

CEFIC Long-range Research Initiative Request for Proposals (RfP)

Title and Code Number: Experimental assessment of inhalation and dermal exposure to chemicals during industrial and professional activities - **LRI-B20**

Background

Lower tier exposure assessment tools, like the ECETOC TRA, are widely used to assess dermal and inhalation exposure to chemicals in regulatory risk assessment for workers, consumers and the environment. These tools require limited information and are developed to generate conservative estimates of exposure. The reliability and representativeness of these tools needs to be established by comparing them with good quality exposure survey data or representative experimental data. Although the recent ETEAM project (BAuA, 2015) evaluated the TRA for some workplace settings (PROCs), its findings were not complete or conclusive and several substantive issues have subsequently been identified in the manner the ETEAM analyses were undertaken (Bachler et al, 2016). However, for many of the process categories that could be evaluated, the results indicate that both inhalation exposure estimates generated with the ECETOC TRA and other tier 1 tools are generally conservative. These findings have been further substantiated for the dermal exposure estimates of the TRA (Schinkel and Marquart, 2016). For some of the process categories though, results suggest that predictions may not be conservative enough to be reliably used in a Tier 1 assessment. For these activities, additional empirical data is needed to provide insight into why differences between model estimates and measured data are observed. Furthermore, any new data should provide guidance on changes that may need to be implemented in currently used exposure assessment tools. Alternatively, their applicability domain may need to be re-defined or restricted to ensure the exposure estimates that are generated using these tools are sufficiently conservative for all uses included in a risk assessment.

Objectives

The purpose of this project is to generate inhalation and dermal exposure data that can be used to evaluate the ECETOC TRA worker exposure estimates for key industrial and professional uses of chemicals (including formulated products). The scope of these activities would be expected to cover those where insufficient data were identified by the ETEAM to yield conclusions (such as PROCs 3, 4 (solids] and 10 [solids]) as well as those PROCs considered to potentially underestimate 'true' exposures. In addition, it would be expected to cover those common workplace situations not addressed by the ETEAM (such as PROCs 2 and 17). It is not intended that the project covers either industrial or professional spraying activities or those PROCs with limited application (e.g. PROCs 6, 12 and 18). It would be the expectation that the project addresses the exposure potential presented by both solids and liquids across the relevant fugacity range. The data should be sufficient to enable the evaluation of the findings from previous studies and provide additional insight into the performance of ECETOC TRA. It should also provide insight into the possible reasons for differences observed between the measured data and the model estimates generated with the ECETOC TRA.

It is expected that the majority of the data will be generated in experimental settings to obtain representative base concentration estimates for both inhalation and dermal exposure. The experiments should as much as possible reflect real life use situations. In

CEFIC Long-range Research Initiative Request for Proposals (RfP)

the case of dermal exposure, a quantitative comparison of the hands will be expected, as well as a qualitative assessment of the extent to which significant exposure of other body surfaces may also be associated with the activity.

This project should address

- The extent to which representative and reliable personal exposure measurement data may be available for those PROCs not dealt with by the ETEAM project
- A brief review of the findings of the ETEAM and other previous work that highlight potential concerns with the TRA estimates and which may need to be filled with the experimental data.
- Define a set of use scenarios based on the review and input from industry that should be included in the experimental testing.
- Provide a very clear and transparent description of how the selected use scenarios will be translated into experimental tests to obtain baseline exposure estimates for both dermal and inhalation exposure (including, for dermal, the exposure of relevant body surfaces) and how this information is connected to model parameters.
- Agree a detailed study plan with the LRI project monitoring team to work out the scenarios, included determinants, experimental set-up and what information to collect.
- Provide clear insight on how the results of the experimental tests are representative for real life uses and applications of products with various vapor/dustiness bands and what limitations there may be.
- Based on the experimental data and the previous work, provide an overall assessment of the performance of the ECETOC TRA across the described scenarios
- Based on the outcome, a report will be produced with a full description of the approach, the choices made based on previous work and industry input and final results of the experiments. The report will also contain an in-depth analysis of how these results relate to prior findings and real life exposures with a specific focus on the contribution of the vapor/aerosol fractions to the total exposure for different vapor bands.

Scope

CEFIC is seeking to support the generation of inhalation and dermal exposure data that can be used to evaluate the ECETOC TRA worker exposure estimates for key industrial and professional uses of chemicals (including formulated products). The scope of these activities would be expected to cover those where insufficient data have been identified by previous studies, such as the ETEAM, as well as those TRA settings where 'true' exposures have been considered to be potential underestimates

This project will need to account for:

- Previous work in related areas that has sought to identify and collect relevant and reliable measured workplace exposure data
- The identification of appropriate scenarios that simulated to provide representative (inhalation and dermal) exposure data for the scenario/PROC

CEFIC Long-range Research Initiative Request for Proposals (RfP)

- Undertaking a series of simulations with different forms of chemicals (volatility and dustiness)
- Comparing the findings against the relevant TRA estimates to help identify areas of the TRA that may benefit from further refinement.
- The final report shall contain an executive summary (2 pages max), a main part (max. 50 pages) and a detailed bibliography.
- It is expected that the findings will be developed into at least one peer reviewed publication, following postering(s) and presentation(s) at suitable scientific conference(s).

Cost and Timing

Start January 2018

Duration: 18 months.

Budget in the order of €175K

Partnering/Co-funding

Applicants should provide an indication of additional partners and funding opportunities that can be appropriately leveraged as part of their proposal. Partners can include, but are not limited to industry, government/regulatory organizations, research institutes, etc. Statements from potential partners should be included in the proposal package.

Fit with LRI objectives/Possible regulatory and policy impact involvements/ Dissemination

Applicants should provide information on the fit of their proposal with LRI objectives and an indication on how and where they could play a role in the regulatory and policy areas. Dissemination plans should also be laid down.

References

BAuA (2015) Evaluation of Tier 1 Exposure Assessment Models under REACH (ETEAM) Project <http://www.baua.de/en/Publications/Expert-Papers/F2303-D26-D28.html>

Bachler G, Barone N, Keller D, Money C, Noij D, Tibaldi R (2016) Re-analysis of the ETEAM Database for the ECETOC TRAv3 Model. Poster 2016 ISES conference, Utrecht

J. Schinkel, H. Marquart et al. (2016) External validation of Tier-1 workers dermal exposure estimates in ECETOC TRA. Executive Summary report on CEFIC LRI website. <http://cefic-lri.org/projects/b16-tno-external-validation-of-tier-1-workers-dermal-exposure-estimates-in-ecetoc-tra/>

DEADLINE FOR SUBMISSIONS: 31 August 2017

Please see www.cefic-lri.org for general LRI objectives information, project proposal form and further guidance for grant applications