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Nanotechnology

Regulation and Public Discourse

Chapter 1

Rethinking Ethical, Legal and Societal Frameworks for Assessing and Governing Nanomaterials*

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Over the last two decades, nanotechnology has been considered a central means for fostering positive technological and economic developments in the European Union, the United States, and other industrialised countries. At the same time, it is widely recognised that nanomaterials could have potentially negative impacts on human health, animal health, and the environment. Hence, various societal actors, such as natural scientists, ethicists, policy makers, lawyers, social scientists, and civil society organisations (CSOs), have conducted assessments and come up with governance proposals. Yet, there are still unanswered questions of whether and under what conditions specific nanomaterials may include risks for humans, animals, and the environment. The development and refinement of ethical standards, legal regulation, and societal integration mechanisms for nanomaterials remains a work in progress.

On 1–2 December 2016, the Research Platform Nano-Norms-Nature at the University of Vienna, in cooperation with the Institute of Law of the University of Natural Resources and Life Sciences (BOKU), held an interdisciplinary, international conference titled "Good Nano–Bad Nano: Who Decides?" The conference sought to explore the current state of the art and the role of evaluative processes and normative assessments in the academic and societal

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debate on nanotechnology. For this purpose, scholars from the fields of ecology, ethics, philosophy, and law, as well as social and political sciences, convened and discussed how shortcomings of the existing ethical, legal, and societal frameworks could be addressed and countered. In this volume, we collect some of the core ideas and opinions that were brought up at the conference as well as selected contributions from an interdisciplinary workshop on "Standardisation in the Nano-Field: For the Common Good?" (19 May 2017), which was also organised by the editors of this volume. Standardisation serves as one of the most important tools for channelling further development in nanotechnology. In doing so, it attracts particular scholarly attention. In this introductory chapter, we distil and further develop central arguments raised in these two academic discussion settings. Moreover, based on our explorations, we also formulate normative calls for rethinking current ethical, legal, and societal frameworks in order to strengthen reflexivity among stakeholders in the area of nanotechnology. We thereby seek to contribute timely insights for those actively involved in the governance of nanotechnology.

The consideration of the ethical, legal, and social aspects (ELSA) of new and emerging technologies has gained increasing relevance since 1988, the year in which the director of the US Human Genome Project (HGP), James Watson, announced that work on the ethical and social implications of genomics should accompany the research of natural scientists. In the HGP, a specific funding programme was established which was dedicated to this kind of research. It received 3 to 5 percent of the annual HGP budget, with similar programmes following in other countries. In the context of the European Union (EU), ELSA was integrated into European research policy from the second Framework Programme onward (FP2, 1987–1991),[1] starting with expert committees and research on bioethics and later turning into a more fundamental and integrated element of science and engineering research projects.

Over the last fifteen years, both policy and academic discourse have shifted toward the concept of "responsibility," which incorporates and further develops ELSA and other previous governance approaches, such as technology assessment, applied and engineering ethics, or stakeholder and public engagement. In contrast to ELSA, the responsibility framework is less restricted to mapping and assessing impacts. Rather, its interest lies in early collaboration and reflexivity among stakeholders in research and development processes. Nanotechnology is one of the first fields in which this shift took place (Grunwald 2014; Shelley-Egan, Bowman, and Robinson 2017). The "responsible development" of nanotechnology has been on the policy agenda since the US 21st Century Nanotechnology Research and Development Act[2] (2003) and the UK Royal Society and Royal Academy of Engineering report (RS-RAE 2004) made it a central objective alongside technological and

economic achievements. Later, the concept of "Responsible Research and Innovation" (RRI) became a cross-cutting element in the EU's Horizon 2020 framework programme (2014–2020). The focus on responsibility in all these cases conveys the commitment that research and innovation activities should not simply follow the objectives of scientific progress and economic profits, but also enhance human health and contribute to environmental and social sustainability (van den Hove et al. 2012). In our view, such an understanding of responsible research, innovation, and development needs to be established in an interdisciplinary framework in which regulation is evolving within an extensive research process, including an investigation of ethical and socio-political issues, and a broad societal debate.

This introductory chapter provides not only an overview of current research but also attempts to interpret its background and to provoke further discussions. It starts with reflections on definitional attempts with respect to nanomaterials (section 1) and with suggestions on how to improve regulatory frameworks (section 2). Subsequently, we discuss ways in which societal perspectives can be integrated into governance processes and explain why self-reflection among researchers in ELSA and the RRI domain is necessary (section 3). Lastly, we develop a specific ethical framework for assessing nanomaterials (section 4) before giving a general overview of the structure and the chapters of this volume (section 5). Overall, we hope that this volume will provide concepts, ideas, and theories not only of value for the reassessment of nanotechnology, but more generally for rethinking the regulation and societal shaping of contested new technologies.

1. TOWARD DEFINING NANOMATERIALS

The existing regulation of nanomaterials in Europe and in other parts of the world is neither comprehensive nor consistent (Eisenberger 2016). One of the most intricate issues is the very definition of "nanomaterials." Throughout this volume, the well-established classifications of nanomaterials are applied. Yet, as a common denominator of the contributions, we identify the claim that current classifications of nanomaterials can be improved and shortcomings of existing regulatory instruments need to be addressed.

In the Recommendation of the European Commission (EC 2011) a definition is proposed that focusses on size of particles and the relative quantity of particles occurring in a specific material. The following wording has attracted broad attention:

> "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where,

> for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm–100 nm. (EC 2011)

The stipulated size range refers to the International Organization for Standardization's (ISO) term "nanoscale," which determines the range between 1 and 100 nm.[3] Considering the relative quantity of 50 percent of the particles, the recommendation acknowledges that in specific cases, materials that do not exceed this threshold may also have certain undesirable properties for human or animal health or for the environment. Nevertheless, it is concluded that a pragmatic stance toward a conceptualisation of nanomaterials would support this condition while leaving open different assessments in specific cases. Based on a recent study of stakeholders' opinions on the definition, the Institute for Health and Consumer Protection of the Joint Re-search Centre argues for a refinement (EC 2015b). The recommendation mainly concerns adjustments of the thresholds. Because of the aim to serve regulatory purposes, the institute's findings indicate little support for deviating from the exclusive focus on size and quantity. Primarily, it is considered to expand the thresholds without accounting in more detail for the specific characteristics of the material.

In more specific EU regulations of products that include material produced with nanotechnological procedures, a further condition is identified: In contrast to the mere occurrence of nanomaterials by coincidence, the intention to include these materials is seen as a necessary component. In this vein, the EU cosmetics regulation[4] highlights the producer's intent to apply the material. Furthermore, the regulation acknowledges some specific properties, such as bio-persistence, insolvability, and external dimensions. The EU regulation of novel foods[5] defines engineered nanomaterials. Thus it distinguishes these materials from natural particles. The formulation provides an account to determine nanomaterials by their characteristic properties, such as surface reactivity or chemical properties only applying to nano-sized particles (which differ significantly from those of the same material when occurring in non-nanoform). The EU's biocidal regulation[6] does not uphold the distinction between natural and manufactured materials. Still, the intention of applying a certain material in a biocidal product is seen as a necessary condition for the declaration of the product as including nanomaterial. Furthermore, the regulation sets the focus on activity of the materials and their external dimensions.

For regulatory purposes, in general, two aspects of a definition of nanomaterials are added beyond size and quantity. First, the producers need to have the intention to include the material in the product. Second, certain characteristic properties of these materials, which deviate from the properties of the same material at a larger scale, are defined. Reflecting on a definition of nanomaterials, we would give some recommendations regarding which

additional aspects ought to be taken into account. For ethical, legal, and societal considerations the definition needs to not only address technical concepts but also properties that enable a normative assessment of how to handle the development, application, production, and supply of nanomaterials.

On the one hand, reactivity and relational toxicity need to be accounted for. Toxicity of nanomaterials is dependent on their surface reactivity, which depends on the core material, the coating compounds, its functionalisation, and the absorbing material. When released into other materials that do not support cohesion or produce toxicity in other ways, the release of nanomaterials may have undesirable effects.

On the other hand, the fact that a product consists of certain nanocompounds is not as important for a normative assessment as the possibility that during its life cycle the product releases nanomaterial into the environment. Due to difficulties of re-detecting nanomaterials in the natural environment, the irreversibility of the act of release cannot be overstated. Some nanomaterials may contribute to significant changes in the biotic or the abiotic environment, particularly when becoming "agents" themselves (this concept will be outlined below).

2. REGULATORY INSTRUMENTS: BETWEEN LEGAL AND MARKET REGULATION

By now the regulatory debate has moved past the more general question of whether nanotechnology should be regulated to the question of how effective specific regulatory instruments are for dealing with specific nanomaterials (Bowman 2017; Eisenberger 2016). In the EU context, labelling of nanomaterials in specific product groups (cosmetics, food, biocides) has emerged as an important regulatory instrument. A label can have various purposes, such as providing consumer information, hazard prevention information, or risk management information. Even though limited in its scope, it enhances consumers' decision procedures. The third function, risk management, became part of the European Union's legal framework in the legislation on genetic engineering that has been adopted for nanotechnology. Applying labelling as an instrument implies that consumers have to decide individually whether they consider nanomaterials in certain products to be risky or not risky. Consumers thereby perform a task that is traditionally subject to the state and governing bodies. Without adequate information that allows for a rational and informed choice, such a shifting of responsibility onto the consumer is problematic. Assigning consumers with risk assessment and management competences is only fair in a context in which this assessment and management can actually be performed on sufficient epistemic grounds. At the moment these

grounds are not provided with the current practice of labelling (Shelley-Egan and Bowman 2015; Eisenberger 2016; Schwarz-Plaschg, chapter 10 in this volume).

Although very important in the area of nanotechnology, law is just one means of regulating nanomaterials. The alternatives are mechanisms such as industrial codes of conduct or co-regulation between CSOs and the industry that yields voluntary reporting schemes. The co-regulation of the industry, as proposed in BASF's "Code of Conduct" (2014, 2015), however, can also be seen critically because it tends to attach too much weight to the interests of industry and commerce. It might also end up shifting decision-making procedures to markets. Insurance companies provide an example in the United States. They represent a central actor, because, by insuring against adverse effects, firms (if they are held liable) may distribute the financial risk on numerous other developers. This clearly supports developments by lowering potential costs. However, insurance companies may also exclude certain technologies from coverage, if they cannot properly estimate the risk at stake (Wilson 2006, 710). Therefore, the risk assessment of insurance companies has a great impact on the decision-making of developers.

Academic engagement from a variety of disciplines (e.g., ethics, social sciences, legal studies) will be needed to address and critically discuss the impact of responsibility-shifting mechanisms on individuals and markets and their role in a democratic society facing more and more "risky" technologies. Regulating new technologies, such as nanotechnology, might need to move beyond legal and market regulation. Smart regulation combines scientific expertise with ethical, legal, and social science expertise, such as safer-by-design concepts (Schwarz-Plaschg, Kallhoff, and Eisenberger 2017), deep ethical assessments (Kallhoff and Moser, chapter 2 in this volume), or experimental regulation (Eisenberger and Bereuter, chapter 8 in this volume).

3. INTEGRATING SOCIETAL PERSPECTIVES AND SELF-REFLECTION OF ELSA RESEARCHERS

In recent years, we have witnessed a need to integrate the opinions and perspectives of citizens and civil society actors into the development and regulation of nanomaterials and nanoproducts. In particular, the assessment of environmental impact has gained importance. Policy makers feel increasingly obliged to foster nanotechnological innovation that potentially benefits society and the environment. In order to achieve these objectives, we need to assess the previous ways of integrating the voice of society into research and policy decision-making and offer suggestions on how to improve feedback mechanisms. Researchers exploring ELSA in nanotechnology have played an

integral part in bringing actors from science, policy, and civil society closer together. We want to highlight that it is time to reflect on the past and future roles of ELSA researchers as well as to gauge the ways in which they may continue to shape the debate on nanotechnology and its assessments.

A central concern addressed in this volume are the ascribed and actual roles of publics and CSOs in debates on possibilities, implications, and regulations of nanomaterials. Even though CSOs play an important role in representing the public, it is important not to equate CSOs with the general public. Authors in this volume hold the view that CSOs cannot represent civil society at large, nor should they be invited into co-regulatory processes only to accomplish societal acceptance. A representational model of CSO engagement is suspected to falsely assume that societal issues are either known or can be easily identified. In fact, these issues only appear when concrete choices have to be made (Krabbenborg and Mulder 2015). Arguably, the public voice is only raised when people are affected by a specific issue or a problematic situation. From such a perspective, controversy is not something to be avoided but rather becomes a resource for social learning. In contrast to current public engagement initiatives at the EU level that are primarily focused on gaining acceptance for nanotechnological developments, this implies fostering critical debate instead of compliance.

Regarding the involvement of the public, there exists a dilemma between the intention to include publics "upstream" (i.e., when, practically, there is still an opportunity to influence developments) and the problem that members of the public often find it difficult to relate new technologies with their everyday lives. In order to allow for early engagement, authors have proposed that designers and facilitators of engagement processes develop and use creative methods to stimulate imagination (Felt et al. 2014; Felt, Schumann, and Schwarz-Plaschg 2017). Furthermore, Coenen recommends addressing the political economy of techno-science, which includes the ways in which capitalism and techno-science are entangled (Coenen 2016). Although it appears to be important to inform publics about nanotechnology and to raise attention, such activities are sometimes based on problematic assumptions on public opinions and their emergence, such as imputations of a knowledge or opinion deficit, or even general technophobia in citizenry (Schwarz-Plaschg 2018a). Despite the "nano hype" in science and policy and concomitant attempts to make it a topic of broad public debate, nanotechnology remains a marginal issue in public discourse.

Thus, the field of nanotechnology also provides a perfect case for a revision of the models and myths held among actors in the science policy field. Such a revision must account for the ways in which and the reasons why publics or counter-publics evolve around novel techno-scientific developments in specific cultural contexts. Because public attention is a scarce good in an age

of information overload, many issues only come to public attention through catastrophic events or scandals rather than through orchestrated top-down efforts. In this vein, this volume deviates in some respects from a far too naïve model that either ELSA researchers, marketing of nanotechnologies, or government-sponsored public engagement can incite broader public attention for the issue or that they are even capable of producing public opinions in any predefined way.

Nevertheless, beyond being mere observers, ELSA researchers can be reflexively aware of their agency in configuring the regulatory and societal debate around nanotechnology. For instance, they have played a central role in shaping the "deliberative turn" in nanotechnology governance, which has led to the growing involvement of public voices and CSOs. Understanding the role of ELSA researchers as the advocates and catalysts of policy allows deliberative experimentation. This focus also entails critical reflection on the so-called folk theories and narratives that are constructed and repeated in ELSA circles to influence policy actors in specific ways—for example, the analogy between genetically modified organisms (GMOs) and "nano" (Schwarz-Plaschg 2018b). Additionally, ELSA researchers need to critically reflect on and address their dependency on external funding (Coenen 2016). Thus, we also need to reimagine the conditions under which researchers can work continuously on topics and explore these in inter- and transdisciplinary settings, instead of moving from one field of research to the next.

4. AN ETHICAL FRAMEWORK FOR ASSESSING PRODUCTION AND RELEASE OF NANOMATERIALS

Critical to the interpretation of nanomaterials and to the assessment of possible risks are not only empirical studies of how nanomaterials interact with the environment but also theoretical accounts on the conceptualisation of the status of nanomaterials. According to Bensaude-Vincent (2010, 2013), nano-objects raise the question of their ontological properties. In particular, nano-objects blur the boundary between nature and artefacts, life and inert matter, matter and mind (when embedded in smart materials), and structural and operational units. A promising approach to conceptually grasping nanomaterials is to look at them as "relational objects." Nanoparticles cannot be conceived of as independent objects since they are blended in associated milieus: They exist in combination and interaction with materials of which they become an integral part (Bensaude-Vincent 2013, 316–317). As such, nanomaterials become "co-agents," and it is difficult to fully control their behaviour and to predict how they will develop in the future. Hence, we must learn to assess these new materials in relation to their respective environmental contexts during their life cycle.

Thus, ethics should no longer exclusively stick to assessing consequences and effects in terms of "risks," but rather be based on a new normative approach that focuses on concepts of coexistence and coevolution. This includes paying attention to the interactions of nanomaterials with the environment and with living beings (other than humans). This also demands empathy and respect for life, apart from human life, as well as an awareness of the essential services that natural ecosystems provide. Instead of relying on metaphors of domination, control, and risk prevention, such a reevaluation needs to include biocentric and eco-centric approaches (Kallhoff 2017b). An eco-centric approach pays tribute to the affordances of living and non-living beings in a shared world and interprets human life as one incident of evolution that proceeds in long-term phases and that for the sake of human life should pay tribute to the affordances resulting from natural integrity (Kallhoff 2017b). This ontological-ethical framework can be applied in three ways.

First, the results of studies in the field of nano-(eco)-toxicology depend upon many variables, such as test equipment, particle coatings, or interactions with dispersants. Undoubtedly, these variables affect the outcome of tests. In other words, the way in which toxicity tests are designed has an influence on whether nanoparticles are labelled as either "toxic" or "non-toxic" (Wickson and Forsberg, chapter 3 in this volume). As a consequence, a critical exploration of current testing models and conditions—and tacit assumptions about what "toxicity" means—is needed. This is important because toxicological studies are central to informing risk regulation of the application nanotechnologies. Moreover, we need to account for the relational nature of nanomaterials. They should be classified by their interaction with surrounding material and their behaviour in the environment and not simply by their size or their relative quantity (Bensaude-Vincent 2013). The effect of the release of nano-objects on the environment ought to be evaluated in relation to their product life cycle (Filser, chapter 7 in this volume). Even though this is particularly demanding, a study of interactions with the natural environment is necessary in order to really understand toxicity and the trajectories of material in living surroundings.

Second, new technologies are peculiar with regard to the significant increase in the pace of innovations. The dynamics of new technologies are rapid. In this respect, the slow adjustment of assessment processes has to be considered. In some specific scenarios and within constitutional boundaries, moratoria (e.g., European Environment Agency 2013) might also be considered as preliminary legal instruments to govern new and emerging technologies. Practically, this means restraining developments that could have negative effects on either the environment or human health, in order to allow time for researchers to provide an in-depth assessment. At a minimum, the normative case of precaution should include that worst-case scenarios (e.g., McKee and Filser 2016) be taken seriously.

Yet it also should be noted that the hypothetical scenarios of extremely hazardous developments have played a central role in shaping the early public debate on nanotechnology. While the public debate, to some extent, has overstated possible threats, dystopian visions have triggered research on the potential negative effects of nanoparticles on human health, animal health, and the environment. Today, risk research is guided by a more balanced approach that neither praises nanotechnology as undisputedly good nor condemns it as profoundly bad. Instead, a fine-grained approach to a variety of ethical methods of assessment has to be developed (Kallhoff and Moser, chapter 2 in this volume). Nonetheless, scientifically inspired worst-case scenarios are still relevant for any assessment of nanomaterials.

Third, it is also important to note that certain ideas, such as the conviction that technological developments are fully controllable or the hope that all major risks can be prevented, are not realistic with regard to new technologies. If we conceive of nanomaterials as agents, there is no full control. In contrast, we promote conceptions such as "precaution," which are more open to a variety possible outcomes. Some clarifications are needed in case of the latter. When the effect of a new substance on nature cannot be anticipated, it might seem reasonable to shift the "burden of proof" onto inventors, developers, or companies applying these new materials by holding them responsible to show that the product has no hazardous effect on human health, animals, or the environment. It is generally acknowledged that the so-called precautionary principle (PP) effectuates such a shift of the onus of proof (Martuzzi and Tickner 2005). The principle demands that with regard to potential risks, certain remedies should be taken to avoid them. In our opinion, it is reasonable to apply PP in situations where potential risks can (to some degree) be measured and anticipated.

Yet there are also many reasons why this could be problematic in the case of nanomaterials. Given that nanotechnology is a risk technology and risk information is essentially lacking, shifting the burden of proof onto inventors, developers, or companies would equal a ban (Kallhoff and Moser, chapter 2 in this volume). Banning nanotechnology would, however, be a disproportionate interference into fundamental rights (for safer-by-design practices, see Kallhoff 2017a). Even if appropriate assessment tools were available, these assessment procedures would be very cost-intensive. High costs for assessment procedures favour big companies over start-ups and small and medium-sized enterprises (SMEs), but pushing start-ups and SMEs out of the nanotechnology market or other emerging technologies' markets should in the end be a deliberate and democratic decision (for a similar argument with regard to gene editing, see Stelzer und Eisenberger 2019).

Beyond legal and pragmatic arguments, ethical accounts have developed a range of procedures in order to anticipate not only risks, but also beneficial

developments. In order not to overstate risk, authors engage in evaluative practices that support cooperation in favour of a shared vision of a natural good (Kallhoff 2017b). An alternative ethical principle that is also used to assess the eligibility of nanomaterial is the so-called beneficiary-first principle. It states that in order to be permitted, the application of a specific material should not only be anticipated to be beneficial, but should objectively be proven to be beneficial. But standards for the "goodness" of developments and materials should not be reduced to utilitarian or economic values. What should matter are the effects not only on human health and animal health, but also on the natural environment (i.e., the shared world of humans and other living beings).

5. CONTENT OF THIS VOLUME

In this volume, we propose the mentioned normative recommendations as potential starting points for rethinking and reforming existing ethical, legal, and societal frameworks for assessing and governing nanomaterials. We consider them equally relevant for academics and other stakeholders such as regulators, policy makers, CSOs, and industry. The three parts of this edited volume provide a discussion of these issues from the viewpoints of various disciplinary and interdisciplinary approaches.

The first part, titled "Evaluation and Standardisation," is edited by Angela Kallhoff and Elias Moser. It encompasses four chapters that present and engage with evaluation and standardisation practices of ethical, legal, and economic backgrounds. In chapter 2, Angela Kallhoff and Elias Moser outline different ethical approaches of relevance for a normative assessment of nano-release. They elaborate on traditional risk assessment and the well-known notion of PP in order to demonstrate that these accounts need to be complemented to provide ethical guidance with regard to environmental influence of emerging technologies. They conclude that it is obligatory to engage in what they call an "eco-centric evaluation" of nano-release. In chapter 3, Fern Wickson and Ellen-Marie Forsberg draw attention to an implicit aspect of current discussions on RRI, but which has a highly significant impact on scientific research, innovation, and policy—namely, the interstitial space of international standardisation. They argue that although current models for RRI provide a promising attempt to make research and innovation more responsive to societal needs, ethical values, and environmental challenges, such approaches will need to encompass and address a greater diversity of innovation system agents and spaces to prove successful in their aims. Chapter 4 explores the effects of patenting in nanotechnology on innovation and competition. Some of these effects may be seen as positive in terms of

stimulating investments in innovation and also enabling interoperability and comparability. Yet some effects run counter to the aims of protection and standardisation—namely, where "bottlenecks" are created for competition in downstream markets or when patenting leads to obstacles for follow-on innovation. Thomas Jaeger seeks to pinpoint the positive and negative effects of standardisation and patenting in the nanotech field and assesses tools for better balancing and avoiding overprotection. Chapter 5 focusses on standardisation. Henk de Vries's contribution proposes voluntary standardisation as an instrument to mitigate risks while enabling innovation rather than hindering it. He describes the current efforts of developing international standards for terminology, measurements, health, safety and environment, and material specifications. Additionally, he discusses how legislation and standardisation can also be used in combination, thus avoiding the danger of legislation obstructing innovation.

The second part of this volume, edited by Iris Eisenberger, focusses on "Norms and Regulation." It assembles chapters that analyse and assess existing regulatory frameworks in different national contexts. In chapter 6, Diana Bowman and Lucille Tournas explore the question of who is in charge of regulating nanomaterials and adopt a more comprehensive account of thinking about regulation, drawing upon Black's notion that regulation "produce[s] changes in behaviour" (Black 2001, 108). Bowman and Tournas argue that all sectors of society are currently "regulating" nanotechnologies, with insurance and reinsurance markets as well as consumers playing a significant regulatory role. They conclude that nanotechnology serves as a powerful illustration of how emerging technologies may be regulated in the future. In their opinion, the multifaceted regulatory framework captures the complexity of the technology. Juliane Filser, in her very critical examination, observes that, historically, risk assessment procedures have been developed for conventional chemicals, and they do not account for the fact that nanoparticles (because of their size) behave and react differently in the natural environment. In chapter 7, she suggests that current regulatory practices for nanomaterials do not sufficiently protect the environment and that they significantly differ from one country to another. Furthermore, Filser argues that standardised guidelines for environmental hazard assessment underestimate the potential risks of engineered nanomaterials by not accounting for biotic interactions. In chapter 8, Iris Eisenberger and Franziska Bereuter analyse nanotechnology research as a phenomenon with dual use potential—it can be used for good and for bad. The conflict between promises of beneficial innovation, on the one hand, and concerns about possible harmful consequences, on the other hand, makes nanotechnology research an object of regulation. Its twofold character, however, makes this difficult. Regulation of nanotechnology research needs to balance freedom of research with the right to life or physical integrity.

Thus, fundamental rights both limit and oblige the legislator in the context of dual use research. According to Eisenberger and Bereuter, regulation is best placed between law and science, where tools such as "safety by design" combine legal and scientific strategies. The contribution of Emad Yaghmaei, Andrea Porcari, Elivio Mantovani, and Steven Flipse describes and discusses a possible method to quantitatively assess the value of RRI strategies in innovation departments in the commercial industry. In chapter 9, they outline their experience within the EU-funded project PRISMA,[7] which aims to help industries implement RRI strategies in their innovation processes as part of their corporate social responsibility (CSR) policy. Moreover, they attempt to provide evidence on how the RRI approach and its explicit attention to the gender dimension can improve the innovation process and its outcomes.

The third and final part of the volume, titled "Politics and Publics," is edited by Claudia Schwarz-Plaschg. It comprises contributions that investigate the role of political actors, institutions, publics, and civil society in the ongoing societal debate about nanomaterials. In chapter 10, Schwarz-Plaschg scrutinises whether nano-labelling and the concomitant shifting of decision-making responsibility onto consumers represents an adequate governance mechanism under uncertain epistemic conditions. In order to provide an answer, she explores the current state of nano-labelling regulation in Europe and contrasts this with members of the Austrian public's ideal nano-labelling scenarios. Based on a detailed discourse analysis, she diagnoses that nano-labels are often not very meaningful and sometimes even produce a dilemma for consumer-citizens. To counter-steer such confusion, she calls for an epistemic transparency—in combination with the material transparency that a nano-label purports to provide—that openly communicates the limits of existing (scientific) knowledge and institutional processes for establishing certainty and safety with regard to the application of nanomaterials in consumer products. In chapter 11 Lotte Krabbenborg studies the important role of CSOs in the evaluation processes surrounding emerging technologies. She argues that two problems arise when CSOs are positioned as "voices of civil society." First, these organisations do not always see themselves as representatives of civil society. Second, such positioning underestimates the socio-technical complexity involved when emerging technologies become a topic for deliberation and negotiation. Building upon the work of philosopher John Dewey, Krabbenborg shows that in order to attain the societal evaluation of emerging technologies, the challenge is not to involve more CSOs (even though they could play a valuable role), but rather how to investigate the indeterminate situations that arise, both on a small and large scale. Franz Seifert begins chapter 12 with the observation that there is general hype around nanotechnology, which not only promotes discourse and rhetorical hyperbole, but also carries substantial financial, scientific, and innovative

influence. He provides some explanation for the structure of public discourse on nanotechnology and then explores the discussion on nanotechnology in EU technology policy from a critical viewpoint. Finally, he proposes certain lessons that we may learn from the nanotechnology field in terms of emerging technologies and their accompanying social science research.

All contributions share the presumption that nanomaterials withstand a clear categorisation as being either beneficial or harmful. Existing research does not yet provide definitive evidence on their (eco)toxicological effects. Despite this ambiguity, we have witnessed a growing number of academic and political initiatives that establish norms and practices to govern emerging nanotechnologies over the last two decades. In bringing together approaches from ethics, ecology, economics, law, science, and technology studies, as well as other social and political sciences, we wish to combine these disciplinary perspectives to address existing challenges and provide a forward-looking normative frame that also offers space for public debate. We hope that the recommendations and the arguments developed in the individual chapters can stimulate further debate among ELSA and RRI scholars, nano-scientists, (eco)toxicologists, policy makers, regulators, industries, CSOs, and other stakeholders in the nano-field, and also inspire them to question widespread and well-established assumptions, definitions, and structures.

NOTES

1. CORDIS, "FP2-Framework 2C—Framework Program for Community Activities in the Field of Research and Technological Development, 1987–1991," available at https://cordis.europa.eu/programme/rcn/24_en.html.
2. Public Law 108–153, 21st Century Nanotechnology Research and Development Act (2003).
3. ISO 8000–1:2015, 2.1.
4. Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, 22 December 2009, O.J. (L342) 59–209 (2009).
5. Regulation (EU) 2015/2283 481 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001, recital 10, 11 December 2015, O.J. (L327) 1–22 (2015).
6. Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, 27 June 2012, O.J. (L167) 1–123 (2012).
7. Piloting RRI in Industry: A Roadmap for tranSforMAtive Technologies, 2016–2019. https://cordis.europa.eu/project/rcn/203531/factsheet/en.