and management of STOFFENMANAGER accounts for the exercise is also gratefully acknowledged. We are also very grateful for the substantial assistance given by Marlyn Davis at the IOM in relation to the successful organisation and administration of the remote-completion exercise and workshop.

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Appendix 1 BURE workshop report

IOM

WORKING FOR A HEALTHY FUTURE

BURE workshop preliminary report
19th March 2013

Preliminary Report on eteam Between-User Reliability Exercise (BURE) Workshop, 6-7th Feb 2013, Edinburgh

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World Health Organisation Collaborating Centre for Occupational Health

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CONTENTS

1 INTRODUCTION

In October 2011, the Institute of Occupational Medicine (IOM) was commissioned by the German Federal Institute for Occupational Safety and Health, (BAuA) to carry out a comprehensive evaluation of the exposure assessment tools identified as suitable for use in Tier 1 assessments under REACH- the ECETOC TRA, MEASE, EMKG-EXPO-TOOL, RISKOFDERM and STOFFENMANAGER.

In collaboration with colleagues at the Fraunhofer Institute of Toxicology and Experimental Medicine (ITEM), the IOM is carrying out an investigation of the underlying concepts of each of the tools, assessing their user-friendliness and comparing tool predictions with real workplace inhalation and dermal measurement data.

To help us assess the consistency of tool users' choices in comparison with other users, volunteers were recruited to participate in a Between-User Reliability Exercise that took place during November – December 2012. To complement this exercise, the eteam project also held an invitation-only workshop, 1pm Wed. 6th - noon Thur. 7th February 2013, to gather more detailed feedback on specific issues of importance identified from the main testing exercise results.

The final agenda for the workshop is outlined below

Time	**Wednesday 6th February 2013**	
13.00	Welcome & introductions	M van Tongeren (MvT)
13.10	Overview of eteam project	J Lamb (JL)
13.25	Between user reliability exercise and scope of workshop	JL
13.40	Plenary – General feedback on the BURE	MvT
15.00	*Break / refreshments*	
15.15	Focus group session – Application of the Tier 1 tools for a given exposure situation	
	Group 1 – dermal tools	Karen Galea (KG)/ MvT
	Group 2 – inhalation tools	JL/ Sally Spankie (SS)
17.00	Close of day	

Time	**Thursday 7th February 2013**	
09.00	Focus group session – Application of the Tier 1 tools for a given exposure situation	
	Group 2 – dermal tools	KG / MvT
	Group 1 – inhalation tools	JL / SS
10.30	*Break / refreshments*	
10.45	Feedback on focus group sessions	KG / MvT / JL / SS
11.15	General discussion and model requirements/needs	MvT
12.00	Workshop close	

The workshop included a mixture of plenary presentations by the eteam, plenary discussion sessions and focus group sessions discussing the application of inhalation and dermal Tier 1 models for given exposure situations. Digital recordings were obtained of the group discussions. This draft report summarises the discussions that took place during the event for the key discussion sessions. A previous version of this report was forwarded to delegates' for comment. Following receipt of these comments the report was updated as presented and circulated to the eteam Advisory Board for their information.

Copies of the plenary presentations given during the workshop have been circulated separately and so are not duplicated or discussed within this report.

2 WORKSHOP PARTICIPANTS

Twenty participants from the BURE exercise were invited to attend the workshop with twelve individuals attending (Table 1). There was a fairly even representation of delegates working for industry (n=4), regulators (n=3) and research/consultancy (n=5).

Table 1: List of workshop delegates

First name	Surname	Grouping*	Focus group
[redacted]		Regulator	A
		Industry	A
		Research/consultancy	A
		Research/consultancy	B
		Research/consultancy	B
		Regulator	B
		Industry	A
		Regulator	A
		Research/consultancy	A
		Industry	B
		Industry	B
		Research/consultancy	B

*Delegates response to the background questionnaire 'What type of organization they worked for?'

In the preliminary sessions of the workshop, the delegates were invited to provide a short overview of their use of the various Tier 1 tools and it was clear that there was a range of experience across both the different models being discussed and occupational exposure assessment.

Workshop delegates were split into two groups for the focus group sessions (A and B); with group A participating in the dermal focus group in the first instance and Group B the inhalation focus group. The two groups then swapped over on the second day of the workshop so that both groups were given the opportunity to discuss the inhalation and dermal Tier 1 tools.

3 GENERAL FEEDBACK ON BURE – SUMMARY OF DISCUSSIONS

3.1 INTRODUCTION

In the first plenary discussion session, delegates were asked to provide feedback on the BURE exercise that they had participated and completed in Nov-Dec 2013. Delegates were asked to consider and discuss the following points:

a) Assessment of impacts of the study design on the scientific quality and merits of the results obtained.
b) Impact of factory or site visits on the modelling process.
c) Assessment of relevance of the exposure situation description e.g. breadth of situation and level of detail and how realistic the information contained in the situation was compared to that received during participants' usual modelling work.
d) Evaluation of ease of use of the tools and identification of any parameters or tools that presented problems to the participants.
e) Degree of confidence and trust in the results, including any tendency to modify the modelled result if it did not appear to be realistic and whether this was done during completion of the exercise.
f) Suggested improvements concerning the ease of use (not accuracy) of tools which would reduce variability of the results.
g) Good' and 'bad' points of the BURE.

The discussions are summarised as bullet points in the sub-sections below.

3.2 ASSESSMENT OF IMPACTS OF THE STUDY DESIGN ON THE SCIENTIFIC QUALITY AND MERITS OF THE RESULTS OBTAINED

It was mentioned by the eteam project team that not all of the assigned BURE situations were designed to match the applicability range of the different tools and so in some cases tools were applied to situations that were out with their stated applicability domain. It was emphasised that this was a consequence of ensuring that the number and type of situations was sufficiently varied in terms of activity and exposure route. Delegates indicated that they had noticed the requirement to apply tools that they felt were out with their applicability domain. Delegates mentioned in some cases that the correct error messages appeared in the tools highlighting this issue, but that they reported the results as instructed.

3.3 IMPACT OF FACTORY/SITE VISITS ON THE TOOL MODELLING PROCESS

The impact of not being 'on-site' to carry out the exposure assessment 'in situ' was not considered a drawback by delegates - it was discussed that assessors would not normally have this opportunity and would not have any contact with the workplace being assessed.

3.4 ASSESSMENT OF RELEVANCE AND REALISM OF SITUATION DESCRIPTIONS COMPARED WITH INFORMATION TYPICALLY AVAILABLE FOR ASSESSMENT

For delegates from a regulatory or consultancy background they highlighted that the level and heterogeneity of information supplied in the BURE situations was considered to be better and more informative than what would typically be received from downstream users (DSU). It was however recognised by the delegates that there is a generality of approach used in assessing exposure for REACH via exposure scenarios. This arises because a number of users or producers have to be grouped together under a generic situation whereas the situation is very specific considering a single site for a workplace assessment. In the former case less detailed information is normally available and in the latter case very detailed information is required. It was considered that the BURE was less realistic for assessing downstream uses for substances under REACH where assessment often involves making gross assumptions to fill data gaps.

Industry delegates broadly considered that access to, and level of information received was sector-dependant. Some sectors have a good knowledge of conditions of use of their products by DSU, e.g. pigments and fuels, compared to other chemicals. Delegates from industry felt that the BURE depended on the assessors' level of experience for that specific situation i.e. there would be a tendency to use a more conservative approach where the assessor was unfamiliar with a process and that there would be an iterative process of amending the assessment based on the modelling outcome.

3.5 EASE OF USE OF THE TOOLS AND IDENTIFICATION OF 'PROBLEM' PARAMETERS

The delegates highlighted that prior experience / knowledge of the various tier 1 tools would have made completion of the BURE exercise easier than for those participants who had with little or no experience of the tier 1 tools. They reported that there was a 'learning process' throughout the BURE, with delegates reporting that it was quicker for them to complete their allocated exposure situations in Week 4 than it had been in the earlier weeks, in part because it was easier for them to navigate round the tools and they knew what was expected in the exercise. This resulted in some delegates reviewing and correcting their earlier evaluations because they had gained clarity on the tool performance after using it for three rounds of exercises. It was not thought that this affected the results from modelling exposure with the tool. It was commented that IOM's explanations on how to use the tools were very helpful.

Delegates found selection of some model parameters e.g. volatility and dustiness difficult to make, even though the situation descriptions were sufficient. However, it was noted that this is a reflection of the real-life situation of workplace exposure assessments where choices have to be made on the basis of limited information for many parameters. The delegates reported that a conservative or 'best guess' approach would then have to be applied and this would introduce some level of subjectivity in the result.

Risk Management Measures (RMM) selections were considered difficult especially by delegates less experienced in modelling with occupational exposure tools. For a RMM such as ventilation, there was a difference in the options between tools. Delegates again reported that they would select a more conservative choice of parameter. For glove selection, delegates said they made assumptions about the choices of materials where necessary. However it was acknowledged that in industry there would be the opportunity to seek further RMM information from the factory to inform re-estimation of exposures.

Realistic rather than worst case (conservative) options for parameters (dustiness and vapour pressure) were considered to be a better input value into an already cautious Tier 1 tool based on the available information. The level of information provided by the situations (too good for some delegates and insufficient for others) was considered to be sufficient for a Tier 1 assessment but not for Tier 2 where educated guesses would have to be used to fill information gaps, however one delegate did note that the 'line' between moving from use of a tier 1 to tier 2 tool is not always clear. It was felt that apart from the variability introduced by an inconsistent PROC code choice, more variability would be expected for these situations in the Tier 2 model assessments because of a lack of information.

3.6 DEGREE OF CONFIDENCE IN GENERATED EXPOSURE ESTIMATES

Modelling with the tools was considered as simple to start and complete (put in values, press a button and get an exposure result) but understanding the significance/accuracy of the result in terms of uncertainty was problematic. Some delegates felt further reassurance was needed that the generated exposure estimates are indeed conservative enough to ensure that workers and consumers would always be protected. In response to this it was pointed out that for around 100,000 low tonnage band chemicals, sophisticated exposure assessments would not be feasible and conservative and reliable (trusted) modelling tools have to be available.

It was pointed out that the use of modelled exposures to establish a Risk Characterisation Ratio (RCR) of below 1, without understanding how representative the modelled estimate actually was, could allow random or incorrect parameters to be entered and generate a (possibly acceptable) result that could then be used for compliance purposes.

3.7 ADDITIONAL POINTS ON THE BURE AND THE TIER 1 TOOLS

Several additional comments were mentioned during the discussions including

1. The usefulness of availability of a photograph or video clip of the workplace and activity to clarify the situation.
2. Prior instructions for tool use and help functions in the tool were found helpful for completing the exercise. Delegates tended to read the instructions of use provided in the BURE, only referring to the tool help functions when necessary.
3. Given that there would be a learning process in the BURE it was suggested that the Week 1 assessments should be discounted. It was acknowledged by the workshop Chair that the impact of learning was being considered in the data analysis.
4. It was considered by some delegates that the BURE worksheet was too generic in parts and that too many parameters requiring comment on uncertainty on input were grouped together which may result in relevant information being lost i.e. one parameter may be uncertain whilst others aren't and a respondent may then select 'major uncertainty' based on this one parameter.
5. Measurement data is available for some of the 20 situations and this was requested by the delegates as it would be helpful in training and evaluating performance. In addition delegates asked about the possibility of obtaining information about their own individual performance and a comparison of the modelled estimates and

measurements. The workshop Chair advised that this would need to be discussed with the eteam Advisory Board. One delegate also asked if the model developers would also undertake the assessment using the same situations. The Chair agreed that this would be interesting exercise and that this would be discussed further.

Participation in the BURE gave delegates the opportunity to try Tier 1 tools other than those they routinely used so they felt it was a valuable learning exercise. The eteam was congratulated on number and retention of participants in the project.

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4 APPLICATION OF DERMAL TIER 1 TOOLS – SUMMARY OF FOCUS GROUP DISCUSSIONS

4.1 INTRODUCTION

The dermal exposure assessment tool focus groups was chaired by Martie van Tongeren and facilitated by Karen Galea. The Chair introduced the sessions by reflecting on three issues that had become apparent during the introductory plenary session:

- few delegates had been involved in collecting dermal exposure measurements;
- delegates reportedly found it more difficult to 'visualise' dermal exposure and generally considered it to be more complicated that inhalation exposure assessment; and
- delegates had a better understanding of the processes leading to inhalation exposure than those for dermal exposure.

Three main points were to be considered during this focus group these being how delegates selected dermal model input parameters, the issues surrounding the selection process and how the selected parameters impact on the modelled dermal exposure estimates. To facilitate the discussions delegates were asked to complete (as a group) three dermal exposure situations selected from those used in the BURE (Table 2) and consider the relevant input parameters including physical form, composition, PROC codes or equivalent, scale, duration, operating conditions and RMM.

Table 2 Model/situation combinations used during the dermal focus group sessions

Exposure situation	Model discussed
Scenario 15 (Packing of Nickel Metal Powder)	MEASE
Scenario 14 (Use of phenol in Adhesives: Gluing of Rotors)	RISKOFDERM (ROD)
Scenario 13 (Filling tanker with Heavy Fuel Oils)	ECETOC TRA v 2 and ECETOC TRA v3

The Wednesday focus group (session 1 on 6th February, 2013) discussions were transcribed from a recording of the session and the Chair's notes. Thursday's focus group (session 2 on 7th February, 2013) discussions were transcribed from the Chair's notes only due to the digital recording instrument failing. The discussions from each of the sessions have been summarised using bullet points by tool / exposure situation considered, however it should be considered that in many instances the comments raised were relevant to more than one dermal exposure assessment tool or situation.

4.2 MEASE AND SITUATION 15 (PACKING OF NICKEL METAL POWDER)

In MEASE the skin surface area considered is the hands and forearms (dependent on PROC code selected) and not the whole body. The lack of whole body exposure was not considered an issue as delegates considered the hands and forearms acceptable as the main exposed area for a Tier 1 tool, given the uncertainty in exposure of other body parts, lack of underlying data within the model for these body areas and perceived relative lack of exposure. However; it was raised that the face may be touched by the hands inadvertently, leading to dermal exposure and ingestion exposure by hand-to-mouth contact, but that this may be protected against by the wearing of respiratory protection.

Panellists were reminded that required input parameters in MEASE are green coloured where they apply to both inhalation and dermal and yellow coloured where they apply exclusively to dermal. These input parameters were the focus of the session.

For physical form, many delegates selected high dustiness with the following points being raised in the discussions:

- High dustiness choice was based on personal opinion or through delegates erring on the side of caution.
- Preference for medium dustiness for heavy metal powders which were considered denser, likely to settle more quickly and less friable was expressed.
- Medium or high dustiness definitions were considered both acceptable fits for Ni and so for assessment purposes the tool could be run on both parameters and the outcome compared.
- It was agreed that prior experience and knowledge (chemical information) influences the selection of this parameter.

There was an extensive discussion concerning PROC code selection. Many delegates found this one of the most difficult parameter to fill in confidently. PROCs 8a (transfer at non-dedicated facilities) and 8b were used during the exercise but the definition of 'large' was felt to be ambiguous. PROC 26 (handling of inorganics) is suggested by the tool and is metal specific. This was considered to best cover the situation since MEASE is calibrated with metal exposure data. Additional points covered in the discussion concerning PROC codes included:

- Many delegates were unaware of the drop down list of options and did not review all the PROCs, instead using the first appropriate choice found.
- Where unable to decide on a PROC, some delegates indicated that they would run the tool a number of times, in each instance using a different PROC and would select what was considered the 'best' PROC.
- One delegate noted that the BURE exposure situations matched PROCs so assigning codes was easy.
- Many PROC codes could be selected when making sure a use is fully covered for REACH registration. It was suggested by one delegate that ECHA wishes to avoid an extensive list of PROC codes.
- There are difficulties with more general codes e.g. for transfer and handling and their assignment is therefore more complicated in these cases.

Duration of exposure is given as time intervals in many tools, which may not always be mutually exclusive. The option of selecting the longer duration in instances where two intervals could reasonably be selected, because something may happen to extend the duration (taking a cautious approach) or choosing the lower time interval (since the tool is already conservative), was discussed. Delegates considering that the tool was already sufficiently conservative would in principle use a lower time range for duration.

MEASE (and other tools) allow users to identify whether the exposure situation is industrial or professional. Delegates agreed that in general, less controlled environments would be professional rather than industrial. A delegate reported that there was the same description in the ECHA guidance, R12, for PROCs 8a and 8b but the tool assigns a higher reduction factor for industrial domain. Points describing industrial and professional were considered and are summarised below:

- A packing station suggested an industrial operation
- Manufacturing is industrial and professional is use or handling in any non-manufacturing facility
- Professional suggests the application of a technique, for example in the use of fine craft work, rather than mass production.
- Industrial would have dedicated and closed facilities and this has too much hand work for industrial so must be professional
- Open work places can be industrial
- All tools are written in English so it is easier for an English speaker to see subtle differences in words which may influence parameter selection
- Higher exposure would be expected for a process in a professional environment rather than an industrial one because it is assumed that the professional site is less controlled. However this does not mean less controlled processes are automatically professional
- It was felt that the MEASE glossary was not entirely helpful on this point.
- One delegate suggested choosing professional in order to preserve a good level of conservatism i.e. in EASE professional was reported to be wide-dispersive use. It was also noted that ECHA guidance also directs assessors to select 'professional' when a clear decision cannot be reached.

When selecting Operating Conditions for dermal exposure assessment only, delegates requested to refer to the glossary. There was a lively discussion around the impact of a previous choice on a subsequent one (would an attempt be made to try to compensate for/balance out an earlier conservative choice with less conservative one later on) and on consistency. *Contact level* was found to be open to interpretation when considering whether using hands or tools and degree of dustiness. 'Extensive' was considered applicable to high dustiness and 'intermittent/incidental' to medium dustiness. Some delegates referred to the glossary however the description given is complex as it includes two variables (number of events and whether hands or tools are used) which should be separate variables. Additional points covered in the discussion included:

- Delegates did not tend to feel they used any 'compensatory' system in their assessment, rather that they used a 'best guess' approach.
- There was a need to be coherent in earlier choices and decisions to convince an authority that the assessment was properly carried out.
- Inexperienced users may use a different approach where they just 'push buttons' to get an adequate final answer (less than RCR) for the exposure estimate.

Delegates not actively involved in occupational exposure estimation felt they did not know very much about some RMM such as LEV and how relevant they are to dermal exposure. Delegates agreed that gloves were really the more relevant RMM for dermal exposure. When considering glove use two options are provided, either no gloves or the wearing of properly designed and selected gloves worn by trained operators. Other points discussed included:

- The option to select 'no gloves' may be considered when gloves are being worn but they are considered to be inappropriate by the assessor.

- When the tool is used as part of a REACH assessment then can prescribe gloves to be worn for that exposure situation or otherwise use is not covered by the scenario.
- There is a need to communicate the correct type of gloves down the supply chain
- Assessors with less knowledge may not think about the positioning of LEV or the material for the glove but would select 'proper gloves' anyway, irrespective of why the assessment was being done
- The nature of the specific training, indicated as required for using gloves, is unclear. There is fit testing for RPE but nothing is rigorously defined for gloves.
- Wearing of appropriate gloves is related to the hazardous nature of the substance. When dealing with an acute hazard, such as concentrated acid or alkali, suitable and appropriate controls would be implemented straight away without considering the exposure level (as for substances without exposure limit).
- Downstream and professional users may be less likely to use gloves

When asked to comment on the exposure estimates generated by the tool, delegates often expressed that it was 'hard to imagine' the measurement and expressed that it was difficult for them to assess whether this was realistic or a significant under or over estimation.

4.3 RISKOFDERM AND SITUATION 14 (USE OF PHENOL IN ADHESIVES: GLUING OF ROTORS)

Rather than being PROC code driven RISKOFDERM requires the selection of a relevant Dermal Exposure Operation (DEO), which then leads to the selection of further parameters. This can be a difficult choice and delegates reported that they often return to the DEO list after looking at the next set of options to confirm or change their original DEO selection.

RISKOFDERM is the one tool that requires input of an application rate. Delegates agreed that in the absence of information on the application rate, they would use the measured range stated by the tool and use the upper value. Delegates highlighted that illustrative examples would be helpful to estimate this parameter when there is no information supplied to make an informed choice. It was also raised that the term 'rate' gives the impression of a very regular and constant application but this is unlikely to be found for a manual application.

There was discussion around which percentile should be used to express the dermal exposure estimate. It was highlighted that for modelled exposure the 90^{th} is a standard percentile recommended by ECHA guidance. Delegates felt this was acceptable unless it results in an exceptionally high number.

Many tools do not take the concentration of a substance within the product into consideration and RISKOFDERM is an example of this. The delegates felt it was important to adjust for very low concentrations e.g. < 5 or 1% with a correction factor. In this situation the phenol concentration is 1% so it was considered that exposure may be overestimated and should be reduced by the same factor (as product concentration).

Delegates agreed that a correction factor for concentration may be applied either 'within' the tool (by altering the application rate) or 'outwith' the tool (by adjusting the modelled result using a concentration-related factor). However it was found that these options when input into the model did not yield the same estimate for dermal exposure and there is no advice on which of these adjustment methods is the most appropriate. Delegates agreed that it would be better to change the final result, as the relationship between the application rate and dermal exposure is likely to be affected by the capacity of skin to "accept" exposure.

When considering the derived dermal exposure estimate, delegates felt unable to decide if the exposure estimate was sensible or otherwise because it was difficult to understand what it represented or put it into a familiar exposure context. One delegate mentioned there is no benchmark to compare estimates against to determine if the modelled exposure is significant. In addition DEOs do not express dermal exposure in same units which makes the tool disconcerting for delegates to use. However some delegates considered RISKOFDERM to be the best model for dermal exposure assessment due to the measurement basis from which it was developed.

4.4 ECETOC TRA V2 AND SITUATION 13 HEAVY FUEL OILS

This modelling tool is PROC code driven, like MEASE and unlike ROD. Similar comments as those raised during the use of MEASE were discussed concerning the difficulty in selecting appropriate PROC codes. It was considered that the definition of 'large' for some PROCs was ambiguous. Concerns were raised as it was perceived that the exposure estimate depends too much on the PROC category which is difficult to select.

There was again discussion on the selection of industrial or public domain (which is described in the user guide as professional use). Delegates reported that for this exposure situation it was easier to make the distinction. It was assumed by delegates that the relationship between public and professional is that anyone can go into a craftsman premises but they ordinarily do not have access to an industrial establishment.

In ECETOC TRA v2 the choice of parameters for duration is again not mutually exclusive. The duration in the exposure situation was given as 1 hour so the tool users must select from two options. This selection resulted in further discussion on what the actual exposure situation relates to and when dermal exposure is realistically likely to occur. For example, it was discussed that dermal exposure occurs only when removing the loading arm and wiping and this would take place in less than 15 mins therefore it was questioned as to whether the correct PROC code had been selected or whether two were indeed warranted. The importance of a clear definition of the task and number of tasks being assessed became apparent. Filling of tanker and preparation and removal of loading could be one entire task or two different tasks. In addition it was highlighted that REACH focuses on activities but exposure may arise post-activity e.g. cleaning or through accidental/incidental contact with contaminated work areas, which is difficult to include and assess in the tools. It was also raised that PROC codes are broad to cover a wide scope of activities and they consider the whole duration.

For this tool the exposure estimate is expressed as a dose (it is assumed everything is absorbed) rather than a dermal load (on the skin) and wearing of gloves is not taken into account.

4.5 ECETOC TRA V3 AND SITUATION 13 HEAVY FUEL OILS

This modelling tool is also PROC code-driven and is more complex than v2, including additional exposure modifying parameters such as use of ventilation and gloves.

Delegates initially chose a protection factor of 10 or 20 for gloves. The protection factor scale for gloves was not considered to be well defined. Glove use was considered generally poor in industry leading, for example, to gloves becoming contaminated on the inside. If surfaces are 'sticky', dirty and obviously contaminated or hazardous, glove use and training in glove use was considered to be very likely.

Delegates chose a protection factor of 5 for gloves after the discussion. The exposure estimate was half that obtained using ECETOC TRA v2 which in part will be driven by the consideration of protective gloves.

A delegate asked if anyone had opinion about LEV on controlling dermal exposures (modification to ECETOC TRA v3 and is automatic in v2). They felt this would not control exposure to splashes but might be expected to have an effect on exposure from the vapour form. Another delegate reported this was intended for control of exposures in spray booths. Nobody could cite any evidence to support LEV controlling dermal exposure but deposition from air onto skin was felt to be less than direct deposition onto skin. Impact of LEV on dermal exposure was concluded to be low.

4.6 SUMMARY OF THE DERMAL FOCUS GROUP DISCUSSIONS

The focus group facilitator provided a short feedback summary of the discussions that took place during the dermal tool focus group sessions. Both focus group sessions completed the three given exposure situations using the dermal exposure assessment tools. Comparison of the exposure estimate results from both groups showed that the same exposure assessment result was obtained for 3 of 4 tools. There was a significant difference in the estimates obtained from both groups for ES5 (packing of nickel metal powder) using MEASE. It was established that this arose from the choice of two different PROC codes, namely 8 and 26, by each groups. Both groups obtained the same estimates for both ECETOC tools (v2 and v3) but the parameters entered in the tools were different. Three of the dermal tools are PROC code driven (ROD does not use PROC codes) and there were issues around how to assign these parameters. There was also some ambiguity about choosing professional and industrial domains and the impact of the selection was not clear because the tools defined these terms slightly differently. In general, the selection of parameters was consistent with a cautious or best estimate approach and iteration was used to revise the initial estimate. However delegates felt that it was unclear to them what would represent a sensible or reasonable dermal exposure result. In addition the effect of LEV on dermal exposure was also unclear.

5 APPLICATION OF INHALATION TIER 1 TOOLS – SUMMARY OF FOCUS GROUP DISCUSSIONS

5.1 INTRODUCTION

The inhalation exposure assessment tool focus groups were chaired by Judith Lamb and facilitated by Sally Spankie. Three main points were again to be considered during this focus group, these being how delegates selected inhalation model input parameters, the ease of translating the given exposure situation into the input parameters and uncertainties surrounding the parameter selection process and finally their satisfaction with the exposure estimate generated and general thoughts on the tools.

To facilitate the discussions the following inhalation exposure situations and tools were used. These exposure situations were selected from those used in the BURE (Table 3). Again, key inhalation modelling parameters were discussed during the focus groups.

Table 3 Model/situation combinations used during the inhalation focus group sessions

Exposure situation	Model discussed
Situation 5 (Use of Naphtha in Coatings – Solvent tank emptying and refilling)	Stoffenmanager and ECETOC TRA v2 and v3
Situation 11 (Weighing of Powdered Pharmaceutical Products)	EMKG-EXPO-TOOL
Situation 15 (Packing of Nickel Metal Powder)	MEASE

Both focus group discussions were transcribed mainly from the Rapporteur's notes. The discussions from each of the sessions have been summarised using bullet points mainly by input parameters due to their cross-cutting nature across the tools and situations.

5.2 VAPOUR PRESSURE

The discussions began with the difficulties of allocating those parameters most open to interpretation during the application to ES5 (Use of Naphtha in Coatings-Solvent tank emptying and refilling). Certain determinants are required and the difficulty in choosing a satisfactory option for these where there is a choice of parameters was investigated.

Panellists were asked where they obtain vapour pressure data, which value they would select if there was a range of values or the vapour pressure lay on a boundary point between categories, if the different banding of VP between different tools was confusing and finally how they allocated vapour pressure for mixtures of substances, such as naphtha's.

Key points emerging during the discussions were as follows:

- A varied response was obtained with respect to the information sources. These included safety data sheets, ECHA guidance, IARC monographs and chemical safety cards and handbooks. There was a general agreement that the ECHA website will become more used and that the source has to be a reliable.

- In instances where the vapour pressure range overlapped more than one volatility band, delegates would typically select the more volatile option but acknowledged that the choice can make a significant difference in exposure.
- For some mixtures delegates will typically apply the vapour pressure of a key substance. It was generally agreed that selecting the ideal vapour pressure of the pure substance is the easier, less time consuming and cautious approach. It was discussed that using a slightly lower value for vapour pressure would produce a lower result than that of the vapour pressure of the pure substance and so using the latter would represent applying a conservative approach.
- Delegates reported that they may consider how a small increase in a workplace condition such as temperature might affect the vapour pressure and select a more conservative option rather than modelling the exposure situation twice.
- Delegates reported that the different vapour pressure bands in each tool did not cause confusion when moving between tools.
- There was discussion concerning the ambient temperature that should be used and what delegates considered this to be - in the BURE 20°C was selected. Delegates felt that this was the most suitable value. If the VP values at 20°C were not available then it was considered appropriate to use the value at 25°C.

5.3 PROC CODES

As was highlighted in the dermal focus groups, assigning appropriate PROCs to a given exposure situation considered challenging by many delegates, with some of the key discussion points being summarised below:

- It was considered that additional descriptive data, e.g. list of more common/popular activities for PROC codes, would be helpful rather than referring only to the PROC numbers.
- It was felt by one delegate that different sectors need different PROC codes and that the choice is perhaps deliberately difficult, with precise interpretation of PROCs avoided so that definition is left open between sectors.
- Exposure situations involving sampling of substances or products, for example for quality control purposes, can give rise to the selection of several PROC codes by delegates e.g. PROC 3, 4 and 8a etc. however it was also raised that certain PROCs apply to processes, not activities and it was considered that sampling was an activity.
- It was considered that in some tools it was easier or harder to select PROCs depending on whether a description of the process was provided.
- PROC 1 and 2 is significant for exposure to highly volatile substances
- It is difficult to judge what PROC is realistic or conservative if the assessor does not know what is realistic and is conservative in the actual situation.
- Given the uncertainty in the exposure estimate there must be confidence in the choice of parameters selected in the tools (such as PROCs) so that the value generated is 'correct'.
- PROCs are not related to the quantity of substance used (whereas for example EMKG-EXPO-TOOL specifies an amount of a chemical used) and this was thought to be a weakness of using the PROC system in exposure assessment.
- Delegates with experience in REACH registration viewed PROC codes as a means to make quick assessments. Another delegate felt that a system with too many PROC codes would make no sense as the codes need to be standardised so they can be usable in a tool and specific enough so that the derived exposures 'feel safe'.

5.4 DOMAIN – INDUSTRIAL OR PROFESSIONAL

Delegates working in the area of REACH registration generally found this parameter easier to assign than those who worked in other sectors. It was agreed by delegates that a number of factors need to be considered when assigning an exposure situation to an industrial or professional domain. These include size of operation, control measures, facilities, sector, location (fixed/mobile) and degree of specialisation.

Delegates raised the following points and examples in the discussion:

- An example of a car plant with a spray shop where more instructions/rules would apply would be industrial whereas spraying cars in small garage space would be considered professional.
- The level of cleaning was regarded by a delegate as indicative of the domain. The industrial setting would be considered to have regular cleaning as part of policy whereas professional would not.
- Another example considered ceramic tiles and mass manufacture of these as being industrial whereas if finishing involved specific individual decoration by an artist this would be considered as more professional.
- An ambiguous example considered the case of using paint stripper in a closed bath. Enclosure is required by the nature of the chemicals used but this could be industrial or professional.
- It was considered that if there was any doubt in the assignment, a professional domain would be selected so to err on the side of caution as this would result in higher exposure estimates.

5.5 DUSTINESS

Delegates reported that there are a number of options available in a pick list for assessors to choose from. There was differing opinion about how easy it was to assign dustiness and their decision making processes. These are summarised below:

- There is a lack of consistency in the descriptions of 'Dustiness' between the tools which complicates matters.
- Delegates thought the options were 'fine' but it was remarked that some assessors may not know how to discriminate between the options and it would not be possible to undertake a sufficient assessment without knowing how dusty the activity was. Those delegates with access to company sites said they would look at the material form in the workplace.
- It was agreed that a standard test for dustiness, definition of the boundaries and more objective criteria (there is not a strong basis for a measure of dustiness levels) would be helpful in decision making e.g. density-based because delegates find it hard to justify a choice of category which cannot be measured.
- The issue of dustiness changing within a process, for example, where materials are reported in the delivered form then processed by micronisation and so become dustier, was also discussed. Lifecycle assessment is important because levels may change and no longer be relevant e.g. milling by DSU.

5.6 GENERAL VENTILATION AND SELECTION OF 'INDOOR' OR 'OUTDOORS'

A good description to define this categorically was considered to be using 5-10 air changes per hour which highlighted the changes in ECETOC TRA from LEV (yes/no response) in v2 to more options for ventilation in v3. ECETOC V3 gives options for indoors & outdoors together with a helpful category for LEV where it is 'on-tool'.

Delegates were asked whether it was easy to select indoors or outdoors and delegates generally felt there was a clear distinction and that was it simple to choose and apply the correct option.

5.7 ROOM SIZE AND DURATION

When selecting room size in Stoffenmanager, delegates tended not to err on the smaller room sizes but instead tried to be realistic about space requirements when details of this parameter where unknown.

When the duration of an exposure situation lay on the boundary of two exposure periods delegates preferred to select a more realistic, rather than conservative, option. It was also highlighted that only the tool EKMG-EXPO-TOOL takes the volume of production and task duration of a very short time into consideration when modelling inhalation exposure.

5.8 RISK MANAGEMENT MEASURES

There appeared a lack of clarity amongst the delegates on how parameter choice might impact on the exposure generated, making it difficult to know how realistic and relevant their choice is. .

Delegates felt a need for transparency to understand what is the underpinning exposure reduction via ventilation. This was seen as consistent with a requirement for training to undertake assessments properly rather than simply relying on pushing any buttons to adjust exposure to obtain a value that will be below the DNEL.

A number of points were raised during these discussions and they are highlighted:

- The same reduction factor may apply to different forms of ventilation.
- Huge variability in 'efficiency' or 'effectiveness' of notionally similar types of LEV.
- A gradation in applying ventilation is linked to efficiency in MEASE.
- With the ECETOC TRA tool, enhanced ventilation has 10 air changes per hour but where using measurements, the rate and reduction factor may be unknown.
- Discrimination between integrated and exterior LEV in the MEASE tool was felt to be unclear by some delegates.
- Transparency is required in the tools regarding the reduction in exposure from each ventilation option.
- Some delegates use the ECETOC TRA without RPE or control measures and add these afterwards if choice is limited.
- Enclosure is an option in MEASE but not in the ECETOC TRA.
- Can use closed systems in MEASE but not PROC 1.
- There was wide agreement that there were no control measures at source for ES5. Delegates used the descriptions in the accompanying tool glossary to

define integrated, exterior and general ventilation in MEASE and generally selected the lower confidence limit (25[th] percentile) when applying LEV. They considered the options in Stoffenmanager (in breathing zone/cabin/ far field and LEV are separated out) were easy to use.

- For RPE selection, delegates reported that they would typically model exposure without the use of RPE and then run the tool again with this selected. This was because RPE is considered a last resort in control but it was noted that in some cases control was impossible without RPE.

5.9 GENERAL DICUSSION ON EXPOSURE ASSESSMENT UNDER REACH

In a closing general discussion on the use of exposure assessment results under REACH, delegates were asked to comment on the information that passes both to and from DSUs in the REACH process. For example, does the addition of exposure scenarios to extended SDS (eSDS) and supply of detailed toxicological and environmental information reduce the documents' usefulness. One delegate highlighted a number of points: that as short data sheets are often not read, it was unlikely that longer ones would be accessed, therefore information should be filtered and modified compared with the one in the dossier; that the ES information for DSU should be targeted in terms of relevance; and that translations into other languages necessitated the use of standard phrases rather than free text, which reduced the level of detail.

5.10 SUMMARY OF THE INHALATION FOCUS GROUP DISCUSSIONS

The inhalation focus group discussed various features of the tools to establish delegates' thoughts about the ease of use and issues surrounding the selection of an option for the input parameters and the representativeness (as realistic or over-cautious) of the exposure estimate.

Some parameters were found to be wide open to interpretation e.g. extremes in dustiness, ambiguity in domain, assignment of PROC codes and efficiency of LEV. Delegates considered that additional descriptive information or relevant examples were a good aid to improving ease of and accuracy in parameter selection. It emerged that delegates tended to apply PPE and a correction factor to adjust exposure for very low concentrations after running the tool and tended to use a realistic, rather than a cautious, approach when assigning values in the tool where proximity to the boundary of a range of values was an issue.

6 GENERAL DISCUSSION AND TOOL REQUIREMENTS/NEEDS – SUMMARY OF CONCLUDING REMARKS

The closing discussions of the Workshop aimed to give delegates the opportunity to discuss any further issues concerning the Tier 1 tools, as well as highlight further any key points previously discussed during the sessions. These are summarised in no particular order of relevance below.

- The ease of using the Tier 1 tools was considered to be dependent on the level of experience developed through using and applying the tools. It was also highlighted that in instances where there is less knowledge of and familiarity with the tool, then a more conservative approach may be adopted (e.g. have two options for a parameter user will choose the highest).

- It was considered that Tier 1 tools should be conservative, with some delegates suggesting that they gave 'safe' exposure estimates, under certain conditions, which were fit for purpose. It was agreed that such tools were largely based on sound principles and designed for estimating exposure quickly, using the minimum amount of information and producing an assessment within an acceptable range at the Tier 1 level. This was considered to be a realistic representation of information availability for assessors undertaking such assessments. If more, better information is available then there was the possibility of moving to a Tier 2 tool. It was highlighted that, overall, the amount of information given in the BURE exposure situations was 'better' than would normally be received by consultants and regulators when undertaking or evaluating assessments. Assessors with access to the working environment being considered and who are typically able to collect information to fill any data gaps or for clarification found the data quality in the BURE situations reasonable. The impact of not being able to carry out the assessment 'in situ' (on-site) was not considered a drawback as most assessors would not have this opportunity.

- The estimates generated by the dermal tools were generally less trusted than the estimates generated by the inhalation exposure assessment tools. There were three main reasons for this, these being i. the limited experience of the delegates in quantifying dermal exposure; ii. the identification of pathways and mechanisms for dermal exposure and iii. a lack of confidence in the basis and validity of the underlying models. This lack of experience means there is poor understanding of what is considered to be a reasonable or realistic dermal exposure assessment. A lack of transparency about uptake in dermal models may contribute to this. This is contrary to that for the inhalation exposure assessment tools where there is an awareness of the effect of vapour and dust levels on exposure from industrial experience, measurement data and information e.g. publications in the literature.

- Dermal exposure was considered to be more variable with a wider spread of values round the central tendency because of a greater opportunity to arise from incidental exposure, how a person works and how often they washed their hands, other behaviours, which may not realistically be possible to model.

- It was difficult to separate out in the discussions improvements to the tools which would be classified exclusively as 'ease of use'. It was felt that PROC codes should not be part of a model because they may be assigned by a DSU or be difficult to assign with certainty. It was considered that the use of task descriptions may be more useful than PROC codes. Careful ways of working, such as following good hygiene practice and minimising exposure through good working practice and adhering to workplace instructions, were not considered by the tools and it was considered that these should be addressed.

The workshop Chair advised that the eteam will analyse the data collected from the BURE and workshop findings and will prepare feedback for participants and the wider community. It was stated that a summary of the workshop would be circulated to delegates for comment before submission to the Advisory Board to ensure that there has been a fair reflection of the discussions. The dissemination of this draft report fulfils this action.

It was indicated that feedback on the BURE and the eteam project as a whole would be reported to the Advisory Board and data providers first. Discussions with the Advisory Board would take place before any individual modelling scores or measurement data are distributed to workshop delegates or beyond but it was emphasised that this would only be likely to take place upon completion of the overall eteam project. The eteam project team were again congratulated on the BURE study design and organisational efficiency. The eteam project team in return thanked the delegates for their helpful and considered contributions during the workshop.

Appendix 2 BURE Background questionnaire

eteam Between-User Reliability Exercise

Participant background information questionnaire

Dear <ForeName>,

Thank you for agreeing to take part in this exercise. To help us interpret the results, we would like to collect some background information on your previous experience in exposure assessment and of using the tier 1 tools.

In the following questionnaire, we will ask you to complete two different types of question - those that require an option to be selected (please click on the yellow highlighted section to choose your response) and those which require a free text response (with response box shaded in grey). For the free text questions, please delete the grey highlighted section and type in your response.

We would be grateful if you would complete and return this questionnaire by email, no later than <ReturnDate>. The information you provide will be stored electronically and will remain confidential. No individual respondents will be identified in the publication of any results from this study.

1. **We currently hold the following contact details for you. Please indicate in the spaces below if there are any changes to your preferred contact information (free text response)**

Name:	<ForeName> <SurName>	First name Surname
Email:	<Email>	Preferred Email Address
Telephone number:	<Phone>	Telephone number

2. **How old are you?** Please select an option

3. **In which country do you work?** Enter the country name

4. **How would you describe your computer skills?** Please select an option

Novice I have basic knowledge of computer software

Intermediate I have good working knowledge of common software packages e.g. Microsoft Office

Expert I have advanced knowledge of complex software packages/ programming

<ESTCID>

5. How would you describe your English language ability?

Spoken	Please select an option
Reading	Please select an option
Written	Please select an option

6. What type of organisation do you work for? Please select an option
   If you selected Other, please specify.

7. At present, what is your main role in the organization that you work for? Please select an option
   If you selected Other, please specify.

8. Approximately how many years have you worked in occupational exposure assessment?

   Please select an option

9. For what purpose do you mainly complete occupational exposure assessments?
   Please select an option
   If you selected Other, please specify.

10. Please indicate your level of knowledge regarding the tool(s) to be used in this assessment (please select an option for each of the tools indicated).

A	I fully understand how to use the tool and have an in-depth understanding of its underlying concepts and limitations
B	I have a good working knowledge of how to use the tool for my purposes and am aware of its limitations
C	I know how to use the tool to generate exposure estimates but am unfamiliar with its underlying concepts and limitations
D	I am not aware of how to use the tool and am unfamiliar with its underlying concepts and limitations

ECETOC TRA v2	ECETOC TRA v3	MEASE	STOFFEN MANAGER v4.5	RISKOF DERM	EMKG-EXPO tool
Select	Select	Select	Select	Select	Select

<ESTCID>

11. How often do you typically use each of the tool(s)? (please select an option for each tool)

A Once a week or more

B 2-3 times per month

C Once every 2-3 months

D 2-3 times per year

E Less than once a year

F Never used tool before

ECETOC TRA v2	ECETOC TRA v3	MEASE	STOFFEN MANAGER v4.5	RISKOF DERM	EMKG-EXPO tool
Select	Select	Select	Select	Select	Select

12. When did you last use each of the tool(s)? (please select an option for each tool)

A Within the last week

B Within the last month

C Within the last 2-5 months

D Over 6 months ago

E Never used tool before

ECETOC TRA v2	ECETOC TRA v3	MEASE	STOFFEN MANAGER v4.5	RISKOF DERM	EMKG-EXPO tool
Select	Select	Select	Select	Select	Select

13. A small number of between-user reliability exercise participants will be invited to participate in a one-day feedback workshop to be held at IOM, Edinburgh, UK on Thursday 7th February 2013.

Would you be interested in attending this event? Select

Thank you for completing this questionnaire. Please save this document as "Background" and return this to eteam.project@iom-world.org by <ReturnDate>, taking care to type in the Subject of the email "<ReturnName>". Alternatively click on the email address above and the email will open with the subject line already entered (please note this does not work for Web based email).

<ESTCID>

Appendix 3 BURE Exposure situation descriptions

Situation 1: Use of Styrene-Resin in Fibre-Reinforced Plastics

Please assess inhalation and dermal exposure to **styrene** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure styrene**) given in the table below.

1. General Description of Exposure Situation

The work activity takes place in a commercial coach building factory, where glass fibre-reinforced plastic mouldings are manufactured. There are 10 workers carrying out the activity in the area (Work Area A).

The work involves covering a mould with alternate layers of glass fibre matting and plastic resin dissolved in styrene. The resin (Product A) is applied as a gel using a paintbrush in a downwards direction. Approximately 20 litres of Product A are used per shift.

Any air trapped in the matting is removed by tapping downwards with a paint brush or rolling with a serrated hand roller. This process results in a large amount of gel falling onto the worker and the floor.

The articles are left in the workshop until the resin is cured.

The process takes place at room temperature (20^{o}C)

No local exhaust ventilation systems are used on the process. Cotton coveralls and safety boots are worn.

The levels of general ventilation are poor and the workers open the large roller door to provide fresh air.

The activity takes place for 6 hours out of an 8 hour shift.

2. Product/ Substance Information

Product	Supplier	Substance Name	CAS Number	Molecular Weight/ $gmol^{-1}$	Vapour pressure at 20^{o}C/ Pa	Concentration of styrene in Product A (%)
Product A	Supplier A	Styrene	100-42-5	104	670	35

Situation 2: Cleaning of Floor Using Hand Brush

Please assess inhalation and dermal exposure to **magnesium stearate** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value given in the table below.

1. General Description of Exposure Situation

The activity takes place in a room within a manufacturing facility (Work Area B), with one worker in the room during the activity. Product B (magnesium stearate powder), has been spilt on the floor of the room (approximately 25kg).

The worker sweeps the room floor using a hand brush, generating a visible cloud of dust.

The process takes place at room temperature (20^{o}C).

There is no localised ventilation provided and there is poor general ventilation in the room.

There is no personal protective equipment or respiratory protective equipment used during the activity.

The task is undertaken for 20 minutes over the 8 hour shift.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of Magnesium Stearate in Product B (%)**
Product B	Supplier B	Magnesium stearate	557-04-0	591	1 (Negligible)	100

Situation 3: Use of Toluene in Coatings- Spray painting in furniture manufacturing industry

Please assess inhalation and dermal exposure to **toluene** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure toluene**) given in the table below

1. General Description of Exposure Situation

The company manufacture a range of furniture from wood and metal. Wooden and metal furniture is spray painted with Product C by an operator in front of a spray wall in the workshop (Work Area C).

The spray wall provides localised ventilation. There is mechanical ventilation in the workshop.

The process takes place at room temperature (20^{o}C)

Product C contains 80% toluene.

There is no personal protective equipment or respiratory protective equipment worn during the activity.

The task is undertaken for 6 hours out of an 8 hour shift.

2. Product/ Substance Information

Product	Supplier	Substance Name	CAS Number	Molecular Weight/ gmol^{-1}	Vapour pressure at 20^{o}C/ Pa	Concentration of toluene in Product C (%)
Product C	Supplier C	Toluene	108-88-3	92	2800	80

Situation 4: Use of Xylene in Formulations- Mixing of chemicals in an Open Vessel

Please assess inhalation and dermal exposure to **xylene** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure xylene (mixed isomers)**) given in the table below.

1. General Description of Exposure Situation

This situation involves industrial mixing of liquid chemicals, including xylene. The operator stands on a platform above the vessel to mix the raw materials for the process, which takes place in Work Area D.

The mixed product (Product D) contains 60% xylene (mixed isomers). Product D is mixed in 50 litre batches.

The process takes place at room temperature (20^{o}C).

There are fixed capture hoods above the mixing process and adequate general ventilation.

The activity takes place for 5 hours per 8 hour shift.

There is no personal protective equipment and no respiratory protective equipment worn during the activity.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of Xylene in Product D (%)**
Product D	Supplier D	Xylene (mixed isomers)	1330-20-7	106	1200	60

Situation 5- Use of Naphtha in Coatings- Solvent tank emptying and re-filling

Please assess inhalation and dermal exposure to **naphtha (heavy)** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure naphtha (heavy)**) given in the table below.

1. General Description of Exposure Situation

The situation involves removal of waste solvents (Product E) from process machinery followed by topping up with clean solvents.

Solvent tanks are emptied manually using a removal pump by the operator and the waste solvent is transferred to 25 litre drums on a pallet in front of the tanks. There is some spillage when the pump is moved between drums.

On completion of the waste solvent removal, the machinery tanks are topped up with fresh Product E solvent, containing 80% naphtha (heavy). The 25 litre solvent drums are lifted from a pallet onto a scissor lift trolley. The trolley is raised up to the level of the tank lid and the drum is tipped over onto its side and the contents emptied into the tank.

There is no local exhaust ventilation fitted on the tanks. The operator wears rubber gauntlets, safety goggles and a respirator during the solvent removal and refilling activity.

There is general ventilation in the work area (Work Area E).
The activity takes 1 hour out of an 8 hour shift

The activity takes place at room temperature (20^{o}C).

2. Product/ Substance Information

The solvent mixture used contains naphtha (heavy) (80%).

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of Naphtha (heavy) in Product E (%)**
Product E	Supplier E	Naphtha (heavy)	64741-98-6	140	500	80

Situation 6- Use of Toluene in Adhesives- Manufacture of Rubber Garments

Please assess inhalation and dermal exposure to **toluene** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure toluene**) given in the table below.

1. General Description of Exposure Situation

The situation describes the manufacture of rubber garments in a dedicated room (Work Area F), with a total of nine workers present.

The garments are assembled by cutting, sewing, gluing and sealing the rubber pieces together. The glue (Product F) used in the assembling area is applied by hand using a small brush and/or a hand held applicator. Approximately 1 litre of Product F is used per shift.

Product F contains 15% toluene.

Local exhaust ventilation is present over the garment assembly area. There are ventilation fans in the ceiling which are used for the majority of the time.

The activity is carried out for 7 hours per day out of an 8 hour shift.

The activity takes place at room temperature (20^{o}C).

There is no personal protective equipment or respiratory protective equipment worn during the activity.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of Toluene in Product F (%)**
Product F	Supplier F	Toluene	108-88-3	92	2800	15

Situation 7- Use of N-methyl pyrrolidone in formulations- Changing of air filters in a vehicle paint spray booth

Please assess inhalation and dermal exposure to **N-methyl pyrrolidone** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure N-methyl pyrrolidone**) given in the table below.

1. General Description of Exposure Situation

This situation involves the changing of air filters inside a vehicle paint spray booth (Work Area G).

The worker removes the filters from the inside of the paint booth. The filters are saturated with polyurethane paint (Product G) containing N-methyl-pyrrolidone (2%) as an additive. The worker also comes into contact with paint on surfaces within the booth.

Clean filters are then installed into the booth and the dirty filters placed into bags for disposal.

The activity takes place at room temperature (20°C).

The worker wears cotton gloves and a respirator when carrying out the activity.

There is no local exhaust ventilation used during the activity.

The duration of the task is approximately 5 minutes per 8 hour shift.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ $gmol^{-1}$**	**Vapour pressure at 20°C/ Pa**	**Concentration of N-methyl Pyrrolidone in Product G (%)**
Product G	Supplier G	N-methyl pyrrolidone	872-50-4	99	45	2

Situation 8: Cleaning of Endoscopy Equipment in a Hospital

Please assess inhalation and dermal exposure to **glutaraldehyde** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **glutaraldehyde in solution**) given in the table below.

1. General Description of Exposure Situation

The situation takes place in Work Area H in the endoscopy unit of a hospital, where dirty medical equipment is sterilised before being used to examine patients.

The employee places soiled medical instruments by hand into the sterilising equipment. The equipment contains an aqueous solution of Product H, containing glutaraldehyde (2%).

The sterilising equipment is closed during operation. There is mechanical ventilation in the room.

Following completion of the sterilisation process, the employee removes the instruments from the sterilising equipment and places them on trays.

The employee wears nitrile gloves when carrying out the task. Respiratory protective equipment is not worn.

The activity lasts for around 3 hours per 8 hour shift.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ $gmol^{-1}$**	**Vapour pressure at 20°C/ Pa**	**Concentration of glutaraldehyde in Product H (%)**
Product H	Supplier H	Glutaraldehyde	111-30-8	100	1	2

Situation 9: Packaging of Sodium Resinate Powder in a Factory

Please assess inhalation and dermal exposure to **sodium resinate** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value given in the table below.

1. General Description of Exposure Situation

This exposure situation describes the packaging of powder in a small room within a factory (Work Area J).

Before packaging sodium resinate powder (Product J), the worker dumps a large bag (25 kg) of the product into a galvanised metal bath on a table, built into which there is a weighing scale.

The worker holds a plastic bag open with one hand and uses a scoop to transfer powder from the tub to the bag until the desired weight is achieved. There are frequent dust spills.

The activity lasts one hour in an 8 hour shift.

A small, kitchen–type exhaust fan in the wall above the work table operates during the entire activity.
The worker wears disposable latex gloves, safety glasses and disposable coveralls. No respiratory protective equipment is worn.
The activity takes place at room temperature (20°C)

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ $gmol^{-1}$**	**Vapour pressure at 20°C/ Pa**	**Concentration of sodium resinate in Product J (%)**
Product J	Supplier J	Sodium resinate	61790-51-0	220	1 (Negligible)	100

Situation 10: Dipping of Metal Parts during Manufacture of Electrical Connectors

Please assess inhalation and dermal exposure to **isopropanol** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure isopropanol**) given in the table below.

1. General Description of Exposure Situation

The exposure situation describes the preparation of metal shells during manufacture of electrical connectors for use in the electronics and automobile industries.

In the assembly area of the factory (Work Area K), one employee dips metal electrical shells containing rubber inserts into a lubricant solution of Product K, which contains 50% isopropanol/ 50% water.

Workers in the assembly area do not wear gloves, and no ventilation controls are present in this area. The activity takes place at room temperature (20^{o}C).

No respiratory protective equipment is used during the activity.

The activity takes place for 5 hours out of an 8 hour shift.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of Isopropanol in Product K (%)**
Product K	Supplier K	Isopropanol	67-63-0	60	4400	50

Situation 11: Weighing of Powdered Pharmaceutical Products

Please assess inhalation and dermal exposure to **amoxicillin trihydrate** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value given in the table below.

1. General Description of Exposure Situation

This situation describes the weighing of small amounts of Product M in ventilated weighing enclosures in the pharmaceutical industry.

The operator scoops 50g aliquots of Product M (containing 65% amoxicillin trihydrate) into containers. The activity generates some visible dust.

There is good mechanical ventilation of the room (Work Area M).
The employee does not wear respiratory protective equipment or gloves during the activity.
The activity takes place at room temperature (20^{o}C)

2. Product/ Substance Information

Name	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of amoxicillin trihydrate in Product M (%)**
Product M	Supplier M	Amoxicillin trihydrate	61336-70-7	419	1 (Negligible)	65

Situation 12: Re-filling of Dry Cleaning Equipment with 1-Bromopropane in Retail Premises

Please assess inhalation and dermal exposure to **1-Bromopropane** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure 1-Bromopropane)** given in the table below**)**.

1. General Description of Exposure Situation

This situation describes the refilling of dry cleaning machines with 1-Bromopropane solution.

The activity takes place in small retail premises in Work Area N, at room temperature (20^{o}C).

Machine operators refill the dry cleaning machines with Product N containing 1-Bromopropane (80%). Around 10 litres of product is added.

The operator does not wear any respiratory protective equipment. Rubber gloves are worn.

There is general ventilation in the shop.

The task is undertaken for 30 minutes per 8 hour shift.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of 1-bromopropane in Product N (%)**
Product N	Supplier N	1-Bromopropane	106-94-5	123	14800	80

Situation 13: Top loading of Tankers with Heavy Fuel Oil

Please assess inhalation and dermal exposure to **heavy fuel oil** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure heavy fuel oil)** given in the table below**)**.

1. General Description of Exposure Situation

This situation describes the top-loading of heavy fuel oil into tanker-trucks.

Road tankers are top loaded with heavy fuel oil (Product P) in dedicated outdoor loading bays (Work Area P). A top loading arm is manually swung into place above the tanker and the driver positions it into the tank inlet. The manhole of the tanker and end of the loading arm are covered with a rag to prevent splashes.

Following completion of loading, the driver removes the loading arm and wipes it using the same rag, which is usually soaked with solvent.

Safety helmet, coveralls, hi-visibility vest and safety boots are worn during general work activities.

Safety glasses and impervious gloves are worn by the tanker drivers during loading. No respiratory protective equipment is worn.

The loading operation takes around 1 hour in total per 8 hour shift.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of heavy fuel oil in Product P (%)**
Product P	Supplier P	heavy fuel oil	68476-33-5	3000	100	100

Situation 14: Use of Phenol in Adhesives: Gluing of Rotors

Please assess inhalation and dermal exposure to **phenol** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure phenol)** given in the table below.

1. General Description of Exposure Situation

The work activity takes place in a factory producing metal rotors. The activity involves the use of pressure-sensitive adhesive solution (Product Q) to join metal work pieces. The worker applies the adhesive manually to the metal at a gluing workstation within Work Area Q. Around 5kg of Product Q are used per shift.

There is local exhaust ventilation at the workstation. There is no natural ventilation as the windows and doors are closed.

No personal protective equipment or respiratory protective equipment is worn.

The activity is carried out for 7 hours per 8 hour shift.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ $gmol^{-1}$**	**Vapour pressure at 20°C/ Pa**	**Concentration of Phenol in Product Q (%)**
Product Q	Supplier Q	Phenol	108-95-2	94	53	1

Situation 15: Packing of Nickel Metal Powder

Please assess inhalation and dermal exposure to **nickel** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value given in the table below.

1. General Description of Exposure Situation

This situation describes the packing of nickel powder in drums.

The operator removes excess powder (Product R) from a pre-weighed drum using a hand scoop and places the surplus material into a storage bin located at the packing station (Work Area R). If the containers are below the required weight, the operator uses the scoop to transfer powder back from the storage bin into the drum.

The operator then fixes a sealing cap onto an open aperture on the top of the drum.

The packing station is provided with local exhaust ventilation at the filling point. An air assisted filtering visor fitted with P3 filters is worn. All packing operators wear cotton overalls and safety boots. Gloves are not worn during scooping of powders.

The activity takes place at room temperature (20^{o}C) in a small room with general ventilation.

The activity takes place for approximately 3 hours per 8 hour shift.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of Nickel in Product R (%)**
Product R	Supplier R	Nickel	7440-02-0	59	1 (Negligible)	100

Situation 16: Filling of vessels with Isopropyl Benzene

Please assess inhalation and dermal exposure to **isopropyl benzene** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure isopropyl benzene)** given in the table below.

1. General Description of Exposure Situation

The situation describes the filling of vessels with Product S (isopropyl benzene).

The process takes place indoors at room temperature (20°C) in a dedicated work room (Work Area S). The 100 litre vessels are filled slowly from the top, through a small filling opening.

The task is carried out by a single operator and is carried out for 1 hour in total per 8 hour shift.

There is mechanical ventilation in the room. There is no local exhaust ventilation.

The operator wears a face shield and chemical resistant gloves. No respiratory protective equipment is worn.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ $gmol^{-1}$**	**Vapour pressure at 20°C/ Pa**	**Concentration of isopropyl benzene in Product S (%)**
Product S	Supplier S	Isopropyl benzene	98-82-8	120	1070	100

Situation 17: Cleaning of Solder Dross during Manufacture of Electronic Components

Please assess inhalation and dermal exposure to **lead** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value given in the table below.

1. General Description of Exposure Situation

During large scale fabrication of electronic components using wave soldering, lead solder dross is collected from the top of a tank of molten solder in Work Area T.

A ladle is used to remove any dross floating on top of the molten solder (Product T). Any solder accidentally collected during the dross cleaning operation is separated using a sieve, and the remaining dross is disposed of in a drum that is sealed with a lid.

The solder contains 40% lead, and has a melting point of 185^{o}C. The solder tank is maintained at 250^{o}C during the process.

There are local exhaust ventilation hoods over the solder process. There is some general ventilation from windows.

During dross cleaning, the operators wear heat resistant gloves over the disposable nitrile gloves, a face shield, and an apron. No respiratory protective equipment is worn.

The task takes 30 minutes out of the operators' 8 hour shift.

2. Product/ Substance Information

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular Weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of lead in Product T (%)**
Product T	Supplier T	Lead	7439-92-1	207	1 (Negligible)	40

Situation 18: Use of hexabromocyclododecane (HBCD) additive during production of Extruded Polystyrene

Please assess inhalation and dermal exposure to **hexabromocyclododecane** (HBCD) in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value given in the table below.

1. General Description of Exposure Situation

During production of extruded polystyrene, granules of polystyrene containing hexabromocyclododecane (HBCD) (Product V) are added to a closed reactor via a hatch.

The activity takes around 30 minutes per 8 hour shift and is carried out by one operator in Work Area V. The process takes place at room temperature (20^{o}C).

No respiratory protective equipment or gloves are worn.

There is no local exhaust ventilation on the process.

There is good natural ventilation in the room.

2. Product/ substance Information

Product	Supplier	Substance Name	CAS Number	Molecular Weight/ gmol^{-1}	Vapour pressure at 20^{o}C/ Pa	Concentration of HBCD in Product V (%)
Product V	Supplier V	hexabromocyclo-dodecane	3194-55-6	642	1 (Negligible)	10

Situation 19: Casting of Aluminium into Blocks

Please assess inhalation and dermal exposure to **aluminium** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value given in the table below.

1. General Description of Exposure Situation

Molten aluminium (Product W) is siphoned from the bottom of a furnace by the operator, then transported in open containers (crucibles) to a holding furnace before being cast into blocks. The melting point of aluminium is 660^{o}C. Casting takes place at a temperature of 700°C.

The whole of the situation described above takes place in Work Area W.

2. Product/ substance Information

Product	Supplier	Substance Name	CAS Number	Molecular Weight/ gmol^{-1}	Vapour pressure at 20^{o}C/ Pa	Concentration of aluminium in Product W (%)
Product W	Supplier W	aluminium	7429-90-5	27	1 (Negligible)	100

Situation 20: Use of acetone in formulations- Batch Manufacture of Automotive Paints

Please assess inhalation and dermal exposure to **acetone** in the situation described below.

When entering data into the tools during the exercise, please use the CAS number, molecular weight and vapour pressure value (which is for **pure acetone)** given in the table below.

1. General Description of Exposure Situation

This situation describes the preparation of batches of automotive paints in Work Area X.

During preparation of an automotive paint, Product X, containing acetone (95%), is added directly to the closed mixing vessel by an employee using a pump. The activity takes place at room temperature (20^{o}C).

No respiratory protective equipment is used. Gloves are worn.

The activity is carried out for around 90 minutes per 8 hour shift.

There is good general ventilation in the area.

2. Product/ Substance Information#

Product	**Supplier**	**Substance Name**	**CAS Number**	**Molecular weight/ gmol^{-1}**	**Vapour pressure at 20^{o}C/ Pa**	**Concentration of acetone in Product X (%)**
Product X	Supplier X	Acetone	67-64-1	58	24000	95

Appendix 4 BURE worksheet

E-TEAM between-user reliability exercise

Instruction and worksheet for completion of exposure scenario Situation 18 using tool(s) EMKG-EXPO (inhalation) and RiskOfDerm (dermal)

1. Instructions

Dear Karen,

This worksheet provides details of the exposure situation to be assessed and of the tier 1 tools that we are asking you to use to assess inhalation and dermal exposure.

A series of questions are included as you work through this worksheet - those with drop-down lists (highlighted in yellow) from which you can click on your chosen answer and those that require a free text response (with response box shaded in grey). For the free text questions, please delete the grey highlighted section and type in your response.

At the end of this worksheet you will find instructions for returning the completed worksheet and a copy of the tool displaying the completed exposure assessment. Please return these by no later than 16/11/2012.

The information you provide will remain confidential. No individual respondents will be identified in the publication of any results from this study.

2. The exposure situation to be assessed

Please read the attached Situation 18 document carefully. We would like you to complete an inhalation and dermal exposure assessment exercise (as appropriate) for this.

A. Please rate your previous experience of this exposure situation

Extensive - I have assessed exposure to this situation previously using exposure assessment tools and have completed walk-through surveys

Reasonable - I have carried out measurements to assess exposure for a similar situation

Limited - I have read papers or seen other information about this situation but have not actively carried out any exposure assessment

None

Please Select an option

3. Tool to be used in completing the exposure situation assessment

For this exposure situation assessment we would like you to use the following tool(s) EMKG-EXPO (inhalation) and RiskOfDerm (dermal). Simple instructions for using the tool(s) were provided in the Between-User Reliability Exercise introductory pack.

Please open up the tool(s) and complete the exposure assessment for both inhalation and dermal exposure using the information provided in the attached Situation 18 document.

B. **In the tables below, please insert details of the outputs obtained from your EMKG-EXPO (inhalation) and RiskOfDerm (dermal) exposure assessment of this exposure situation.**

For some tools there will be multiple values generated, which we would like you to record. Please record your outputs for all of the relevant estimate descriptions by entering the numerical value or range that you obtained in the box beside each of the output descriptions for that tool.

Note that for some of the situations, the tools may indicate that the exposure estimates generated are inappropriate or out of scope. Please ignore these messages and record the results that you have obtained in the relevant boxes within this worksheet.

Do not enter any results in the boxes for tools which have not been used in this particular situation - these boxes should remain empty.

Inhalation		Dermal	
TRAv3 long term inhalative exposure estimate (ppm for volatiles, mg/m³ for solids)	Number	TRAv3 Long term dermal estimate	Number
TRAv3 long term inhalative exposure estimate (mg/m³)	Number	TRAv3 Local dermal exposure estimate	Number
TRAv2 Inhalative exposure estimate	Number	TRAv2 Dermal exposure	Number
MEASE Inhalation exposure estimate	Number	MEASE Dermal exposure estimate	Number
EMKG Predicted exposure level for vapour	Range	MEASE Total dermal loading	Number
EMKG Predicted exposure level for solids	Range	RISKOFDERM Hands loading 50th percentile	Number
STOFFENMANAGER 50th percentile	Number	RISKOFDERM hands loading 90th percentile	Number
STOFFENMANAGER 75th percentile	Number	RISKOFDERM body loading 50th percentile	Number
STOFFENMANAGER 90th percentile	Number	RISKOFDERM body loading 90th percentile	Number

Next, we would like to gather information on how clear you were about the choices you made in assessing exposure using the tools.

C. Please indicate the level of uncertainty you experienced in selecting the required input parameters for assessing INHALATION exposure

	no uncertainty-choice of correct parameter was clear	minor uncertainty-choice of parameter reasonably clear	major uncertainty-choice of parameter was unclear
Substance characteristics, for example dustiness	***Please Select an option***		
Operational conditions, for example, general work environment, process temperature	***Please Select an option***		
Task/ activity description	***Please Select an option***		
Risk management measures / controls, for example local exhaust ventilation, personal protective equipment,	***Please Select an option***		

D. Please indicate the level of uncertainty you experienced in selecting the required input parameters for assessing DERMAL exposure

	no uncertainty-choice of correct parameter was clear	minor uncertainty-choice of parameter reasonably clear	major uncertainty-choice of parameter was unclear
Substance characteristics for example dustiness	***Please Select an option***		
Operational conditions, for example, general work environment process temperature	***Please Select an option***		
Task/ activity description	***Please Select an option***		
Risk management measures / controls, for example local exhaust ventilation, personal protective equipment	***Please Select an option***		

E. Overall, how easy or difficult did you find it to translate the exposure situations into the required input parameters for the inhalation and dermal assessment?

Inhalation	Dermal
Please Select an option	***Please Select an option***

F. Please indicate your thoughts on the level of under/over estimation of inhalation and dermal exposure estimates obtained for the situation by selecting an option below

Inhalation	Dermal
Please Select an option	*Please Select an option*

G: Did you feel that the tool used was suitable (i.e. within its range of applicability) for the exposure situation that you were asked to assess?

Inhalation	Dermal
Please Select an option	*Please Select an option*
If you selected Other, please specify.	If you selected Other, please specify.

4. Saving and returning your completed exposure assessment

IMPORTANT: Please return both this completed worksheet and a saved copy of the tool(s) that you used to carry out the assessment.

Please save a copy of the tool(s) you have used as "4143-2-1-EMKG-EXPO and 4143-2-1-RiskOfDerm" and this worksheet as "4143-2-1-Worksheet".

In the event of STOFFENMANAGER being used to undertake the assessment, please save your inhalation exposure risk assessment by clicking on "save" at the bottom of the STOFFENMANAGER page. This will store your results and input choices within your STOFFENMANAGER account.

Please return this worksheet and the saved copies of the tool(s) to eteam.project@iom-world.org by 16/11/2012 taking care to type in the Subject of the email "BURE Return reference:4143-2-1", or click on the email address above and the email will open with the subject line already entered (please note this does not work for Web based email).

Appendix 5 BURE Feedback questionnaire

eteam Between-User Reliability Exercise

Participant feedback questionnaire

Dear <Forename>,

Thank you for taking the time and effort to participate in the eteam Between-User Reliability Exercise. This questionnaire aims to collect feedback on your experience of completing the exercise and using the tier 1 tools.

We will ask you to complete two different types of question - those that require an option to be selected (please click on the yellow highlighted section to choose your response) and those which require a free text response (with response box shaded in grey). For the free text questions, please delete the grey highlighted section and type in your response.

We would be grateful if you would complete and return this questionnaire by email, no later than <ReturnDate>.

The information you provide will be stored electronically and will remain confidential. No individual respondents will be identified in the publication of any results from this study.

1. **Did you complete all 20 exposure situations assigned to you? (tick box that applies)** Select
   If you selected Yes, please go to question 3
   If you selected No, please go to question 2

2. **If you did not complete all 20 exposure situations, please indicate the main reason why.**
   Please select an option
   If you selected Other, please specify.

3. **Overall, how helpful or otherwise did you find the worksheet instructions in helping you complete your assigned exposure assessments?**
   Please select an option

4. **Thinking back to when you started the Between-User Reliability Exercise - for each of the tools used, please indicate how easy or otherwise you found them to generate the required model output. (Please select an option for each tool).**

ECETOC TRA v2	ECETOC TRA v3	MEASE	STOFFENMANAGER	RISKOFDERM	EMKG-EXPO tool
Select	Select	Select	Select	Select	Select

<ESTCID>

5. Now that you have completed the Between-User Reliability exercise and have (more) experience of the tools used, please indicate how easy or otherwise you now find them to generate the required model output. (Please select an option for each tool).

ECETOC TRA v2	ECETOC TRA v3	MEASE	STOFFENMANAGER	RISKOFDERM	EMKG-EXPO tool
Select	Select	Select	Select	Select	Select

6. Please indicate how helpful or otherwise you found the help functions contained within each of the tools (e.g. comment boxes, glossary). (Please select an option for each tool).

ECETOC TRA v2	ECETOC TRA v3	MEASE	STOFFENMANAGER	RISKOFDERM	EMKG-EXPO tool
Select	Select	Select	Select	Select	Select

7. Overall, how easy or difficult did you find it to translate your assigned exposure situations into the tool input parameters for INHALATION exposure estimates? (Please select an option for each tool).

ECETOC TRA v2	ECETOC TRA v3	MEASE	STOFFENMANAGER	EMKG-EXPO tool
Select	Select	Select	Select	Select

8. Overall, how easy or difficult did you find it to translate your assigned exposure situations into the tool input parameters for DERMAL exposure estimates? (Please select an option for each tool).

ECETOC TRA v2	ECETOC TRA v3	MEASE	RISKOFDERM
Select	Select	Select	Select

Legend for Questions 9 and 10

A Greatly over-estimated exposure

B Appropriately over-estimate exposure

C Sometimes over-estimate and sometimes under-estimate exposure

D Under-estimate exposure

E Greatly under-estimate exposure

9. Overall, do you think the exposure estimates provided for INHALATION exposure by each of the tools during the Between-User Reliability exercise .....? (Please select an option from the legend for each tool).

ECETOC TRA v2	ECETOC TRA v3	MEASE	STOFFENMANAGER	EMKG-EXPO tool
Select	Select	Select	Select	Select

10. Overall, do you think the exposure estimates provided for DERMAL exposure by each of the tools during the Between-User Reliability exercise .....? (Please select an option from the legend for each tool).

ECETOC TRA v2	ECETOC TRA v3	MEASE	RISKOFDERM
Select	Select	Select	Select

<ESTCID>

11. For INHALATION exposure estimation, please tell us what you think are the strengths and limitations of the various tools. (Free text response).

	Strengths	Limitations
ECETOC TRA v2		
ECETOC TRA v3		
MEASE		
STOFFENMANAGER		
EMKG-EXPO tool		

12. For DERMAL exposure estimation, please tell us what you think are the strengths and limitations of the various tools. (Free text response).

	Strengths	Limitations
ECETOC TRA v2		
ECETOC TRA v3		
MEASE		
RISKOFDERM		

13. For each of the tools, please indicate whether you intend to use them again and if so, for what purpose (e.g. REACH exposure assessment, compliance with OEL). (Tick one box for each of the tools).

		If yes, please indicate intended use (free text)
ECETOC TRA v2	Select	
ECETOC TRA v3	Select	
MEASE	Select	
STOFFENMANAGER	Select	
RISKOFDERM	Select	
EMKG-EXPO tool	Select	

14. Please use the space below to provide any additional feedback that you have on the Tier 1 tools, for example suggestions for improvements to layout, guidance, user training or general user-friendliness.

Thank you for completing this questionnaire. Please save this document as "Feedback" and return this to eteam.project@iom-world.org by <ReturnDate>, taking care to type in the Subject of the email "<ReturnName>". Alternatively click on the email address above and the email will open with the subject line already entered (please note that this does not work for Web-based email).

<ESTCID>

Appendix 6 Results tables

6.1 Demographic information about Participants

Table 6.1 Participant characteristics

Characteristic	Category	Number of Participants (%)
Sector	Consultancy	43 (29)
	Industry	41 (28)
	Research	24 (16)
	Government/ Regulator	22 (15)
	Other	16 (11)
Country	European Union	123 (84)
	United States/ Canada	9 (6)
	Asia/ Middle East	4 (3)
	Other	8 (5)
	Missing	22 (15)
Age (years)	<30	12 (8)
	30-49 years	93 (64)
	>50	40 (27)
	missing	1 (1)
Job Title	Chemical risk assessor	37 (25)
	Occupational hygienist	38 (26)
	Product stewardship expert	5 (3)
	REACH advisor	17 (12)
	Researcher/ scientist	21 (14)
	Toxicologist	11 (8)
	Other	17 (12)
English Language- Reading ability	Native	31 (21)
	Excellent/ Good/	107 (73)
	Average/ Poor	8 (5)
English language- Writing ability	Native	31 (21)
	Excellent/ good	101 (69)
	Average/ poor	14 (10)
Reason for Performing Exposure Assessments	REACH exposure assessment	58 (40)
	Compliance with OEL	30 (21)
	Identification of RMMs	28 (19)
	Other	29 (20)
	Missing	1 (1)
Experience in Exposure Assessment (years)	< 1	22 (15)
	1-4	33 (23)
	5-9	33 (23)
	10-19	33 (23)
	>20	25 (17)

Table 6.2 Participants' level of knowledge of exposure assessment tools

Level of Knowledge of Exposure Assessment Tool (Number of participants/ %)					
Tool	**Full/ Good**	**Limited**	**None**	**Missing**	**Total**
ECETOC TRAv2	67 (46)	38 (26)	39 (27)	2 (1)	146
ECETOC TRAv3	58 (40)	36 (25)	49 (34)	3 (2)	146
EMKG-EXPO-TOOL	26 (18)	23 (16)	94 (64)	3 (2)	146
MEASE	27 (18)	30 (21)	86 (59)	3 (2)	146
RISKOFDERM	29 (20)	43 (29)	71 (49)	3 (2)	146
STOFFENMANAGER	50 (34)	35 (24)	59 (40)	2 (1)	146

Table 6.3 Frequency of use of tools by participants/ Number of participants

Tool	Frequency of Use of Tool							
	Weekly	2-3 times per month	Every 2-3 months	2-3 times per year	< Once per year	Never	Missing	Total
ECETOC TRAv2	17	15	23	22	25	40	4	146
ECETOC TRAv3	17	17	19	14	20	55	4	146
EMKG-EXPO-TOOL	2	2	5	15	21	96	5	146
MEASE	1	6	10	9	21	95	4	146
RISKOFDERM	3	5	18	17	28	72	3	146
STOFFENMANAGER	5	11	19	26	22	60	3	146

6.2 Summary of data

Table 6.4 Number of returns completed by situation (across all tools)

Situation	Number of Assessments
1	104
2	104
3	107
4	105
5	98
6	96
7	97
8	95
9	99
10	104
11	103
12	101
13	104
14	103
15	99
16	104
17	105
18	106
19	99
20	100
total	2033

Table 6.5 ECETOC TRAv3: Description of data

	ECETOC TRA v3							
	Inhalation				Dermal			
Situation	**No. of original returns**	**Missing data**	**Excluded**	**No. for analysis**	**No. of original returns**	**Missing data**	**Excluded**	**No. for analysis**
1	24	2	1*	21	24	2	1*	21
2	21	4	0	17	21	4	0	17
3	20	3	0	17	20	3	0	17
4	20	1	1	18	20	1	1	18
5	19	0	0	19	19	0	0	19
6	26	3	1**	22	26	3	1**	22
7	20	1	0	19	20	1	0	19
8	14	2	0	12	14	2	0	12
9	20	1	0	19	20	0	0	20
10	21	1	0	20	21	1	0	20
11	22	3	0	19	22	3	0	19
12	22	2	0	20	22	2	0	20
13	20	1	1*	18	20	1	1*	18
14	22	0	0	22	22	0	0	22
15	16	5	1*	10	16	5	1*	10
16	21	1	0	20	21	1	0	20
17	19	2	1*	16	19	2	1*	16
18	17	3	0	14	17	3	0	14
19	16	8	0	8	16	7	1*	8
20	21	2	0	19	21	3	0	18
TOTAL	401	45	6	350	401	44	7	350

* unable to check outlying value as either no tool entry saved and/or one of inhalation/ dermal estimate in pair missing from tool worksheet
**participant had been allocated the ECETOC TRAv3, however had used the ECETOC TRAv2 in error

Table 6.6 ECETOC TRAv2: Description of data

	ECETOC TRA v2							
	Inhalation				Dermal			
Situation	**No. of original returns**	**Missing data**	**Excluded**	**No. for analysis**	**No. of original returns**	**Missing data**	**Excluded**	**No. for analysis**
1	20	0	0	20	20	0	0	20
2	18	0	0	18	18	0	0	18
3	21	0	0	21	21	0	0	21
4	18	1	0	17	18	1	0	17
5	22	0	0	22	22	0	0	22
6	21	0	0	22	22	0	0	22
7	19	0	0	19	19	0	0	19
8	18	0	0	18	18	0	0	18
9	21	1	0	20	21	1	0	20
10	26	0	0	26	26	0	0	26
11	19	1	0	18	19	1	0	18
12	20	0	0	20	20	0	0	20
13	24	0	0	24	24	0	0	24
14	23	0	0	23	23	0	0	23
15	16	0	0	16	16	0	0	16
16	24	0	0	24	24	0	0	24
17	25	0	0	25	25	0	0	25
18	18	1	0	17	18	1	0	17
19	18	3	0	15	18	3	0	15
20	20	0	0	20	20	0	0	20
TOTAL	**412**	**7**	**0**	**405**	**412**	**7**	**0**	**405**

Table 6.7 EMKG-EXPO-TOOL and STOFFENMANAGER: Description of data

	EMKG-EXPO-TOOL (inhalation)				STOFFENMANAGER (inhalation)			
Situation	**No. of original returns**	**Missing data**	**Excluded**	**No. for analysis**	**No. of original returns**	**Missing data**	**Excluded**	**No. for analysis**
1	22	0	0	22	21	4	0	17
2	22	0	0	22	20	3	0	17
3	25	1	0	24	20	5	0	15
4	22	0	0	22	22	6	0	16
5	19	1	0	18	16	3	0	13
6	14	2	0	12	19	8	0	11
7	18	0	0	18	21	5	0	16
8	23	0	0	23	22	4	0	18
9	20	0	0	20	16	4	0	12
10	21	1	0	20	20	6	0	14
11	18	0	0	18	23	6	0	17
12	18	0	0	18	21	6	0	15
13	20	0	0	20	20	2	0	18
14	19	1	0	18	20	4	0	16
15	23	0	0	23	23	5	0	18
16	21	1	0	20	14	5	0	9
17	22	1	0	21	19	5	0	14
18	21	0	0	21	27	7	0	20
19	20	1	0	19	20	5	0	15
20	18	0	0	18	20	2	0	18
TOTAL	**406**	**9**	**0**	**397**	**404**	**95**	**0**	**309**

Table 6.8 MEASE: Description of data

	MEASE							
Situation	**Inhalation**				**Dermal**			
	No. of original returns	**Missing data**	**Excluded**	**No. for analysis**	**No. of original returns**	**Missing data**	**Excluded**	**No. for analysis**
1	17	1	0	16	17	1	0	16
2	23	0	0	23	23	0	0	23
3	21	0	0	21	21	0	0	21
4	23	1	0	22	23	1	0	22
5	22	0	0	22	22	0	0	22
6	16	0	0	16	16	0	0	16
7	19	2	0	17	19	2	0	17
8	18	1	0	17	18	1	0	17
9	22	0	0	22	22	0	0	22
10	16	0	0	16	16	0	0	16
11	21	1	0	20	21	1	0	20
12	20	0	0	20	20	0	0	20
13	20	1	0	19	20	1	0	19
14	19	2	0	17	19	2	0	17
15	21	0	0	21	21	0	0	21
16	24	1	0	23	24	1	0	23
17	20	0	0	20	20	0	0	20
18	23	0	0	23	23	0	0	23
19	25	3	0	22	25	3	0	22
20	21	0	0	21	21	0	0	21
TOTAL	411	13	0	398	411	13	0	398

Table 6.9 RISKOFDERM (hands 90th percentile): Description of data

RISKOFDERM (hands) 90th percentile									
Situation	**Tool used with EMKG-EXPO-TOOL**				**Tool used with STOFFENMANAGER**				
	No. of original returns	**Missing data**	**Excluded**	**No. for analysis**	**No. of original returns**	**Missing data**	**Excluded**	**No. for analysis**	**Overall total for ROD (hands)**
1	22	1	0	21	21	1	0	20	41
2	22	8	0	14	20	6	0	14	28
3	25	0	0	25	20	1	0	19	44
4	22	1	0	21	22	0	0	22	43
5	19	1	0	18	16	0	0	16	34
6	14	0	0	14	19	0	0	19	33
7	18	7	0	11	21	11	1	9	20
8	23	2	1	20	22	1	0	21	41
9	20	1	0	19	16	0	0	16	35
10	21	4	0	17	20	1	0	19	36
11	18	2	0	16	23	0	0	23	39
12	18	0	0	18	21	0	0	21	39
13	20	0	0	20	20	0	0	20	40
14	19	0	0	19	20	1	0	19	38
15	23	1	0	22	23	1	0	22	44
16	21	0	0	21	14	0	0	14	35
17	22	3	0	19	19	3	0	16	35
18	21	0	0	21	27	2	0	25	46
19	20	3	0	17	20	4	0	16	33
20	18	0	0	18	20	0	0	20	38
TOTAL	**406**	**34**	**1**	**371**	**404**	**32**	**1**	**371**	**742**

Table 6.10 RISKOFDERM (body 90th percentile): Description of data

Situation	RISKOFDERM (body) 90th percentile with EMKG-EXPO-TOOL No. of original returns	Missing data	Excluded	No. for analysis	with STOFFENMANAGER No. of original returns	Missing data	Excluded	No. for analysis	Overall total for ROD (body)
1	22	1	0	21	21	1	0	20	41
2	22	13	0	9	20	12	0	8	17
3	25	0	0	25	20	1	0	19	44
4	22	22	0	0	22	22	0	0	0
5	19	18	0	1	16	16	0	0	1
6	14	0	0	14	19	0	0	19	33
7	18	8	0	10	21	4	3	14	24
8	23	2	0	21	22	0	0	22	43
9	20	20	0	0	16	16	0	0	0
10	21	4	0	17	20	0	0	20	37
11	18	18	0	0	23	23	0	0	0
12	18	18	0	0	21	20	0	1	1
13	20	17	0	3	20	17	0	3	6
14	19	0	0	19	20	1	0	19	38
15	23	23	0	0	23	21	1	1	1
16	21	21	0	0	14	14	0	0	0
17	22	13	0	9	19	12	0	7	16
18	21	20	1	0	27	25	1	1	1
19	20	17	0	3	20	16	0	4	7
20	18	18	0	0	20	18	1	1	1
TOTAL	**406**	**253**	**1**	**152**	**404**	**239**	**6**	**159**	**311**

Table 6.11 Number of inhalation exposure estimates generated by tool/ situation

Situation	ECETOC TRAv2	ECETOC TRAv3	EMKG-EXPO-TOOL	MEASE	STOFFEN-MANAGER
1	20	21	22	16	17
2	18	17	22	23	17
3	21	17	24	21	15
4	17	18	22	22	16
5	22	19	18	22	13
6	22	22	12	16	11
7	19	19	18	17	16
8	18	12	23	17	18
9	20	19	20	22	12
10	26	20	20	16	14
11	18	19	18	20	17
12	20	20	18	20	15
13	24	18	20	19	18
14	23	22	18	17	16
15	16	10	23	21	18
16	24	20	20	23	9
17	25	16	21	20	14
18	17	14	21	23	20
19	15	8	19	22	15
20	20	19	18	21	18
TOTAL	**405**	**350**	**397**	**398**	**309**

Table 6.12 Number of dermal exposure estimates generated by tool situation

Situation	ECETOC TRA v2	ECETOC TRA v3	MEASE	RISKOF-DERM (hands)	RISKOF-DERM (body)
1	20	21	16	41	41
2	18	17	23	28	17
3	21	17	21	44	44
4	17	18	22	43	0
5	22	19	22	34	1
6	22	22	16	33	33
7	19	19	17	20	24
8	18	12	17	41	43
9	20	20	22	35	0
10	26	20	16	36	37
11	18	19	20	39	0
12	20	20	20	39	1
13	24	18	19	40	6
14	23	22	17	38	38
15	16	10	21	44	1
16	24	20	23	35	0
17	25	16	20	35	16
18	17	14	23	46	1
19	15	8	22	33	7
20	20	18	21	38	1
TOTAL	**405**	**350**	**398**	**742**	**311**

6.3 PARTICIPANTS' LEVEL OF UNCERTAINTY

Table 6.13 Inhalation tools- participants' level of uncertainty in selecting input parameters (across all situations)/ Number of participants (%)

Parameter group	Level of uncertainty				
	no uncertainty	**minor uncertainty**	**major uncertainty**	**missing**	**total**
Substance characteristics	1299 (64)	462 (23)	179 (9)	93 (5)	2033
Operational conditions	1009 (50)	719 (35)	210 (10)	95 (5)	2033
Task/ activity	717 (35)	844 (42)	371 (18)	101 (5)	2033
Risk management measures	1058 (52)	658 (32)	220 (11)	97 (5)	2033

Table 6.14 Dermal tools- participants' level of uncertainty in selecting input parameters (across all situations)/ Number of participants (%)

Parameter group	Level of uncertainty				
	no uncertainty	minor uncertainty	major uncertainty	missing	total
Substance characteristics	1338 (66)	467 (23)	193 (9)	35 (2)	2033
Operational conditions	1030 (51)	721 (35)	251 (12)	31(2)	2033
Task/ activity	678 (33)	834 (41)	489 (24)	32 (2)	2033
Risk management measures	1095 (54)	657 (32)	251 (12)	30 (1)	2033

6.4 PARTICIPANTS' FEEDBACK ON BURE and TOOLS

Table 6.15 Reasons for participants' partial or non-completion of the BURE/ Number of participants

Main reason for partial or non-completion of exercise	Number of participants
Exercise too time consuming	1
Work commitments	8
Holiday commitments	1
Problems using tool(s)	11
Other	16
Missing (includes those who completed the whole exercise)	109

Table 6.16 Participants' opinions on usefulness of BURE documentation

Response	Number of participants
Very helpful	35
Helpful	66
Neither helpful nor unhelpful	6
Unhelpful	1
Very unhelpful	0
Missing	38
Total	146

Table 6.17 Participants' assessment of help functions within tool/ Number of participants

Tool	very helpful/ helpful	neither helpful/ unhelpful	unhelpful/ very unhelpful	missing	total
ECETOC TRAv2	69	31	5	41	146
ECETOC TRAv3	58	27	17	44	146
EMKG-EXPO-TOOL	65	28	9	44	146
MEASE	83	20	1	42	146
RISKOFDERM	67	24	13	42	146
STOFFENMANAGER	68	24	10	44	146

Table 6.18 Participants' assessment of level of over- or underestimation of inhalation tools / Number of participants

Tool	Greatly over-estimated exposure	Appropriately over-estimated exposure	Sometimes over-estimated/ sometimes underestimated exposure	Under-estimated exposure	Greatly under-estimated exposure	Missing	Total
ECETOC TRA v2	12	53	32	1	0	48	146
ECETOC TRA v3	10	52	31	1	0	52	146
EMKG-EXPO-TOOL	29	34	34	1	0	48	146
MEASE	11	38	47	0	0	50	146
STOFFEN-MANAGER	6	57	31	0	0	52	146

Table 6.19 Participants' assessment of level of over- or underestimation of dermal tools (across all situations)/ Number of participants

Tool Type	Greatly over-estimated exposure	Appropriately over-estimated exposure	Sometimes over-estimated/ sometimes underestimated exposure	Under-estimated exposure	Greatly under-estimated exposure	Missing	Total
ECETOC TRA v2	23	35	33	3	1	51	146
ECETOC TRA v3	12	46	30	3	0	55	146
MEASE	11	36	43	2	0	54	146
RISKOFDERM	24	35	36	1	0	50	146

Table 6.20 Participants' further use of tools/ Number of participants/ Intention to use tools in future

Tool	Intend to use tool in future	Do not intend to use tool in future	Missing	Total
ECETOC TRAv2	51	44	51	146
ECETOC TRAv3	79	18	49	146
EMKG-EXPO-TOOL	39	53	54	146
MEASE	62	30	54	146
RISKOFDERM	61	33	52	146
STOFFENMANAGER	74	19	53	146