Code Number and Title

LRI-B16: External validation of Tier-1 workers dermal exposure estimates in ECETOC TRA

Background

When the REACH technical guidance was developed for the chemical safety assessments, the dermal exposure route was treated in the same way and with the same priority as the inhalation route. However, for inhalation exposure assessment we have many years of experience of measuring exposure using established sampling methods, agreed sampling strategy protocols, as well as the availability of quite advanced models based on consolidated databases of exposure measurements. For dermal exposure assessment, on the other hand, the available methods, data and models are much more limited. There are some well-known chemicals for which the dermal exposure route is known to be very important e.g. through past 'emergency' incidents, but for the bulk of the health hazardous substances the REACH required quantitative dermal exposure assessment represented a new development. At the time that the REACH Technical Guidance was being developed, there were several academic, EU-funded projects that were ongoing or had recently concluded, which aimed at improving knowledge and standardisation of dermal exposure assessment. Previous research had focused on the pesticides area and had produced some generic approaches such as the BEAT and EUROPOEMs model but it was clear that these could not be readily extended to the industrial chemicals that fall under REACH.

ECETOC embedded in its Tier-1 Targeted Risk Assessment (TRA) tool the dermal exposure predictions, with some refinements, from the UK-HSE EASE model that had been used in the previous Risk Assessments under the Existing Substance Regulation. The majority of 2010/2013 dossiers have used the ECETOC TRA worker component to develop the exposure assessments. One reason for using the TRA is that it provides a direct link to the Process Categories (PROCs), the REACH Use Descriptors for worker activities that have become the information exchange currency in the supply chain communications. Importantly, ECHA has now adopted the logic of the TRA (version 3) in their assessment platform CHESAR. The inhalation exposure predictions of the TRA have in part been validated: the German BAuA recently conducted the E-Team project in which the inhalation predictions of several Tier-1 tools were compared against available exposure measurement data. The conclusions of this project are pending. However, the E-Team activity was not able to address dermal exposures due to a lack of suitable measured data in the databases supporting that project. No such external validation project has hence been undertaken for the dermal predictions. CEFIC is therefore proposing an independent validation based on available literature and study reports. No new experimental work is foreseen.

This project will need to account for:

- Dermal exposure assessment is not standardized and is compounded by differences in monitoring methods, sampling position, timing of sampling, fate of substance deposited on the skin
- Reliable, representative measurement data are not available for the vast majority of substance/application combinations

- Need for simplified/standardised modelling aligned with PROCs
  - Including affected/exposed skin surface area and loading levels

A desk-top validation is needed based on critical assessment of available field study reports with consideration of potential impact on the results of:

- Task/activity being undertaken and dermal deposition profiles (aligned with one or more PROCs or sub-PROC);
- Substance/product properties and theoretical fate when deposited on the skin;
- Affected/exposed skin surface area;
- Employed monitoring method;
- Sampling strategy;
- Efficiency of any exposure controls other than PPE in place and suitable for Tier-1 assessment.

The validation may result in revised values (both higher and lower) being identified/ proposed for external dermal exposure for selected PROCs.

Objectives

To obtain a set of dermal exposure estimates aligned with PROCs suitable for Tier-1 chemical safety estimates.

- Need to demonstrate no exposure underestimation for substances hazardous via dermal route
- Reliable conservative prediction of potential and actual dermal exposure needed
- Avoid inaccurate exposure estimates which could otherwise lead to inappropriate control advice
- Identify those situations where a lack of measured data constrains any ability to draw conclusions

Scope

CEFIC is seeking an independent validation based on available literature and study reports. No new experimental work is foreseen.
This project will need to account for:

- Dermal exposure assessment is not standardized and is compounded by differences in monitoring methods, sampling position, timing of sampling, fate of substance deposited on the skin
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A desk-top validation is needed based on a critical assessment of available field study reports with consideration of potential impact on the results of:

- Task/activity being undertaken and dermal deposition profiles (aligned with one or more PROCs or sub-PROC);

- Substance/product properties and theoretical fate when deposited on the skin;
- Affected/exposed skin surface area;
- Employed monitoring method;
- Sampling strategy;
- Efficiency of any dermal exposure controls other than PPE in place and suitable for Tier-1 assessment.
- The ability to 'read across' measurement data for similar substance types and/or exposure situations

If appropriate, revised values may be proposed for external dermal exposure and control efficiency for selected PROCs.

Deliverables

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 in 2015, duration 12 months.
Budget in the order of €100,000

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

www.echa.eu
www.cefic.org
www.ecetoc.org

DEADLINE FOR SUBMISSIONS: 31 January 2015

Please visit www.cefic-lri.org for general information about the LRI funding programme, guidelines for grant applications and links to application documents.

For further assistance do not hesitate to contact the LRI Secretariat by e-mail at lri@cefic.be or by phone on 0032 (0)2 676 7368.