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EDITORIAL

Making Nanomaterials Safer by Design?

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Safer by design, safe by design, safety by design (hereafter SbD for all versions): These slightly different terms all point towards a concept that has been becoming increasingly relevant for the development and risk assessment of engineered nanomaterials (ENM) in recent years [1–6]. The common idea behind these different SbD terms is to integrate knowledge of nanomaterials' potential adverse effects on human health, animals and the environment into the process of designing nanomaterials and nanoproducts—and to engineer these undesirable effects out of the respective materials or products. This entails that functionality and safety be considered in an integrated way right from the earliest phases of the research and innovation process. SbD can thus be distinguished from a risk assessment paradigm which seeks to address and regulate nanomaterials downstream, i.e. at a point in time when new materials and products are fully developed and ready for market. Consequently, the popularity of SbD approaches can be (partly) attributed to the fact that with regard to ENM these downstream regulatory measures have proven notoriously difficult to implement, due in part to the lack of adequate (eco)toxicology data. SbD's promise of anticipating safety issues at the design stage hence appears to be a potential avenue to circumvent the difficulties of risk regulation.

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The idea of designing materials and products that do not impact negatively on human health, animals or the environment is certainly not the invention of those applying it to ENM. Engineering design has a long tradition of aiming to design in safe(r) ways, the most relevant precursor approaches being 'benign by design', 'prevention through design' [2], 'inherent safety', 'green chemistry' [4], 'privacy by design' [7], 'security by design' and principles from drug discovery and development [8]. While nano-related SbD may draw on these existing concepts in some respects, its main origin can be traced back to the Center for Biological and Environmental Nanotechnology (CBEN) at RICE University in Houston, Texas. CBEN's director Vici Colvin coined 'safety by design' around 2004/5 as an alternative framing to the hitherto dominant focus on implications and applications and employed it to direct more attention to the environmental and biological risks of nanomaterials [9]. This early use of the SbD concept is significant in the way it allowed the transformation of characteristic elements of safety such as toxicity into quasi-properties of materials and thus made safety a concern of engineers and developers—and not just of toxicologists [9]. The label was thus almost immediately embraced by chemists and nanotechnologists alike, while toxicologists reacted much more sceptically [5].

However, since that time it is not only scientists from the engineering and safety research community that have come to place high hopes in SbD, other actors such as policy makers, regulators and businesses have also identified it as a potential solution to avoid the expected risks of ENMs. Most significantly, the concept has been taken up in European research policy [10], which has led to SbD becoming a central concern of several EU-funded nanosafety projects (for a good overview of SbD-focused projects funded in FP7 and Horizon 2020 see [8]). In almost a dozen projects to date, SbD appears as a buzzword [11] and boundary object [12] that draws together diverse actors from academia, industry and government under a common goal—getting EU funding. Yet only three of these projects—NanoREG, NanoREG II and ProSafe—have so far engaged in a more explicit exploration of SbD by conceptualising it as a risk assessment framework across the product life cycle, that is, from production to usage and end of life disposal. The projects' commitment to making ENM safe(r) for human health and the environment, however, is to a large extent based on economic concerns: 'to promote the sustainable and responsible development and competitiveness of companies involved in nanotechnologies' [13]. On the one hand, one could criticise how safety thus becomes instrumentalised as an enabler of innovation and is not considered as a value worth promoting in itself. On the other hand, getting industry actors on board could strengthen the safety agenda and therefore contribute to its success. The aforementioned EU projects embed SbD into existing innovation management frameworks such as product life cycle analysis and the stage gate model, which entails two main limitations [14]. First, these models have been developed for innovation and decision processes in companies and thus may not be easily transferable to the global and multi-actor networks with their heterogeneous interests and safety expectations which underpin the development and commercialisation of ENM [8]. Second, the linear innovation approach of these models implies knowledge that is not existent at certain stages and also does not take into account that research and innovation processes may better be conceptualised as non-linear collective and iterative learning [for how SbD could integrate iterative learning see 4].

Thus, in order to further develop and assess the current application of SbD, we need to critically engage with the underlying assumptions of different SbD frameworks and the ways in which safety is—and may be better—conceptualised with regard to design possibilities. On a conceptual level, many SbD approaches share the assumption that safety can be treated like a property of materials or products, similar to fundamental physical and chemical properties such as thermal conductivity or light absorption. Yet this excludes the fact that exposure and use context co-shape the effects of nanomaterials. In contrast to an essentialist view that considers safety as an inherent property of materials, safety could be better understood as a relational category; that is, ENM become meaningfully safe or unsafe only in relation to other entities. While it may be relatively easy to define human bodies as entities that ENM should relate to in safe ways, the matter becomes much more complicated when we speak of something as vague as 'the environment' [8]. ENM will always react with their environment; thus making them completely safe may not be desirable or even possible. From this perspective, SbD approaches may imply an unrealistic vision of control because safety testing has so far not yielded any definitive knowledge of nanomaterials' (eco)toxicological effects which could be implemented in the design of ENMs. Against this background, the term 'Safer by Design' represents a better alternative to 'Safe/ty by Design' as it does not suggest unrealistic aspirations towards complete safety [for similar positions see 1, 8].

SbD approaches share a focus on the value of safety (or innovation), which consequently may lead to the marginalisation of other values or concerns that might be equally or even more relevant to the governance of ENM (see Kallhoff, this Special Section). A focus on safety sidelines broader socio-political issues and does not engage with the societal desirability of innovations and the powerful underlying imaginary in which technology becomes the ultimate problem-solver [8, 15]. Thus, we can also understand the recent focus on SbD and safety in the EU context as a narrowing down of the nano-debate to safety concerns instead of pursuing broader innovation governance questions that were still on the agenda at the beginning of the debate about nanotechnology. Although this Special Section highlights safety, we also want to encourage a broader discussion about the current ranking of values that is solidified by SbD and other safety-focused approaches. To gain a more encompassing perspective, it is necessary to look beyond safety and explore which other values and concerns should likewise be integrated into the early-stage evaluation of ENM and nanoproducts. This could be achieved by further theoretical exploration and the inclusion of public opinion. Public participation could highlight that potential consumers consider some functionalities irrelevant, and thus prevent investment in risk assessment procedures for products that will not ultimately be accepted.

As critical commentators on the SbD movement, we also need to take a step back and observe what it achieves for the actors involved. From this perspective, SbD can be interpreted as a strategy that allows difficult regulatory and political decisions to be shifted towards scientists and industry actors, thereby reframing the regulatory problem as a scientific or management issue [8]. In this respect, SbD contributes to a more general trend towards the scientisation of public policy, i.e. the reduction of policy, ethical and value disagreements to science problems [16]. Natural scientists might have ample reason to welcome the current popularity of SbD as a means to strengthen their role in the regulatory process. For regulators who face restricted possibilities with regard to regulation of ENM, SbD approaches might also provide a way out of regulatory inaction. At the same time, however, SbD approaches could also be (mis)used to postpone regulatory measures and thereby justify inaction. Moreover, scientisation disregards the fact that risk-related decisions are inherently political choices. Societal interests and values cannot be disentangled from risk assessment because it is always people who decide what counts as a risk and which and how many data are considered essential for performing the assessment [17]. A main deficit of existing SbD concepts is that they do not account for the fact that safety is always a matter of interpretation. Tackling the socially constructed nature of safety opens up questions with regard to who has or is given the power to define safety levels, and to the processes through which safety is negotiated among societal actors. This also entails an exploration of how the promise of making nanomaterials 'Safe(r) by Design' may use exaggerated claims to persuade non-scientific stakeholders such as funders to invest in SbD approaches and the projects that promise to develop them. Hence, the debate about SbD could benefit from a more thorough empirical investigation of the actor-networks aligned via the concept and their specific interests in promoting, exploring and adopting it. Such research into the hidden politics of SbD research projects and the political visions they reinforce can embody an important mirroring effect and raise awareness among natural scientists engaging in these kinds of projects of how their research might be co-opted by other actors and agendas. This Special Section represents a starting point for this much needed analysis and reflection.

The contributions in this Special Section are based on talks given at the workshop "Making Nano 'Safer by Design'", which was held at the University of Vienna on May 18, 2016.[1] The workshop aimed to explore the concept of SbD in an interdisciplinary dialogue. We consider such interdisciplinary engagement as a prerequisite in this context because SbD needs not only insights from the natural sciences (e.g. on the transport and degradation of ENM in ecologies), but also other ethical, social, political and legal viewpoints, due to the socially constructed nature of safety. Thus, the workshop sought to investigate ways in which an interdisciplinary perspective could contribute to a better understanding and evaluation of SbD. In this vein, the four contributions in this Special Section span the fields of natural sciences (Reimhult), ethics (Kallhoff; van de Poel and Robaey) and law (Hildebrandt).

In the first contribution, Erik Reimhult provides an important background perspective for the debate about SbD by examining whether it is in fact possible to identify the risks of nanomaterials with currently existing techniques. He argues that the debate about nanorisks has largely neglected basic insights from colloidal physics and chemistry. In an accessible and lively manner, Reimhult argues that the specific properties of nanoparticles impede their characterisation and hence also the implementation of SbD approaches. For example, nanoparticles are drawn to each other and therefore have a tendency to become non-nano by natural design. Still, nano-specific risks may emerge when colloidal nanoparticles are freely dispersed in air or water, as well as when nanoparticles are produced and recycled. However, also in these cases, a range of problems emerge with the existing methods that are employed to identify, quantify and measure the properties of nanoparticles (e.g. light scattering and electron microscopy). Based on these scientific limitations, Reimhult formulates a critique of current regulatory promises to control the risk of nanoparticles as 'purely illusionary for simple physical reasons'.

In the second article, 'Safer by design and trump rights of citizens', Angela Kallhoff addresses the SbD

[1] The workshop was organised by the Research Platform Nano-Norms-Nature (Angela Kallhoff and Claudia Schwarz-Plaschg) at the University of Vienna, in collaboration with the Institute of Law at the University of Natural Resources and Life Sciences, Vienna (Iris Eisenberger).

approach from an ethical perspective by drawing on Dworkin's idea of trump rights. Instead of framing safety as a property of a material or product as most SbD approaches do, the presented rights-based framework considers safety as a value that is employed to enable the protection of basic legal rights of citizens such as bodily integrity and health. This reframing shifts the emphasis from the object (nanomaterial) to the subject (living being) and also calls for the inclusion of further equally important rights such as freedom of choice. It thus opens up the narrow focus on safety towards a wider spectrum of values and rights that should already be taken into account during the design phase of nanomaterials. In a second move, the article broadens the scope of safety concerns to the environment, thereby highlighting the potential of nanotechnology in terms of environmental cleansing and other environmentally beneficial nano-applications.

The third contribution by Ibo van de Poel and Zoë Robaey discusses SbD as one strategy to enhance the safety of products. Their discussion focuses on uncertainty in a distinct way: They explore whether or not SbD is useful in reducing indeterminacy. The contribution starts with a helpful distinction between five types of uncertainty: risk, ignorance, uncertainty in the narrow sense, ambiguity and indeterminacy. The latter is an openness of causal chains towards the future, including openness due to operators who employ a device differently from the ideas of the designer. A polar case is provided by an 'idiot-proof design'; the authors challenge this option in two ways. Firstly, they argue that taking safety for granted is in itself risky, because it rules out the attention to risks, whereas the person using an item might be the first to experience problems. Secondly, they argue that ruling out certain practices by design also is in a way undemocratic. In contrast to SbD, they support and discuss 'designing for responsibility.'

The fourth and final contribution 'Saved by design? The case of legal protection by design' by Mireille Hildebrandt focuses on the need of 'legal protection by design' (LPbD) in relation to data-driven infrastructures. Since our reality today is framed by data-driven machines that feed on our behavioural data and a choice architecture for humans in a so-called 'onlife', Hildebrandt argues that this architecture is designed rather than given. Therefore, fundamental tenets of the law, such as individual consent, fairness and legal certainty, can no longer be taken for granted in complex computational systems. The law's ability to regulate is in dire need of LPbD, since current technological ecosystems are disrupting the substance of legal effect and the protection of fundamental rights. In reference to LPbD, Hildebrandt further argues that, in order to reinvent and sustain human capabilities in the environment of nanotechnology, there is substantial need for 'legal protection by design' (in the case of nanotechnology, for 'safer by design') in order to bring nanotechnology under the rule of law.

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References

1. Fadeel B (2013) Nanosafety: towards safer design of nanomedicines. J Intern Med 274:578–580
2. Geraci C, Heidel D, Sayes C et al (2015) Perspectives on the design of safer nanomaterials and manufacturing processes. J Nanoparticle Res Interdiscip Forum Nanoscale Sci Technol 17:366
3. Morose G (2010) The 5 principles of "Design for Safer Nanotechnology". J Clean Prod 18:285–289
4. Jacobs JF, Van de Poel I, Osseweijer P (2010) Towards safety and sustainability by design: nano-sized TiO2 in sunscreens. In: Fiedeler U, Coenen C, Davies SR, Ferrari A (eds) Understanding Nanotechnology Philosophy, Policy and Publics. IOS Press, Heidelberg, pp 187–198
5. Kelty C (2009) Beyond implications and applications: the story of 'safety by design. NanoEthics 3:79–96
6. OECD (2016) Alternative testing strategies in risk assessment of manufactured nanomaterials: current state of knowledge and research needs to advance their use. Environment Directorate, Paris
7. van Rossum H, Gardeniers H, Borking J (1995) Privacy-enhancing technologies: the path to anonymity. Registratiekamer, Den Haag
8. Hjorth R, van Hove L, Wickson F (2017) What can nanosafety learn from drug development? The feasibility of "safety by design". Nanotoxicology 11:305–312
9. Kelty C (2010) Safety by design. In: Guston DH (ed) Encyclopedia of Nanoscience and Society. SAGE Publications, Thousand Oaks, pp 689–690
10. Savolainen K (2013) Nanosafety in Europe 2015–2025: towards safe and sustainable nanomaterials and nanotechnology

innovations. Finnish Institute of Occupational Health, Helsinki

11. Bensaude-Vincent B (2014) The politics of buzzwords at the interface of technoscience, market and society: the case of 'public engagement in science. Public Underst Sci 23:238–253
12. Star SL, Griesemer JR (1989) Institutional ecology, "translations" and boundary objects: amateurs and professionals in Berkeley's Museum of Vertebrate Zoology. Soc Stud Sci 19:387–420
13. Bottero JY, Rose J, de Garidel C et al (2017) SERENADE: safer and ecodesign research and education applied to nanomaterial development, the new generation of materials safer by design. Environ Sci Nano 4:526–538
14. Klaessig FC (2016) The nexus of innovation management, safer-by-design and responsible research and innovation. In: Bowman DM, Dijkstra A, Fautz C et al (eds) Responsibility and emerging technologies: experiences, education and beyond. Akademische Verlagsgesellschaft, Berlin, pp 11–23
15. Felt U, Wynne B (2007) Taking European knowledge society seriously: report of the Expert Group on Science and Governance to the Science, Economy and Society Directorate, Directorate-General for Research. European Commission, Luxembourg
16. Fleischer T (2016) Why the current popularity of SxD approaches in nanomaterials-related innovation policy? Presentation at the interdisciplinary workshop "Making nano 'safer by design'", 18 May 2016. University of Vienna, Vienna
17. Miller G, Wickson F (2015) Risk analysis of nanomaterials: exposing nanotechnology's naked emperor. Rev Policy Res 32:485–512