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RESEARCH ARTICLE

# Modeling for nano risk assessment and management: The development of integrated governance tools and the potential role of technology assessment

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Anja Bauer\*<sup>1</sup> , Daniela Fuchs<sup>2</sup> 

**Abstract** • In nano risk governance, we observe a trend toward coupling and integrating a variety of computational models into integrated risk governance tools. This article discusses the development and design of such integrated tools as ‘nano risk governance imaginaries in the making.’ Using an illustrative example, the SUNDS tool, we show how the tool manifests conceptual shifts from risk to innovation governance, a technocratic evidence culture based on the quantification of risks, and an envisioned application in industrial innovation management. This conceptualization runs the risk of narrowing the view of nano risks and cementing the widely lamented democratic deficit in risk governance. We therefore conclude that the development and application of integrated governance tools are highly relevant for technology assessment (TA) and TA should actively engage in their development processes.

**Modelle für Risikobewertung und -management von Nanomaterialien:** Die Entwicklung integrierter Governance-Instrumente und die potenzielle Rolle der Technikfolgenabschätzung

**Zusammenfassung** • In der Nanorisiko-Governance beobachten wir einen Trend zur Kopplung und Integration einer Vielzahl computerbasierter Modelle zu integrierten Governance-Instrumenten. In diesem Beitrag wird die Entwicklung und Gestaltung solcher Instrumente als

„Risiko-Governance-Imaginaries im Entstehen“ betrachtet. Anhand eines illustrativen Beispiels, dem SUNDS-Tool, zeigen wir, wie das Tool konzeptionelle Verschiebungen von der Risiko- zur Innovations-Governance, eine technokratische Evidenzkultur, basierend auf der Quantifizierung von Risiken, und eine geplante Anwendung im industriellen Innovationsmanagement manifestiert. Diese Konzipierung birgt die Gefahr einer verengten Betrachtungsweise von Nanorisiken und der Zementierung des weithin beklagten Demokratiedefizits in der Risiko-Governance. Wir folgern daher, dass die Entwicklung und Anwendung integrierter Governance-Instrumente für die Technikfolgenabschätzung (TA) von großer Bedeutung sind und TA sich aktiv in deren Entwicklungsprozesse einbringen sollte

**Keywords** • nanomaterials, risk governance, in silico methods, governance imaginary, technology assessment

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## Introduction

Nanomaterials have been recognised as promising since the late 1990s, offering research and innovation opportunities in diverse areas such as energy, medicine, electronics, or food. Early on, these expectations were accompanied by concerns about unintended consequences on human health and the environment. Consequently, nanomaterials have increasingly become the subject of regulatory debates and initiatives in the EU and internationally, encouraging the quest for reliable and efficient risk assessment and management approaches.

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Traditionally, risk assessment has strongly relied on ‘in vivo’ (i.e., on animals) and ‘in vitro’ (i.e., on cells) methods. The abundance of nanomaterials, unclear effect mechanisms, and ethical concerns about animal testing have challenged these testing regimes and fostered the interest in ‘in silico’, i.e. computational methods in scientific and policy communities (Worth et al. 2017). Over the past 15 years, a wide variety of models has been developed for distinct risk assessment aspects such as environmental release, fate and exposure, or the toxicological effects of nanomaterials (Isigonis et al. 2019). Besides, computational models have been developed for risk management approaches like control banding. In recent years, we have observed a growing interest in coupling and integrating these single models into integrated risk governance tools. In the following, we use the shortened terms ‘integrated tools’ or ‘tools’, implying that they consist of several models. The term ‘tool’ is used because it is the term used in the respective community and debate and because it refers to its intended use by non-modelers. Over the past decade, the European Commission has funded a range of projects that aimed at developing and testing such integrated tools, linking a variety of screening and assessment methodologies with management, communication, and monitoring tools (EU NanoSafety Cluster 2022; Isigonis et al. 2019). Developing such integrated tools involves various scientific disciplines, including toxicology, lifecycle assessment, or computer sciences, as well as industry partners and consultancies. We observe that technology assessment (TA) or social sciences are less involved in developing such tools and if they are, their role is often limited to ensuring the integration of user needs. The absence of TA is puzzling

*Analytical techniques for assessing nano risks have only rarely been addressed or even critically reflected upon by technology assessment.*

given its long and active engagement in nano risk governance debates. TA has brought attention to the safety of nanoparticles for human and environmental health early on, presented the respective state of knowledge and uncertainties, frequently organized public dialogues, advanced risk communication and facilitated respective governance structures. In comparison, the analytical techniques for assessing nano risks (e.g., in toxicology), have only rarely been addressed or even critically reflected upon.

This suggests a continued divide between scientific-technocratic approaches to risk governance, (limiting TA and broader societal perspectives), and reflexive approaches of anticipatory governance, including general awareness of risks and the facilitation

of public risk debates and communication (as core to TA). We challenge this division by pointing to the value-laden and political nature of analytical techniques in risk governance (Hartley and Kokotovich 2018). Drawing on an illustrative case, the SUNDS tool (section 2), we discuss the development and design of integrated tools as ‘nano risk governance imaginaries in the making’ (section 3). Concludingly, we reflect on the potential role of TA in such analytical and technical processes (section 4).

## SUNDS as an example of integrated governance tools

Our discussion draws on the EU project Sustainable Nanotechnologies (SUN, 2013–2017) and the resulting integrated governance tool SUNDS (Sustainable Nanotechnologies Project Decision Support System). SUNDS (2022) serves as an illustrative case for integrated tools, i.e. to demonstrate and understand how ideas of risks and their governance are (re)produced in tool development and design, without claiming representativeness for all such projects and tools. We perceive SUNDS as an information-rich case (Patton 1990) because the project had been concluded by the time of our research, provided open access to the resulting tool and its documentation, and has been assessed as a comparatively well-designed tool by stakeholders and scientists (Isigonis et al. 2019). Our case study was informed by a critical reading of respective modeling literature and project documentation and ten semi-structured interviews with seven scientists and model developers, one consultant and one industry stakeholder that have been involved in the project as well as one regulator. The interviews focused on the development process and envisioned application of SUNDS, have been recorded, transcribed, and thematically analysed.

SUN was funded under the 7<sup>th</sup> Framework Programme with a budget of more than 13 million euro. The consortium consisted of 35 partners, including universities, other public and private research institutes, consultancies, organisations for technology transfer, and companies. The project aimed to assess environmental and health risks of manufactured nanomaterials along their lifecycle and to develop the governance tool SUNDS. Industrial partners were involved in testing the tool in product case studies. Moreover, stakeholders from industry, regulation and the insurance sector were engaged through interviews and workshops to ensure the tool’s usability.

SUNDS is a web tool for sustainable manufacturing which conducts risk assessment of manufactured nanomaterials and nano-enabled products and determines risk management strategies. It consists of two tiers: The first low-threshold tier includes models for screening environmental, economic, and societal benefits and environmental, occupational and consumer risks of nanoproducts; the second tier offers models to assess environmental life cycle impacts and economic and social aspects in different modules. Users are “expected to insert test results from in-house-tests and literature or to run exposure and haz-

ard models connected to the SUNDS tool” (Malsch et al. 2017, p. 466). A decision-support module allows the weighing of alternatives including non-nano options and defining risk management strategies (Subramanian et al. 2016). SUNDS has been adapted in subsequent projects, notably in the Horizon 2020 project ‘Performance testing, calibration and implementation of a next generation system-of-systems Risk Governance Framework for nanomaterials’ (CaLIBRAte, 2016–2019).

## Risk governance imaginaries in the making

In developing integrated tools, key issues of nano governance are raised: What should be assessed and why? How can risks be assessed, and by whom? How should risks and benefits be weighted? Who should use the tool, and how? These are not neutral technical questions, but they entangle scientific paradigms and policy discourses (Demortain 2017). We, therefore, conceive of the SUN project and the SUNDS tool as manifestations of risk governance imaginaries. Transferring the notion of “sociotechnical imaginaries” by Jasanoff and Kim (2015, p. 4) from the level of the nation state to the level of scientific and policy areas, we understand risk governance imaginaries in our context as collectively held visions of the (future) governance of nanomaterial risks. Imaginaries motivate and become materialised in sociotechnical developments, in our case, integrated computational tools for nano risk governance. These tools, in turn, structure how we think about nano risk assessment and management, making the collective vision permanent.

In the following, we trace the risk governance imaginary in the making along three dimensions that were central in the tool development. First, the tool development involves explicit and implicit framing activities, inter alia, concerning the need and purpose for risk governance and the conception of risks and relevant assessment dimensions. Second, the development and use of analytical techniques, including computational models, are interwoven with particular evidential cultures, i.e. ways of producing evidence of risks (Boullier et al. 2019; Bösch 2013). Third, our analysis showed that the envisioned application of the tool strongly guided and challenged the development process.

### Conceptual framing: towards innovation governance

Questions of why nano risk assessment and management tools are needed, what should be assessed, and which dimensions and principles should guide the assessment, have been vital for the design of SUNDS. Interviews and project documentation indicate that the SUN project and SUNDS tool are firmly embedded in a unison narrative of environmental and health risks potentially hindering industrial innovations. The purpose of SUNDS is to anticipate those risks to facilitate innovation:

“[I]magine that nanotechnology is a boat [...] that includes all the stakeholders – the innovators producing nanotech-

nology, the regulators making sure that the risks are assessed, the policymakers that are steering the ship – and the ship is going to the shore of making innovation. But there is the sea of uncertainty [where] you have multiple risks like storms, like icebergs, and then the people in the ship are trying to steer the ship to the shore of innovation by dealing with all the risks [...] And [SUNDS] is one of the tools to detect the risks and to help the ship navigate in a way to avoid the risks and to reach innovation and shorten the time of reaching innovation” (I3, scientist).

Such framing includes clear value choices favouring nanotechnology innovations and market development. Innovations should be facilitated as efficiently as possible by detecting risks early on. This framing largely excludes questions regarding the innovations’ social desirability or acceptance. Its orientation towards sustainable manufacturing determines the conceptualisation of the tool. For example, instead of nanoparticles, SUNDS assesses manufactured nanomaterials and nano-enabled products to better reflect their use in consumer and industry products. This implies the assessment of risks based on actual exposure of affected groups (e.g., consumers), which, according to an industry partner (I2), allows for more realistic scenarios. In addition, the focus on the life cycle allows for assessing risks from the synthesis of the material to the production, use and disposal of the final product. While lifecycle analysis (LCA) traditionally focuses on environmental indicators, SUNDS also offers socioeconomic assessments. This broadening of the assessment not only indicates a more comprehensive view in the light of sustainability but also supports the innovation agenda:

“[...] since we were using LCA for the environmental aspects, we were trying to align [with] the LCA for the economic parts and social LCA [...]. REACH<sup>1</sup> – they have two modes, when you submit something for authorisation, [...], you have to either show that you control the risks well or you show that you cannot control the risks, but then you have to show that this is a really important product for the economy and there is no substitute. And the social benefit of having this is unique, so we have no substitute, so we are going to go there even though there are some risks. [...] we wanted to [use] this kind of thinking [...], so we are not thinking in direction of: oh, there is a harm, let’s take it out, but a little bit *how to push the sustainability profile of your product forward*” (I10, scientist, own emphasis).

As the quote suggests, the widening of the scope towards economic and social aspects serves to weigh (environmental and health) risks against (social and economic) benefits to ease in-

1 Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) is a European Union regulation dating from 2006, addressing the production and use of chemical substances, and their potential impacts on human health and the environment.

dustrial innovations. Lastly, the project took the first steps in integrating the innovation concept ‘safety-by-design’ into the tool, which was continued in the follow-up project CaLIBRAte and shifted the focus from assessing the final product to reducing hazards from the start.

In sum, SUNDS reflects ongoing debates about moving from risk to innovation governance (Isigonis 2019). This conceptual shift includes important value decisions, such as the balance between innovation and precaution or the (individual or societal) weighting of the environmental, social and economic dimension. The project consortium discussed whether the tool should reflect preferences of users regarding individual analyses (SUN consortium 2015). However, such discussions were closed in favour of the less controversial approach to assigning equal weight to each module.

### Evidential culture: quantifying risks, communicating uncertainties

Different ways and techniques exist to produce evidence of risks. The notion of ‘evidential culture’ “refers to strategies and criteria that frame the collective validation of knowledge” (Boullier et al. 2019, p. 139); in our case, how risks can and should be assessed, whose expertise is sought and how to deal with uncertainties.

In developing SUNDS, different epistemic traditions and cultures came together, from ecotoxicology and lifecycle assessment to human health risk assessment and computational modeling. An understanding of the tool as science-based served as the unifying basis (SUN consortium 2015) and the tool’s development was guided by the premise that risks are predictable, measurable, and calculable, putting the quantification of risks (and benefits) at the core. Because of this quantitative paradigm, SUNDS is highly dependent on a wide variety of data; in turn, a lack of accurate, high-quality, and available data is considered the most limiting factor for modeling (I1, consultant). Therefore, SUN dedicated significant resources to collect, systematise and validate existing data. Moreover, as typical in risk assessment methods, semi-quantitative and qualitative approaches were considered additionally or as an approximation, e.g., by using screening tier one when data are missing (Subramanian et al. 2016).

Another challenging task was the integration of various risks and impacts (I6, scientist). While the project team initially intended for the tool to provide ‘one single number’, this turned out to be non-desirable for stakeholders:

“Initially, we wanted to integrate everything in a single score [...] But [...] one of the key findings of the stakeholder consultations was: ‘even if you gave us a single number in the end with respect to the sustainability of the material, what would we do with it? We would rather see a dashboard, seeing this is going well, this is going kind of well, and this is not going well [...]’ – A single number – how would a stakeholder know how to interpret that? How to improve their product?” (I10, scientist).

Hence, stakeholders considered the inclusion of semi-quantitative or qualitative elements and transparent communication of individual assessments as a valuable feature of integrated tools, while the scientists’ and modelers’ aspiration to quantify and therewith to gain ‘more accurate’ results persisted (I10, scientist).

Uncertainties in the modeled results and their communication was a core issue in SUN. On one side, the project aimed to reduce models’ uncertainties by gathering experimental evidence (Marcomini and Hristozov 2017). On the other side, transparency and communication of uncertainties were recognised as key to risk management. Accordingly, SUNDS explicates uncertainties in the outputs and provides users with uncertainty analyses, including magnitude and sources of model uncertainty (Isigonis et al. 2019).

In sum, we observe both the reproduction of a technocratic evidential culture of risk assessment based on quantitative methods and the consideration of reflexive elements by strengthening qualitative and semi-quantitative approaches or focusing on risk communication. The quantitative paradigm (in particular of tier two) guides the assessment focus towards those things that can be measured and, in the short run, also those things for which data exist, while other less measurable aspects (risk perceptions or different framings) may be excluded. Moreover, the hegemony of scientific risk assessment expertise is stabilised: The tool development strongly relied on scientific expertise and industry stakeholders, yet broader social scientific expertise or societal perspectives were marginal. Actor groups with potentially critical stances, such as consumer groups, health activists or environmental NGOs, were considered mainly as ‘imagined actors’, i.e., their perspectives were included as a context factor, yet not directly sought.

### Envisioned application: REACH(ing) experts

Tools like SUNDS are developed with a view to their application for specific tasks in risk governance. Thus, their envisioned function and the roles of different groups vis-à-vis the model are crucial. In which situations, by whom, and how should the tool be used?

Though specifications for nanomaterials only came into force after the SUN project had been finalised, REACH served as the central reference point for SUNDS, implying its application in the context of industrial risk assessment and management to comply with current (and future) regulations. While initially, the SUN project aimed to address policymakers, industry and the insurance sector (Malsch et al. 2017), the focus on REACH combined with diverging stakeholder interests narrowed down the main target groups:

“[...] you try to wield the tool for so many users and at some point, you realise ... the insurance sector we could not help much. [...] The regulators told us what would be acceptable scientifically and [...] submission and stuff, but we ended up *majorly building the tool for industry*.”



The regulators were on board, but it was just very difficult bridging all of them” (I10, scientist, own emphasis).

Thus, the tool became more exclusionary during its development and eventually was designed for large industries and small and medium enterprises (SMEs) (I3, scientist). Concerning when and how to use the tool, the REACH context suggests a use for risk-benefit analyses. Yet, the tool’s design goes beyond this application and facilitates guidance on decision-making in risk management (I3, scientist) and transparent communication. For example, the tool proposes “technological alternatives and risk management measures to reduce risks to acceptable levels” and allows the “comparison of scenarios with and without these measures” (Isigonis et al. 2019, p. 14). Most prominently, it features workplace safety measures like protective gear and technical equipment to be selected for the respective risk scenario. While the extension of the tool beyond regulatory demands, in principle, allows for its broader application in industrial innovation management, it also adds to its complexity, with consequences for its potential to be adopted. Due to the science-based and data-driven nature, combined with the multitude of assessments, the tool ultimately depends on a high level of technical expertise and a large amount of data to be used (I1, consultant).

Interviewees strongly suggest that the tool may not be usable for all intended users; particularly SMEs might be excluded, by design rather than intention, as they often neither have the expertise nor data to appropriately use the tool (SUN consortium 2015, p. 3). Partly, this limitation is accepted for developing a science-based and comprehensive tool. Moreover, this exclusion is partly mitigated by the modular design of the tool, with the semi-quantitative tier one being useable for most stakeholders and the fully-fledged risk assessment of tier two being targeted to experts in large companies (I10, scientist). Moreover, further activities to facilitate the application have been undertaken in follow-up projects. Still, the tension between a high degree of scientific rigour (drawing on data and quantification) and pragmatic usability persists.

In sum, the strong orientation towards the regulatory context restricts the range of intended users of the tool, excluding various stakeholders and non-expert publics from its use, even if it provides open access. Beyond that, we observe a further unintended narrowing down of potential users due to the tool’s comprehensive, complex and data-driven design. In the short run, this might result in the non-utilisation of the tool. In the long run, a wider (mandatory) use of modeling tools may imply that some actors (e.g., SMEs) need to adapt their risk assessment and management practices.

## Discussion and conclusions

In this article, we sketched the risk governance imaginary that became materialised in the integrated tool SUNDS, characterised by a conceptual focus on innovation management, a tech-

nocratic evidential culture based on the quantification of risks, and an envisioned application by industry experts. This imaginary partly reflects ongoing debates on nano risk governance and regulatory contexts, notably REACH with the demand for risk-benefit considerations or the focus on industry. However, the tool also exceeds current regulations when shifting further towards innovation governance and including additional analyses. By incorporating broader expectations and visions about future regulatory and governance needs, the tool may have performative effects on future regulatory regimes by technically allowing specific questions and assessments or by including or excluding actors.

In our discussion, SUNDS served as an illustrative yet not representative example of the design of integrated governance tools. Other tools may include different concepts or technical design choices, yet our argument that a particular imaginary of nano risk governance materialises in computational tools holds. Since the tools are tailored to specific regulatory demands and the concerns of specific groups with specific ideas about risks, there is a danger of narrowing the ways of seeing, debating and assessing risks (Demortain 2017, p. 145). Such tools may disguise value choices in favour of “technological innovation and market development in scientific methods [...] of quantifying the risks and benefits of technologies” (Demortain 2017, p. 145). Moreover, technologically-framed rather than socially-framed risk assessment (and governance) tools (McLaren 2018) exclude or marginalise actors such as environmental and health activists. In this way, the respective governance imaginaries imply a risk of closing down nano risk governance and further cementing the widely lamented democracy deficit, which TA has long aimed to counter.

Concludingly, we suggest a role for TA in countering the closing down of nano risks governance imaginaries by engaging in the debates and development processes of analytical techniques such as integrated computational tools. In doing so, TA can draw on its broad repertoire of advancing nano risk debates in other sites (e.g., policy fora or public deliberations). As our analysis has illustrated, the tool development and respective imaginary touch upon a range of issues that have long been of interest for TA, including risk communication, the balance between precaution and innovation, risk perceptions, decisions under conditions of uncertainty, the balancing of environmental, social and economic concerns or the inclusion of wider societal perspectives in risk debates.

First, TA could open up conceptual discussions beyond user preferences by clarifying the broader visions, dominant framings, and values that guide the tool development. This opening could also challenge taken-for-granted assumptions and goals, for example, about innovations, sustainability, or consumer safety. Second, building on its long tradition of fostering participation in technology governance, TA could guide the development of such tools towards more inclusive and democratic activities. Thus, stakeholder inclusion could be widened from users towards broader societal participation that includes lay publics

and alternative or counter expertise (for example, environmental or consumer NGOs). Scholars have recently outlined how to best integrate these perspectives into risk assessment and governance (Hartley and Kokotovich 2018; Hartley et al. 2022). Lastly, we see a role for TA in promoting alternative ways in which computational models could be employed in governance. What is underrepresented in the discussions of such tools is their potential to serve as boundary objects to coordinate different actors and their perspectives (Star and Griesemer 1989). This would, for example, mean strengthening discussions around objectives, parameters, values, and scenarios. Such alternative visions of the tools' functions exist, pointing to its use in developing regulations or to use them in international governance (Malsch et al. 2018), yet remain marginalised. TA could help make such perspectives more prominent.

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