The ProScale Suite: A Regulatory-Aligned, Risk-Based Chemical Footprinting Tool for Assessing (Eco)Toxicity Potential

Therese Kärnman[1], Pernilla Andersson[1], Maja Halling[1] , Amanda Lundberg[1] , Efstathios Reppas-Chrysovitsinos[1] , Rosella Telaretti Leggieri[1] and Tomas Rydberg[1]

[1.] IVL Swedish Environmental Research Institute

INTRODUCTION

The Safe and Sustainable by Design (SSbD) framework requires simple tools for assessing (eco)toxicological risks and impacts that cover all exposure pathways along the life cycle of a product. Here we introduce **the ProScale Suite**, a regulatory-aligned, risk-based chemical footprinting method to assess product/ process/ system (eco)toxicity potential from a life-cycle perspective.

Objectives

- Advance the worker and environmental modules of ProScale to align with the most recent advancements of CLP (EU Regulation No. 1272/2008).
- Develop new modules for assessing (eco)toxicity potential in Service Life and End-of-Life via direct exposure as well as Indirect human Exposure via the environment.
- Ensure consistence between all modules to allow for coherent chemical footprinting assessments.

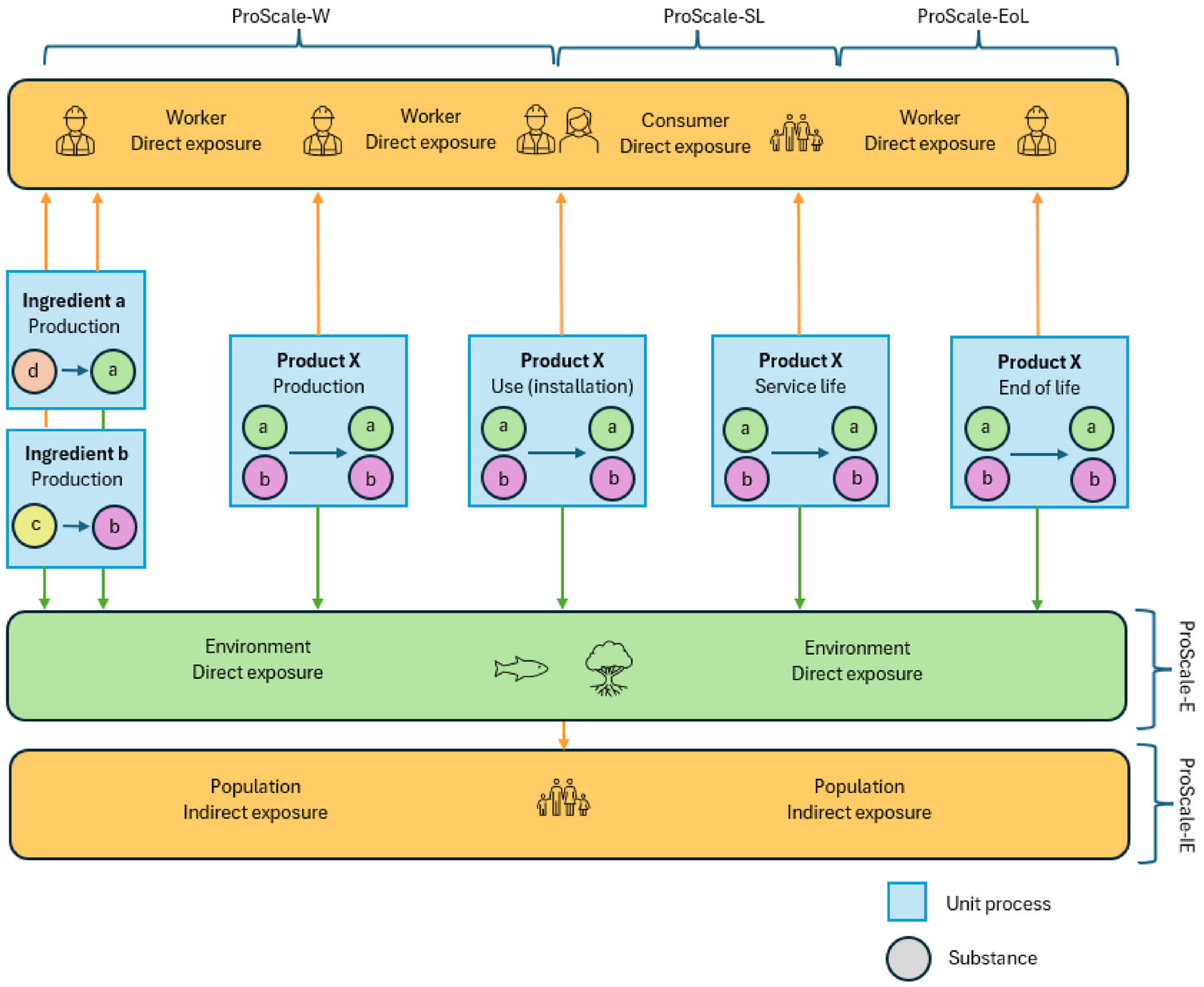

Figure 1. Conceptual illustration on the coherence of the for modules (W/EoL, SL, IE and E), allowing for a comprehensive chemical footprint. W = Workers; SL = Service Life; EoL = End of Life; E = Environment, IE = Indirect Exposure

Materials and method

The development of the ProScale Suite followed a consensus-based process within the ProScale Consortium, including internal review among consortium members and consultation with externally invited experts. The process was guided by four overarching methodological principles:

- Utilize hazard and exposure information already generated within regulatory practice.
- Ensure transparency, simplicity, modularity and applicability in early-stage assessment such as Tier 1 SSbD needs.
- Apply a conservative approach for uncertainties and data gaps, in line with Tier 1 exposure assessments as recommended in the SSbD framework.
- Aggregate RA information at a system level to ensure compatibility with LCA logic.

Acknowledgement – We thank the ProScale Consortium for their contribution in the development process: BASF, Covestro, Deutsche Bauchemie, DOW, Envalior (former DSM), Kingspan, Merck and Syensqo (former Solvay). We gratefully acknowledge and thank Peter Saling at BASF, Johannes Tolls at ECETOC, Pearl Németh at the Anthesis group and Anthanasios Gkrillas at Merck for expert advice. Projects are partially funded by the European Union with the numbers 101135372, 101060546, 101137990, 101178011 & 101057014. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union.

Result and discussion

The consensus-based process led to the ProScale Suite, preserving a common methodological backbone in all modules while allowing for module-specific adaptations, Table 1.

The exposure information is derived from exposure modules as recommended by ECHA in guidance documents for exposure assessments under REACH (EU Regulation No. 1907/2006). The hazard information and potency modifier is also regulatory aligned, allowing for continuous refinement of the modules as legislations are advanced.

The methodological backbone of the modules follow the structure of multiplying a mass flow with module-specific screening characterization factor. For ProScale-E and IE, the CFs is built upon hazard, release and route-relevance multipliers while ProScale-W and SL also include person-time-based factors that translate the RA derived exposure information into LCA compatible descriptors.

Table 1. Parameters and sources identified relevant for combining RA data with LCA parameters to obtain a risk-based screening level tool for assessing (eco)toxicity impact potential in LCA for all life cycle stages.

	ProScale-W	ProScale-SL	ProScale-E	ProScale-IE
Exposure or release basis	Worker TRA	Consumer TRA	ERCs	ERCs
Hazard basis	GHS (H3XX)	GHS (H3XX)	GHS (H4XX)	GHS (H3XX)
Potency or fate modifier	OEL/DNEL	OEL/DNEL	Readily / Not readily biodegradable	OEL/DNEL
System-level aggregation/translation	Exposed persons	Exposed persons	Degradation factor	Degradation factor and route relevance
Functional unit scaling	Mass flow	Mass flow	Mass flow	Mass flow

CONCLUSIONS

- The ProScale Suite captures direct and indirect exposure to humans and the environment across the full life cycle, delivering a comprehensive chemical footprint.
- The ProScale Suite bridges the methodological gap between RA and LCA.
- The tool is particularly relevant for Tier-1 assessments under the SSbD framework where practical, transparent and modular tools are needed.