Code Number and Title:

LRI-B15: Efficiency of Risk Management Measures

Background

REACH and other European regulations such as the Industrial Emissions Directive 2010/75/EU require demonstration and documentation of safe use of substances based on quantitative exposures and exposure reduction by Risk Management Measures (RMM). Guidance on RMM for REACH registrations has been developed jointly by the European Chemicals Agency (ECHA) in its Guidance document R.13 and by Cefic in a RMM library hosted on its public website. Further exposure and emission control advice is contained in a new Cefic library of standard phrases (ESCOM). Exposure modeling tools such as the ECETOC Targeted Risk Assessment tool version 3 contain a limited range of RMM with assigned default reduction efficiencies. The domains for which RMM's must be specified include worker, consumer and environmental exposures.

The efficiency of any RMM is a function of a number of determinants including its design; appropriate matching of the RMM to the emission or exposure situation and to the agent to be controlled; state of maintenance of the RMM; operator awareness of RMM limitations; and more. Often the efficiency under 'as-used' conditions is lower than under the 'as-built' conditions. However, there are few specific RMMs for which empirical data are available to substantiate this difference. One such example is for the protection efficiency of respiratory protection for workers where the Assigned Protection Factor represents the 'as-used' protection versus the Nominal Protection Factor which indicates the manufacturer's protection claim based on test data in a standard set of circumstances.

It is highly unlikely that the efficiency of any RMM can be characterised by a single figure; it will rather constitute a continuum. The Cefic RMM library presents a 'default' number, as well as a reasonable worst case number. Indeed, RMM efficiency is likely to follow a distribution characterized by a central tendency and a measure of spread such as a standard deviation. Regulatory risk assessment guidance such as ECHA's R.13 recommends that RMM efficiency is considered in both default and reasonable worst case conditions, the latter defined as a 95th percentile of the efficiency distribution. In principle, the abatement efficiency of each RMM is quantified separately in most assessment tools, although some integrated RMM solutions are also listed in the Cefic RMM library.

Knowledge of RMM efficiency under 'as-built' conditions may be available from RMM equipment manufacturers, but is not frequently reported in the open scientific literature. Similarly, knowledge of RMM efficiency under 'as used' conditions may be available from

practicing environment, health and safety professionals in industry as well as regulatory institutes, but is not frequently reported. Both sources of knowledge could be unlocked for example via smart social network initiatives in a first project phase. Results should be mapped against the Cefic library and selected RMM's should be further studied in controlled and field conditions through novel research approaches in order to develop robust and defensible RMM efficiency data for use by the chemical industry. An additional advantage will be the generation of good practice guidelines for industry to further enhance exposure and emission control standards.

Objectives

This project is looking to improve knowledge and understanding of factors affecting efficiency of risk management measures to control human and environmental exposures resulting from emissions in the chemical industry and the downstream users of its products including private consumers.

The project's objectives are to:

1. Create a flexible data structure to collect and collate RMM efficiency information, building on previous work done in Cefic, ECHA and others.
2. Approach holders of RMM efficiency information via traditional and novel channels and encourage them to submit this information into the database, acknowledging the intellectual property nature and commercial interest of RMM manufacturers, and the potential liabilities of RMM users.
    a. Bidders are requested to submit Letters of Intent to Collaborate from a selection of their contacts.
3. Develop pooled estimates of 'as-built' and 'as-used' RMM efficiencies of classes of RMM's and identify key determinants.
4. Conduct verification studies under controlled and field conditions of selected RMM's in order to substantiate efficiency estimates.
5. Create an updated and enhanced RMM library for use by the chemical industry.

Scope

The project is aimed at human and environmental exposures resulting from manufacture and all downstream use of chemical substances. Its principal use is in regulatory risk assessment, but further dissemination of RMM efficiency knowledge is encouraged.

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

Cost and Timing

Start in January 2014, duration 18 months

Budget in the order of €250.000

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

DEADLINE FOR SUBMISSIONS: 1 September 2013

Please see www.cefic-lri.org for general LRI objectives information, project proposal form and further guidance for grant applications. For further assistance do not hesitate to contact lri@cefic.be.