NanoRIGO RGF web-platform and tool practical demonstration Stakeholder's Workshop

27th- 28th April 2022

Joining instructions:
GoToMeeting: https://meet.goto.com/741820453

Workshop objectives:

- Presentation of the usage of selected tools via case studies and collection of feedback from stakeholders regarding different aspects of a set of selected or developed tools.
- Practical demonstration of the current structure of the web-based RGF prototype and collection of stakeholders' feedback on its utility.

Agenda – Wednesday 27th April 2022

Time (CEST)	Agenda Item	Presenter
13:00 – 13:10	Welcome and introductions	Isabel Rodríguez (GAIKER)
13:10 – 14:40	NANORIGO Risk Governance Framework Web Platform	Blanca Pozuelo (ITENE)
14:40 – 15:00	Coffee break	
15:00 – 16:00	Prospective Early Risk Screening Tool (PERST)	Michael Steinfeldt (UBREMEN) Fadri Gottschalk (ETSS)
16:00 – 17:00	Multiple Criteria Decision Analysis (MCDA) – an early-decision aiding tool	Bernd Giese & Carina Lalyer (BOKU)

Agenda – Thursday 28th April 2022

Time (CEST)	Agenda Item	Presenter
09:00 – 09:10	Welcome and introductions	Isabel Rodríguez (GAIKER)
09:20 – 10:00	CoDo, a Combined Dosimetry model to help link in vitro data to in vivo exposures	Daina Romeo (EMPA)
10:00 – 10:15	SEG4Nano – Simple approach for ecotoxicological grouping of nanoforms	Dana Kühnel (UFZ)
10:15 – 10:45	An Integrated Approach to Testing and Assessment of High Aspect Ratio Nanomaterials from the Gracious project	Gerard Vales (FIOH)
10:45 – 11:00	Coffee break	
11:00 – 12:00	RiskGONE tools, guidelines and guidance for risk governance of nanomaterials	Panagiotis Isigonis (UNIVE)
12:00 – 13:00	Gov4Nano governance tools: Introduction to a stage-gate risk governance framework A framework tool for classifying risk governance tools Identification of high performance risk governance tools Use example in tool-supported stage gate risk-innovation governance framework	 Keld A Jensen (NRCWE) Neeraj Shandilya (TNO) Carla Ribalta (NFA) Keld A Jensen (NRCWE)
13:00 – 13.10	Wrap-up	Aarto Säämänen (FIOH)

NANORIGO

NANORIGO, RiskGONE and Gov4Nano have each received funding under the European Union's Horizon 2020 Research and Innovation Programme under grant agreement No 814425, 814401 and 814530

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Background:

As innovation on nanomaterials is moving towards more complex processes and products, there is an increasing need for advanced tools&models to assist stakeholders in the prevention, assessment and management of risks of nanomaterials, and provide them with guidance for the safe production and use of nanomaterials. After the stakeholders workshop that took place in January 2021 in where a theoretical verification of the developing Nanorigo tools was carried out, we aim to demonstrate the practical usage of those tools alongside other tools selected for the Nanorigo governance framework (RGF) via case studies, as well as to present the current structure of the web-based RGF. An update on the status of tools in RiskGONE and Gov4Nano NMBP-13 sister projects will also be given.

Further Information:

NANORIGO web-based RGF prototype

In order to guide users along the Nano Risk Governance framework of the NANORIGO project, a web-based platform is under development. During this session, the current version of this platform will be shown. After this presentation we would like to receive some feedback with the aim of improving the current platform.

CoDo, a Combined Dosimetry model to help link in vitro data to in vivo exposures

The CoDo model combines in vitro and in vivo dosimetry to estimate the exposure levels corresponding to the doses used in submerged in vitro systems. The model can be used for the assessment of existing in vitro data, or during the planning of new experiments, to select realistic doses. Moreover, it can link the responses observed in vitro to the corresponding in vivo doses.

SEG4Nano – Simple approach for ecotoxicological grouping of nanoforms

The SEG4nano system (Simple Ecotoxicological Grouping System for nano) is a grouping and read-across species-dependent tool that addresses the aquatic and the terrestrial compartments. It is based on the identification of the driving physico-chemical properties relevant for ecotoxicity.

An Integrated Approach to Testing and Assessment of High Aspect Ratio Nanomaterials from the Gracious project

The Integrated Approach to Testing and Assessment (IATA) to support the grouping of different types of High Aspect Ratio Nanomaterials (HARNs) based on their potential to cause mesothelioma has been developed in the Gracious project. The HARN IATA prompts users to address relevant questions at decision nodes regarding the morphology, biopersistence and inflammatory potential of the HARNs under investigation to provide the necessary evidence to accept or reject the grouping hypothesis.

Prospective early risk screening tool (PERST)

PERST is, conceptually and ideally, a new type of stochastic-probabilistic risk prediction tool (service) developed for predicting and monitoring over extended periods (100 years) the general exposure load of humans and other organisms to potentially critical product materials, their toxicity and vulnerability as well as their life cycle fate covering all product material phases from use, technical treatment, and release to the environment to bioaccumulation in human, flora and fauna. This tool has a strong orientation toward the needs of enterprises and product manufacturers, however, it may potentially be of interest also for regulators and other stakeholders committed to product risk monitoring and prediction.

MCDA (multiple criteria decision analysis) - an early-decision aiding tool

The multiple-criteria decision analysis (MCDA) approach is envisioned as part of the Risk Governance Framework (RGF) to act as an early-screening tool for the potential impacts of nanotechnology on the environment, society and economy. The results of the analysis represent a benefit (impact) profile of the nanomaterials. This information is based on the answers given by the user for each criterion relevant to environmental impact (from Life Cycle Assessment, LCA) and socio-economic aspects (from Socio-Economic Assessment, SEA). Together with the PERST the user will be able to judge the benefits and risks of the new nanomaterials and will be supported in decision making.

RiskGONE tools and guidance

RiskGONE has aimed at the development of functional tools (e.g., decision trees, guidelines, toolboxes, training material and more), all within a transparent, guided decision scheme (risk governance framework) considering the needs and expectations of the various stakeholders for risk governance of NMs. In these terms, the guidance of the RiskGONE cloud platform has been divided into clusters of topics, such as the 'expertise of the user' (e.g., novice or experienced) or the 'topic of interest' (e.g., Hazard assessment, Risk assessment, Ethical Impact assessment and more) to facilitate the flow of information, in an easy to use and easy to update way.

Gov4Nano tools and guidance

Identification of high-performance risk governance tools and example of use in a risk governance process.

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PERST --- Executive Summary

PERST is a prototype of a prospective early risk screening tool developed in the EU-based project NANORIGO. It integrates predictive computations for humans and environments based on various questions concerning exposed organisms' risk and vulnerability by combining the load contamination of potential pollutants with toxicity and ecotoxicity considerations and data. The source of such potential risks (contamination) is identified as the manufacturing and use of any products and in the emission (exposure) of their materials to humans and nature, particularly product ingredients that should not be emitted. Thus, PERST aims to predict target and specific product ingredients, including but not exclusively new engineered nanomaterials, as well as their life cycle-long location in and migration through environmental (human) and technical systems (Fig. 1). Such product material monitoring also considers its degradation or deposition and accumulation in any of the receiving media mentioned above. Material load (exposure) concentrations are computed for various target environments and bioaccumulation bodies (listed below), and they are then compared to toxicological or ecotoxicological concentration data for the target material. From such comparisons, risk is predicted for humans and the environment. The following compartments and organisms (creatures) potentially at risk are considered: air, freshwaters, marine waters, groundwater, saline groundwater, freshwater sediments, marine water sediments, soil, soil treated with sewage treatment sludge, freshwater flora, marine water flora, freshwater fauna, marine water fauna, adult humans and children humans.

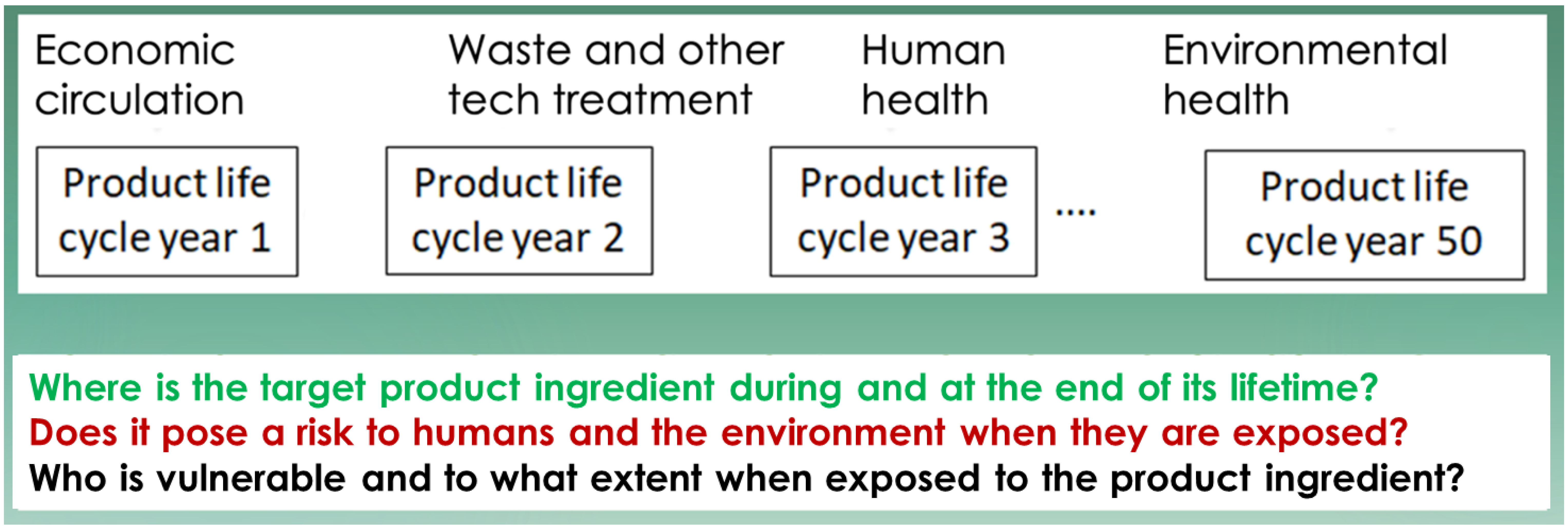

Figure 1: Stochastic-probabilistic long-term product material (ingredient) interaction between life phases and different media and environments.

For its routine use the status quo of available information on a material's use, emission patterns, and—to some extent—fate (residence time) in potentially exposed compartments (bioaccumulation bodies) will be needed in a form that can be linked to the tool computations. In doing so, PERST's services would remain easy to use, as there is no need for the user to deal with any probabilistic data and prediction routines, meaning no specific programming skills are required. Users (producers or stakeholders) must provide, among others, some data on the(ir) target product ingredient(s), production or use volumes and some product (material) life cycle properties, the geographic region (EU country) of interest, and other information not specified here. The collaboration can be protected by a confidential agreement between the user and service provider. One key property of this prototype predictive software for risk (vulnerability and other) is that it is designed to do its best when encountering scanty and uncertain data (as is often the case in environmental and health contexts). This however only works when the above-mentioned background database can be established such that it provides a large spectrum of data for optimistic to worst case-value ranges of model input information. The main outputs (see examples in Fig.

2) distinguish risk, vulnerability (fraction of organisms and creatures potentially negatively affected), and concentrations (potential contamination load concentrations).

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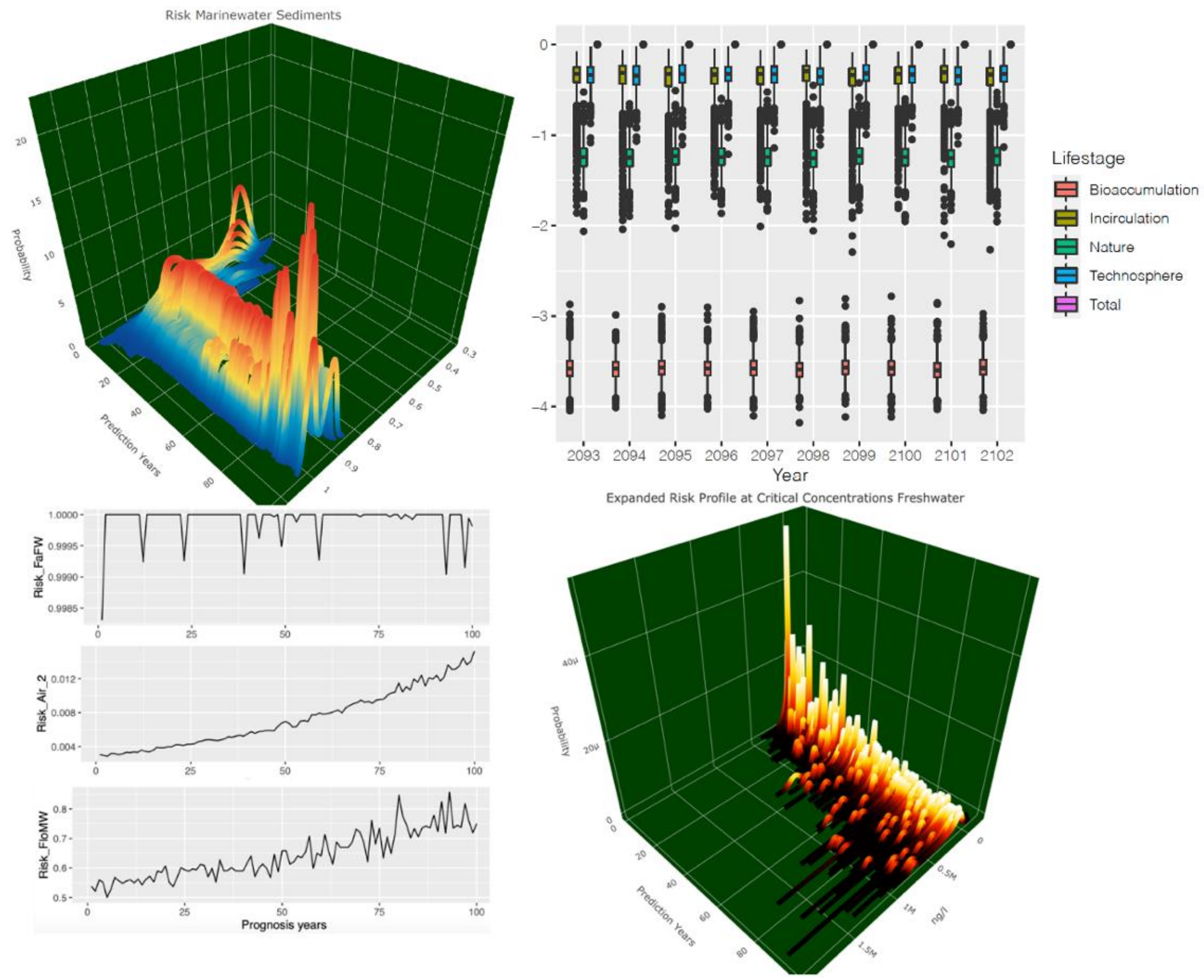

Figure 2: Some fundamental PERST output types, such as 3D graphics (probability is used synonymously with density [z-axis]), boxplots summarizing these output distributions over time, and line charts visualizing the evolution of a particular target variable.

The PERST risk etiquette as another possible form of evaluation will be presented and put up for discussion.

Brief description of Screening MCDA

Bernd Giese, Sebastian Purker, Carina R. Lalyer

University of Natural Resources and Life Sciences, Vienna (BOKU)

The multiple criteria decision analysis for screening purposes ("Screening MCDA") developed in the EU-project NANORIGO is designed to assist its users in a screening process on whether the use or development of a nanomaterial (NM) is beneficial. It considers the potential impact of nanotechnology on the environment, society and the economy. It serves as a strategic radar system to identify promising technological opportunities in a culture of innovation. It is dedicated to stakeholders from industry, research, governance, organizations for consumer or nature protection and not least the interested public to contribute to processes of reflexive innovation.

The main idea for MCDA in NANORIGO is to take up developments in probabilistic algorithms for decision support and experience with previous tools to create a robust and easy to use screening system that provides a rough overview on the performance of nanomaterials and its alternatives. In a prospective approach, uncertainty regarding the final design of processes or products and also the application context complicate investigations. Prospective technology assessment therefore, has to find ways to handle the associated non-knowledge. A probabilistic approach represents an option to deal with this challenge.

The screening MCDA determines a **benefit profile** of different material options for the criteria of environmental impact (related to life cycle assessment, LCA) and socio-economic aspects (socio-economic assessment, SEA) (Figure 1). The applied criteria are weighted according to their relevance either by the user or by a predefined set of weights.

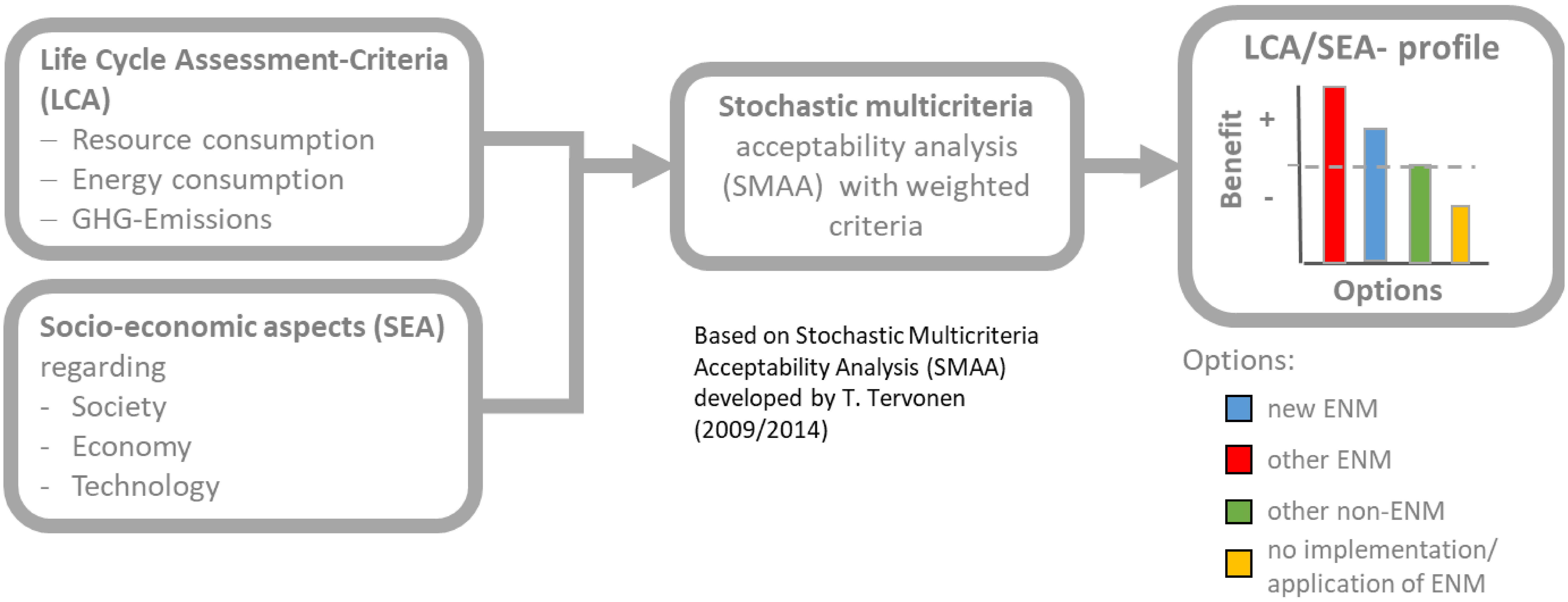

Figure 1: Simplified scheme of screening MCDA. Different material options are compared based on their performance under LCA and SEA criteria.

for the criteria is obtained via a questionnaire. For all categories of evaluation, the information needs are kept as low as possible. Depending on the experience level of the user, the questionnaire is divided into three **tiers** (Inexperienced, Advanced, and Experienced) which unfolds with the experience of the user. Input is accepted in the form of semi-quantitative estimations without the need to keep exact numbers at hand.

A comparison is required to evaluate the relative performance of the new NM. Therefore, the NM being evaluated is compared to a **reference alternative**, such as the material on the market (for example, a non-NM or other NM or even the "no action/no additional material" option (see Figure 1). The result shows the option that performs best with respect to the criteria studied.

Screening MCDA applies a probabilistic approach to cope with uncertainties and lack of knowledge. It uses the Stochastic Multicriteria Acceptability Analysis (SMAA) open source software developed by Tommi Tervonen (Tervonen, 2014) to rank material options. Results can thus be obtained even with incomplete input for the socio-economic and environmental impact.

Conclusion

Screening MCDA in the context of the Risk Governance Framework is intended to become a screening tool to avoid path dependencies in later stages of innovation processes and is therefore designed to provide access to this method for a wider range of users.

The following aspects characterise the progress of Screening MCDA:

- Different material options (not only nanomaterials) can be ranked (and compared) according to their acceptability with regard to numerous criteria at once
- The proposed approach exploits the full power of MCDA by using weighting to account for the varying relevance of its criteria and improve differentiation between comparable alternatives
- The graduated structure of knowledge requirements for the input is designed to be suitable for both laypersons and experts
- Imprecise input information (even ranges or no input for some criteria) is accepted
- No absolute values are needed, the analysis only requires semi-quantitative information

References

Tervonen, T., Figueira, J.R., Lahdelma, R., Dias, J.A., Salminen, P., 2009a. A stochastic method for robustness analysis in sorting problems. Eur. J. Oper. Res. 192, 236–242. https://doi.org/10/cjnpc5

Tervonen, T., 2014. JSMAA: open source software for SMAA computations. Int. J. Syst. Sci. 45, 69–81. https://doi.org/10.1080/00207721.2012.659706