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ProScaleE – user needs and perspectives

Interview study for the development of the ProScaleE methodology

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MISTRA SAFECHEM

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Abstract

The Mistra SafeChem toolbox includes several tools, among them is the ProScale method that was developed as a scoring system based on both hazard and exposure for assessing direct chemical risks to workers, professionals and consumers associated with products in a life cycle perspective. However, a need for a sibling, ProScaleE, that focuses on the effects on the environment was identified. The aim of the task reported herein is to continue the work of developing the ProScaleE method by collecting user needs and perspectives from the members of the ProScale consortium and other stakeholders. The work has been performed by interviews focusing on expectations, thoughts, and ideas on how the ProScaleE method can be developed and what features it should include.

All interviewed participants expressed a strong need for a tool like ProScaleE and agreed on its value. Due to new upcoming legislative proposals from the EU Commission the interest on environmental effects of chemicals is expected to increase and become an even more important issue for industry.

The feasibility and practicability of the tool is of utmost importance. Having a database that already includes the relevant input parameters for different substances would greatly enhance the ease of use. Preferable easily accessible data derived from a common source, such as the REACH should be used. Developing an easy-to-use method is crucial since ProScaleE's target audience should primarily be people without ecotoxicological expertise who need to be able to quickly evaluate chemicals based on H-phrases.

While emphasizing the importance of user-friendliness, it is crucial to ensure that the method does not become excessively simplified, resulting in a loss of relevance. To enhance its relevance, more specific data, in addition to H-phrases, such as persistence, bioaccumulation potential, toxicity, mobility, and endocrine disruption, should be included. It is also crucial to incorporate different compartments of the environment, such as water, soil, and air.

In short, two types of input data should be needed to evaluate a substance with ProscaleE, information about the intrinsic ecotoxicity of the substances, as described above, and an exposure estimate for the related uses along the entire life cycle.

The importance of proper bases of description of the hazard as well as the relevance of the ranking of H-phrases was stressed. It is advisable to utilize the descriptors provided by REACH to ensures consistency and compatibility with existing frameworks and data sources, when developing ProScaleE, not the least consistency with ProScale on human health. The most relevant descriptors to consider would be environmental release categories (ERCs), specific environmental release categories (SPERCs) and risk management measures (RMMs).

It is recommended to have the same approach when developing ProscaleE as when ProScale was developed. When developing the method, it is recommended to begin with a simple approach. Starting with a minimum set of parameters, such as H-phrases for environmental effects, allows for initial validation and testing of the method's performance. Once the basic functionality is established and proven successful, additional functions can be added. There is a strong desire for future versions of ProScale and ProScaleE to be seamlessly integrated into Life Cycle Assessment (LCA) software platforms like GaBi or SimaPro. This integration would eliminate the need for duplicative modelling efforts and align with the long-term goal of ProScale to streamline and enhance environmental impact assessments.

Abbreviations:

ART: Advanced REACH Tool

Chesar: CHEmical Safety Assessment and Reporting tool

CSA: Chemical Safety Assessment

ECETOC TRA: European Centre for Ecotoxicology and Toxicology of Chemicals - Tiered Risk Assessment

ERC: Environmental Release Category

EPD: Environmental Product Declaration

ESPR: Ecodesign for Sustainable Products Regulation

EUSES: European Union system for the evaluation of substances

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

LCA: Life Cycle Assessment

PBT: Persistent, Bioaccumulative, and Toxic

PEF: Product Environmental Footprint

PMT: Persistent, Mobile and Toxic

PROC: PROcess Categories

QSAR: Quantitative Structure-Activity Relationship

REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals

RMM: Risk Management Measures

SPERC: SPecific Environmental Release Category

SSbD: Safe and Sustainable by Design

STP: Sewage Treatment Plant

vPvB: very Persistent, very Bioaccumulative

vPvM: very Persistent, very Mobile

Reading References for the Report

The report is a compilation of information from several different interviews with members of the ProScale consortium. All content presented in the report is derived from the interview material. To increase readability, facts about details and concepts mentioned in the interviews have been presented and explained briefly. Where there has been a need for adding information to broaden the understanding this has been noted as “note from the author”.

ProScaleE – User Needs and Perspectives

The Mistra SafeChem toolbox includes several tools, among them is the ProScale method. ProScale was developed as a method for a scoring system based on both hazard and exposure for comparing direct chemical risks to workers, professionals and consumers associated with products in a life cycle perspective. However, a need for a sibling, ProScaleE that focuses on the effects on the environment was identified. The aim of this task was to continue the work of developing a ProScaleE method by collecting user needs and perspectives from the members of the ProScale consortium and other stakeholders. The work has been performed by interviews focusing on expectations, thoughts, and ideas on how the ProScaleE method can be developed and what features it should include.

The ProScale™ method has been developed during 2016-17 in an industry consortium with expertise both from the life cycle assessment (LCA) and risk assessment areas (Rydberg et al, 2017; ProScale, 2017). The founding members being BASF, Covestro, Deutsche Bauchemie, DSM, IVL, Kingspan and Solvay. The purpose of the development was to achieve an easy-to-use method for assessing direct-exposure related human toxicity potentials for product systems (LCA perspective), ideally compatible with Product Environmental Footprint (PEF). Since ProScale only focus on exposure to human along the product value chain a need was identified to develop a ProScale method, ProScaleE, with focus on environmental exposure.

Introduction to ProScaleE- Previous Work

Prior the work reported herein several activities have been executed with the aim to develop a ProScale based method for ecosystem impacts:

- A method developed by Lindström (2019) called Ecoscale, was presented as a proposal . Ecoscale was based on a H-phrase ranking method for ecotoxicity characterization and was further developed with focus on fully aligning it with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

- In parallel to the task of interviewing members of the ProScale consortium (i.e. the work reported herein) a student project (Kruse, 2023), was initiated November 2022 where a comparison was made between the Ecoscale, USEtox (www.usetox.org) and the BASF method (Saling et al. 2005).

- During 2022 a case study with plasticizers resulted in recommendations for further work on ecosystems (Lundberg & Kärnman, 2022).

Lessons learned from the above conducted studies, together with outcomes reported herein, form the basis for the further development of ProScaleE.

Aim

The aim of the study was to through interviews with members of the ProScale consortia and other stakeholders collect thoughts and input to the development of ProScaleE. The compiled result would work as a starting point in the further work of developing ProScaleE.

Method

Interviews was held with, in first hand members of the ProScale consortia, and other partners with interest in ProScale. Representatives from the following companies were interviewed: Kingspan represented by Anthesis group, Corvestro, Clariant, DBC, DSM, DOW and Merck group. Most of the informants have a background in LCA, chemistry, ecotoxicology, regulatory affairs or Product Safety. Several of the participants have deep knowledge in exposure assessments. Several of the informants were part of the development of the ProScale method and can draw parallels to that work. Most, but not all informants, are familiar with the ProScale method.

An interview protocol was established and utilized as a guiding framework during the interviews. This protocol, which provides a structured set of questions and topics, can be found in the Appendix section of the research documentation. The interviews were conducted remotely using Teams, and for some interviews, the conversations were transcribed verbatim to aid in data collection and analysis. Following each interview, the interview protocols were compiled, and the drafts were shared with the respective informants for their approval and verification. This ensured the accuracy and reliability of the collected information.

Result

In the following section results from the interviews are presented. The findings are presented under different themes.

Need and Usage

Is There a Need for Another Method?

All participants who were interviewed expressed a strong need for a tool like ProScaleE and agreed on its value. As one informant says, “The whole concept is only complete if we have an alternative method for human health and for the environment as well”. Another informant noted that the timing for the development of ProScaleE is opportune, particularly in light of new classifications for substances with properties such as PBT (persistent, bioaccumulative, and toxic), vPvB (very persistent, very bioaccumulative), PMT (persistent, mobile, and toxic), and vPvM (very persistent, very mobile). These evolving classifications underscore the necessity for a tool like ProScaleE to address the complex and changing landscape of chemical assessments.

According to one informant, there is a strong industry focus on carbon footprint evaluation, primarily due to the pressing concern of global warming. Consequently, the level of interest and attention given to ecotoxicity effects is unfortunately relatively low. This observation highlights a potential imbalance in environmental priorities within the industry.

There is several new upcoming legislative proposals from the EU Commission: the Safe and Sustainable by Design (SSbD) framework, the Ecodesign for Sustainable Products Regulation (ESPR) and the revision of the Construction Products Regulation (CPR) with the aim at making sustainable products the norm in the EU and boosting circular business models, The GreenClaims Directive which is a new criteria to stop companies from making misleading claims about environmental merits of their products and services, and European Green Deal. Due to these new upcoming legislative proposals from the EU Commission, the interest on environmental effects of chemicals are expected to increase and become a more important issue for industry. New legislative proposals could also lead to an increased demand for LCA, Environmental Product Declarations (EPDs), and Product Environmental Footprint (PEF) for products, and even legal requirements on including the LCA indicators toxicity and ecotoxicity when performing EPDs for example.

Some of the informers are not completely satisfied with current conventional methods, such as the USEtox method and see a need for an alternative method. This is partly due to the methods sensitivity to substances like heavy metal ions from technical equipment, which heavily influences the results.

One informant highlights the importance of promoting the adoption and utilization of ProScale and ProScaleE to generate industry interest. By actively encouraging the industry to embrace these tools, their value and benefits can be effectively communicated.

How Can ProScaleE be Used?

One of the informants see a direct use for ProScaleE in pilot studies comparing alternative solutions. For example, ProScaleE could be of good use in one of their pilot projects for screening various flame retardants for environmental effects. Another company expect that the ProScaleE method would be more for external use than internal use and could fit in well in the SSbD concept.

Relevance and High-Valued Features of ProScaleE

User Friendliness

The question of feasibility and practicability is of utmost importance. Having a comprehensive database that already includes the relevant input parameters for different substances would greatly enhance the ease of use. If such a database were to include data for commonly used raw materials, ProScaleE would become an easily accessible tool. Therefore, it is emphasized that building such a database should be a primary objective.

Developing an easy-to-use method for evaluating environmental effects is crucial. Many company representatives have emphasized the importance of a user-friendly and straightforward approach that can be seamlessly integrated into existing tools without requiring excessive work effort. This highlights the need for a method that is efficient, accessible, and does not place an excessive burden on users.

ProScaleE's target audience should primarily be people without ecotoxicological expertise who need to be able to quickly evaluate chemicals based on H-phrases.

Relevance

While emphasizing the importance of user-friendliness, it is crucial to ensure that the method does not become excessively simplified, resulting in a loss of relevance. Currently, persistence is only integrated into the H-phrases for chronic toxicity. Therefore, it is imperative to incorporate persistence and bioaccumulation potential into the method. To enhance the method's relevance, more specific data, including persistence, bioaccumulation potential, toxicity, mobility, and endocrine disruption, should be included.[1] Additionally, it is essential to incorporate the upcoming H-phrases for PMT. To maintain the method's relevance, it is vital to include pertinent information such as water solubility, vapor pressure, and distribution coefficient. These factors enable us to comprehend how the molecule behaves in the environment and predict substance toxicity accurately.

In comparison to the current ProScale, there are three dimensions, the water, air and soil compartment, and various exposure routes that need to be considered in a ProScaleE assessment. The current ProScale focuses on inhalation and dermal exposure in relation to the human target organism. However, when assessing the environment, multiple target organisms and exposure routes need to be considered. This complexity can pose challenges when attempting to capture them using a relatively simple method.

It is crucial to incorporate different compartments of the environment, such as water, soil, and air, as they play significant roles. Substances behave differently within each of these compartments, highlighting the importance of including them in the method.

[1]Author's note: Since the interviews were conducted, CLP has been revised and H-phrases for PMT, PBT and endocrine disruption have now been implemented.

Input Data and Data Sources for ProScaleE

In short, two types of input data will be needed to evaluate a substance with ProscaleE, information about the intrinsic ecotoxicity of the substances, and an exposure estimate for the connected use.

A suggestion has been made to utilize data from an existing database instead of creating a new one. One informant emphasizes the advantage of basing ProScaleE on easily accessible data derived from a common source, such as the REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) registration process. There is a desire for the method to leverage the available data in REACH dossiers and align with established concepts, such as the use descriptor system (USD). The use descriptor system is a categorisation system by ECHA to provide a uniform description of substances through specified use descriptors (ECHA, 2015a). By utilizing existing data sources and frameworks, ProScaleE can benefit from the wealth of information already compiled and established under REACH.

Another suggestion is that dataset from EUSES, which is the European reference tool for companies, authorities and researchers to prepare their environmental exposure assessments under the REACH Regulation and the Biocidal Products Regulation, could be used to run environmental data. For REACH one can also use Chesar, the chemical safety assessment and reporting tool. The EUSES 2.1.2 software in Chesar utilizes release factors determined by vapour pressure and water solubility. These factors should be incorporated into the ProScaleE method to ensure its accuracy and relevance. By considering these parameters, the method can provide more comprehensive and reliable estimations of potential environmental impacts.

Another important aspect that concerns the source of input data, is the importance of and the possibility to distinguish if the data are generated from a tool or if measured data are used.

Developing the ProScaleE Method

Structure of the Method

Several informants stress the importance to have the same approach when developing ProscaleE as when ProScale was developed. Preferably one should aim for mimicking ProScale in structure and try to find corresponding data/tools/input that can used in ProScaleE. By making the ProScaleE similar to ProScale one also increases the ease of use for users who are already familiar with ProScale. There is also a wish for that the development of ProScaleE should mirror the ProScale method in how to concur the risk management measures (RMM) and the estimated release. In other words, emissions should be predictable via systems similar to process categories (PROC) and risk mitigation measures should be considered quantitatively.

Recommended Workflow

When developing the method, it is recommended to begin with a simple approach and ensure that the system functions effectively. Starting with a minimum set of parameters, such as H-phrases for environmental effects, allows for initial validation and testing of the method's performance. Once the basic functionality is established and proven successful, further phases of the method can be built upon.

However, before progressing to subsequent phases, it is crucial to evaluate the method's performance through real-world applications. This evaluation provides an opportunity to assess the method's accuracy, reliability, and applicability in practical scenarios. By thoroughly evaluating the

method in various applications, any necessary adjustments or improvements can be identified and implemented, ultimately enhancing its overall effectiveness.

Weighting of Data

One informant emphasized the significance of the process by which data are consolidated, factored, and weighted to generate a final number or outcome. The approach to weighing data are always a critical consideration and holds substantial importance.

Factors

Hazard Phrases

One informant stressed the importance of proper bases of description of the hazard as well as the relevance of the ranking of H-phrases. Since the ranking is the starting point, it becomes very relevant as the outcome will depend strongly on the choices made here. During the development of ProScale, an existing UK starting system was utilized as a basis for the method. This system had been modified and adapted to suit the specific requirements of ProScale. A corresponding system for environmental H-phrases does unfortunately not exist. As a result, there is a clear need to build experience and expertise in the area of how to rank and weight the environmental H-phrases against each other.

One informant suggest that the GreenScreen method might an interesting approach to consider, although it may be too complex for integration into ProScaleE. However, certain aspects of the GreenScreen method could potentially be adapted and incorporated into ProScaleE. One area of interest is the decision mechanism employed by GreenScreen to combine human and environmental hazards. It may be valuable to explore the possibility of incorporating a similar decision mechanism in ProScaleE. This could involve combining the ProScaleH factor (representing human hazards) with the ProScaleE factor (representing environmental hazards) to generate a ProScale H+E factor (representing combined hazards). Such a decision mechanism would help provide a more comprehensive evaluation of the overall hazard potential.

Descriptors: ERCs, SPERCs and RMM

It is advisable to utilize the descriptors provided by REACH when developing ProScaleE. In the original ProScale method, PROCs were employed as descriptors. For ProScaleE, the corresponding and most relevant descriptors to consider would be environmental release categories (ERCs) and specific environmental release categories (SPERCs). SPERCs contain information on the environmental release factors for a use and the related conditions of use. They are usually generated by downstream user sector organisations for the uses relevant to their membership. SPERCs are meant to support registrants under REACH as input information to their Chemical Safety Assessment (CSA) (ECHA, 2015b). By aligning ProScaleE with the descriptors used in REACH, it ensures consistency and compatibility with existing frameworks and data sources. One informant has suggested that it would be beneficial for ProScaleE to accept SPERCs instead of ERCs, as SPERCs provide a more specific description of exposure scenarios. This refinement is implemented by certain sectors and allows for a more detailed assessment of different risk management waste treatments at a particular site. By incorporating SPERCs into ProScaleE, it would enable a more nuanced evaluation of environmental release and potential impacts in specific exposure scenarios. This approach can enhance the accuracy and relevance of the method's results, particularly in sectors where SPERCs are commonly used. For example, different risk management waste treatments at the site will be covered by a SPERC.

The next level of specificity after SPERCs in the ProScaleE method is represented by RMMs. RMMs refer to the actions and strategies implemented to manage and mitigate risks associated with chemical substances. While SPERCs provide information on the environmental release factors and conditions of use, RMMs focus on the measures taken to minimize potential harm to the environment (ECHA, 2012).

To enhance usability and streamline the selection process, implementing a drop-down menu with a decision tree structure could be beneficial. See example below:

1. Choose ERC
2. Choose SPERC
3. Choose sub-SPERC if that is relevant
4. Choose RMM

Additional Factors to Include in the Method

In addition to ERCs and SPERCs, the inclusion of the following data used in EUSES is suggested to be important to enhance the method:

- Vapour pressure
- Water solubility
- Tonnage/day per site, or percentage of EU tonnage used at regional scale (%)
- Sewage treatment plant (STP) default discharge rate (e.g. 2000 m^3/day) or site specific STP data
- STP default removal effectiveness (%) or site specific STP release as fraction of input
- Discharge rate
- Fraction of STP sludge applied to agricultural soil, and for other uses such as filler material (note from the author).

Other Ecotoxicological Methods

This section presents a selection of different ecotoxicological methods, methods that are currently used in risk assessments of chemicals, but which can also serve as inspiration for how ProScaleE could be designed. For example, it is suggested that selected parts of the ECETOC TRA could be included as part of ProScaleE.

ECETOC TRA (European Centre for Ecotoxicology and Toxicology of Chemicals - Tiered Risk Assessment) is a widely recognized tiered approach for conducting human health risk assessments of chemicals. It is a comprehensive framework that allows for the systematic evaluation of exposure to chemicals in various scenarios and settings. It is a conservative approach used in the ProScale method to assess potential risks associated with chemical substances. The tool is used by several of the informants (ECETOC TRA, 2023).

ART (Advanced REACH Tool) is a software tool developed by the European Chemicals Agency (ECHA) to support chemical safety assessments and registrations under the REACH regulation. It is designed to assess the exposure and potential risks of chemicals to human health and the environment. ART is a higher tier exposure assessment tool used for conducting more detailed and realistic exposure assessments in the context of the European Union's REACH regulation (ART, 2023).

EUSES (European Union System for the Evaluation of Substances) is a software tool developed by the European Chemicals Bureau (ECB) to assess the environmental exposure and risk of chemicals. EUSES allows for the estimation of concentrations of substances in various environmental compartments such as air, water, soil, and sediment, and the subsequent evaluation of their potential effects on the environment. EUSES can be considered as the corresponding exposure assessment tool for the environmental part to ART (EUSES, 2023).

Chesar (CHEmical Safety Assessment and Reporting tool) is a software tool developed by the European Chemicals Agency (ECHA) to support the chemical safety assessment and reporting requirements under the European Union's REACH regulation. It is designed to assist registrants in conducting comprehensive chemical safety assessments for their substances and generating the necessary documentation. Chesar is considered an easy to use web-based tool (CHESAR. 2018).

GreenScreen® for Safer Chemicals is a method for chemical hazard assessment designed to identify chemicals of high concern and safer alternatives. It is primarily focused on evaluating the intrinsic hazards of chemicals to human health and the environment. The GreenScreen method provides a systematic approach to identifying and categorizing chemicals based on their potential impacts. The GreenScreen method uses a hazard assessment framework that assigns chemicals into different benchmark levels or ranks based on their inherent hazards (GreenScreen, 2023).

The EPI (Estimation Programs Interface) **Suite™** is a Windows®-based suite of physical/chemical property and environmental fate estimation programs developed by EPA's and Syracuse Research Corp. (SRC)(EPI Suite, 2023). EPI Suite™ is a screening-level tool that uses QSAR for its predictions.

QSAR stands for Quantitative Structure-Activity Relationship. It is a computational modelling approach used to predict the properties and activities of chemical substances based on their molecular structure. QSAR models are developed by establishing mathematical relationships between the structural features of chemicals and their corresponding biological, physical, or chemical properties (ECHA, 2023).

Usage of Existing Chemical Assessment Methods

One company describes how they utilize multiple tools to generate predictions and then comparing the results. By using this strategy, it is possible leverage the strengths of different methods, as the performance can vary depending on the specific substance being analyzed. How well the method works, i.e., how good the method is at predicting a reliable value, is also influenced by the molecular structure of the substance under consideration. The results obtained from different methods are compared and evaluated to arrive at a prediction. This comparative analysis enables the informant to make more informed decisions and enhance the accuracy of the predictions.

Proposed Continued Work

There is a strong desire for future versions of ProScale and ProScaleE to be seamlessly integrated into LCA software platforms like GaBi and SimaPro. This integration would eliminate the need for duplicative modelling efforts and align with the long-term goal of ProScale to streamline and enhance environmental impact assessments. By incorporating ProScale and ProScaleE into existing LCA software, users would have access to a comprehensive suite of tools and data, making the assessment process more efficient and facilitating more informed decision-making.

Note from the author: In the future work with ProScaleE, the tool will be further developed by the ProScale consortium and in the framework of other research projects. It is worth noting that the ambition of developing ProScaleE (and ProScale) is not to replace Chemical Safety Assessment (CSA), as the ProScale tools have another scope (having the product or service, i.e. function, as starting point rather than the individual substance) and with that aim to contribute to sustainable development in the field of chemicals rather than safety in specific locations.

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Appendix

Interview protocol

Date:
Company:
Attendees:

1. What is your background?
2. And do you have you any experience of ProScale?
3. Do you see a need for ProScaleE, thinking broad?
4. Why do you want to use ProScaleE? /Do you see a need for ProScaleE in your organisation?
5. And how would you like to use the model, in what applications?
6. Are there any features that you think should be included in the ProScaleE model?
   At the moment H-phrases, ERCs SPERCs, any thought on that? McKey to predict fate-fugacity.
7. Any experience of using ERCs and SPERCs?
8. Do you know or are familiar with any other models or methods that aim to predict Ecotoxicological effects?
9. Advantages, disadvantages of these?
10. According to you, what are the important things to take in account when developing ProScaleE?
11. Other comments:

About Mistra SafeChem

Mistra SafeChem is a research programme with the vision
to enable and promote the expansion of a safe, sustainable, and green chemical industry.

The programme is developed with the twelve principles of green chemistry as a fundament.

The research combines the potential of innovative manufacturing processes,
tools for hazard and risk screening, and life cycle assessment
with ambitions and opportunities for the development and growth
of a safe and sustainable chemical industry.

More information:
News from the programme, publications, and persons to contact
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