# ECEL v3.0: An Integrated Risk Management Measure (RMM) library

## Executive summary

The main goal of the CEFIC LRI B15 project was to develop a well-designed and user-friendly tool with up-to-date information that is supportive to industry for a wide range of Risk Management Measure (RMM) applications. This information is required in the context of the European Chemicals policy (REACH - Registration, Evaluation and Authorization of Chemicals) and other European regulations to demonstrate and document safe use of substances based on quantitative exposures and exposure reduction by Risk Management Measures (RMM). The CEFIC LRI B15 project was therefore intended to support guidance documents from the European Chemicals Agency (ECHA) and to compile REACH registration dossiers.

To achieve this goal, TNO developed ECEL v3.0 - an Integrated Risk Management Measure (RMM) library as part of the CEFIC LRI B15 project. The key objectives were twofold: (1) to develop a web-based user-friendly and stable database structure with functionalities that are suitable to search for relevant information on RMM, (2) to populate the library with up-to-date information on RMM for both occupational and environmental settings. Two user groups were targeted. First, registrant users who wish to evaluate the quantitative effectiveness of a specific RMM for registration purposes, and secondly downstream users (industry, research, consulting) who require information on the most suitable or optimal RMM by evaluating different types of control systems and their effectiveness for an exposure or emission scenario.

The project was conducted in two parts and in line with the objectives (technical development and data population) and executed in tandem. The 1st part involved the building of a database structure in a stable IT environment. The TNO DIAMONDS platform (https://diamonds.tno.nl/) was chosen for this purpose. The library was designed to accommodate two separate modules: occupational and environment. Some important aspects of the technical development were the development of an intuitive user interface, the inclusion of functionalities for fit-for-purpose searching & saving of data, the uploading of RMM data and testing of the tool.

The 2nd part consisted of the data population of the database. For both the occupational and environmental modules, a systematic literature review (2012-2020) was performed with an abstract screening tool in the DIAMONDS platform. Using a structured approach and screening criteria, suitable data was evaluated, extracted and entered into the database. One of the criteria applied was that it should be possible to derive a quantitative effectiveness value (% reduction in exposure or concentration) for a RMM from the study in question. Besides the data obtained from the peer-reviewed literature and grey literature (case studies, etc.), data was also extracted from various existing (open-source) datasets and databases (<2020) that contain relevant information.

The two parts of the project were brought together in a user-friendly and multi-functional tool – named ECEL v3.0. It was designed to fulfil the needs of registrant or downstream users. The library operates by using a filtering system. A tool user can search for relevant records & studies by selecting filters and focusing on a scenario of their choice. From a *registrant user perspective*, a  user can search for a specific RMM – and refine a search further by selecting other filters related to the substance and the activity (or process). From a *downstream user perspective*, instead of searching for a given RMM, filters can be used to define a scenario. In this way a user can identify all the different RMMs that are available in ECEL for a specific scenario of interest. For each record found during a search, e-cards are available that provide more details of the study in question (e.g.

abstract, images, key parameters). Using the filters and information in e-cards, a user can (de-)select records based on their relevance of a users' scenario. A user can also filter on the quality of each study that was assigned with a value (strong, moderate, limited) to indicate the completeness and reliability of the information available.

There are two visualizations possible in ECEL. First, the data selected by a user for a specific RMM can be analysed and visualized by estimating an effectiveness value (%) estimated from the selected studies and records by using the 50th percentile (median) and a credible interval (95%) value. The latter 95% credible interval is indicated as the lower and upper 95% HDI (Highest Density Interval) and is obtained by running a Bayesian bootstrap estimation of the posterior distribution. Secondly, if a user is interested in multiple RMMs, a 2$^{nd}$ visualization is possible that plots the median and credible interval of each RMM on a single plot. This allows for a comparison of effectiveness outputs of different RMMs.

The library has various features that allows for easy registration and access to the library, together with the option to edit, copy and save previously compiled scenarios and to get access to them during a next login session. This feature will be helpful for library users when searching for information for (for example) REACH dossiers. Another valuable feature is the Summary PDF, which contains all the information of a search, including the selected filters, results, overview of records and the list of references for a given search. A help button is provided with all the information needed by a user, including a user manual and Question & Answer (Q&A) section that provides detail on the content of each module.

The literature review and data population conducted during the CEFIC LRI B15 project (2019-2020) resulted in a considerable number of new records in ECEL. Currently, the ECEL v3.0 occupational module contains >3300 records, while >1100 records are available in the environmental module. Besides the new B15-3 literature review conducted in 2019/2020, additional datasets and databases were coded and uploaded in ECEL. For the occupational module, previously entered data from ECEL v1.0 and v2.0 (engineering controls) were included, as well as nano-specific, pesticide and RMM manufacturers' data. The environmental module also reviewed and uploaded sources such as the IPPC BREF documents and LUSS.

ECEL v3.0 therefore integrates a broad spectrum of data and includes a wide range of RMM applications in different industrial settings. However, the data available for different types of RMMs remain highly variable. For example, in the occupational module, a considerable number of records are available for local exhaust ventilations systems (LEV) with 1246 records (360 studies), whereas suppression techniques gives 266 records (62 studies) and for product / substance control only 52 records (8 studies) are available. Although the overall number of available records are promising, the availability of sufficient reliable RMM effectiveness data for some less known RMM types are either limited or not available.

It was concluded in this project that, despite the current data gaps in RMM effectiveness, ECEL v3.0 offers a comprehensive source of information. It combines the data with a user-friendly interface and ample functionalities to search for relevant data. It is envisaged that this open-source database will be beneficial to both registrants and downstream users, and it is our mission to promote ECEL to all relevant stakeholders and to motivate industry and researchers to share RMM effectiveness data and work together to expand on the ECEL database in the future.