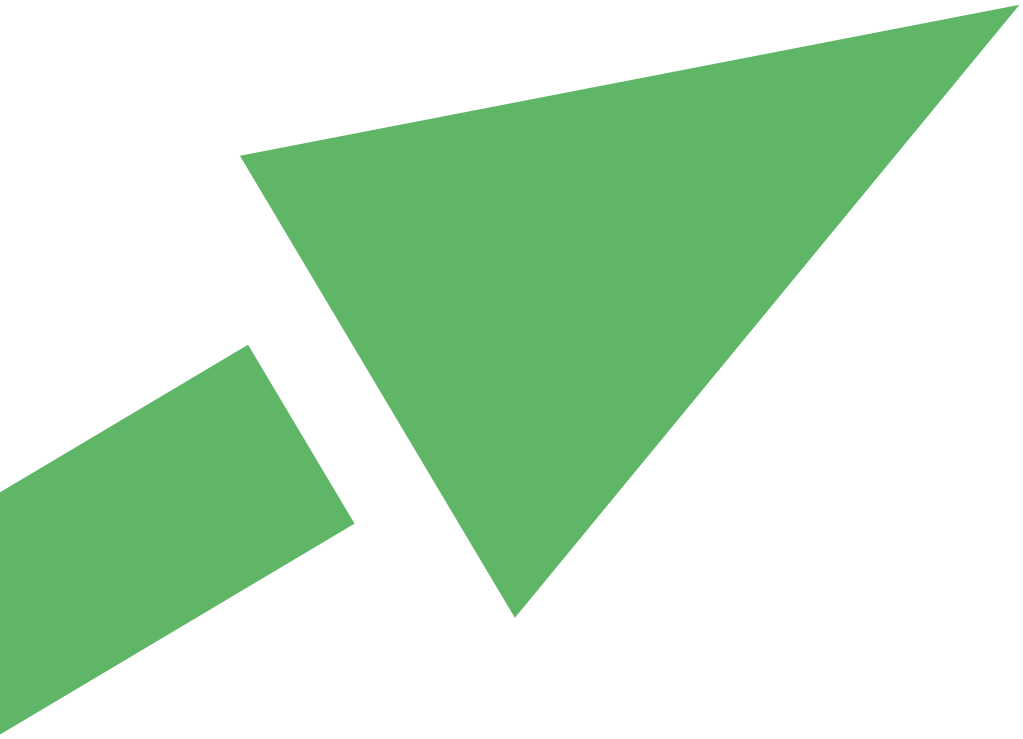

Targeted Risk Assessment

User Guide for TRA Worker Stand-alone tool - Version 3.2

Brussels, October 2023

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PREFACE

A few changes have been introduced to the TRA-Worker module in the new version 3.2 of the TRA tool (2023) compared to the previous version 3.1, related to how exposure assessments are conducted within the context of REACH. This guide addresses these changes and the way the TRA can be applied to support REACH exposure assessments.

Specifically, the changes to the TRA-Worker module are as follows:

- LEV efficiency for industrial PROC 7 (inhalation) has been reduced from 95% to 90%.
- LEV efficiency for professional PROC 8b has been reduced from 90% to 80%.
- Industrial PROC 10 medium volatility liquids base estimate has been increased from 50 ppm to 100 ppm (vapour).
- Professional PROC 10 medium volatility liquids base estimate has been increased from 100 ppm to 200 ppm (vapour).
- Industrial PROC 8a base estimate (liquids and solids) for dermal exposure has been increased from 13.71 to 27.43 mg/kg/day.
- Professional PROC 8a base estimate for dermal exposure (liquids and solids) has been increased from 13.71 to 27.43 mg/kg/day.

Contents

1. INTRODUCTION

This User Guide is to help the reader in operating the ECETOC TRA Worker stand-alone tool v3.2 and contains some guidance on the technical basis of the TRA. For additional guidance the reader is referred to the ECETOC Technical Reports (TRs)[1] 93, 107, 114, 124, 131, 140 and 141 where a detailed explanation of the basis for the TRA can be found and which should help answer most technical questions concerning the tool.

The ECETOC TRA v3.2 uses colour codes to mark the difference between data fields.

The ECETOC TRA v3.2 can be operated for up to twenty exposure scenarios (industrial and or professional) for each substance.

The ECETOC TRA has been developed in Microsoft Excel. The Worker TRA tool exists as a stand-alone version and as part of the integrated TRA tool (which includes the Consumer, Worker and Environment tools).

[1] https://www.ecetoc.org/publications/technical-reports/

2. STARTING / EXITING THE APPLICATION

2.1. Starting

The TRA Worker stand-alone tool is Excel based and this version does not contain macros.

The TRA Tool and supporting documentation are available from:
https://www.ecetoc.org/tools/tra-main/

Click on the download button for the required tool and complete the download request form.

An e-mail will be sent to you containing a download link. This should arrive within a few minutes; if it does not appear in your inbox then please check your spam mail settings and spam/junk mailboxes.

Download the file with the link provided in the email.

Copy the Excel file to the folder where it will be used. It is recommended to keep a back-up of the original files.

2.2. Exiting the ECETOC TRA tool

Unlike the integrated tool, the TRA Worker stand-alone tool can be closed directly after saving.

3. USER INTERFACE

3.1. Overview

The user interface allows for the exposure and risk assessment of a single substance in multiple uses for workers.

3.2. Identification of substance and physico-chemical data entry

This part asks the user to enter required data for the identification of the substance to be assessed such as its name, CAS number and molecular weight (Figure 1).

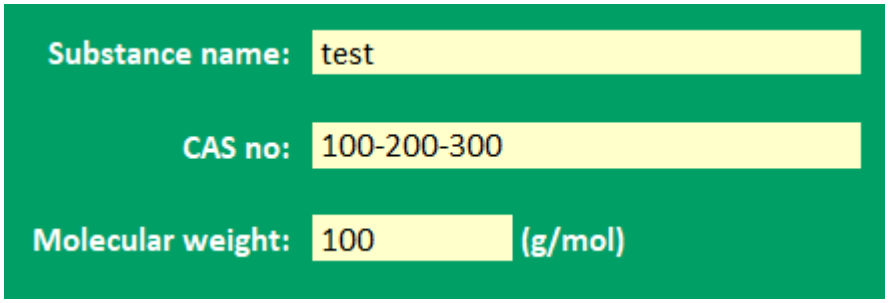

Figure 1. Identification of substance

Cell B5 (Substance name) is a mandatory input. Please enter the name of the substance. Additionally, Cells B7 (CAS no) and B9 (Molecular weight) need to be added. These cells are important for substance description and its assessment.

In the entry fields for worker exposure scenarios the fugacity needs to be selected. Guidance for how to select the correct fugacity band for liquids is provided in Figure 2.

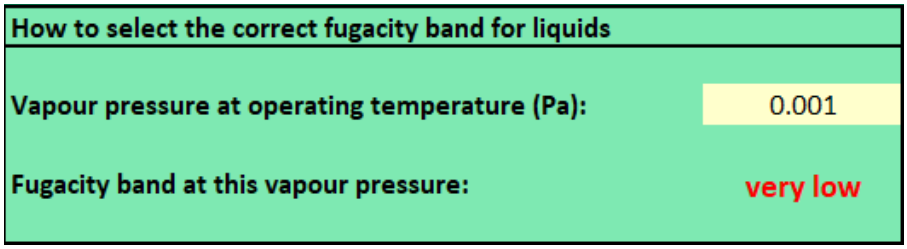

Figure 2. Vapour pressure/fugacity band for liquids

In Cell N6 (Vapour pressure) a numerical value needs to be inserted and a fugacity band is automatically displayed in text at Cell N8 based on the vapour pressure value previously inserted (N6).

The association between fugacity band and vapour pressure is presented below:

I. Vapour pressure of <0.01 Pa will show “very low” fugacity.
II. Vapour pressure between 0.01 and < 500 Pa, will display “low” fugacity.
III. Vapour pressure from 500 Pa and up to 10000 Pa sets fugacity at “medium”
IV. Vapour pressure above 10000 Pa will show fugacity as being “high.”

Guidance on how to select the correct fugacity band for solids is provided in Figure 3.

Select the correct fugacity band based on the description of the dustiness of the material.

How to select the correct fugacity band for solids			
General description	*Relative dustiness potential*	*TRA fugacity*	*Typical materials*
Not dusty	1	Low	Plastic granules, pelleted fertilisers
Slightly dusty	10 - 100 times dustier	Low	Dry garden peat, sugar, salt
Dusty	100-1000 times dustier	Medium	Talc, graphite
Very/extremely dusty	> 1000 times dustier	High	Cement dust, milled powders, plaster, flour, lyophilised powders

Figure 3. Vapour pressure/fugacity band for solids

3.3. Reference values (DNEL or OEL) entry

In this section (Figure 34) the DNELs (Derived No Effect Levels) or other reference values (e.g. Occupational Exposure Limits (OELs)) are inserted for the worker risk assessment. For more details on the parameters please refer to the ECETOC TRs 93[2], 107[3] and 114[4].

Reference values (DNEL or OEL):		
Long-term inhalation:	10	(mg/m3)
Long-term dermal:	10	(mg/kg/day)
Short-term inhalation:	10	(mg/m3)
Local dermal:	10	(µg/cm2)

Figure 3. Reference values data entry

In Cells G6-G9 the respective reference numerical values need to be added for long and short-term inhalation, and dermal (systemic and local) endpoints. These values are required for the tool to perform the risk characterisation of the substance.

The units are displayed in column H (H6-H9) and described in mg/m^3 for inhalation exposure, mg/kg/day for systemic dermal exposure and µg/cm^2 for local dermal exposure.

[2] ECETOC. 2004. TR 93: Targeted Risk Assessment. Brussels, Belgium. https://www.ecetoc.org/wp-content/uploads/2021/10/ECETOC-TR-093.pdf
[3] ECETOC. 2009. TR 107: Addendum to Targeted Risk Assessment Report No. 93. Brussels, Belgium. https://www.ecetoc.org/publication/tr-107-addendum-to-ecetoc-targeted-risk-assessment-technical-report-no-93/
[4] ECETOC. 2012. TR 114: TRA version 3: Background and Rationale for the Improvements. Brussels, Belgium. https://www.ecetoc.org/publication/tr-114-ecetoc-tra-version-3-background-and-rationale-for-the-improvements/

3.4. Worker Assessment-data entry

This part includes the entry fields for worker exposure scenarios. Twenty different scenarios can be entered here (Lines 12-31), either industrial or professional. Besides the scenario name (Column A) which is a free-text field all other entry selections need to be done from drop-down menus (Figure 45). The relevant parameters that need to be selected from the respective drop-down menus are: PROC, Industrial/Professional use, Physical state, Fugacity, Ventilation, Duration, Concentration, LEV, RPE mask, PPE gloves and LEV for dermal. Guidance on selecting these parameters is given in the next section (Section 4).

ECETOC TRA Worker version 3.2 (stand alone tool)

DISCLAIMER: please note that the tool is provided for personal use only. It should not be copied or forwarde
guarantee that the ECETOC TRA tool works error-free. ECETOC is making this tool available for users to aid th
tool and of the provided information or to the conclusions or assumptions made by any user on the basis of
ECETOC is not liable for any consequences resulting from such use.

Substance name: test
CAS no: 100-200-300
Molecular weight: 100 (g/mol)

Reference values (DNEL or OEL):

Long-term inhalation:	10	(mg/m3)
Long-term dermal:	10	(mg/kg/day)
Short-term inhalation:	10	(mg/m3)
Local dermal:	10	(µg/cm2)

How to select the correct fugacity band f
Vapour pressure at operating temperatu
Fugacity band at this vapour pressure:

Scenario name	PROC	Ind/Prof	Physical state	Fugacity	Ventilation	Duration	Concentration	LEV	RPE mask	PPE gloves	LEV for dermal
	PROC1	ind	liquid	very low	indoors - no or basic ventilation	>4hr	>25%	no	no RPE	no PPE	no
	PROC2	ind	liquid	very low	indoors - no or basic ventilation	>4hr	>25%	no	no RPE	no PPE	no

Figure 4. Worker exposure entry fields

4. GUIDANCE ON PARAMETER SELECTION

4.1. Process Category (PROC)

TRA Worker covers twenty-six different conditions of workplace uses of chemicals (termed process categories, PROCs) and enables exposure estimates to be obtained for a range of different types of liquids and solids. Consulting Chapter R.12[5] (Appendix R12-3) from ECHA will assist in selecting the appropriate PROC. Further information is also given in ECETOC TR 131[6]. Note that the TRA does not provide predictions for PROC 28, cleaning and maintenance. If assessors need to estimate exposure for this activity, then another PROC such as PROC 8a (Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities) can be assigned.

The PROC has to be selected in column B.

4.2. Industrial/professional

By selecting the appropriate use type (industrial or professional), the tool will align the respective condition of use across all fields. To ensure consistency across the tool an error message “change input” will be displayed in Column M if an erroneous PROC and use combination is used e.g., PROC7 for professional uses or PROC 11 for industrial uses or the combination of solid and very low fugacity.

Note that the TRA Worker is a conservative tool. The use type ‘industrial’ should only be selected when the worker situation meets characteristics that are typical for industrial use (e.g., well designed and maintained technical equipment and technical control measures and a well implemented health and safety management system (specific task training, operating procedures, supervision, etc.)).

The use type industrial/professional has to be selected in column C.

4.3. Physical state

The appropriate physical state (solid or liquid) needs to be selected in column D.

The TRA Worker tool provides base estimates for inhalation exposures from vapours released by liquid substances and from dust released by solid substances. In addition, it estimates dermal exposures for all substances regardless of physical state.

[5] ECHA. 2015. Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.12: Use description. ECHA-15-G-11-EN

[6] ECETOC. 2018. TR 131: Targeted Risk Assessment: Further Explanation of the Technical Basis of the TRA v3.1. Brussels, Belgium. https://www.ecetoc.org/publication/tr-131-targeted-risk-assessment-further-explanation-of-the-technical-basis-of-the-tra-v3-1/

4.4. Fugacity

As seen in chapter 3.2, for liquids, the fugacity band will appear at cell N6 based on the vapour pressure value that was inserted at cell N4. For solids, the fugacity bands are displayed at cells T6-T9 based on the dustiness. It can be used respectively to all PROCs the user would like to assess in combination with the relevant conditions of use. In general, higher fugacity values indicate a greater tendency for a substance to move from one phase to another (i.e., from liquid to vapour), which can increase the potential for inhalation exposure.

The correct fugacity band needs to be selected in column E.

4.5. Ventilation

Ventilation can contribute to reducing exposure levels, although not to the same level of effectiveness as local exhaust ventilation (LEV) (Section 4.8). For further guidance on how the different selections will impact the assessment refer to ECETOC TRs 114[7] and 124[8].

Ventilation status has to be selected in column F.

4.6. Exposure duration modification and short-term prediction

4.6.1. Task/activity duration modifier for 8-hour exposure predictions

One of the exposure estimates provided by the TRA Worker model is an exposure estimate as an 8-hour average value for the activity (or PROC) selected, and this value can be used for comparisons with limit values such as a long-term DNEL or a TWA (time-weighted average) OEL. The reference period for these limit values is 8 hours.

The duration of activity needs to be entered in column G to ensure the tool selects and applies the appropriate exposure modifying factor in calculating these 8-hour exposure estimates. Table 1 below, shows the duration of activity modification factors applied to the 8-hour exposure estimates.

[7] ECETOC. 2012. TR 114: TRA version 3: Background and Rationale for the Improvements. Brussels, Belgium. https://www.ecetoc.org/publication/tr-114-ecetoc-tra-version-3-background-and-rationale-for-the-improvements/

[8] ECETOC. 2014. TR 124: Addendum to TR114: Technical Basis for the TRA v3.1. Brussels, Belgium. https://www.ecetoc.org/wp-content/uploads/2021/10/ECETOC_TR_124.pdf

Table 1: Duration Factors applied to TRA outputs for 8-hr exposure estimates.

Duration of activity	Exposure modifying factor
> 4 hours	1
1 - 4 hours	0.6
15 mins - 1 hour	0.2
< 15 mins	0.1

The duration of activity modification factors are applied to the 8-hr exposure estimates for inhalation for substances of all fugacities.

The effect of duration of the work activity on the dermal exposure estimation is difficult to predict as it is related to the fate of the substance once it has been deposited onto the skin, with liquids of low/very low volatility and 'dusty' solids remaining on the skin well beyond the cessation of the activity unless intentionally removed by washing etc.

However, it is reasonable to assume that for certain types of substance that are unlikely to reside on the skin due to their physical properties, task duration can be applied as a modifying factor in 8-hr exposure estimates.

There is no simple way to express the relationship between final concentration, duration and task/substance characteristics, but liquids of higher volatilities and less dusty solids are less likely to reside on the skin for extended periods. Liquids of higher volatilities will likely quickly disappear from the skin after cessation of the work activity due to evaporation, whilst less dusty solids will likely not remain on the skin when the work activity has stopped.

Therefore, the same modifiers as for inhalation exposures are applied for dermal exposure for liquid substances in the medium to high fugacity bands in the TRA tool, i.e. vapour pressure >500 Pa, and for solid substances in the low fugacity band in the TRA tool, i.e. solids considered not dusty or slightly dusty.

4.6.2. Short-term (peak) inhalation exposure estimation

The TRA Worker model also provides a short-term exposure estimate for inhalation exposure, for comparison with short-term DNEL or STEL (short-term exposure limit), with a reference period of 15 minutes. Exposures will vary during a workday and are not constant, so there will be periods of time where increased levels of exposure will occur. The short-term exposure estimate is intended to represent the peaks in exposure during a workday, expressed as a 15-minute average value. The short-term exposure estimate is derived by the TRA tool by multiplying the 8-hr inhalation exposure estimate, excluding duration modifiers but including LEV/general ventilation, substance concentration in product and RPE modifiers, with a 'Short-term' factor of 4.

4.7. Concentration

The concentration of the substance in a mixture (preparation) is clearly an important modifying factor and needs to be selected in column H. Table 2 shows the modifying factors used in the TRA Worker in dependence of the percentage of a substance in a preparation.

Table 2: Concentration modifying factors applied to TRA output

Percentage of substance in preparation	Exposure modifying factor
> 25 %	1
5-25 %	0.6
1-5 %	0.2
< 1%	0.1

4.8. Local exhaust ventilation (LEV)

LEV is a type of engineering control that captures and removes contaminants at the source, just after their release into the air, before workers can inhale them, provided it is correctly installed and operated.

When industrial use is selected in the drop-down menu, LEV will be set at a standard of 90% efficiency, while for professional uses the prediction is set at 80% efficiency. This eliminates the higher efficiencies embedded in version 3.1 for some PROCs like 7 and 8b. For additional guidance refer to ECETOC TR 141[9]. LEV has to be selected in column I.

4.9. Respiratory protective equipment

Respiratory protective equipment (RPE) should be considered as a last resort when other control measures such as LEV or process changes are not feasible or effective in reducing workers chemical exposure. When selecting RPE mask in column J, consider the nature of work being performed and the availability and effectiveness of other control measures.

To select appropriate types of RPE mask the type and concentration of the chemical, duration and frequency of exposure, and individual worker characteristics such as medical conditions need to be considered.

It is recommended to select RPE mask with an assigned protection factor (APF) that is appropriate for the level of exposure and provides adequate protection against inhalation hazards. The TRA provides

[9] ECETOC. 2023. TR 141: ECETOC TRA v3 Worker module: Comparison of measured and modelled shortterm inhalation and dermal exposure; Changes to tool settings. Brussels, Belgium. https://www.ecetoc.org/wp-content/uploads/2023/10/TR-141-Comparison-of-measured-and-modelled-short-term-inhalation-and-dermal-exposure_20230914.pdf

a percentageof reduction of actual inhalation exposure if this option is selected. Since wearing a mask for a longer period is a physical burden for the worker, the wearing time of RPE is in some countries legally restricted. It is therefore recommended to limit the wearing time as much as possible, e.g., consider choosing up to 4h duration instead of >4h.

4.10. Personal protective equipment (PPE) for the skin

TRA versions 3 and 3.1 already allowed for the use of dermal protection to be factored in (ECETOC TRs 107[10], 114[11]). Similarly, in this version (v3.2) professional uses options are limited to: No PPE, PPE of 80% and 90% effectiveness. For industrial uses, besides the aforementioned 95% effectiveness is also available. Select the PPE gloves in column K.

4.11. LEV for dermal

The use of LEV can be an effective means of reducing dermal exposure to chemicals. In a closed, continuous process with occasional controlled exposure the use of LEV can result in a reduction in dermal exposure of 90%. However, for processes where dermal exposure occurs due to direct contact with contaminated objects, or where the body/hands are positioned between the emission source and the LEV, use of LEV will hardly lead to a reduction of dermal exposure.

Applying LEV reduction factors to the initial dermal exposure estimate is justifiable from a scientific point of view. However, the user should not apply the LEV reduction factor for dermal exposure, when based on the description of working activities it is likely that the reduction of dermal exposure due to LEV is not very effective.

Select LEV for dermal in column L.

For additional information on how LEV can affect dermal exposure the user is referred to ECETOC TR 114[12] (section 2.3).

[10] ECETOC. 2009. TR 107: Addendum to Targeted Risk Assessment Report No. 93. Brussels, Belgium. https://www.ecetoc.org/publication/tr-107-addendum-to-ecetoc-targeted-risk-assessment-technical-report-no-93/

[11] ECETOC. 2012. TR 114: TRA version 3: Background and Rationale for the Improvements. Brussels, Belgium. https://www.ecetoc.org/publication/tr-114-ecetoc-tra-version-3-background-and-rationale-for-the-improvements/

5. OUTPUT OF RESULTS

5.1. Output of the worker exposure and risk

The generic inhalation exposure predictions in the stand-alone TRA-Worker are expressed in mg/m^3, using the values in ppm in the look-up tables in ECETOC TR 141 and converting these for the specific substance being assessed via the formula of 1 ppm = molecular weight/24 mg/m^3.

The output of the estimated exposures and RCRs for workers can be found in columns M-T (Figure 6). The predicted exposure and RCR results are always adjacent to the entry columns of the use inputs in the same line. In case of an RCR>1 the value will be displayed in red text format. The endpoints assessed match the respective reference values described in section 3.3 and are namely, inhalation long-term exposure (mg/m^3), dermal long-term exposure (mg/kg/day), short-term inhalation exposure (mg/m^3), local dermal exposure and their respective RCRs.

For substances with systemic toxicity, it is common practice to assess all relevant exposure routes together. For workers' exposure and risk characterisation, in practice it is advised to add up the RCRs for inhalation exposure and dermal exposure.

If an incorrect entry combination was selected in the entry part e.g., PROC 11 (non-industrial spraying) for an industrial use scenario, then an error will appear in red text format at column M stating to "change input".

Predicted 8hr inhalatory exposure (mg/m3)	Predicted 8hr dermal exposure (mg/kg/day)	Predicted short-term inhalatory exposure (mg/m3)	Predicted local dermal exposure (µg/cm2)	RCR (long-term inhalation)	RCR (long-term dermal)	RCR (short-term inhalation)	RCR (local dermal)	Remarks
4.17E-02	3.40E-02	4.17E-02	1.00E+01	4.17E-03	3.40E-03	4.17E-03	1.00E+00	
4.17E-01	1.37E+00	4.17E-01	2.00E+02	4.17E-02	1.37E-01	4.17E-02	2.00E+01	
4.17E-01	6.90E-01	4.17E-01	2.00E+02	4.17E-02	6.90E-02	4.17E-02	2.00E+01	
4.17E-01	6.86E+00	4.17E-01	1.00E+03	4.17E-02	6.86E-01	4.17E-02	1.00E+02	
4.17E-01	1.37E+01	4.17E-01	2.00E+03	4.17E-02	1.37E+00	4.17E-02	2.00E+02	

Figure 5. Worker output fields

6. PRACTICAL CONSIDERATION FOR USERS

There are known limitations which need to be considered when using the TRA tool (see Table 2 of the ECHA guidance R.14[12]).

In case the situation at the workplace could not be sufficiently covered with the parameters offered by the TRA tool, the exposure should be evaluated differently, e.g., using another exposure assessment tool.

The exposure at a workplace is influenced by many factors including workplace design, task properties, and the efficiency of existing control measures. To be able to accurately assess and transfer this information into ECETOC TRA, the risk assessor should have sufficient knowledge in the field of occupational hygiene and safety. It is thus recommended that the assessment should be done by a competent risk assessor or team of individuals with sufficient knowledge of the situation being studied.

Although the working of the TRA tool is simple, ECETOC expects users to be knowledgeable about workplace exposure assessment principles, including the hierarchy of control for situations requiring risk management. As such, the use of the tool in the calculation sheet (or as the look-up tables in combination with the exposure modifiers) to produce inhalation and dermal exposure estimates as the basis for risk characterisation is best assigned to a competent professional in the field.

The use of the ECETOC TRA tool is intended to provide exposure estimates for exposure scenarios as part of the chemical safety assessment under REACH. The results must therefore not be used to conclude on control measures at existing individual workplaces.

[12] https://echa.europa.eu/documents/10162/17224/information_requirements_r14_en.pdf/bb14b581-f7ef-4587-a171-17bf4b332378?t=1471941453181