Making Nano “Safer by Design”

An interdisciplinary workshop

Book of Abstracts

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A colloidal scientist's perspective on nanosafety: The challenge of staying nano and seeing nano in complex environments

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Nanoparticles in the broad meaning of the word are ubiquitous in nature from volcanic soils, bubbles and sands to functional nanoparticles such as protein, viruses and exosomes in biological systems. Despite this, researchers and industry spend enormous efforts to try to create and maintain (stabilize) nanoparticles. Why? A major reason is that the physical reasons that make nanomaterials inherently highly functional are the same that drive them to aggregate and degrade very quickly in the environment. An understanding of these colloidal limitations to the stability of nanomaterials can help us not only to design functional nanomaterials, but also to evaluate where to expect the greatest risks as well as the possibility for and limitations of “safety by design” of engineered nanomaterials. After a short tutorial on these limiting colloidal aspects of nanomaterials with examples from our research on biomedical nanoparticles I will also introduce the challenge of investigating or even identifying nanomaterials in natural environments. With new laws being introduced to regulate the synthesis and introduction of nanomaterials in food, medicine and the environment, are we up to the challenge of determining if industry comply with those laws? Is the legal definition of an engineered nanomaterial even a physically meaningful concept which can be independently used? I will briefly introduce how current experimental techniques do not uniquely identify nanomaterials when we try to “see” the “invisible”.

Making Nano “Safer by Design”
The “Safe-by-Design concept”: Not a panacea in itself

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In the public discussion about nanomaterials and products containing nanomaterials (MNMs), the idea of safe or safer by design (SbD) is often brought into the discussion as a way to reduce the (perceived) risks and hazards associated with MNMs. However, there is no generally accepted Definition of SbD and the understanding about SbD is diffuse and sometimes misleading.

This presentation will give an overview over the Safe-by-Design concept as developed in the EU research programs SINN, NanoReg, NanoReg2 and ProSafe and talk about the first experiences with it.

More specifically, the presentation will touch the following points:

- Misconceptions and definitions of terms such as safety, risks, uncertainty, hazard, exposure, (legal) responsibility, customer/consumer etc.
- Nanomaterial value chains: How and where can exposure to nanomaterials occur?
- 5 factors determining the safety of materials and products
- Underlying principles: Precautionary principle, state of the art
- Safe-by-Design concept: what is it?
- Early stage risk assessment: exposure scenarios and control banding tools
- Data handling: Safety Dossiers
- Stakeholders
Can Safer by Design approaches to nanotechnology deal with uncertainty?

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Safer-by-design or design for safety approaches have some distinct advantages when it comes to addressing safety in nanotechnology. They help to address safety pro-actively and early in the life cycle of products, and may so help to avoid or at least diminish safety issues at later stages of the life cycle. At the same time, it seems obvious that not all safety issues can be fully addressed at the design stage. In my contribution, I will discuss two possible pitfalls of safer-by-design approaches, namely 1) a focus on products and 2) a focus on known risks.

Regarding the first, while it is understandable that safer-by-design in nanotechnology focus on products given the potential risks of products containing nanoparticles, a better approach would be to focus on the entire life cycle of such products and to include for example also sustainability considerations in addition to safety considerations. One way to do is to start from earlier developed approaches like green chemistry. Although the principles from green chemistry cannot be directly applied to nanotechnology, it is possible to abstract them to four more general principles that can be applied (Jacobs et al. 2010b): product safety, low environmental impact, material & energy efficiency and process safety. It should be noted that if we approach safe-by-design from a broader perspective –including the whole life cycle and other values than safety– it may turn out that design features or options that are desirable from a more narrow product safety approach may turn out to be undesirable.

The second issue is whether safer-by-design approaches can deal with uncertainty or only with known risks. To this end, I will distinguish four types of uncertainty, i.e. uncertainty about the probability of known effects, unknown effects, indeterminacy (i.e. open causal chains) and normative ambiguity (disagreement about what is desirable) (e.g. Renn and Roco 2006). For each type of uncertainty, I will discuss whether, and to what extent, it can be addressed during the design stage. I will argue that some uncertainties can be by addressed in design through such notions as redundancy, robustness, resilience and adaptability, while other requires attention for the later phases of the life cycle. In particular, it requires on-going monitoring of possible risks during the entire life cycle, learning from these and feeding these back to the design phase (Jacobs et al. 2010a).

References


Why the current popularity of SxD approaches in nanomaterials-related innovation policy?

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The question whether nanomaterials or nanomaterials-based products merit specific regulations in the various phases of their life cycles is still highly controversial. The reasons for this are manifold, among them are more technical ones like uncertainties in the scientific risk assessment (e.g. choice and relevance of endpoints, characterization of the noxious agent, causes for concerns) or resource limits of individual test strategies, but also more socio-political ones like the plurality of risk perceptions and regulatory expectations in modern societies, a diverse range of interests and levels of affection among the different actors in nanomaterials and nanoproducts innovation or a broader trend toward a “scientization” of genuinely political problems.

As one approach to address this, the European Commission and some of its advisers have intensively promoted (and funded research into) so-called “safe-by-design (SxD)” approaches in nanomaterials development and application. In fact, they became a prominent narrative in the EC’s Horizon 2020 nanotechnology work program. Although the official documents avoid to present a consistent description or even a definition of SxD, one may conclude from the existing texts that the understanding of SxD in nanomaterials is similar to the broader SxD idea: a set of practices aiming at anticipating and “designing out” potential safety and health hazards and risks associated with novel materials, structures, processes and products.

The presentation will discuss the current developments in nanomaterials-related innovation policy within the framework of the promise-requirement-cycles-model and explore the potential and the limitations of the SxD idea in the nanoregulation policy context. It will argue, i.a., that the “safe-by-design” rhetoric may induce political and public expectations that cannot be met in real life, for instance because of general epistemic limitations in anticipating hazards and risks of new substances and because of potential misconceptions about the context-dependent acceptable risk-benefit profile that is needed to translate the specific properties of nanomaterials into new products, and that a prevalence of this rhetoric carries with it the danger to “bite back”. SxD may also attribute roles to regulatory actors that cannot be fulfilled by them. By putting a focus on understanding the relationship between the intrinsic properties (the ‘synthetic identity’) of a material and its behaviour in living systems (the ‘biological identity’) and implementing this knowledge in the safety culture and practices of innovators, the general idea may nonetheless contribute to make future applications of nanomaterials safer(!) for humans and the environment.
Legal Protection by Design: Interfacing Legal Conditions and Technical Requirements

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In law, a new awareness is emerging of the fragility of its deep-linked alliance with the technologies of the word. Written law often seems insufficient to protect fundamental rights such as privacy, non-discrimination and the presumption of innocence from the disruptive effects of transformations in the technological landscape. This is notably the case on the cusp of security measures and the fundamental rights they may infringe. To protect the delicate balance that must be struck here, I have proposed to develop the concept of Legal Protection by Design, of which Data Protection by Design is an apt example. In my talk I will briefly discuss the challenges of designing architectures that can achieve security in a way that safeguards our fundamental rights, instead of trading the one against the other. I will also face the challenge of translating legal norms into requirements for and specifications of technical systems employed by police, criminal justice authorities or intelligence agencies. It is important to note what is lost in translation and what is gained. We need to be transparent about (1) which problems are solved, (2) which issues are not solved and (3) what new problems may be created when implementing e.g. security by design. Finally, I will raise the question of the relationship between ‘safety by design’ and ‘legal protection by design’, including the question of whether we have a right that companies and government agencies implement ‘safety by design’ and what this could mean.
Safety: A trump value?

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In discussing “Safer by design” from the point of view of ethics, three different meanings of safety will first be distinguished. The meanings of safety in the context of nano-sciences and nano-release relate to, yet are not identical with containment, with not being harmful and with controllable. After having differentiated three meanings of safety, I shall argue that none of these aspects has the qualities to figure as a trump value. In order to explain the latter, I shall expand on the concept of a trump right that has been coined by Ronald Dworkin. Then, I shall translate the notion of a “trump value” into the specific context of nano-research and nano-release. Finally, I wish to demonstrate that even though a reasonable constraint, “safety” needs to be contextualized within a frame that addresses more basic issues, in particular basic values that contribute to shifting the burdens of proof towards values of nano-products in the first place.
Design: Who gets to decide?

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Safer-by-design concepts are implemented at a very early stage of the innovation process. Hence, academia and industry are in charge of incorporating norms and values into materials, products or processes. Safer-by-design concepts also aim to design out hazards and risks for human beings and the environment. As a result, these concepts often neglect many other interests, such as freedom of choice, consumer sovereignty, equality or public engagement. Safer-by-design concepts shift the normative power from democratically legitimized parliaments to academia and the private sector. I will illustrate the societal repercussions of these power-shifts. In addition, the implementation of norms and values into design is increasingly challenging the law and its normative power. I will argue the democratic perspective, thus I advocate for the re-empowerment of democratically legitimized parliaments with regard to innovation processes.