The EU and Nanotechnologies

A Critical Analysis

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Introduction

Regulating the Invisible

IN MARCH 2006, the bathroom cleaner *Magic Nano* went on sale in Germany under the slogan: 'Scrubbing? Never again!' Within hours more than 110 incidents of health disorders related to *Magic Nano* were reported to the German poison control and treatment centres. All of the users suffered from breathlessness, several were hospitalised with water in the lungs. Soon, the 'nano' in *Magic Nano* was declared the culprit.[1] Three days later, the product was taken off the market. The case attracted international attention.[2] For the first time, nanotechnologies were publicly discussed. Questions were posed: What actually is 'nano'? Why would the inhalation of nanoparticles lead to adverse health effects? And how could such a product be marketed in Germany? The fact that it transpired in the end that the product did not even contain nanoparticles faded into the background.

At first glance, nanotechnologies seem not to be a big issue, in the truest sense of the word. One imagines something small, something unfathomable, something invisible that escapes the average person's notice. Nanotechnologies denote the manipulation of matter or the creation of structures at the atomic and molecular level.[3] To give a sense of scale, a human hair is 80,000 times the width of a nanometre.[4] And yet, nanotechnologies have recently become associated with big terms. The idea of 'never scrubbing again' is only the tip of the iceberg. It is claimed that inconceivable economic, environmental and health implications are at stake—in positive and negative terms alike, inseparably linked. Nanotechnologies, it is said, will help overcome the economic crisis by creating jobs and growth, save lives through improvements in cancer treatments and resolve energy problems by generating renewable sources. In the same breath, we are told that the impact and possible harms nanotechnologies might inflict upon the human body and the environment are yet unknown. The rise of nanotechnologies hence embraces the

[1] Bundesinstitut für Risikobewertung, *Vorsicht bei der Anwendung von 'Nano-Versiegelungssprays' mit Treibgas!* (Caution in applying 'nano sealing sprays' with propellant!) (2006) www.bfr.bund.de/de/presseinformation/2006/08/vorsicht_bei_der_anwendung_von__nano_versiegelungssprays__mit_treibgas_-7678.html.

[2] See eg The Economist, 'Has All the Magic Gone?' *The Economist* (London, 12 April 2006) www.economist.com/node/6795430 and Barnaby J Feder, 'Technology's Future: A Look at the Dark Side' *The New York Times* (New York, 17 May 2006).

[3] Q Chaudhry, 'Nanotechnology' (Presentation held at ICoMST, Copenhagen, August 2009).

[4] ibid.

fundamental tension between scientific and technical progress and its unsolicited side effects. The arena of this tension is the interface between science, politics and law. Thus the phenomenon of nanotechnologies may be viewed as a proxy for broader challenges contemporary societies are facing.

This book investigates the role of law in confronting these societal challenges. Where, by whom and how are decisions taken? The aim of this book is to critically analyse the current European Union (EU) regulatory developments in the area of nanotechnologies, thereby putting to the test the EU institutional set-up and decision-making process in the face of risks. The issue is topical. It is not only the financial crisis that has placed the regulation of risk into the spotlight; more and more regulatory activity is being (re)defined in terms of risk: 'Chemicals, pharmaceuticals, GMOs, transport, stem cell research, nuclear power, even financial engineering, all have prompted the development of risk regulation regimes'.[5] Nanotechnologies have joined this list since the early 2000s.

I. DEFINING THE PROBLEM

A. Regulating in the Shadow of Scientific Uncertainty

The emergence of nanotechnologies is accompanied by severe scientific uncertainties. Although the body of knowledge about nanomaterials is developing, significant gaps persist as to their physicochemical properties.[6] These knowledge gaps render it difficult to evaluate, model and predict nanomaterials' ecological and toxicological behaviour.[7] Research has, however, confirmed that nanomaterials may enter the human body via several channels: through ingestion via the digestive tract, through inhalation via the respiratory tract and potentially through the skin in the case of direct exposure.[8] As soon as the tiny particles have entered the body, they may reach various organs.[9] However, what happens once nanomaterials have entered the different parts of the human body is impossible to determine conclusively at present.

[5] J Black, 'The Role of Risk in Regulatory Processes' in R Baldwin, M Cave and M Lodge (eds), *The Oxford Handbook of Regulation* (Oxford, Oxford University Press, 2010) 304.

[6] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Opinion on 'Risk Assessment of Products of Nanotechnologies' (19 January 2009), www.ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf, in which SCENIHR advocates a case-by-case approach for risk assessment; European Food Safety Authority, 'The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety' (2009) 7 *EFSA Journal* 1; Observatory-Nano, 'Development in Nanotechnology Regulation and Standards' (FP7 Report, May 2009).

[7] Physical-chemical properties of nanomaterials include size, shape, composition, reactivity, surface area, and/or chemistry. ibid.

[8] European Commission, 'Nanotechnologies: A Preliminary Risk Analysis' (Workshop DG Sanco, Brussels, 1–2 March 2004) 19, www.ec.europa.eu/health/ph_risk/documents/ev_20040301_en.pdf.

[9] J Kreuter, D Shamenkov, V Petrov, P Ramge, K Cychutek, C Koch-Brandt and R Alyautdin, 'Apolipoprotein-mediated Transport of Nanoparticle-bound Drugs Across the Blood–Brain Barrier' (2002) 10 *Journal of Drug Targeting* 317.

B. Who Decides When Nobody Knows?

Intrinsically linked to the existence of scientific uncertainty is the question: who regulates, who decides 'how safe is safe enough'[10] in the face of scientific uncertainty and controversial knowledge claims? To be sure, the determination of the adequate level of protection is likely to significantly affect the everyday life of citizens. If the regulator decided to eliminate all risk by banning the development of nanotechnologies altogether, the impact on the competitiveness of industry could be immediate; a moratorium might deprive society of the opportunities to make important breakthroughs in medical treatment or to develop alternative energy sources. Vice versa, if the regulator decided not to interfere with nanotechnological development, people would be exposed to nanomaterials in their everyday lives—through their food, cosmetics, conditions at their workplace—potentially resulting in irreversible adverse effects to public health and the environment.

Decisions are hence required as to 'where and how one draws the line between still acceptable and no longer acceptable exposures', as Ulrich Beck frames it, and whether 'the possibility of an ecological catastrophe [should] be accepted, for instance, in order to satisfy economic interests. What are necessities, supposed necessities, and necessities that must be changed?'[11] Each affected societal actor, ranging from industry to environmental associations, consumer organisations and ethical groups, has its own reply to these questions. The presence of scientific uncertainty enables the diverse actors to interpret the available knowledge differently, pursuant to their own societal perspective. Industry is grasping nanotechnologies in economic terms, while consumers, trade unions and environmental organisations fear the environmental hazards posed by nanotechnologies and are anxious about consumer safety and the workers' health.

This book argues that continued scientific uncertainty renders the answer to the question at which point the regulation of nanotechnologies achieves its desired result, and hence at which point it becomes 'effective',[12] subjective in nature.[13] This turns the regulation of nanotechnologies into a contentious matter.[14] A rational

[10] S Funtowicz, I Shephard, D Wilkinson and J Ravetz, 'Science and Governance in the European Union: A Contribution to the Debate' (2000) 27 *Science and Public Policy* 327, 330 and S Jasanoff, *The Fifth Branch: Science Advisors as Policy Makers* (Cambridge, Harvard University Press, 2004) 232.

[11] U Beck, *Risk Society: Towards a New Modernity* (M Ritter (tr), London, SAGE Publications, 1992) 29.

[12] See further on the rationale of regulatory intervention in the area of nanotechnologies and the desired result of this intervention, chapter 1, section III.

[13] K Purcell, L Clarke and L Renzulli, 'Menus of Choice: The Social Embeddedness of Decisions' in MJ Cohen (ed), *Risk in the Modern Age: Social Theory, Science and Environmental Decision-Making* (Basingstoke, Palgrave MacMillan, 2000) 68. Or, as Giddens puts it, 'there is no risk that can be described without reference to a value', see A Giddens, 'Risk and Responsibility' (1999) 62 *The Modern Law Review* 1, 5.

[14] See for instance M Lee, 'Risk and Beyond: EU Regulation of Nanotechnology' (2010) 35 *European Law Review* 799; GA Hodge, DM Bowman and AD Maynard (eds), *International Handbook on Regulating Nanotechnologies* (Cheltenham, Edward Elgar Publishing, 2010); G Van Calster, 'Regulating

calculation of the 'optimal' result is precluded.[15] The nature of the potential risks at stake is unknown, so too by implication, when these risks are controlled. Where the definition of effectiveness becomes subjective, value judgements naturally enter the debate. Pursuant to Dahl, 'judgements about trade-offs among different ends are not "scientific"'.[16] They should not be left to technicians, to scientists, to 'the experts'. Or, the other way around, 'there is no expert on risk'.[17] Instead, subjective risk perceptions and controversial knowledge claims should be exposed to debate in the political arena.[18] The common interest of citizens in the area of nanotechnologies is yet to be identified. Questions regarding the democratic legitimacy of the regulation of nanotechnologies arise.

C. The Global Impact of the Nano Size

The regulation of nanotechnologies becomes even more complex by virtue of its transboundary, global implications. The potential risks faced by one individual, company or state depend not only on its own choices but equally on those made by others.[19] There are two sides of the coin. On one side, the interdependency of today's world has transformed issues such as food safety and consumer and environmental protection into global concerns. We are confronted with the globalisation of markets and the implied increasingly global nature of the supply chain.[20] To the contrary, the inherently subjective nature of the concept of risk, and its variation according to histories, local politics and value systems,[21]

Nanotechnology in the European Union' (2006) 15 *European Environmental Law Review* 238; E Stokes, 'Regulating Nanotechnologies: Sizing Up the Options' (2009) 29 *Legal Studies: the Journal of the Society of Public Teachers of Law* 281; O Renn and MC Roco, 'Nanotechnology and the Need for Risk Governance' (2006) 8 *Journal of Nanoparticle Research: An Interdisciplinary Forum for Nanoscale Science and Technology* 1; KH Ladeur, 'Kommunikation über Risiken im Rechtssystem. Das Beispiel Nanotechnologie' in C Büscher and KP Japp (eds), *Ökologische Aufklärung* (Wiesbaden, VS Verlag für Sozialwissenschaften, 2010); T Ehnert, 'The Legitimacy of New Risk Governance: A Critical View in Light of the EU's Approach to Nanotechnologies in Food' (2015) 21 *European Law Journal* 44.

[15] S Funtowicz et al, 'Science and Governance in the European Union' (n 10); S Jasanoff, *The Fifth Branch* (n 10) 232.

[16] RA Dahl, *On Democracy* (New Haven, Yale University Press, 1998) 72. Alvin Weinberg would call them 'trans-scientific', see AM Weinberg 'Science and Trans-Science' (1972) 10 *Minerva* 209.

[17] U Beck, *Risk Society* (n 11).

[18] A Giddens, 'Risk and Responsibility' (n 13) 7; J Habermas and M Rosenfeld, 'Paradigms of Law' (1996) 17 *Cardozo Law Review* 771.

[19] O Renn and MC Roco, 'Nanotechnology and the Need for Risk Governance' (n 14) 8 and 29.

[20] F Cafaggi, 'Private Regulation, Supply Chain and Contractual Networks: The Case of Food Safety' (2010) European University Institute Working Paper, RSCAS 2010/10, 6 www.cadmus.eui.eu/bitstream/handle/1814/13219/RSCAS_2010_10.pdf?sequence=1&isAllowed=y.

[21] E Fisher, 'Risk and Governance' in D Levi-Faur (ed), *The Oxford Handbook of Governance* (Oxford, Oxford University Press, 2012) 423. A Giddens, 'Risk and Responsibility' (n 13).

leads to different regulatory regimes in different countries, sectors or 'contexts'.[22] The international trade in nanoproducts may thus result in the presence of nanoproducts subject to potentially less rigorous and precautionary regulatory requirements on the domestic market of countries implementing either considerably higher or entirely different product standards. On the other side of the coin, the externalities of nanotechnologies, most notably their environmental, health and safety risks, are not confined within domestic borders.[23] The risks inherent in nanotechnologies are of a transnational nature.[24]

II. THIS BOOK

A. An EU Lens

Despite the transnational impact of nanotechnologies, not only beyond the confines of the EU Member States but also beyond the territory of the European Union itself, this book focuses on the European Union's regulatory activity in the area of nanotechnologies. The rationale for this choice is a pragmatic one. First, the fields in which nanotechnologies are or will be applied, such as chemicals, food, cosmetics and medicines, affect shared competences, which have already been harmonised at the EU level.[25] Secondly, appropriate institutional structures have not (yet) been developed at a global level. The international governance of nanotechnologies is currently restricted to scientific and technological standardisation and coordination efforts directed by a few Organization for Economic Cooperation and Development (OECD) countries while 'no deeper structures for global governance of nanotechnology have been created'.[26] Research on the potential of coordination efforts through international organisations, such as the OECD, the International Organization for Standardization (ISO) and within the United Nations (UN) framework, is essential in view of the global impact, not

[22] C Hood, H Rothstein and R Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford, Oxford University Press, 2001) 20.

[23] H Nowotny, P Scott and M Gibbons, *Re-Thinking Science: Knowledge and the Public in an Age of Uncertainty* (Cambridge, Polity Press, 2001) 13.

[24] U Beck, *Risk Society* (n 11) 44.

[25] The legislative frameworks identified by the Commission in its Communication 'Regulatory Aspects of Nanomaterials' are predominantly based on art 114 of the Treaty on the Functioning of the European Union (TFEU) (internal market), art 153 TFEU (worker protection), art 43 TFEU (Common Agricultural Policy), art 168 TFEU (public health) and art 192 TFEU (environmental protection), see European Commission, 'Regulatory Aspects of Nanomaterials' (Communication) COM (2008) 366 final.

[26] R Falkner and N Jaspers, 'Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap' (2012) 12 *Global Environmental Politics* 30, 46.

least because of its implications for international trade,[27] but that discussion falls beyond the scope of this book.[28]

B. Research Question and Relevance

The aim of this book is to provide a critical analysis of the current EU risk regulation in the area of nanotechnologies. Thereby, the analysis will be guided by the overall research question:

How does the EU confront the emergence of nanotechnologies?

The objective of this book is to contrast normative demands or ideas of how the law should respond to the challenges of scientific uncertainty, conflicting knowledge claims and legitimacy concerns, which at European level are commonly captured under the loose notion 'new governance', with the empirical reality of the EU's regulatory approach to nanotechnologies. This book thereby strives to fill two gaps in the existent literature. First, it tackles a topic that has so far been largely neglected, at least from a legal point of view, but that is of great economic, social, political and environmental importance. Much more fundamentally, however, this book asks questions which greatly transcend the area of nanotechnologies. These questions touch upon the pressing issues of knowledge production and the creation of legitimate regulation in modern societies, as well as the capacity of the EU's institutional and constitutional set-up to confront those concerns. These broader questions are explored based on the specific—though exemplary, as it will be argued—case of nanotechnologies, thereby providing current, often abstract, academic debates with a detailed empirical foundation.

C. Method

This book undertakes an analysis of the evolving regulatory framework for nanotechnologies—encompassing the relevant EU legislation, provisions in the

[27] As Van Calster predicts, 'the regulation of nanotechnology announces itself as a future battleground for pitching regulatory ambitions against free trade', see G Van Calster, 'The Role of the World Trade Organisation in Nanotechnology Regulation' in G Hodge, D Bowman and K Ludlow (eds), *New Global Frontiers in Regulation: The Age of Nanotechnology*, Monash Studies in Global Movements (Cheltenham, Edward Elgar Publishing, 2007). See also J Black, 'The Role of Risk in Regulatory Processes' (n 5) 314.

[28] For research on international cooperation in the area of nanotechnologies see for instance R Falkner and N Jaspers, 'Regulating Nanotechnologies' (n 26); GE Marchant, DJ Sylvester and KW Abbott, 'Risk Management Principles of Nanotechnology' (2008) 2 *NanoEthics* 43; L Breggin, R Falkner, N Jaspers, J Pendergrass and R Porter, 'Securing the Promise of Nanotechnologies—Towards Transatlantic Regulatory Co-operation' (Project of the London School of Economics and Political Science, Chatham House, the Environmental Law Institute and the Project on Emerging Nanotechnologies, 2009) www.chathamhouse.org/sites/files/chathamhouse/public/Research/Energy,%20Environment%20and%20Development/r0909_nanotechnologies.pdf.

EU Treaties, case law of the EU courts and the pertinent policy documents—following a classical legal methodology. Yet, this book will do this by embedding these processes in their societal context.[29] It thereby follows Snyder's vision of an 'EU law in context':

> So far, EC law has been conceived mainly as 'black-letter law', based on the exposition of legal doctrine and the analysis of judicial decisions. Now, however, it is time to draw upon perspectives from other social sciences and to move in new directions. We must place EC law in its social, economic and political context. Only in this way can we achieve the deeper and broader understanding—both practical and theoretical—of EC law that is required to meet the exciting challenges of our time.[30]

The merit of Snyder's plea has been demonstrated in the preceding introductory sections. In order to study the regulation of nanotechnologies, it seems crucial to comprehend its societal context. Or rather the other way around, the societal context largely determines whether or not a specific regulatory measure can at all be considered effective or legitimate. As well as the legal literature, therefore, this book also draws on insights from political science, sociology and, particularly, on the valuable contributions from science and technology studies. To gauge the general public opinion, it also looks to newspaper articles, reports or position papers drafted by affected societal actors. Furthermore, a handful of semi-structured qualitative interviews were conducted with representatives from the European Commission, EU agencies and stakeholders. These interviews, however, are not taken as a formal source of information. They are used to test assumptions made in this book and to enrich the theoretical study of legal procedures and mechanisms with a practical dimension of more anecdotal than evidential value.

D. Structure of the Book and Case Studies

Chapter one will set the scene for the ensuing theoretical and empirical chapters. Its first aim is to introduce the topic of nanotechnologies and the controversy surrounding it: what actually are nanotechnologies? The chapter subsequently moves to a further fundamental question: does one need to regulate nanotechnologies? After having established the presence of risk as a rationale for regulatory intervention, the chapter closes with a bird's eye perspective on the current EU regulatory developments in the area of nanotechnologies. This overview will serve as a reference—a point of orientation—for the more detailed analysis that will follow in the empirical part of this book.

In line with the 'EU law in context' approach, chapter two opens by considering three concurrent societal transformations—those of globalisation, functional

[29] R Van Gestel and HW Micklitz, 'Why Methods Matter in European Legal Scholarship' (2013) 20 *European Law Journal* 292, 298.

[30] FG Snyder, *New Directions in European Community Law*, Law in Context (London, Weidenfeld & Nicolson, 1990) 2.

differentiation and the rise of the risk society. These societal transformations, it is argued, are exemplified by the emergence of nanotechnologies. Chapter two then introduces two theoretical approaches, Habermas's discourse theory of law and democracy and Teubner's theory of reflexive law, that offer a normative answer to the research question, how should the EU institutions respond to the rise of nanotechnologies. A synthesis of the two approaches will suggest that, in modern societies, the regulator, on its own, increasingly lacks the capacity to master the diffused knowledge and to ensure the legitimacy of its regulatory activities. Close involvement by affected societal actors in the regulatory process is proposed in order to strengthen regulatory capacity. The theoretical approaches not only help to structure the subsequent empirical part, they also put this book into the context of the ongoing scholarly debate. The last section of this chapter will analyse how these societal transformations and theoretical considerations have influenced the discourse on regulation in the EU context. This will constitute an intermediate step between the normative ideas set out in the theoretical accounts and the empirical analysis of the case studies. It will be shown that a reform process was launched towards the end of the 1990s under the label of 'European governance' or, in EU scholarship, 'new governance' with the aim of increasing the EU's capacity to regulate.

Chapter three, with the theoretical foundations of chapter two at its roots, subsequently defines the scope of the empirical analysis in the case studies. To this end, it first delineates the object of analysis—the *what*—by laying down this book's understanding of 'EU regulation'. Thereafter, the chapter establishes the lenses through which the EU regulation of nanotechnologies will be analysed—the *how*. The analytical lenses will be those of 'regulatory capacity'. Regulatory capacity will comprise the two elements identified in the theoretical sections of chapter two, *viz*. the capacity to master the dispersed knowledge and the capacity to ensure legitimate regulation. Chapter three aims to define these elements. It then identifies the 'tangible impacts' of the governance debate, the legal procedures that the EU institutions have put in place in order to achieve these elements—to pool knowledge and ensure legitimacy, ultimately in order to increase the institutions' capacity to regulate.

It is then left to the empirical part, that is, chapters four and five, to test the applicability and practical operation of these legal procedures in two case studies. Whilst a brief description of the EU's overall approach to nanotechnologies was given in chapter one, due to the cross-sectoral range of potential applications of nanomaterials it is impossible to achieve the necessary analytical depth by continuing with a holistic approach. Instead, the regulatory developments in two sectors affected by nanotechnologies are selected as test cases. The food and chemicals sectors have been considered most suitable for these purposes.

The food sector has been selected mainly due to the particular public sensitivity dominating this area.[31] As the consumption of food plays a fundamental and

[31] Q Chaudhry, L Castle and R Watkins, 'Nanotechnologies in the Food Arena: New Opportunities, New Questions, New Concerns' in Q Chaudhry, L Castle and R Watkins (eds), *Nanotechnologies in Food*, RSC Nanoscience & Nanotechnology no 14 (Cambridge, Royal Society of Chemistry Publishing, 2010) 5.

tangible role in people's lives, new technologies in the food sector often meet with scepticism.[32] Nanotechnological applications in food are no exception.[33] Additionally, the food sector has been burdened by several recent food scares. Regulators, stakeholders and the general public are already on the alert, which puts great pressure on the EU institutions to act. It is therefore hardly surprising that EU food legislation is among the first pieces of legislation to contain nano-specific provisions.

The selection of the chemicals sector as the second case study was almost imperative. The EU's legislative framework for chemicals—the Registration, Evaluation, Authorisation and Restriction of CHemical substances (REACH)—is widely considered to constitute the cornerstone for the regulation of nanomaterials as the 'data generated under REACH will serve as input to other regulation'.[34] This is because the chemical sector's output constitutes the manufacturing basis for many other sectors, including the food industry. Furthermore, the regulation of nanotechnologies in REACH will be an instructive case to compare to the food sector. On the one hand, the two sectors are regulated by a similar institutional set-up. In both cases an independent EU agency was created to provide the process with scientific and technical advice. Both sectors also constitute key industries in the EU economy. On the other hand, the comparison of these two sectors will benefit from a chronological asymmetry. While EU food legislation was among the first EU regulatory frameworks to contain nano-specific provisions, REACH has been under review more recently. It will be telling to see whether differences in approach are visible and, if so, what these differences are.

The final chapter, chapter six, contains concluding remarks. It will be seen that this book walks a tightrope between the well-meaning rhetoric of a more inclusive, transparent and expertise-based regulation, often captured under the term 'new governance' in EU scholarship, and the actual applicability and operation of the legal procedures established for these purposes. Rhetoric and practice, it will be shown, diverge substantially. This book hence separates normative ideas from empirical reality, thereby revealing not only significant shortcomings in the application of the procedures by the EU institutions but also in their design, ultimately questioning their very rationale in the face of this book's theoretical foundations.

[32] Science and Technologies Committee, *Nanotechnologies and Food* (HL 2009–10, 22–I) 5.

[33] International Risk Governance Council, 'Policy Brief—Appropriate Risk Governance Strategies for Nanotechnology Applications in Food and Cosmetics' (2009) 11 www.irgc.org/IMG/pdf/irgc_nanotechnologies_food_and_cosmetics_policy_brief.pdf.

[34] European Commission, 'Regulatory Aspects of Nanomaterials' (n 25). This is also the view of the European Commission in its second regulatory review on nanomaterials, see European Commission, 'Second Regulatory Review on Nanomaterials' (Communication) COM (2012) 572 final, 11.