



Targeted Risk Assessment

Frequently Asked Questions on using the tool

Q: Could you please indicate which is the basis (daily, yearly...) for the tonnage that has to be indicated in cells E114 to E128 of "Interface excel sheet", for the Environmental Assessment?

A: The unit is /year, so tons per year.

Q: I have downloaded and installed the ECETOC tool. Is there a databank with the established physical-chemical properties of substances that can be integrated into the tool? This would clearly save putting in lots of data (boiling point, CAS number, etc.) which is well-established and not specific to the use scenarios.

A: We suggest that you refer to the ECHA registration database for this information:

<http://apps.echa.europa.eu/registered/registered-sub.aspx>

Q: How are the Risk Characterisation - Inhalative Margin of Exposure, Risk Characterisation - Dermal Margin of Exposure and Risk Characterisation - Total Margin of Exposure calculated and how to interpret them?

A: Please refer to the TRA TR no. 107 and the ECHA guidance document IR&CSA R14. Furthermore, the RCR for inhalation and dermal is calculated by dividing the exposure estimate by the corresponding DNEL. The total margin of exposure is not really of relevance for the REACH risk assessment and will therefore not be further explained.

Q: I have downloaded the ECETOC TRA tool however when extracted this doesn't seem to exhibit the upgraded parameters as detailed in Report 107. e.g. I cannot see where you specify effectiveness of LEV. Can you confirm where I can download the most up to date version which includes these additional functionalities.

A: The version of the TRA that is downloadable from the ECETOC website reflects the TGD ChR14 Tier 1 expectations i.e. set assumptions are made concerning the effectiveness of LEV that usually differs between industrial and professional settings and between different circumstances of use (PROCs). Although TR107 discusses the ability of using alternative LEV efficiencies at the Tier 1.5 level, no facility is included for their incorporation within the current tool (although users are clearly able to further manipulate the exposure predictions within the xls files created during each 'TRA run').

Q: How is the PNEC for sediment exactly calculated? I calculated the PNEC sediment according to REACH (RIP R.10) and using the ECETOC TRA Tool and I do not find the same results. I attached my calculations and a copy of the ECETOC calculations. I would be very grateful if you could have a look at these calculations and give me a feed-back. Alternatively, are the calculation steps as performed in ECETOC exactly documented elsewhere?

A: ECETOC TRA cannot be used to calculate PNEC. The PNECs derivation is described e.g. in the EU TGD of 2006. The PNEC calculation is an integral part of the EU TGD model which has been integrated into the

TRA. The only modification we introduced was the conversion of the wet weight-based output into dry weight (by using a constant factor also available in the EU TGD model). So I refer to the documentation of the EUTGD 2003, section 3.5:

http://ecb.jrc.ec.europa.eu/documents/TECHNICAL_GUIDANCE_DOCUMENT/EDITION_2/tgdpart2_2ed.pdf

The documentation for EUSES should also give the appropriate information as it is based on the same principles. For advanced users, the other option is to trace the calculation in the "EUTGDsheet-TRAM" and via the named fields for all parameters (naming pretty much consistent with guidance).

Q: I have tried to do a risk assessment for acetone in Chesar. I wondered which data ECETOC TRA uses in IUCLID when the program does an exposure calculation in Chesar?

For me it doesn't matter if the calculations are for inhalation (Acute systemic, long term, acute local, long term local) or for dermal (Acute systemic, long term, acute local, long term local). I have imagined a DNEL for an assessment but I can't get any exposure from ECETOC TRA. Which data must I fill in to a dataset in IUCLID to get e.g. exposure for inhalation (acute systemic) in Chesar?

A: This is not a request that ECETOC can answer. It relates to how ECHA has chosen to implement the TRA within Chesar and its interfaces with IUCLID. The request needs to be addressed to ECHA.

Q: I have an issue about Excel's range name in ECETOC TRA integrated tool. In fact the following name gets "#REF!" value.

ESNos

AC_3_1_n

AC_3_2_n

Could you indicate me if it is normal and if I can delete this range named?

A: It appears that the version used is outdated. The selections referred to for the consumer assessment are no longer possible in the newer versions because the "..._n" indicated that these ACs were not covered by the TRA. Please download the latest version of the TRA, but use another tool for these assessments anyway.

Q: Why can only 24 exposure scenarios be entered in the environmental part of the tool? While in the worker and consumer part up to 60 exposure scenarios can be entered? It is a problem when we have more than 24 scenarios.

A: There are only 24 environmental scenarios because this is the number of ERCs.

Q: I have saved new substances in the tool. However, I have not been successful in saving subsequent modifications to the substances i.e. adding of physical data.

A: All new data saving subsequent to the initial establishment of the substance must be done through the datasheet.

Q: I have downloaded the tool from the website. I'm unable to generate reports for new scenarios as it asks whether the substance is used in a preparation but the drop-down box for Yes or No is grayed out and will not activate.

A: The drop-down box (in column L "Substance in preparation?") is linked to column F ("is substance a solid?"). First select 'No' in column F and then the drop-down options in column L will appear.

Q: I use ECETOC TRA for a tier 1 worker inhalation assessment for a liquid substance dossier and we have a technical question: The VP is 0.8 kPa at 50°C (medium fugacity in ECETOC model) and at 0.05 kPa at 25°C (low fugacity in ECETOC model). During the production, in the plan, the substance is at 50°C during the first steps and at 25°C during the last steps. Which fugacity did we have to use : both of them, low (25°C), medium (50°C)?

A: Basically, you would start out with using both for the two stages of the process (25 and 50 degrees). If it has limited impact on the outcome of the assessment you can later on integrate the two stages.

Q: I am working on the REACH registrations for a series of metal salts and have been considering using ECETOC TRA for environmental risk assessment. Could you please confirm that this tool is suitable for inorganics and let us know if there is anything particular, we need to bear in mind when using the tool for this type of substance?

A: In principle, the tool can be used for metal salts. Bear in mind that in its standard setting, the tool assumes that intermedia partition coefficients, bioconcentration factors, etc. are estimated from hydrophobicity (Kow), which obviously does not work for metal salts. Instead, the model user should enter known (measured) intermedia partition coefficients for the metal cation as well as for the counter anion.

Q: I am trying estimate worker exposure under 4 process categories for an industrial gas (carbon monoxide). My question is whether the TRA worker tool and/or the TRA integrated tool are appropriate for the calculation of exposure to gases?

A: No, the tool does not address industrial gases. For information on the limitations/boundaries of the tool, refer to the ECETOC Technical Report 107.

Q: I work as a toxicologist and risk assessor. When I describe the uses of a chemical and perform a task-by-task description I experience unexpected situations. For instance, I have a chemical reaction made under PROC 2 conditions (use in closed batch process) with some sampling of my chemical and occasional maintenance work. The description of PROC2 mentions that these additional tasks are covered by the PROC2 exposure factor. But is it the same for all the PROCs? For instance, do PROC3 or PROC4 also cover sampling and maintenance? Does PROC 54 (mixing or blending) also cover the vessel charging with the raw materials? I've read that these process categories came from the work done by the HSE UK in the frame of the COSHH essential project; unfortunately, I was not able to find the original document describing these generic exposure scenarios. Therefore, may I ask you to provide me with the background documentation allowing me to better understand your codification of the exposure related to technological processes?

A: We are unable to advise regarding filling a CSA dossier. However, for PROC2, 3 and 4 this is correct (please look at the PROC descriptions in R12; it is stated there that it also covers sampling). For PROC 5 and higher, note that these PROCs are activity based. So as a general rule they do not include a sub-activity like sampling. For documentation on the work, please refer to the ECETOC Technical Report 107.

Q: I'd like to know if the Product Category from 36 to 39 will be added to ECETOC TRA program, and when. Otherwise, is it possible to use another PC, changing a few parameters? If yes, which one?

A: There are currently no plans within ECETOC to make additions to the TRA.

Q: I would like to request the password to unprotect the worker, consumer and integrated tools. I would also like to inquire whether there is any way to assess and refine the risk posed by a substance bound within a material in the professional use of articles in the worker or integrated assessment.

A: In the ECETOC Tools, there are indeed a number of cells that are locked for editing but usually these are values that should not be changed and so the developers decided not to share the password. The answer to the 2nd question is that the TRA is not intended to enable users to assess and refine the risk posed by a substance bound within a material i.e. the TRA assumes 100% release. Users wishing to address this aspect of exposure should either use exposure models developed for this purpose (such as those of the EPA) or other means that they are comfortable with e.g. to treat the % available within the matrix as being akin to the % in the product (i.e. the TRA would not work below an assumed release rate of 10%).

Additional questions from inquiries received since 2019

Q: Do you also offer courses or workshops on how to use ECETOC TRA for formulators? If not, do you know who can support us in getting familiar with the tool?

A: Unfortunately, ECETOC does not offer courses/workshops on how to use TRA for formulators. However, we have contacted one of our members who might be able to help you. We will come back to you as soon as possible.

Q: I've just downloaded TRA version 3.1 and tried to enter some data to the relevant fields. However, while selecting the glove type from the combo box hereunder the field showed "no data", I expected to select AFP 5 or 20 or "No" from this field. Would you please advise or recommend a solution about this problem?

A: ECETOC has not supported version 1 of the TRA since it was superseded by version 2 in 2006 (and again by version 3 on 2012). The TRA website (<http://www.ecetoc.org/tools/targeted-risk-assessment-tra/>) should contain all the information that you require for carrying out an exposure assessment for either workers, consumers or the environment in accordance with the EU REACH Regulation (that specifies the use of version 3), including downloads of the tools and supporting user guides and technical reports.

Q: I would like to know where I can find reduction modifier related to ventilation. There are 7 options for ventilation in ECETOC TRA version 3, but only information that I can get is "for basic general ventilation, 0 and for good, 30%, for enhanced, 70%". Please let me know the guidance or information about the reduction rate for each ventilation option.

A: The technical basis of the worker part of the TRA is described in ECETOC Technical reports, 93, 107 and 114 which can be downloaded from the TRA website. Specifically, the rationale behind the assumptions used in role of ventilation can be found in section 2.1.3 of Report #107, and section 2.2.3 and Appendix A of # 114.

Q: When can the TRA be used?

A: The TRA tool is recommended for use under the EU REACH Regulation as it provides a conservative estimate of the typical exposures of different groups of workers handling chemicals (75th percentile for the group). However, many EU regulators consider that for EU health and safety legislation (such as the Chemical Agents Directive), tools should be able to estimate the 90th percentile exposure for an individual worker. For this reason, ECETOC does not advocate the use of the TRA for estimating the nature of worker exposures at specific workplaces. Rather, we advise the application of alternative models such as the ART model and StoffenManager.

Q: Does Vapor pressure affect to dermal RCR in a result? If it does, how much does it affect to the RCR and where can I find quantitative figure in document?

A: ECETOC Reports TR 093, 107, 114, 124 and 131 all cover different aspects of the TRA. So, in order to gain the fullest technical understanding of what the TRA does (and, equally importantly, does not), together with the supporting technical basis, you will then need to study all the reports. Having said this, TRs 107, 114 and 131 are those which primarily address the current worker version of the tool. TR93 mainly addresses version1 of the tool and TR124 mostly deals with infrequent consumer exposures.

Q: Is it possible to assess product A in the case below with ECETOC TRA? (or is it out of domain of TRA?) Product A (liquid) is composed of substance a (liquid), substance b (solid). Product A's physico-chemical properties are known. The hazards, Exposure limits, DNEL of substance a and b are also known.

A: The TRA (as a Tier 1 model) does not account for how different vapour pressures (VP) might influence dermal exposure predictions. The TRA simply differentiates on the basis of whether a substance is a liquid or solid and the circumstances of use (the PROC). So the RCR will not be affected by VP. In your example where you only have an understanding of the properties of the product's component substances, then TR131 2.1.7 offers some suggestions for how the exposures associated with 'solids in liquids' might be approached using the TRA. Please note, however, that these suggestions have not (yet) been implemented in the TRA tool itself, so you would need to calculate the exposures/RCRs independently. TR114 2.4 deals with exposures to 'mixtures' in more general.

Q: Are there any restrictions or known mistakes up to now for the "Integrated TRA tool" under Windows 10 and Office 365? Are you planning an updated version of your TRA tool for WIN 10/Office 365?

A: To date users have not had any technical issues with the TRA tool under Windows 10 and Office 365. The content of the TRA tool will indeed be updated but this will not affect its use under WIN 10 or Office 365.