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## NOT ANOTHER GMO

Explaining Europe's Approach to  
Nanotechnologies

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Nico Jaspers

No. 44 | September 2012



Freie Universität



Berlin

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**KFG Working Paper Series**

**Edited by the *Kolleg-Forschergruppe* “The Transformative Power of Europe”**

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Jaspers, Nico 2012: Not Another GMO. Explaining Europe’s Approach to Nanotechnologies, KFG Working Paper Series, No. 44, September 2012, Kolleg-Forschergruppe (KFG) “The Transformative Power of Europe” Freie Universität Berlin.

ISSN 1868-6834 (Print)

ISSN 1868-7601 (Internet)

This publication has been funded by the German Research Foundation (DFG).

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# NOT ANOTHER GMO

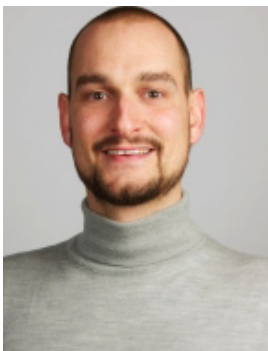
## EXPLAINING EUROPE'S APPROACH TO NANOTECHNOLOGIES

Nico Jaspers

### Abstract

Despite early warnings about “knowledge-enabled mass destruction” and the ongoing battle over agricultural biotechnology, the development of nanotechnology in Europe has been remarkably quiet over the past decade: non-governmental organization (NGO) campaigns against “nano” were all but inexistent and the wider public appears largely uninterested in nanotechnology. Why has Europe's experience with nanotechnologies been so fundamentally different from that with genetically modified organisms (GMOs)? This article argues that differences in the technologies as such cannot fully explain this divergence. Instead, a convergence of interests across key groups of stakeholders, the institutional evolution of the European Union (EU) and the experience from the GMO case enabled and facilitated a highly anticipatory and proactive approach to nanotechnology risk governance. This approach, marked by early capacity building, stakeholder involvement and gradual regulation succeeded in avoiding public polarization and in promoting a responsible development of nanotechnologies.

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## 1. Introduction

Around the turn of the millennium, the emergence of nanotechnologies was accompanied by a series of hyperbolic statements that were reminiscent of the controversy over agricultural biotechnologies. Policy makers, scientists and a number of industry representatives portrayed nanotechnologies as the “next big thing” leading to a new era of socio-economic progress. Ray Kurzweil, a prominent futurologist, predicted that through nanotechnology, mankind can “overcome age-old problems, including pollution, poverty, disease, and aging” (Kurzweil 2003: 17). Mihail Roco, the architect of the US nanotechnology program, argued that nanotechnology will trigger the “next industrial revolution”, generate products worth one trillion dollars and employ two million workers by 2015 (Roco/Bainbridge 2001). The European Parliament speculated that nanotechnology will enable mankind to “get rid of all the waste accumulated up to now” (European Parliament 2001: 16-17).

This enthusiasm was not universally shared and some commentators instead saw the possibility of self-replicating nano-sized structures (“grey goo”) as a threat to the existence of mankind. Bill Joy, the co-founder of Sun Microsystems, argued that “superior competitors” to the human species would cause “knowledge-enabled mass destruction” (Joy 2000: n.pag.) – a scenario that was vividly portrayed in Michael Crichton’s 2002 *New York Times* bestseller *Prey*. Perhaps inspired by warnings that “proponents of nanotechnology are seeking new ways to control the rest of the earth” (ETC Group 1999: 43), a member of the Greens/European Free Alliance, an environmentally-oriented collection of parties in the European Parliament, argued that “the most immediate priority is to prevent those who have the most to gain – big business – from beating the regulation race” (Cordis News 2003a: n.pag.).

Nanotechnologies combine a set of qualities that make them particularly vulnerable to public polarization. They enable the manipulation of matter at the molecular level and the production of materials with entirely new physical and chemical properties. These properties can be used to build, for instance, inexpensive water purification systems, self-assembling organic solar cells, nano-encapsulated nutrients, high-efficiency fertilizers, artificial retinas, photothermal cancer therapy and other revolutionary applications. At the same time, the “invisible” technology comes with profound uncertainties about environmental, health and safety risks. Some nanotubes, for example, share important toxicological similarities with asbestos fibers and nanosilver has caused much concern over potential biocidal effects (ICON 2008). Other nanomaterials can enter the human body – an ability that also makes them interesting for medical applications – and migrate via the bloodstream to vital organs, including the brain. Some can enter cells, interact with their molecular structure and have cytotoxic or genotoxic effects.

Beyond potential risks to human health and the environment, some stakeholders have expressed ethical concerns over the application of nanotechnologies for human enhancement and brain-to-brain or brain-to-machine interfaces that blur the line between human and artificial life; the patenting of fundamental building blocks of life and the role of private corporations therein; and the use of nanotechnologies for military and surveillance purposes (e.g. Altmann 2004; Sandler 2009). Nanotechnologies are being developed in virtually every industrial sector and their most avid proponents come from the military-industrial complex, chemical multinationals, the pharmaceutical sector, cosmetic firms, the food and drink industry, information technology developers and a range of other global industries. Put succinctly, nanotechnologies

amalgamate tremendous commercial and societal potential with uncertain risks and ethical concerns, and thereby produce a regulatory terrain that is rapidly becoming a political minefield.

Considering the experience in Europe with GMOs, the hype and fear surrounding nanotechnologies appeared set to cause a ferocious debate about the role of technology in society. Contrary to what one might have expected, however, the development of nanotechnologies in Europe over the past decade has been remarkably uncontroversial, has not caused much political polarization and is finding its way into an increasing range of products without much public concern. Media reports about nanotechnology risks are few and far between; civil society and NGOs have largely refrained from campaigning against nanotechnologies and often engaged with industry and regulators on a constructive and technical level; Member State initiatives to “regulate nano” are all but inexistent; less than half of Europeans know what nanotechnologies are and only a small fraction of the public is aware of risks (Gaskell et al. 2010); and industry representatives appear to accept – though perhaps not always support – a proactive regulatory approach.

Why has the development of nanotechnologies been so remarkably quiet and why has nano not become Europe’s “new GMO”? This article explores the development of nanotechnologies in Europe over the past decade and argues that a convergence of interests across key groups of stakeholders, the institutional evolution of the EU and the learning from the GMO case enabled the European Union – in particular the European Commission – to follow a remarkably proactive and anticipatory approach to risk governance that avoided the intricate choice between an overly precautionary and an overly reactive approach to technology risks under uncertainty. Due to the novelty of the issue and the still emerging research area of anticipatory risk governance under uncertainty, this paper is exploratory in nature and seeks to introduce the subject of nanotechnology risk management to a wider audience in the public policy arena. Since theoretical frameworks on risk regulation are often driven by practical experience rather than the other way around, this article seeks to investigate whether and in what form Europe’s experience with nanotechnology provides new insights into our understanding of risk governance approaches.

The remainder of the article is structured as follows. The second section explores similarities between agricultural biotechnology and nanotechnologies in their potential to incite public concern. It argues that scientific differences cannot explain the different trajectories of GMOs and nanotechnologies. The third section turns to the past decade of nanotechnology policy in Europe and outlines key events related to agenda setting, information gathering and decision-making processes over that time. Based on this empirical insight, the fourth section then extracts the causal mechanisms behind Europe’s nanotechnology policy. It explains how the institutional evolution of the EU, a convergence of interests among stakeholders and learning processes among key actors enabled the European Commission, jointly with other institutions, to follow a risk governance strategy marked by foresight, capacity building and gradualism that in retrospect turned out to be a rather successful example of how to manage risk under uncertainty. Section five provides some concluding remarks.

## 2. Frankenfoods and Grey Goo: Why Nano could have been another GMO

From a scientific point of view, the ability to genetically modify organisms and the ability to manipulate matter at the nanoscale have little in common beyond the fact that both are revolutionary new technologies. From a public policy point of view, however, nanotechnologies and green biotechnology share some important features. This section discusses these similarities and argues that the scientific and technological differences between agricultural biotechnology and nanotechnologies as such cannot fully explain why the former has attracted so much public controversy but not the latter. The section discusses four key areas of similarity: scientific uncertainty and technical complexity; ethical concerns; risk-benefit relations; and industry structures and interests.

### *Scientific Uncertainty*

Scientific uncertainty about risk is among the most widely cited circumstances for the EU's decision to impose a *de facto* memorandum on the approval of GMOs in the late 1990s (Myhr/Traavik 2002). Uncertainty about whether GMOs can transfer their genetic material to other organisms, whether GMOs introduce new pathogens into the natural environment and whether potential unintended consequences can be controlled led to considerable public concern – fomented by campaigns from NGOs and green parties – and pressured the EU to act precautionary (Van Asselt/Vos 2008).

Scientific uncertainty surrounding nanotechnology risk in many ways exceeds uncertainty on GMO safety. It also increasingly resembles a Hydra-like creature where answering one question often produces more uncertainty than it solves. The discovery that the particular shape and length of a nanotube can affect its toxicity, for instance, has led researchers to wonder whether this is only true for multi-walled, carbon-based tubes or also for single-walled, metal-based ones. Similarly, the fact that different nanomaterials can agglomerate and change over their life-cycle led researchers to wonder whether and how the toxicological profile of incidental new composites develops over time. The adequacy of protective equipments, potential exposure scenarios, the translocation of particles within the human body and the accuracy of measurement and detection instruments, among others, provide further sources of uncertainty.<sup>1</sup>

### *Ethical Concern*

A second rationale for precautionary risk management on green biotechnology relates to ethical concerns over tinkering with the building blocks of life (Wynne 2001). Terms such as “Frankenfoods” have stigmatized GMOs as a frightening and uncontrollable technology in a sector that has experienced a history of scares, ranging from the use of growth hormones in beef production to the BSE scandal, various instances of salmonella and dioxin contaminations and avian flu (see e.g. Knowles et al. 2007).

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<sup>1</sup> A recent overview of the state of research on nanomaterial (eco)toxicology is provided by EASAC and JRC (2011).

Nanotechnologies have an equally emotionally-charged history, albeit not in terms of concrete scares but as a result of science fiction stories. Already in 1986, Eric Drexler envisioned an end-of-world scenario where self-replicating microscopic robots produce “grey goo” that consumes all matter on earth and threatens the existence of mankind (Drexler 1986). Such concerns found resonance in the late 1990s and early 2000s, most notably in the prediction that “superior competitors” to the human species could cause “knowledge-enabled mass destruction” (Joy 2000: n.pag.). Nanotechnologies in the late 1990s provided ample room for ethical concern and emotionally-charged scenarios about uncontrollable risks. Perceived as an “invisible” technology, it is difficult to understand but can have profound implications on everyday life and involves the restructuring of the world from the bottom up.

### *Risk-Benefit Relations*

A third potential explanation for European policies on GMOs relates to the notion – often put forth in campaigns by environmental groups – that the expected benefits of agricultural biotechnology do not justify its potential risks. Considering the degree of uncertainty involved with estimating the long-term effects of new technologies, it is usually difficult to either prove or disprove such claims conclusively. However, having been portrayed as no less than a struggle between world salvation and world destruction, nanotechnologies provide considerable room for inflated perceptions of both risk and benefits and thus easily lend themselves to similar narratives as was the case with green biotechnology.

### *Industry Structure*

Finally, another widely-cited source for Europe’s skepticism towards GMOs relates to the somewhat peculiar structure of the GMO industry, which throughout the 1990s was dominated by only a handful of multinationals with Monsanto, a US chemical company and seed producer, at the forefront. The image of a US conglomerate that uses aggressive business practices, political connections and intensive lobbying to force the adoption of a controversial technology upon European farmers provided a formidable campaign tool for a collection of environmental activists and critics of globalization. Nanotechnology’s most avid developers can be found within the military-industrial complex, chemical multinationals, the pharmaceutical sector, cosmetic firms and the food and drink industry – sectors that have attracted a fair share of public criticism over the past decades. The “nanotechnology industry” is thus equally vulnerable to caricature and public opposition.

In sum, as much as green biotechnology and nanotechnologies differ from a scientific point of view, they share many aspects from a public policy point of view: considerable scientific uncertainty about the nature and extent of risks; the potential of apocalyptic scenarios to trigger public polarization; the scope for hyperbolic and distortionary depictions of ethical risks and benefits; and an industry structure experienced with public controversy and NGO campaigning. It is difficult to explain why the development of green biotechnology and nanotechnologies has been so markedly different merely by considering the technologies



themselves. Instead, a deeper look at the political environment of nanotechnology development over the past decade in Europe is needed.

### **3. Nanotechnology in Europe: Three Phases of Policy Development**

This section provides an overview of nanotechnology policy and development in Europe over the past decade, divided into three phases: the agenda-setting phase, the information gathering phase and the decision-making phase. These different phases, loosely derived from standard policy-cycle models (e.g. Anderson 1975), describe leading themes at each stage of policy development but do not represent a sharp and definite categorization of policy steps.

#### *The Agenda-Setting Phase*

During the first phase of nanotechnology policy, from the late 1990s to the early 2000s, nanotechnologies were just emerging from the laboratories in Europe and applications were mostly still in experimental form. Few nano-enabled products existed aside from the odd application in electronics and sunscreens. Patents had yet to be turned into products on a notable scale, public awareness of nanotechnology was low and concern about nano risks was virtually nonexistent among the wider public. Outside the science and technology promotion bodies at the European level and at Member State level, few policy makers were familiar with nanotechnologies. Yet, this relative calm belied a flurry of activity by the European Union, Member States and civil society organizations.

At the turn of the millennium, the EU decided to become a key player in nanotechnology research and development. It increased its funding on nanotechnologies from about €45 million per year between 1998 and 2002 to a total of €1.3 billion between 2002 and 2006. It framed this investment as a strategic move to strengthen European competitiveness under the “Lisbon Agenda” and as part of an effort to establish a “European Research Area” (European Commission 2002). Shortly after it was established as a strategic policy area, however, nanotechnology development started to attract controversy.

The European Parliament set the stage in early 2003 with a gathering where Caroline Lucas, a member of the European Parliament from the British Green Party, worried that “innovation is running ahead of regulation” (Cordis News 2003a: n.pag.). This claim was echoed by participants calling for a moratorium on nanotechnology research and use. As much as a moratorium frightened researchers and industry, fears about nanotechnology safety were not entirely unfounded. Soon after the meeting, Greenpeace published a report that described how nanoparticles might be able to penetrate living cells and accumulate in organs, and that nanotubes and asbestos fibers might share some important structural similarities (Arnall 2003).

In Member States, different institutions became interested in nanomaterial safety as well. The German Parliament’s Office of Technology Assessment (TAB) in 2003 also highlighted potential health effects of

nanotubes that resemble asbestos fibers; called for more research on the societal effects of nanotechnologies; criticized the state of knowledge on environmental and health effects of nanotechnologies; called for a review of regulatory frameworks for nanotechnologies and for a program to “monitor” applications of nanotechnologies for regulatory purposes; and criticized that uncertainty on environment and health risks may inhibit the successful commercialization of nanotechnologies (Paschen et al. 2003). These claims were echoed by other institutions, including the German Association of Engineers (VDI) (Luther 2004), the UK Health and Safety Executive (HSE) (Aitken et al. 2004: vi) and the insurance company Swiss Re (Hett 2004).

In June 2003, the United Kingdom (UK) Government asked the Royal Society and the Royal Academy of Engineering (RS&RAE) to take a closer look at nanotechnology risks and the potential regulatory implications. Ann Dowling, the chair of the RS&RAE working group argued that, “[i]t is important that we get the regulation of nanotechnology right while the field is still in its infancy” (Dowling 2003: n.pag.). The resulting report marked a watershed in the debate. It dismissed concerns about self-replicating nanobots and instead systematically described possible adverse impacts of nanotechnologies on human health and the environment when nanomaterials cross the blood-brain barrier and other natural defense mechanisms of the human body in the skin, gut and lungs. The report concluded that nanoparticles should be treated “as if they were hazardous” and should be regulated as new substances (RS&RAE 2004: 71).

Amidst this concerted effort to push nanomaterial safety on the agenda, Renzo Tomellini, the head of the Commission’s nanotechnology promotion program, worried that nanotechnologies have become a “show piece” for expectations and hopes but also for “polemics and fears” (Cordis News 2003b). As one of the largest investors in nanotechnologies, the Commission had much to lose from a repeat of the GMO saga and responded quickly to emerging concerns. In 2004, it promised a “timely” regulation of nanotechnologies, a “re-examination and possible revision” of existing legislation, and a “global agreement on base principles for the responsible development of nanotechnologies” (European Commission 2004a: 23). The Health and Consumers directorate also entered the fray and asked experts about their opinion on nanomaterial safety. The response was that “some engineered nanoparticles [...] may have the potential to pose serious concerns” (European Commission 2004b: 11); that nanotoxicity cannot be derived or predicted from known toxicity of bulk materials; that a new Chemical Abstract Service (CAS) registry number should be assigned to manufactured nanoparticles; that institutions to monitor nanotechnologies should be established; and that existing regulations should be revised whenever appropriate.

Within merely three years, nanotechnologies were transformed from an obscure issue into a matter of strategic importance, and nanomaterial safety was turned from an esoteric science fiction scenario into a new field of (eco)toxicology that was subject to considerable regulatory scrutiny.

### *The Information-Gathering Phase*

The broad agenda for nanotechnology development in Europe was set by around 2004: Risks and regulatory questions have to be taken seriously to turn nanotechnologies into a success. The subsequent phase in nanotechnology policy thus focused on the question of what exactly those risks were and what the regulatory consequences of these risks could be. The European Commission rapidly established itself as the key actor on these questions. In 2005, it published an “action plan” in which it called for a “code of conduct” for the responsible development and use of nanotechnology and reiterated the need for more international cooperation, especially in nomenclature, metrology, common approaches to risk assessment and the creation of a database to share toxicological and ecotoxicological as well as epidemiological data (European Commission 2005; Tomellini/Villepin 2005).

To implement this strategy, the Commission started a four-year “Nanosafe 2” project to develop risk assessment and risk management methodologies for a safe development of nanotechnologies in 2005. The Commission’s Committee on Emerging and Newly Identified Health Risks (SCENIHR) also commented on nanotechnology safety and in 2006 argued that existing (eco)toxicological methods may not be adequate to assess risks related to nanoparticles. It further criticized uncertainties with regard to regulatory requirements, in particular guidelines, for risk assessment, and the focus on mass instead of particle size in existing regulations (SCENIHR 2006). Later, however, SCENIHR added that, “the selection of the size limits associated with the prefix ‘nano’ [...] is somewhat arbitrary” and that specific size ranges do not automatically imply greater toxicological, public health or environmental health concern (SCENIHR 2007: 3). Echoing the warnings by SCENIHR, the Commission’s Scientific Committee on Consumer Products (SCCP) argued that for insoluble nanoparticles, conventional risk assessment methodologies may not be adequate (SCCP 2007).

In addition to better understanding the nature of uncertainty, the Commission started to fund civil society capacity building projects, including “Decide”, to conduct and facilitate deliberative democracy debates on nanotechnology policy; “Deepen”, to address ethical issues in nanotechnologies and to engage civil society in relevant debates; “Messenger”, to support informed debate between scientists, journalists and civil society that are involved in producing media coverage of nanotechnology-related risks; “Nanobioraise”, to combine ethics research in nanobiotechnology with science communication; “Nanocap”, to build relevant capacities at NGOs; “Nanodialogue”, to raise public awareness of latest developments in nanotechnologies and to inform the Commission about societal concerns; “Nanologue”, to encourage multistakeholder dialogue on social, ethical and legal aspects of nanotechnologies; and “Path”, to foster participatory processes in science and technology policy (Hullmann 2008).

Amidst these activities, civil society organizations also became more involved with nanotechnology safety. The Alliance of Social and Ecological Consumer Organisations (ASECO) in 2006 called for the application of the “precautionary principle”, labeling provisions and a revision of EU regulatory frameworks “in parallel with science and experience” (ASECO 2006: 4). Vivagora, an NGO that organized debates on scientific and technological innovations, started to organize a series of public debates in France on the role of nanotechnologies in society. In 2007, the UK’s Soil Association, an environmental NGO that certifies organic food, announced that it has developed a standard that bans nanoparticles from organic food (Smithers 2008).

The UK consumer organization “Which?” also organized a citizen’s panel, which was generally in favor of further developing nanotechnologies but stressed the importance of consumer choice and the labeling of nano-enabled products (Which? 2007). These engagements, however, were accompanied by relatively low public interest in the debate with less than half of Europeans having heard about nanotechnology (Gaskell et al. 2006).

In Member States, different institutions expanded their activities on nanotechnologies. The UK’s Institute of Food Science and Technology (IFST) proposed a labeling scheme for nanomaterials in food (IFST 2006); the UK’s Food Standards Agency (FSA) identified gaps and uncertainties in EU food and feed legislation (FSA 2006); the UK Department for Environment, Food and Rural Affairs (DEFRA) launched a voluntary reporting program for industry (DEFRA 2006); and the German Federal Institute of Risk Assessment (BfR), the Federal Environment Agency (UBA) and the Federal Institute for Occupational Safety and Health (BAuA) proposed research strategies to assess the environmental and health risks of nanoparticles (Orthen et al. 2007).

The BAuA also collaborated with the German Chemical Industry Association (VCI) to develop guidance documents on safe handling and use of nanomaterials (BAuA/VCI 2007). In 2006, Germany also started the “NanoCare”, “Tracer” and “INOS” projects to establish a scientific foundation for nanomaterial safety assessment (NanoCare), characterization of CNTs (Tracer) and developing in-vitro test methods (INOS). In 2006, the French Agency for Environmental and Occupational Health Safety (AFSSET) recommended that the EU should work towards a global harmonization of nanotechnology-related regulation (AFSSET 2006). Subsequently, the National Center for Scientific Research began looking at nanomaterials risks (CNRS 2007).

Meanwhile, members of the European Parliament (MEPs) from the Greens/European Free Alliance unsuccessfully sought to change the chemical regulation REACH to treat all nanomaterials as substances of very high concern and to require elaborate safety assessments and complex authorization procedures due to the “very worrying adverse effects by nanoparticles” (European Parliament 2006a: 55). This request came amidst a statement by the German Federal Environment Agency (UBA) that “gaps in the statutory treatment of nanomaterials exist [...] with regard to REACH, where it is particularly questionable whether the quantity thresholds necessary to trigger registration will be attained [...]” (Führ et al. 2006: 25); and amidst a statement by the European Parliament’s Committee on Industry, Research and Energy (ITRE) that the Commission and the Council should “remove any roadblocks in the form of lack of standards and unclear legislation” that hinder the successful development of nanotechnologies in Europe (European Parliament 2006b: 5).

The “nanotechnology industry” kept a relatively low-key profile during these debates. The CIAA<sup>2</sup>, a European food and drinks industry association, asked EFSA to evaluate the safety of titanium nitrate nanoparticles for use as an additive in PET packaging and EFSA found no risk for such applications (EFSA 2008). The chemical industry strongly favored using the yet-to-be implemented new chemical regulation, REACH, to cover nanomaterials. It argued that instead of discussing a new “nano regulation”, efforts should focus

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<sup>2</sup> The Confédération des Industries Agro-Alimentaires de l’UE (CIAA) changed its name to “FoodDrinkEurope” in June 2011.

on definitions, safety research, test guidelines and protocols. Overall, industry actors appeared reluctant to question the need for regulatory policy and instead highlighted the importance of gradually creating meaningful regulatory frameworks that do not hinder innovation and product commercialization. Official statements by industry representatives during this period were few and far between, but EU officials captured what many companies thought: “Uncertainties by the general public about health, safety and environmental effects can restrict available capital and prevent companies from launching products involving nanotechnologies” (European Parliament 2006b: 10). Or, as Janez Potocnik, the former Commissioner for science and research, argued:

*“If the full potential of nanoscience is to be exploited, [...] public concerns must be taken into account, whether or not they are believed to be justified. If Europe does not address problems early on, they will come back later with more force.”* (Cordis News 2006)

This assessment of the situation was a consensus shared across the different branches of the Commission. The Commissioner for Industry, for instance, argued that a “reliable and stable regulatory framework” could be a tool to increase competitiveness; the Commissioner for the Environment highlighted the “regulatory challenge” of “ensuring a high level of protection of health, safety and the environment”; the Commissioner for Health and Consumers stressed the importance of stakeholder involvement; and the Commissioner for Employment and Social Affairs stated that “we must make sure that any potential risks to workers’ health and safety are properly addressed” (European Commission 2008b: n.pag.).

Seeking to follow a proactive approach without hastening into changing regulations prematurely, the Commission in 2008 decided that, “current legislation covers to a large extent risks in relation to nanomaterials [... but] may have to be modified in the light of new information becoming available” (European Commission 2008a: 3). It also published a *Code of Conduct* to address the safe handling of nanomaterials in basic research (European Commission 2008c) and reviewed the regulatory coverage for nanomaterials in a range of legislative areas, including chemicals and worker protection; agricultural, medicinal and consumer products; and environmental protection. It concluded that this legislation could be implemented with regard to nanomaterials by the

*“[...] setting of thresholds, authorisation of substances and ingredients, qualifying waste as hazardous, reinforcing conformity assessment by reclassification, introducing restrictions on the marketing and use of chemical substances and preparations, etc. through ‘Comitology’ procedures.”* (European Commission 2008a: 9)

By the end of the second phase, the European Commission established itself as the dominant actor on nanotechnology policy. It was the largest investor in nanotechnology research and development, guardian of regulatory policy and a key funding body for risk assessment.

### *The Decision-Making Phase*

After a relatively calm debate between 2004 and 2008, the third phase of nanotechnology policy became more controversial as the ongoing risk assessment projects produced some worrying results. In 2009, SCENIHR argued that proper risk assessment suffers from limited knowledge on methodologies for exposure estimations and hazard identification (SCENIHR 2009). At the same time, EFSA claimed that relevant data for risk assessment are “extremely limited” and “any individual risk assessment is likely to be subject to a high degree of uncertainty” (EFSA 2009: 2). A year later, the UK’s House of Lords Science and Technology Committee argued that there are “certain ‘grey areas’ where products containing nanomaterials may slip through the regulatory net” and that “due to the large gaps in the scientific understanding of nanomaterials, it was not yet possible to assess properly their safety in many cases” (House of Lords 2010: 6).

In light of these findings, civil society organizations became increasingly vocal. Friends of the Earth called for a moratorium on the use of nanomaterials in the food sector until “nanotechnology-specific safety laws are established and the public is involved in decision making” (Miller/Senjen 2008: 3). Similar demands were voiced by the Dutch Society for Nature and Environment and other Dutch environmental and consumer organizations (Nanoforum 2008a; Nanoforum 2008b). The European Trade Union Confederation (ETUC) called for the closing of “several loopholes” in relevant EU legislation and “proper legislation” for nanotechnologies (ETUC 2009: n.pag.). The European Environmental Bureau (EEB), a federation of environmental organizations, wanted a “strict regulatory framework” and a “pre-market registration and approval framework” (ETUC 2009: n.pag.).

Other NGOs, including Aseco, the Soil Association and Greenpeace, called for precautionary approaches, the labeling of consumer products, mandatory pre-market safety assessments and a revision or significant amendment of existing regulatory frameworks (EurActiv 2009b). In Grenoble, France, opponents of nanotechnologies made it impossible to hold a debate on nanotechnology and society (Nanoforum 2009) and the Special Commission for Public Debate (CPDP) had to cancel similar debates after interruptions by protesters who argued that “nano” is “totalitarian” (McAlpine 2010).

In part to counter such polarization, the European chemical industry association CEFIC started a “nano dialogue” on nanomaterial risk with different stakeholders in 2008 to “avoid confusion or misunderstanding, due to situations where people make judgements based on limited information” (Malsch 2008: n.pag.). The highest ranking health official at the Commission, Robert Madelin, meanwhile criticized the use of “panic” by some civil society organizations to attract attention as irresponsible and expressed his frustration with conflicting messages from industry and civil society (EurActiv 2009a). He further argued that part of the consumer movement does not have adequate expertise in the area of nanotechnology to support honest debate (EurActiv 2009a). At the same time, he also tried to encourage retailers to more fully engage with the public to better explain the risks and benefits of nanotechnology applications – a request that was met with skepticism by retailers (EurActiv 2010).

A somewhat fragmented position towards nanotechnology policy across the industry became more apparent after 2008. Some industry representatives, for instance, saw the Commission’s *Code of Conduct* as an “effective hybrid regulation mechanism”, while others argued that it is “totally unnecessary” (European

Commission 2009b: 5). Industry representatives also appeared to firmly favor the adaptation of existing legislation over specific “nanotechnology legislation” (O’Hagan 2007). However, a survey by the Commission showed that a majority of industry representatives were favorably disposed towards a new nano regulation and only 30 percent were strictly against it. The survey also showed that almost half of industry representatives was favorably disposed to consumer labeling provisions (less than 15 percent opposed) (European Commission 2010).<sup>3</sup> The chemical industry clearly did not share this view and reiterated its opposition to labeling schemes and nano-specific regulations, and instead worried about loopholes in the implementation of chemical regulations for importers who “in several cases do not meet the correct standards” (EurActiv 2009c: n.pag.).

Amidst uncertainty about safety, greater involvement of civil society and unclear preferences of industry, the European Parliament stepped in and adopted a resolution in 2009 in which it “deplores the absence of a proper evaluation of the *de facto* application of the general provisions of Community law”; requests the Commission to carry out another review of legislation; and calls for the labeling of nanomaterials in consumer products and “stringent ethical guidelines” (European Parliament 2009: n.pag.). The resolution was based on a report by Carl Schlyter, a Swedish Green MEP (Schlyter 2009), who saw his work as “more than a wake-up call for the Commission and the chemical industry” (EurActiv 2009d: n.pag.).

Following this resolution, the Parliament started to systematically introduce nano-specific regulatory amendments. In March 2009, it approved the recast of the EU cosmetics legislation, which created reporting requirements for users of insoluble nanomaterials and mandates the labeling of such materials for cosmetic products (European Commission 2009a: 65) – a move that was widely applauded by NGOs but opposed by Germany who worried that labeling “might be misunderstood by consumers as a warning” (European Council 2009: 2). It was murmured that the cosmetics industry ultimately accepted the labeling provision in order to avoid more extensive pre-market authorization requirement.

The Parliament also planned to introduce nano-specific language and risk assessment requirements for biocidal products (European Parliament 2010b) and electronic equipment. In the latter case, the Parliament’s environment committee (ENVI) proposed to ban the use of nanosilver and carbon nanotubes in electrical and electronic equipment as it deemed the use of nanosilver in such equipment “superfluous” and argued that carbon nanotubes “can have asbestos-like properties” (European Parliament 2010a: 98). An attempt by ENVI to ban foods produced by nanotechnology processes “until they have undergone specific and adequate risk assessments” (European Parliament 2010c: n.pag.) was rejected by the Commission (European Commission 2009c) and the European Council (2010).

The pace of these changes caught some observers by surprise. The scope of the new tools introduced or proposed – from labeling requirements to authorizations, bans, product registers and others – provided the Commission with extensive authority to delay or restrict the marketing of certain products. The Commission meanwhile, partly in reaction to the Parliament’s activities, started to follow a more proactive approach. The European Chemical Agency (ECHA) announced a reconsideration of how nanomaterials are

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3 It should be mentioned though that the survey relied on the self-identification of stakeholder groups so that the correct interpretation of the preferences of each group depends on accurate self-identification.

regulated in mid-2009 and ECHA Executive Director Geert Dancet argued that a review of REACH's coverage of nanomaterials will be conducted and that this will lead to "nanomaterials [being] covered in a more systematic way" after 2012 (Breggin et al. 2011: 228).

Some Member States also started to become more active. In late 2010, the Belgian EU Presidency proposed mandatory consumer labeling of nanotechnologies and a register for nanomaterials under the REACH regulation (EurActiv 2010). Not wanting to wait for European action, the French government adopted a new set of environmental legislation, the "Grenelle II Act", in June 2010, which stipulated a mandatory reporting requirement for "nanoparticulate substances" (OECD 2010: 30-31). In Germany, the Green Party introduced a law into their national Parliament that would ban all consumer products using nanosilver (Maisch et al. 2010).

The recall of a nanotechnology-based pump spray called "NanoCover" caused some controversy and media reporting in 2010. The Danish authorities ordered the recall of the German product, arguing that it contains a chemical – trioxytridecafluorsilane – that is toxic when inhaled (Rapex 2010). Similar to an earlier product recall in Germany for a nanotechnology-based glass and ceramic surface ceiling product, however, the identified risk appeared not to be directly related to nano-specific properties, but rather to the chemical identities of the product's ingredients (NIA 2010).

In part as a response to such events, a former official from the Commission's industry directorate argued that since the Commission has created considerable "hype" around the benefits of nanotechnologies, it must now also facilitate the commercialization of nanoapplications on the market. The development of strict but well-defined regulatory frameworks can contribute to securing public trust and thus increase the acceptance of nanoproducts (Brekelmans 2011).

The pressure on the Commission to find appropriate regulatory responses to nanomaterial risks amidst considerable uncertainty about whether a one-size-fits-all is feasible culminated in the dilemma of finding an appropriate legal definition for nanomaterials. In 2010, SCENIHR argued that there is "an urgent need to identify by clear unequivocal descriptions what can be considered as a nanomaterial" (SCENIHR 2010: 4). When attempting to do so, however, it ended up with a cumbersome 46-page discussion of what a definition should and should not entail, with the conclusion that even this elaborate discussion may need to be adapted to, "specific circumstances regarding risk assessment for regulatory purposes for certain areas and applications [...]" (SCENIHR 2010: 4).

The development of nanotechnologies in Europe over the past decade has been accompanied by a remarkable degree of activities at a technical level from regulators, scientists, academics, legal experts, industry associations, civil society and other stakeholders. Europe rapidly proceeded from acknowledging the importance of risks to creating the necessary capacities to understand these risks, and from acknowledging the importance of regulatory policy to better understanding how meaningful regulations can be designed and implemented. All the while, nanotechnology applications were developed with relatively little political polarization and public concern.



## 4. Explaining Europe's Nanotechnology Policy

This section synthesizes the three key factors that shaped Europe's nanotechnology policy: the institutional evolution of the EU, the convergence of interests among actors and learning processes both within the Commission and by external stakeholders.<sup>4</sup> While these factors are discussed separately in the following, they are closely interrelated. The institutional evolution of the EU with respect to risk assessment and risk management approaches, for instance, is both a cause and consequence of learning processes, which in turn affect stakeholder preferences and interests.

### *The Institutional Evolution of the EU*

As a political entity, the European Union experiences a constant process of structural and constitutional evolution. In the context of risk management practices, three developments are particularly notable: the EU's expanding role as a funding body for research and development, the expansion in risk assessment capacities and the linking of such capacities to regulatory policy and the ongoing revision of relevant legislation and the recast of directives into proper regulations.

Until the late 1990s, the EU was an important funding body for scientific research, but activities in Member States still dominated this policy area. With the goal to turn the EU into the "the most competitive and dynamic knowledge-driven economy by 2010" as part of the Lisbon Agenda (European Council 2000: n.pag) and the related increase in funding for primary research and development as part of the European Research Area, the EU became an increasingly autonomous actor in promoting scientific and technological development. This had three implications: First, nanotechnology development became a very concrete strategic issue to the EU and in particular to the European Commission's Research Directorate; second, the Commission increased its scientific capacity considerably; and third, the EU itself gained a stake in the successful development of nanotechnologies. Together, these factors implied that the importance of nanotechnologies for the EU as a political entity was significantly larger than was the case with earlier technologies including biotechnology. The Commission increased its planned investments in nanotechnology from about €45 million per year between 1998 and 2002 to €3.5 billion between 2007 and 2013, which turned the Commission into the world's largest funding body for nanotechnology research and development.

Over the past decade, the EU also underwent a small revolution in terms of risk assessment structures and capacities, in part driven by the controversy surrounding the regulation of GMOs. In 2002, it established the European Food Safety Authority, reformed the structure of its risk assessment activities and established three new scientific committees: the SCCP to assess the safety of consumer products; the Scientific Committee on Health and Environmental Risks (SCHER) to assess health and environmental risks; and the SCENIHR to assess emerging and newly identified risks. These changes were accompanied by a seeming

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<sup>4</sup> This section focuses on the empirics of how these factors shaped nanotechnology policy. There exists a vast and rapidly expanding literature on the theory of European institutional change (e.g. Béland 2009; Naurin/Rasmussen 2011), interest-based EU policy explanations (e.g. Knodt et al. 2011) and learning processes in the EU (e.g. Montpetit 2009; Kerber/Eckhardt 2007).

realignment of environmental and health policy away from a focus on precaution under uncertainty and more towards the active production of knowledge and information for regulatory purposes. The symbol of this change was the REACH regulation, which was first proposed in 2001 with a draft legislative proposal emerging in 2003. REACH was a revolution in chemicals regulation for it systematically mandated the registration and possible evaluation of chemical substances before they are marketed (see also EurActiv 2003). It has often been described as the largest and most important single piece of legislation the EU has ever enacted.

Finally, as part of the EU's mission to harmonize environment, health and safety (EHS) legislation across Member States if asymmetries impede the proper functioning of the common market, the EU also underwent a process of revising, updating and formalizing legislative recommendations, directives and regulations. This process enabled a proactive yet gradual approach to nanomaterial regulation as no new "nano law" would have to be constructed in order to slowly but steadily extend the regulatory coverage of nanomaterials. The most prominent examples of this process were the development of the REACH regulation, the recast of the cosmetics directive into a proper regulation, as well as the ongoing revision of food, waste, biocidal products and other regulations. In all these cases, the legislative barriers to adding nano-specific clauses to the final document were relatively low and turned the regulatory process into a somewhat obscure and technocratic piecemeal procedure that was difficult to comprehend for a casual observer.

Combined, these factors provided both the incentives and opportunity structures to (a) shift the agenda setting role in regulatory policy further away from individual Member States towards the European Commission and Parliament, (b) create the capacities to coordinate and conduct risk assessment at the European level and with a direct link to regulatory questions, and (c) open legislative room for a gradual and cautious yet targeted and effective regulatory process.

### *Learning Processes*

It is difficult to conclusively prove learning processes of key actors, but statements by officials and other stakeholders as well as the overall nature of the debate suggest that the experiences with agricultural biotechnologies had a profound impact on the direction of nanotechnology policy. Some scholars have suggested that the *de facto* moratorium on GMOs in the EU was an outcome of a coordination failure at the European level (e.g. Falkner 2007) and a "ratcheting-up" effect whereby European policy would follow the most stringent national regulations (Bernauer 2003). Such dynamics undermined the Commission's ability to develop policy proposals and work towards a consensus with the Parliament and the Council. Considering the interest of the European Commission in promoting a successful development of nanotechnologies and its responsibility as the primary architect and harmonizer of EHS regulations, the proactive step to re-examine and possibly revise existing legislation with regard to nanotechnologies as well as the promise of timely regulation can be interpreted as an attempt to forestall activities at the level of Member States and thus maintain the ability to set the agenda. Ann Dowling's call for getting the "regulation of nanotechnology right while the field is still in its infancy" (Dowling 2003: n.pag.) can certainly be interpreted in a similar way.

The relatively rapid focus on risk assessment, both at the level of Member States and at the European level, can be interpreted as a second instance of learning. Amidst calls in the European Parliament to adopt precautionary measures and the controversial role that the precautionary principle has played in the regulation of GMOs, there seemed to be a coordinated effort to better understand the nature and extent of uncertainty, especially with regard to rather speculative ethical concerns about “grey goo”. Between 2003 and around 2007, there was a notable shift in the debate on nanotechnology safety away from the question of whether to apply precaution amidst uncertainty towards the question of how best to reduce uncertainty, including through regulatory means.

A third and final instance of learning appears to be the approach of European and Member State bodies as well as industry organizations towards civil society. Between 2001 and 2012, the European Commission spent almost €19 million to fund projects related to ethical, legal, social and governance aspects of nanotechnologies (Hullmann 2008) and engaged in extensive capacity building program for NGOs (see above). Industry organizations also organized stakeholder dialogues and participated in the dialogues and workshops that were organized by the EU. The call for more engagement with civil society and NGOs can be found in almost any EU and Member State document on nanotechnology policy. It is difficult to ascertain whether these activities had a lasting impact on the nature of decision-making and the *de facto* influence of civil society, but it nevertheless signifies a high degree of willingness to involve civil society, if only to influence their stance and keep track of their activities.

### *Convergence of Interests*

It would certainly be misleading to portray nanotechnology policy in Europe as the result of a sudden collaboration between different groups of stakeholders who share common goals and visions. When compared with earlier instances of regulatory policy under uncertainty and in sensitive sectors, however, one of the most notable developments in the nanotechnology case has been the absence of polarization and divergence of interests among groups of actors.

The role of civil society and NGOs in the debate is particularly noteworthy, especially when compared with their role in the GMO debate. With some notable exceptions – for instance the disruption of public debates in France (Nanoforum 2009) and the accusation by protesters that “nano” is “totalitarian” (McAlpine 2010) – civil society organizations were notable by their relatively calm and measured involvement in the debate. At a time when environmental and consumer NGOs were deeply occupied with the GMO case and with REACH, they had only very limited personnel and financial resources for nanotechnology. Friends of the Earth has argued that a low level of public awareness has further contributed to the fact that, “NGOs have had a limited impact on governance debates and regulation itself” (Miller/Gyorgy 2010: 436). Moreover, the European Parliament and in particular the European Greens were unusually active on nanotechnology and proposed many initiatives to change existing laws. With their political influence and superior financial and human resources, the environment committee of the Parliament appeared to at times “crowd out” deeper NGO involvement.

The interests of industry actors meanwhile were very heterogeneous. On the one hand, there was – unsurprisingly – considerable opposition to a hasty creation of new “nano law” (O’Hagan 2007). By and large, industry actors agreed that applying existing laws to nanotechnology applications would be the best way to proceed. On the other hand, there was considerable awareness that proactive regulatory policy can help avoid a repeat of the GMO saga and create an atmosphere of consumer trust and legal certainty. Downstream users of nanomaterials in the cosmetics, consumer products and food packaging industries were particularly supportive of precise legislation that ensures high quality of intermediate products and thus protects these industries from regulatory uncertainty and public concern.

The European Commission’s interests were very clear and in many cases coincided with those of the industry. On the one hand, the Commission also sought to promote the successful development of nanotechnologies, not least because it had invested enormous resources in its development (Cordis News 2003b). On the other hand, however, the Commission also understood the risks of inactivity and neglect and sought to ensure that nanotechnologies were developed in a safe way before civil society becomes active and wide public concern emerges. Whether or not the Commission truly believed that stringent regulation is required to facilitate the commercialization of nanotechnology applications, as some Commission officials argued, there was considerable awareness that proactive action is required to avoid a repeat of the GMO controversy.

The combination of relatively little NGO involvement, considerable overlap in industry and EU interests towards a proactive yet measured approach and a low level of public interest goes far in explaining the absence of polarization. This relative convergence of interests, the institutional changes and the learning processes mentioned earlier explain to a large extent why nanotechnology development in Europe has been so fundamentally different from the experience with GMOs. It also allowed the Commission to follow a remarkable anticipatory approach to risk governance and avoided the situation of the GMO case where the Commission was forced to react to developments in Member States, often under considerable time-pressure and with inadequate scientific and institutional capacities.

## 5. Concluding Remarks

At the turn of the millennium, nanotechnologies were set to follow agricultural biotechnology down the road of political polarization, NGO campaigning, industry resistance and public fear. Yet, “grey goo” did not become the new “Frankenfoods” and nanotechnologies were developed over the past decade in an atmosphere of relative calm and without much controversy. This article explored the reasons for the stark contrast between the development of agricultural biotechnology and that of nanotechnologies. It argued that the sources of this different development do not relate to fundamental differences in the technologies – both lend themselves to hyperbolic claims about risks and benefits, share similarities in the structure of the industry, have the potential to cause ethical concerns and involve considerable uncertainty about risks. Instead, the underlying cause for a different development relates to the convergence of three factors that allowed the EU to promote a remarkably anticipatory approach to risk management: the institutional evolution of the EU, the convergence of interests among key stakeholders and learning processes after the

experience with agricultural biotechnology.

The development of nanotechnologies in Europe over the past decade presents a useful case for further research. The anticipatory nature of the policy process, for instance, facilitated international cooperation by creating room for consultations, institutional capacity-building and inter-agency exchange. It also reduced the risk of regulatory fragmentation across different executive agencies and levels of government. This is particularly important in the complex political system of the EU where a highly politicized policy issue can lead to significant political frictions between individual Member States. On the other hand, the informality of agenda setting and the obscurity of developing regulatory processes through a relatively small group of experts shift the nature of regulatory policy from transparent decisions to more elusive processes.

This article provides a first introduction to and an overview of nanotechnology policy in Europe. It explores Europe's evolution in managing risks under uncertainty by delineating the structural similarities and differences between agricultural biotechnology and nanotechnologies. As a constantly evolving political entity, the EU's approach to risk governance also changes over time. In the case of nanotechnology policy, this change manifests itself in learning processes as well as new institutional structures and stakeholder preferences. It remains to be seen whether the EU's anticipatory approach to nanotechnology risk governance ultimately succeeds in avoiding future public polarization and whether it can serve as a model for other emerging technologies that come with uncertain risks.

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