



EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS AISBL

## ECETOC Targeted Risk Assessment Tool (TRA) special newsletter July, 2017

**Dear TRA User,**

**A lot has happened since the TRA was first launched in 2004. The TRA is being applied for the vast majority of EU REACH registrations and is also now being closely examined for use by regulators outside the EU. Furthermore, several validation studies on the TRA's performance have recently reported. ECECTOC continues to follow these developments and engage with the relevant groups where appropriate. It is also our desire to ensure the TRA remains current and fit-for-purpose. It is therefore our plan to update the TRA in 2019/20, beginning after the 2018 registrations. In this respect, we will be publishing an updated technical Addendum later this year and hold a stakeholder workshop on potential enhancements early in 2019.**

***Alan Poole, ECETOC Secretary General***

Since the release of version 3 of the TRA in 2012, there have been a number of developments which affect the tool. Some of these developments result from work that ECETOC has directly undertaken or been involved with. Others come about from the role that the TRA now occupies under REACH and the interest that this has generated across a range of stakeholders. In the order that you are both aware of some of the more recent developments and ECETOC's views on them, we have compiled this short newsletter.

### **Release of ECHA Chesar v3 tool**

ECHA recently released Chesar version 3. As you will probably be aware, Chesar uses the TRA for its human exposure estimates (workers and consumers). You will probably also be aware that during the summer of 2016, ECHA concluded its update to those chapters of the REACH technical guidance that describe how exposure assessments should be undertaken for worker and consumers (Chapters R14 and R15 respectively). Under ChR15 the method used in v3.1 of the TRA to calculate exposures to infrequent uses of consumer products is only supported for substances where it can be shown that their kinetics follows the simple Haber's rule. As a consequence, ECHA have chosen to implement an alternative method for estimating the risks arising from infrequent exposures to consumer products. This uses changes to how the DNEL is derived, as opposed to refining the exposure assessment (as is the case with TRA v3.1).

It is ECETOC's view that the assessment of exposures to infrequent consumer uses is best achieved through refinement to the exposure assessment, rather than the introduction of additional factors in the risk assessment process. For this reason, ECETOC will not be making changes to the manner in which v3.1 estimates infrequent consumer exposures (this is also the case with the preferred REACH Tier 2 model, [ConsExpo](#)). Having said this, if users choose to implement this portion of the TRA, then they may be asked by ECHA (during Dossier Compliance Checks or Substance Evaluations) the extent to which they have available supporting data which indicates that their substance is likely to follow the simple Haber's rule. A fuller explanation of this can be found on the

TRA website (<https://goo.gl/UHh5DK> and <https://goo.gl/KhwF22>) and will be further explained in a forthcoming revision to the Technical Addendum.

In developing the software for Chesar v3, ECHA has also implemented the following worker elements that TRA users should be aware of:

Chesar Issue	ECETOC Comment
<ul style="list-style-type: none"> <li>At face value, Chesar appears to apply a default temperature for workers of 40 Celsius whereas the TRA applies 20 Celsius in the base case. Does this mean Chesar predictions will be higher than those of the TRA?</li> </ul>	<p>Chesar does have a default operating temperature of 40°C but ECHA advises sectors developing SWEDs to set the operating temperature to a reasonable one depending on the use. Also, single registrants may adapt the operating temperature. Chesar will then estimate the exposure based on</p> <ul style="list-style-type: none"> <li>A vapour pressure recalculated at the operating temperature if the latter is below 40°C (with the exception of PROC 6)</li> <li>Using the highest fugacity by default if the operating temperature is above 40°C (with the exception of PROC 6) but giving the assessor the possibility to provide the vapour pressure at the operating temperature.</li> </ul> <p>Therefore, these characteristics are unlikely to result in any change to TRA predictions between the standalone tool and Chesar.</p>
<ul style="list-style-type: none"> <li>Chesar allows for the exposure modifier for concentration to also be used for solids in liquids. How does this fit with ECETOC's guidance on solids in liquid products?</li> </ul>	<p>The TRA standalone does not include the facility to estimates 'solids in liquids' as explained in TR114. This is because, for the reasons stated (in section 2.2.7), the relationship between concentration and exposure cannot be concluded to be linear. However, applying the TRA concentration bands for the solid component is both conservative and non-linear and so, when combined with an estimate for high dustiness, will provide a suitably conservative basis for estimating such exposures.</p>

These differences together with other domain issues that ECETOC has been made aware of will be addressed in more detail in a forthcoming Technical Report and are included in a revised TRA user guide published in July 2017 (<https://goo.gl/KhwF22>).

## BAuA ETEAM Findings

In 2015, the BAuA held a workshop on a project (the 'ETEAM') that it had sponsored which aimed to evaluate the performance of different workplace exposure models used under REACH, including the TRA (see [ETEAM reports](#)). ECETOC was a member of the ETEAM's advisory board. Unfortunately, resource constraints meant that many of the suggestions put forward by ECETOC (as well as other advisory board members) were not able to be incorporated into the ETEAM methodology. This meant that there were several shortcomings to the study (and which ECETOC has summarised and shared with BAuA and other interested stakeholders (<https://goo.gl/QTfvvt>)).

In early 2016, BAuA made available the database used by the contractors who undertook the ETEAM analyses. This has provided an opportunity for ECETOC to explore in more detail the underlying data and methods of analysis behind the ETEAM findings. The ECETOC analysis has identified a number of key shortcomings as they affect how the ETEAM data were compiled and analysed by BAuA's contractors. A summary of the findings was presented at the ISES Conference in Utrecht in October last year (<https://goo.gl/XgqbpV>). ECETOC's is now working to transcribe this work and its supporting analyses into a peer reviewed paper.

Due to a paucity of dermal exposure measurements, the ETEAM did not investigate this aspect of the TRA. However, CEFIC-LRI instigated a project in 2015 ([LRI B16](#)) with such an aim. From among a number of potential research groups, TNO in the Netherlands was chosen to undertake this task. TNO recently reported their findings. Although only a limited number of data sets that contained dermal exposure measurements of a reliable quality were identified, the analysis suggests that the TRA has a clear bias towards severe overestimation of dermal exposure at low measured exposure values, while all cases of apparent underestimation by the TRA occurred at high measured exposure values. The high exposure findings can partly be explained by a built-in bias of the TRA in the effect of concentration of substance in product used, duration of exposure and the use of protective gloves. Indeed, the protection afforded by gloves was calculated to be an average factor of 34 from the LRI B16 dataset, while factors of between 5 to 10 are used in the TRA estimations. The analysis also indicated that the effectiveness that the TRA affords to LEV when calculating dermal exposure may be too high, especially for activities where the worker is in close proximity to the emission source. ECETOC will be working with TNO to better understand these findings and to incorporate any learnings into future updates to the TRA.

One finding that the ETEAM study highlighted was the significant variation in the outputs that can occur between different TRA users if users do not properly understand the tool or are familiar with the basis of the REACH Use Descriptor system. This finding is not new and has previously been [highlighted by ECETOC](#). One reason why the TRA domain is clearly stated in the Technical Reports and User Guide is to help minimise such variation. The concepts of Generic Exposure Scenarios (GESs) and Use Maps (UMs) that were developed by CEFIC in 2008-10 were also intended to address this challenge and to reduce such variation. Recently, the ECHA supported ENES activity has endorsed the Use Maps, including referencing relevant SCEDs, SpERCs and SWEDs, many of which are to be found posted on the [ENES website](#). Clearly, the proper understanding of the TRA is also important in ensuring that the tool is used properly. In this respect ECETOC is considering a number of webinars in 2017 which will focus on specific aspects of the TRA. We will be issuing further updates once dates are firmed up. An updated Integrated Tool User Guide (<https://goo.gl/KhwF22>) has also been published in July 2016.

## Worker RMM Options

The effectiveness of risk management measures (RMMs), particularly extract ventilation, within the TRA has been fixed at a level that represents what might be reasonably achieved by users if the RMM has been properly designed, installed and maintained and that workers are trained to use it accordingly. The protection afforded by the TRA differs between professional and industrial users.

In updating v2 of the TRA in 2011/12, ECETOC became aware that some industry groups hold information that suggests that higher efficiencies can be obtained when certain types of RMM are applied in their sector. As these forms of RMM tend to be specific to a type of industry or substance, then ECETOC encouraged these groups to make this type of information publicly available. In this respect, CEFIC has initiated an activity that aims to catalogue such RMMs and the European solvents group, ESIG, has recently published a study that describes the effectiveness of a number of alternative RMMs for volatile solvent ([ESIG RMM study](#)). The TRA task force is following these activities closely in order to ascertain the extent to which their findings can be directly incorporated into the TRA.