

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

### ***Title and Code Number:***

Next generation risk assessment methods for substances associated with mobility concerns. – LRI ECO54

### ***Background***

In environmental exposure assessment, the mobility of chemicals presents two different types of concerns. Initially, mobility was associated with the protection of water resources used as source in the preparation of drinking water. In this context, PMT (persistent, mobile, toxic) criteria have been proposed to identify substances that may pose a hazard to drinking water sources under the EU REACH Regulation ((EC) No 1907/2006) (Neumann and Schliebner, 2019). Mobility is also associated with the transport of chemicals by water, where there is the potential for mid field to far field (often referred to as pristine water resources) exposure which could also have implications for ecological and human health. It has been hypothesized that due to persistence, the exposure to mobile chemicals in a given environmental compartment might increase with time also referred to as “potential accumulation” (ground water, bank water filtrates or far field ecological and human exposure). Regulatory actions, in particular recent nominations for Substances of Very High Concern (SVHC) under the REACH regulation, have raised these issues associated with mobile substances in water.

Recent reviews have pointed to the lack of specificity of the proposed PMT criteria in proactively identifying chemicals of concern, thus pointing to a need for effective screening level and higher tier risk assessment models to identify chemicals of potential concern to drinking water (ref. ECETOC Task Force ‘Persistent chemicals and water resources protection’). A quantitative approach to evaluate concern for increasing exposure over time is not readily available. Finally, contaminants are increasingly detected in all environmental compartments, due to growing knowledge of exposure routes leading to greater exploration, and advances in the field of analytical chemistry improving detection limits. However, the interpretation of monitoring data for evaluating risk has not yet reached a consensus agreement.

As a consequence, there is a need to review and improve risk assessment approaches in support of screening and in the context of chemicals management. These approaches would improve the proactive assessment of substances in development, the registration of chemicals in commerce, as well as support priority setting for regulatory purposes.

This RfP focuses on the development of improved approaches to the tiered risk assessment of chemical substances that may have mobility concerns.

The following challenges need to be addressed:

- 1) Applicability of existing risk assessment models used in regulation.  
The participants of the ECETOC workshop on Advances in (environmental) exposure modelling (WR35, <http://www.ecetoc.org/wp-content/uploads/2018/03/ECETOC-WR-35.-Advances-in-environmental-exposure-modelling.pdf>) recognized that there is a lack of inclusion of scientific advancements in the field of exposure sciences in models currently used in support of chemical regulations. Chemicals on the market represent a wide range of chemistries and thus may not fit in the applicability domain of certain models (chemical space). The choice of the model also depends on the spatial and temporal scales of the evaluation. The potential deviation from the steady-state assumption were also discussed at the workshop in the context of using alternative higher tier assessments approaches.
- 2) Effective screening level and higher tier risk assessment models of chemicals.  
The ECETOC TF “Persistent chemicals and water resources protection”<sup>1</sup> identified gaps in models (EUSES, FOCUS GW, SciGrow) in identifying and supporting the exposure assessment of drinking water contaminants, particularly for drinking water obtained by bank filtration of raw water.

**Objectives:**

**Phase 1:** Review existing regulatory exposure assessment models to:

- Assess the applicability of different modelling tools including EUSES model, RAIDAR and RAIDAR-ICE models, the PROTEX model and other relevant exposure models with regard to the chemical space (chemicals in the EU market) and routes of exposure for the assessment of mobility concerns. These include exposure in drinking water to inform risk for man via the environment and near- and far-field ecological and human risk assessment. A discussion on the adequacy of the routes of exposure for the assessment of man via the environment and the respective quantitative approaches is to be included. Gaps should also be documented to scope phase two of the project.
- Review risk assessment approaches applied in water quality management of raw water for drinking water preparation, which for example helps define the establishment of wellhead protection areas.
- Evaluate the applicability of the steady-state assumption for mobile substances for which the environmental release may occur over extended periods of time (decades).

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<sup>1</sup> <http://www.ecetoc.org/taskforce/persistent-chemicals-and-water-resources-protection/>

- Expand on existing best practices for use of monitoring information in risk assessment by providing guidance on the analysis of monitoring data in the assessment of temporal trends.
- Evaluate the magnitude of increasing exposure that may be expected in the aquatic environment compared to that observed for bioaccumulative substances. Evaluate and set into context the following concern: “The inter-relationship between persistence and mobility to spread widely across an environmental compartment, means that substances can still accumulate to higher trophic levels and have adverse effects”.

**Phase 2:** Based on the results of Phase 1, a tiered and targeted risk assessment approach should be proposed to support screening level and higher tier risk assessment taking into account temporal and spatial scales.

- Develop a model to refine screening level exposure estimates in ground or raw water used for the preparation of drinking water by considering the fate of surface water contaminants in river bank filtration (travel time and associated fate processes). Describe state of the art drinking water treatment technologies, their required efficiencies in support of the development of generic quantitative risk management measures (e.g. Best Available Technologies).
- Develop or expand the development of higher tier risk assessment approaches (e.g. Level IV Mackay modelling) when deviations from steady-state are expected (ECETOC WR 35) and for chemicals outside of the domain of applicability (chemical space) of the screening model. Provide guidance on interpretation of risk and associated uncertainties when models predict exposures over time periods. Exemplify the inclusion of monitoring information.
- Discuss the importance of geographical scales, sources and sinks.
- Shape a scoring system derived from the risk assessment approach by integrating use patterns and substance properties that would support screening assessment and the identification of substances requiring risk characterization in a Chemical Safety Report (REACH). Currently, the need for risk assessment under REACH is mainly based on the identified hazards, however the proposed scoring system would support the assessor in determining if a risk assessment should on scientific grounds be reported in a chemical safety report and the safety data sheet (SDS) communication.

### **Scope**

The focus of the project is the improvement of quantitative risk assessment approaches in support of the prioritisation of chemicals associated with mobility concerns, which are drinking water sources or detected far-from-source, for higher tier risk evaluation.

### **Out of scope (optional)**

The assessment of long-range transport is in scope of LRI project ECO53 <http://cefic-lri.org/projects/eco53-cc-alt-a-chemical-categorisation-approach-for-lrtp-assessment/> ,

and thus has been excluded from this proposal. A review of potential overlap would be beneficial at an early stage of the project.

### ***Deliverables***

- Publish results and recommendation on best practices for tiered risk assessment and inclusion of risk management measures to support the prospective management of emissions to the environment of substances which are likely to become abundant in drinking water sources. A clear communication plan should be outlined in the response to the RfP.
- Provide a review of key differences between the presence in the environmental matrix (and sometimes referred to as accumulation) and bioaccumulation concerns in food webs. Detail quantitative approaches supporting both assessments.
- Provide guidance for interpretation monitoring data in the analysis of temporal trends.
- Discuss the implications of the proposed risk assessment approach in the context of the REACH regulation considering that the legislation defines information requirement mainly on the basis on tonnage, while parametrisation may require specific data.

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 poster(s) and presentation(s) at suitable scientific conference(s).

### ***Cost and Timing***

Start directly after contracting, duration 2 years  
Budget in the order of 250 000 to 300 000 Euro

### ***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.

There is an immediate relevance to propose alternative approaches in evaluating and managing substances with mobility concerns to ensure risk assessment submitted under the REACH regulation evaluate the concern with regard to human and ecological risks.

***References***

Advances in (environmental) exposure modelling: Bridging the gap between research and application. ECETOC WR 35, 4-5 May 2017, Brussels, Published March 2018

Evaluation of using mobility of chemicals in the environment to fulfil bioaccumulation criteria of the Stockholm Convention Reference: PFA.882.000.002, M J Crookes and P Fisk 2018

ECETOC 'Persistent chemicals and water resources protection' Technical Report (in review).

Neumann, M, Schliebner, I. 2019. Protecting the sources of our drinking water - The criteria for identifying Persistent, Mobile, and Toxic (PMT) substances and very Persistent, and very Mobile (vPvM) substances under EU REACH Regulation (EC) No 1907/2006. German Environment Agency

**DEADLINE FOR SUBMISSIONS: August 31, 2020**

Please see [www.cefic-lri.org/funding-opportunities/apply-for-a-grant/](http://www.cefic-lri.org/funding-opportunities/apply-for-a-grant/) for general LRI objectives information, project proposal form and further guidance for grant applications.