Chapter 15
Nanomaterials in Political Life: In the Democracies of Nanotechnology

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Abstract How to deal with nanomaterials in democratic societies? Answering this question requires an understanding of the political qualities of nanomaterials. Rather than discussing "political impacts" that could be assessed once they are properly identified, this paper argues that nanomaterials are inherently political in so far as they are uncertain objects, connected to the future developments of nanotechnology, and tied to public concerns and the mobilization of various publics. It starts by discussing the political dimensions of nanomaterials through the examples of a European "network of excellence" and a carbon nanotube development project in a private company. The paper then describes three democratic formations enacted by the management of nanomaterials. These formations rely on the arrangement between the definition of nanomaterials, expectations about the future, the identification of public concerns, and the mobilization of various publics. I contrast an international "science-based" expertise, a European moral space, and French attempts for the responsible development of nanomaterials.

15.1 Introduction

How to deal with nanomaterials in democratic societies? The answer to this could seem straightforward. As technical objects, nanomaterials would be best studied and controlled with appropriate expertise, which could then inform policy makers if specific measures are to be taken in order to mitigate the potential risks of these substances. For the rest, nanomaterials are produced and used by private

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R. Brayner et al. (eds.), *Nanomaterials: A Danger or a Promise?*,
DOI: 10.1007/978-1-4471-4213-3_15, © Springer-Verlag London 2013

companies, integrated in market products, and live their lives as many other chemicals do, only with a different (and maybe wider) range of potential applications.

In this chapter, I argue that this reading oversimplifies the circulations of and discussions about nanomaterials, and that it is no less than the theory and practice of democracy that are at stake with these substances. I demonstrate this point by discussing the "political dimensions" of nanomaterials, and by reflecting on the ways in which these entities are dealt with in democracies.

The question of democracy has both an empirical and a normative dimension. I am more interested here in the empirical exploration of the various democratic constructions experimented with in order to deal with nanomaterials. Instead of an abstract reflection on the ways in which democracy should be organized about nanomaterials (asking questions such as "who should participate in the public management of nanotechnology?" or "is it necessary to ask people what they think about the development of nanomaterials?"), I propose empirical descriptions of the ways in which democracy functions with nanomaterials.

As previous works have shown, the public management of technical issues organizes democratic life.[1] It distributes roles and responsibilities across public and private bodies, lay and expert actors. It defines legitimate public issues and ways of dealing with them. It organizes decision-making processes. Analyzing these phenomena requires that one describes the instruments through which technical issues are dealt with. Controversies among the actors involved[2] and differences across countries[3] may then illustrate the range of democratic constructions enacted by these instruments.

In the vein of these works, I discuss in this chapter the democratic constructions that the definition and public management of nanomaterials enact. Thus, I describe different technico-political constructions that associate the definition of "nano ness" and its related concerns with the collective organization of democracy.[4] This exploration is situated within a stream of studies interested in the "coproduction" of knowledge and political order.[5] It touches on important political science questions (how does democracy function with technical issues?) using tools and methods developed in science studies. In the meantime, it also raises a very practical issue: that of the legitimate treatment of complex issues in democratic societies.

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[1] See [9, 10] about the science/policy boundary; Jasanoff [11] about risk perceptions; Barthe [3] for an example about nuclear waste; [7] for a critique of risk/benefit evaluation.

[2] A canonical example of controversy about risk evaluation and management is Brian Wynne's study of Cambria sheep farmers, which describes the opposition between the scientific methodology of British administrative experts, and the local knowledge of farmers [29].

[3] International comparison can thus illustrate the variety of technico-political arrangements on which risk regulation is based [13].

[4] I use materials based on my work on "technologies of democracy" and the problematization of nanotechnology [19–21].

[5] The term was introduced and discussed by [12].

I start this chapter by discussing the ways in which nanomaterials have a political life. These objects are connected to global development programs on nanotechnology. They are produced in conjunction with public concerns. They are meant to be represented for and discussed with a variety of publics. Having then described the political life of nanomaterials, I turn to an analysis of the types of democratic constructions that are expected to deal with it. I contrast an international, a European, and a French democratic formation. The three of them define modes of collective and legitimate actions, as well as the “nano ness” of nanomaterials.

15.2 The Political Life of Nanomaterials

Nanomaterials are constructed in industrial and university laboratories, developed in view of applications, measured and studied by scientific instrumentation. Nanomaterials are not elements of a simple “natural category” that could be unearthed in order to build relevant innovation policy or risk regulation. The novelty of these materials and their “nano ness” itself needs to be defined. This section argues that nanomaterials have various “political” dimensions. In so far as they are connected to programs of development, public concerns, and publics, and are of an uncertain “nano” identity, they live a “political life”.

I describe the components of the political life of nanomaterials through the use of two main examples: that of a European project called *Nano2Life*, and that of a French company producing carbon nanotubes. These examples will allow me to describe the interconnections between the development of nanomaterials and the construction of programs for the development of nanotechnology. Nanomaterials will appear as entities associating material elements with anticipations about the future, but also public concerns and publics.

15.2.1 Nanomaterials and Their Programs

The development of nanomaterials in laboratories, particularly for biomedical applications, is supported, for instance, by large-scale research projects funded by public bodies. Consider for instance the European project called *Nano2Life*, launched in 2004, which was the “single European network of excellence funded under the 6th Framework Programme of the European Commission”. *Nano2Life* gathered 23 research institutions in ten different countries across Europe. As a “network of excellence”, it did not add new research projects to those conducted by the partners. Rather, it hoped to “reduce fragmentation in European nanobiotech” by undertaking various common initiatives, such as training programs in nanotechnology, exchange programs among partners, sharing of scientific equipment, and coordinating long-term research objectives among the partners.

Nanomaterials, as they appear in the *Nano2Life* European networks, are not passive entities expected to be unproblematically discovered and harnessed by researchers. They are connected to the development of the European research policy regarding nanotechnology. Thus, part of *Nano2Life*'s activities was the organization of "foresight exercises", through which the project could "identify the future applications or techniques to focus the research efforts on".[6] The coordinator of *Nano2Life* and other members of the networks participated in the writing of a "vision paper", which was the first step in the establishment of a "European Technology Platform" for nanomedicine ("ETP nanomedicine").[7]

The road map that emerged from the ETP nanomedicine and *Nano2Life* was meant to coordinate European research and define objectives for the next nanotechnology policy initiatives. It identified problems to be solved and potential outcomes. For instance, it defined "devices for drug delivery" as "targeted applications", and then pointed to "key R&D priorities" (e.g., biocompatibility of materials and miniaturized systems), needed technologies (e.g., "nanocapsules"), the "challenges" to be met (e.g., the stability of the device), and the diseases supposed to be cured (cancer, diabetes, or cardiovascular disease).[8] The road map considered that nanotechnology required the early identification of promising domains, and the definition of research funding flows. Fundamental and applied research had to come together, and the road map heralded "public–private partnerships" as instruments through which nanotechnology could be developed according to the objectives defined, with limited public funding support. As scholars interested in technico-economic instruments have shown,[9] road maps such as the European nanomedicine one are not descriptions of a world already given, but contribute to shaping it by organizing collective action.

As this example illustrates, nanomaterials live their lives in the science policy world, in which the organization of laboratory research is determined by road maps and policy instruments expected to realize the "potential" of nanotechnology. This implies an organization targeted at the development of certain applications and meant to foster interdisciplinary research practices and industry/academic partnerships. The production of and research about nanomaterials is thus directly connected to the definition of short- and long-term objectives for the development of nanotechnology, and to operations meant to organize scientific and technological research. This is not the case only for academic laboratories. The development of nanomaterials in private companies is also directly linked with national and international science policy research. Ameka,[10] a leading French

[6] www.nano2life.org; accessed January 12, 2011.

[7] European Technology Platforms are coordination mechanisms organized at the initiative of the European Commission and scientific actors. They are meant to contribute to the making of the European research policy.

[8] Nanomedicine vision paper: 30.

[9] See [26] for an example about Moore's Law.

[10] The name is fictional.

producer of carbon nanotubes, decided to enter the nanotubes markets in anticipation of future growth of the domain, and in tight connections with the American and French developments programs for nanotechnology. As its production grew, the modalities of its industrial activities were discussed in conjunction with national and regional nanotechnology policies, and the company was part of numerous local and national programs of support for the development of nanomaterials.

15.2.2 Nanomaterials and Their Concerns

The political life of nanomaterials does not lie only in their connections with public science policy programs and private industrial strategies. As nanomaterials began to appear as both a promising economic market and an interesting research domain, they were also associated with public concerns that were to be taken into account.

Thus, the European nanotechnology policy is supposed to address the "Ethical Legal and Social Aspects" of the domain.[11] These "aspects" comprise the question of informed consent in clinical trials, the potential threats to privacy through the applications of nanoelectronics, and the issues of nanomaterials' potential risks. The "integration" of ELSA in nanotechnology programs means that research projects related to the "implications" of nanotechnology are funded as part of nanotechnology programs, some involving social scientists, others led by toxicologists or environmental scientists. In *Nano2Life*, ethicists and scientists were supposed to work closely together, so that an "ethics board" could publish about the potential concerns related to nanomedicine, while scientists could be trained about the "societal implications" of their research. In other cases, the importance of the integration of nanotechnology concerns is such that some speak about a "safety by design" approach, which would bring materials scientists, biologists, and toxicologists together in the making of new nanomaterials with a collection of precisely tailored properties—among which are toxicological properties.[12] In all cases, this contributes to making nanomaterials a part of public concerns related to potential health risks and ethical issues.

This has implications for private companies as well. The leader of the nanotube project at Ameka described humorously the transformation of the production of carbon nanotubes in his company into a source of public concerns:

> As soon as the production pilot (for nanotubes) was there, then the director of communication, the direction of the environment, the technical direction, the direction of the

[11] Hullmann [8].

[12] Kelty [15] describes the development of the "safety by design" approach by the American chemist Vicky Colvin, who was actively involved in the making of nanotechnology federal programs.

> plant, the préfet, the sous-préfet, the president of the region, the archbishop… Everyone was rushing there… there were so many people coming to see the reactor that we couldn't work anymore. It had become so present in the media… At the same time, nanomaterials were becoming a priority for the whole company. And there was pressure to control what we were doing. (Interview with the author)

That companies are concerned about the risks of nanomaterials depends on a variety of factors, among which the anticipation of potential controversies and the fact that the risks of nanomaterials might well be risks for the development of nanotechnology.[13] This results in different industrial strategies, among which the withdrawal of "nano claims" for industrial products is not to be targeted as "nano".[14] Ameka adopted a different strategy, based on the containment of nanotubes. This was a consequence of its decision to "apply the precautionary principle". But it also resulted from the technical difficulties Ameka met in attempting to mobilize other approaches, most notably predictive toxicology, that is, the demonstration of a causal link between this or that characteristic of the substance and measurable hazards.

Indeed, predictive toxicology soon proved too complex to undertake. What interests a company such as Ameka is its overall properties for products to sell to its customers. Production processes are thus tailored according to the observed properties of the end products, so that Ameka's nanotubes fit in the customers' products. This renders the detailed characterization of nanotubes unnecessary, which is not incidental. Indeed, measurement and identification techniques are not always available for nanomaterials, and not standardized. Ameka's nanotubes are woven together in ways that make detailed characterization impossible. The issue becomes even trickier when one considers the other carbon nanotubes produced by Ameka's competitors. As they are developed in view of specific properties, their physical characteristic (length, diameter, etc.) are potentially all different from each other. This points to a central issue for nanomaterials, that of their characterization and identification as "new" substances. The question is important, because it displaces the "political" dimension of nanomaterials from science policy programs and public concerns to the very definition of nanotechnology objects. This leads me to discuss the ways in which one can differentiate nanomaterials from "non nano" substances.

15.2.3 Defining Nano Ness

Distinguishing between substances relies on the classifications of chemicals (e.g., Mendeleev's table for chemical elements), and instrumented identification technologies (e.g., mass measurement and chemical composition evaluation

[13] MacCarthy and Kelty [23].

[14] The case of nano silver in the U.S. is paradigmatic for that matter.

devices). Once the industry is involved, it is also a matter of regulators and jurists, who need to identify substances in order to manage them (e.g., through the control of industrial products, the limitation of populations' exposure, or the labeling of consumer goods). Thus, regulatory texts define what an "existing substance" is, and thereby perform an ontological work. In Europe, the registration, evaluation, and authorization of chemicals regulation (REACH) defines a "substance" in this way:

> Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.[15]

REACH considers that two substances are distinct if they have different chemical composition (i.e., they are made of different elements), or different "physical parameters", defined as such, in a non-exhaustive manner:

> The other specific main identification parameters to be added depend on the substance. Examples of other main identifiers can be elemental composition with spectral data, the crystalline structure as revealed by X-ray diffraction (XRD), Infra Red absorption peaks, swelling index, cation exchange capacity, or other physical and chemical properties.[16]

Measuring these physical characteristics implies that instrumentation is available in order to identify them in an unambiguous manner.[17] In the US, the toxic substance control act (TSCA) considers as "existing" a substance listed in the TSCA inventory. A substance is "new" if it is not listed in the inventory, that is, if it can be distinguished from the existing ones. The criteria used to draw the distinction are relative to the chemical composition and physical parameters, most notably crystalline arrangements, isotopy, and allotropy. In the American as in the European case, measurable criteria are used to establish the existence of substances. In the latter, the existence of a substance implies constraints for industrialists, in particular that of information distribution through legally defined instruments (e.g., "safety data sheets" for the REACH regulation). This then allows the European administration to impose restrictions on the most dangerous substances.[18]

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[15] REACH, title I, chap. 2, art. 3:1.

[16] European Chemicals Agency, [26] Guidance for identification and naming of substances under REACH, ECHA: 29.

[17] Instruments need to be standardized in order for their measures to be comparable. See [25] for the work needed to do so.

[18] The two texts follow different approaches: REACH forces industries to provide information (controlled by the European Chemicals Agency, ECHA), and to demonstrate the safety of their products [6]. TSCA asks EPA to demonstrate the existence of risks in order to impose restrictions, while the federal agency cannot force industries to provide data on their products. See (Sachs 2009) for a comparison between the two texts and a critique of TSCA. Sachs insists on the limited number of cases where EPA could impose restriction measures.

Thus, what makes a chemical exist is an infrastructure made of legal texts, standardized measurement instruments, technico-administrative instruments such as labeling and registration dossiers, and institutions able to stabilize the criteria being used. Through the instruments on which it is based, the data it circulates, the standardized measures it mobilizes,[19] and the management tools it constructs, this infrastructure defines existences for chemicals[20] at the same time as it defines the problem of the health and safety risks of substances and ways of dealing with it.

Nanomaterials raise additional issues. If two substances differ from each other because of the size of their components, then the criterion of the chemical composition cannot be used to distinguish "nano" from "non nano" (the atomic composition is the same). The distinction according to physical characteristics—for instance, crystalline arrangements—could be possible, but is not straightforward. Consider for instance the case of Ameka's carbon nanotubes. Regulators distinguish between graphite and diamond, two varieties of carbon.[21] According to the same logic, one could consider that nanotubes are an allotropic variety of carbon, and can thus be made "existing". But if the atomic structure is considered as a criterion, why not then differentiate between "multi walls" and "single walls", "rigid" and "flexible", diameters inferior or superior to a certain limit? The question is all the more acute as companies do use these criteria (and many others) to differentiate between their products when they patent them.[22] In order to know the parameter that matters for toxicological regulation, it would be necessary to establish a link between the physical or chemical characteristics chosen as a criterion and toxicological properties. This is predictive toxicology, the very approach that Ameka was unable to undertake because of characterization issues.

Consequently, the definition of nano ness is a crucial stake as soon as it is connected to the construction of regulation. This stimulates considerable debates, as to whether nanomaterials should be considered "nano" solely because of their size, or because of their (toxicological) properties. I will get back to this important point in the second section of this chapter. At this stage, one can notice a central aspect of the political life of nanomaterials: the very definition of "nano ness" can be discussed.

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19 About the importance of standardization activities in scientific practice see [16, 17].

20 This example is another illustration of the importance of the study of classification operations in order to understand the constitution of the social [4].

21 European Chemicals Agency, [26] Guidance for identification and naming of substances under REACH, Helsinki, ECHA. Another case is that of substances "of unknown or variable compositions, complex reaction products, or biological material" (UVCB), which encompasses compounds of several chemical elements produced by organic synthesis, or biological materials themselves. This latter case does not apply to nanotubes (made of a single element, carbon), nor to other nano substances (as their chemical composition is not questioned).

22 A few court cases has been filed at the time of writing, but they all confirmed the patentability (and thus the novelty) of nano substances based on different processes, and having different size characteristics than already patented ones [2].

15.2.4 Nanomaterials and Their Public Lives

Nanomaterials are not just objects of interest for scientists and policy makers. They are expected to be developed for industries to use and consumers to buy. The growth of the market for nanomaterials was heralded soon in the development of nanotechnology programs as a reason for public and private investments in the field. "Publics" were not only considered as potential consumers, they could be potential threats, if too scared by possible health risks or long-term ethical concerns. Accordingly, the European nanotechnology policy, in heralding the "societal dimension" of nanotechnology, insisted on the need…

> to establish an effective dialog with all stakeholders, informing about progress and expected benefits, and taking into account expectations and concerns (both real and perceived) so as to steer developments on a path that avoids negative societal impact.[23]

It meant that nanotechnology's public was yet another component of projects such as *Nano2Life*, which included in its objectives the "education of society", and the "dialogue with civil society". The former related to training programs for students, and materials aimed to communicate the outcomes and objectives of *Nano2Life*. The latter pointed to the identification of public concerns, either related to "risks" or "ethics".

The call for "public dialogue" and the consideration of "citizens' expectations and concerns"[24] was not limited to Europe.[25] Following the reports released by the U.S. National Science Foundation about the "societal implications of nanotechnology", in which the need for "two-way communication with the public" had been expressed,[26] the US Nanotechnology Act required that US nanotechnology programs

> provide (…) for public input and outreach to be integrated into the Program by the convening of regular and ongoing public discussions, through mechanisms such as citizens' panels, consensus conferences, and educational events, as appropriate[27]

Integrating "the public" in nanotechnology policy implies the construction of specific devices: instruments expected to represent nanotechnology for "the public", to "inform about progress and expected benefits" (to reuse the language of the European Action Plan), and also devices aiming to "take into account expectations and concerns", which requires on the one hand to "make the public

[23] European Nanotechnology Action Plan: 8.

[24] Hulmann [8] p 12.

[25] Cf. [14, 24] for comments about the importance of the deliberation theme in nanotechnology policy, and its consequences for the involvement of social scientists. This latter question is important, and will be discussed at further length in other parts of the dissertation (particularly in chapters 3 and 6).

[26] Roco and Bainbridge [27].

[27] U.S. Congress, "21st Century Nanotechnology Research and Development Act", S.189 (P.L. No. 108–153).

speak", and, on the other, to mobilize what the public says in ways that can be said to have taken it into account. The development and public management of nanomaterials is tied to these devices, in ways that can vary. How are "publics" (and which ones) expected to transfer their expectations and concerns into the material constructions of nanomaterials and the definition of nanotechnology programs? The second section of this chapter will provide three different answers to this question.

As for Ameka, the construction of carbon nanotubes was undertaken in public watch (cf. 15.2.2). More than that, the company adopted a strategy of "transparency" about its activities. This implied an involvement in the public initiatives meant to monitor the industrial production of nanomaterials, and an active participation in the design and staging of public exhibitions in science museums about the companies' activities in the production of nanomaterials. For Ameka, the material control of carbon nanotubes through containment was also a discursive control about what was said about the company, who should be informed about its activities, and by whom.

15.2.5 Nanomaterials in Political Life

What should we learn from the previous descriptions? First, the development of nanomaterials occurs in conjunction with the formulation of nanotechnology policy. Second, the question of their potential impacts is raised as soon as they are developed. Third, the characterization of nanomaterials is not an easy task. In the case of Ameka, containment allowed the company not to raise the issue of characterization, but this has no reason to work for less stable objects. Fourth, nanomaterials are expected to meet their "publics" in one way or another. Nanomaterials are not neutral objects lying passively in laboratories for their "impacts" to be discovered. Their very existence is inherently connected to the definition of public problems and ways of dealing with them. They have political lives: they are objects to be defined, which are connected to futures to decide about, public concerns to manage, and publics to engage.

What are the consequences for the organization of democracy? The answer is not straightforward, as it requires a definition of what is meant by "democracy". As a working hypothesis, I consider that democracy is at stake in places where oppositions are voiced and organized for the treatment of public problems. This will allow me to describe, in the following section, three "democratic constructions" (that is, three modes of organizing public problems and defining ways of dealing with them) that shape the definition and management of nanomaterials as much as they are shaped by the components of the political lives of these substances. As it will appear below, these constructions connect the definition and management of nanomaterials with the planning and organization of nanotechnology programs.

15.3 Democratic Constructions

In this section, I follow up on the previous discussion in order to examine the ways in which the political life of nanomaterials results in different democratic constructions. I consider three examples: that of the international standard-making processes about nanotechnology, the European nanotechnology policy, and current French initiatives for the collective management of nanotechnology and nanomaterials.

15.3.1 International Expertise for Nanotechnology

The standardization of nanomaterials is discussed at the international standardization organization (ISO), where a "technical committee" on nanotechnology (TC229) was created in 2005. The work of TC229 is interesting, because it connects the various aspects of the political life of nanomaterials: the committee is expected to define "nano ness" in order to address public concerns related to the potential risks of nanomaterials, and ensure that stakeholders interested in their development (industries, environmental or consumer organizations, and states) are heard.

Standardization at ISO TC229 is done according to a "science-based" process. According to this process, definitions are to be crafted independently from considerations related to the potential risks of nanomaterials. It based the definitions on that of the nanoscale, as going approximately from 1 to 100 nm. The 1–100 nm size limit is a science policy concept stated in various policy reports.[28] It is both an umbrella term able to bring together the many research projects related to the exploration of properties emerging at the atomic scale, and a technological indication characterizing new properties and products. It is considered as a "typical but not exclusive" dimension.

Following the definition of the nanoscale, TC229 defined nano objects as substances with at least one dimension within the nanoscale.[29] Nanomaterials, then, were defined as either nano-objects, or "nanostructured materials", that is, materials displaying nanoscale regularities.[30] Defining nanomaterials as such means that some existing entities become "nano", and that differences are drawn among entities that were previously considered identical. This could be difficult to accept for companies if additional requirements are asked for nanomaterials. But

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[28] The American National Nanotechnology Initiative, the 2004 British *Royal Society* report, and the O.E.C.D. used the 100 nm size limit, as an indication of a size range where new properties may emerge. The 1 nm inferior size limit was added by TC229 in order not to limit the scope of the substances qualified as "nano".

[29] Nanotechnologies—Terminology and definitions for nano-objects—Nanoparticle, nanofibre and nanoplate, ISO/TS 27687:2008.

[30] Nanotechnologies—Vocabulary—Part 1: Core terms, ISO/TS 80004-1: 2010.

the international agreement was eventually possible at TC229 because of the "science based" process. Basing the process "on science" implies that the identification criteria are used "only to describe" the nanoscale patterns. Consequently, the linear logic of the definition of the scale, objects, and nanomaterials avoids defining nanomaterials according to properties that are linked to a "political" objective, that is, in the language of ISO, linked to national regulatory choices. Thus, ISO constructs a boundary between (international) science and (national) politics through a nanoscale-based definition of nanomaterials.

This is important because it means that attempts to define nanomaterials based on their toxicological properties cannot succeed in the international arena. There would be indeed other possibilities for the definition of nanomaterials, in which the "nanoness" would be characterized by properties not necessarily related to size. Thus, researchers propose to define inorganic nanoparticles "from an environment, health and safety perspective."[31] This would lead to define nanomaterials according to "size related properties instead of size itself."[32] For instance, the specific surface area, the oxidation rate, or the ion release rate could be considered as criteria. Defining "nano ness" according to properties other than size was mentioned during the discussions at TC229. The idea was consistent with the TC229 mandate, which included the standardization of "the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter."[33] But the logic of the property-based definition could not be successful at ISO. Indeed, "nano properties" vary from one chemical to the other, and the product of company X to the company Y. Measuring instruments for particle size, surface reaction, or crystalline states are not uniform. And, as the example of Ameka's carbon nanotubes show, the characterization of potential "nano-properties" faces considerable technical difficulties.

This is not only a problem of time available to build technical infrastructures. Indeed, if a property and a corresponding instrument were selected to define nanomaterials, then the ISO members holding the technology were favored at the expense of those who would then be forced to buy it. This is problematic in the context of international negotiation. But a deeper problem lies in the fact that the property-based definitions threaten the logic of the "science based" process itself. They ground the definition of nanomaterials on risk management considerations: this is exactly the "political choices" that international standardization is expected to keep at bay. Contrary to the property-based definitions, the size criterion avoids addressing the cases of each material. It is both a technical requirement, and a criterion for science policy. It is not related to any binding regulation for nanomaterials. Thus, the 1–100 nm size limit can fit in the standardization body, contrary to definitions based on physical and chemical properties of substances that cannot rely on the infrastructure they need, and threaten to tie the definition of nanomaterials with a "political" regulatory objective.

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[31] Auffan et al. [1].

[32] Auffan et al. [1] p 641.

[33] TC229 Business Plan.

ISO is not the only place where international discussions occur about the collective management of nanomaterials. At the organization for economic cooperation and development (OECD), nanomaterials are dealt with at the Working Party on Manufactured Nanomaterials (WPMN), where the problem of "nano ness" is dealt with in a different fashion than at ISO. At WPMN, reference materials are tested and characterized, the evaluation of risks is supposed to follow, and meant to be carefully separated from national political decisions. In this case, the "science-based" process is not grounded on the size criteria, but on material objects chosen after negotiations among the participants in WPMN. The expertise thereby produced is expected to be separated from another one about the public, treated in a separate body of the OECD. The working party on nanotechnology (WPN) is in charge of "policy expertise", and undertakes projects related to the policy framework for the development of nanotechnology and public engagement mechanisms. This division of labor between WPN and WPMN is not incidental, and is central in the everyday work of the OECD.[34] It is another manifestation of the importance of international "science-based" expertise, that is, independent from national regulatory choices. This means that neither the evaluation of nanomaterials' risks, nor the consideration of the modes of doing "public engagement" may displace the boundary between the work of the international organization and the national choices of the country members. This boundary is of course itself a political construct, that defines what can be discussed and what cannot, what is considered as "objective science", and what lies in the "political realm". Accordingly, it constructs a way of doing public engagement in which the preferred mode of action is the measure of public perception regarding an unquestioned technical reality, so that one can measure the perceptions of the public in order to tailor the communication programs adequately.[35]

15.3.2 A European Moral Space

In Europe, the development of nanomaterials is done within a strategy for the "responsible innovation" in nanotechnology. This means that the European programs of support for nanotechnology contend that the development of nanomaterials is supposed to be conducted in conjunction with risk and ethics studies, and in permanent "dialogue" with the European public.

This translates into the organization of the European research policy, as the example of *Nano2Life* illustrates. "ELSA" projects are funded, and are supposed to ensure that nanotechnology is developed according to "European values" such as sustainability, solidarity, transparency, and inclusion. The various science policy instruments mobilized by the European Commission all participate in the

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[34] Laurent [22].

[35] For a discussion of "the political science of risk perception", see [11].

production of a European "moral space" characterized by an attention to principles and values. For example, ethics reviews ask all European projects to define their objectives in accordance with European values. They encourage the use of a "Code of Conduct" expected to define a "European approach" to the research and production of nanomaterials. They suggest specific adaptations of research practices to the case of nanomaterials, for instance by calling for the introduction of exposure limitation device. They encourage the creation of "ethics board" in European projects and the organization of training sessions for scientists to learn about the implications of their work.

The practice of "responsibility" is thus delegated to laboratory scientists, guided by general principles such as those presented in the "Code of Conduct". In the meantime, the European public is to be kept informed, needs to deliberate and dialog about potential applications. The Commission has recently introduced the idea of the "scientific understanding of the public" in order to point to the needed dialog with the public, and the "constant monitoring" of European public opinion supposedly necessary for the efficacy and legitimacy of European nanotechnology policy.[36] The idea of "scientific understanding of the public" would mean that European research programs adapt their objectives to the expectations and constraints of the European public. These initiatives are the components of an approach to the responsible innovation in nanotechnology in which no additional legal constraints are imposed on private industrial actors, and the development of nanotechnology is not hindered by negotiations among stakeholders about future regulations.

This approach is not uniformly accepted within the European Union. While the projects funded with the "ELSA" part of nanotechnology programs herald "lay ethics" and "deliberation" as central concerns, they are often critical of the ways in which the Commission is implementing these very objectives.[37] Within the European institutions, the European Parliament (EP) has voiced an opposition to the initiatives of the European Commission. The EP does not consider that the existing regulatory framework is sufficient to deal with nanotechnology issues. The EP's critical opinion regarding the activities of the European Commission toward nanotechnology was made explicit in an almost unanimous resolution that responded, in 2009, to the Commission's communication regarding the "regulatory aspects of nanomaterials."[38] This communication had explained how the

[36] European Commission [5].

[37] For example, the promoters of projects calling for the redefinition of the framing of public issues by deliberating publics consider that "scientific understanding of the public" reproduces a separation between unproblematic "publics" and unproblematic "applications of nanotechnology".

[38] European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI), hereafter "EP resolution"). 362 votes were casted in favor of the resolution, and four against (five MPs abstainted). The resolution responded to the "Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee regulatory aspects of nanomaterials" (SEC(2008) 2036). It also answered the conclusion of the Competitiveness council on 25 and 26 September 2008 (12853/1/08 REV 1 RECH 264 COMPET 311, Subject: "Council conclusions on responsible nanosciences and nanotechnologies research").

"principle of safety" was operationalized by the European institutions as regards nanomaterials. It had mentioned the code of conduct and the ethical review process. The Communication had concluded that the existing regulatory framework was efficient, and that no adaptation was necessary to deal with nano substances' potential risks. In its resolution, the European Parliament noted the "limited value" of the Communication "due to the absence of information about the specific properties of nanomaterials."[39] Consequently, the EP:

> did not agree (…) with the Commission's conclusions that (a) current legislation covers in principle the relevant risks relating to nanomaterials, and (b) that the protection of health, safety, and the environment needs mostly to be enhanced by improving implementation of current legislation.[40]

The position the EP defended was based on the "consideration of all nanomaterials as new substances."[41] Accordingly, the EP added amendments specifically targeted at nano substances in regulatory texts. For instance, the EP added an amendment to the November 2009 cosmetic regulation that asked companies to label products containing nanomaterials. In this amendment, nanomaterials were defined as follows:

> 'Nanomaterial' means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale 1–100 nm.[42]

This definition restated the 100 nm size limit that had been used at ISO. It also added two conditions, insolubility and biopersistence, which made it clear that the definition was to be used as an instrument for the regulation of risks for human health.[43] Through this amendment, the EP solidified a legal existence for nanomaterials for the first time. It later undertook similar regulatory actions for the novel food and the biocide directives, in which it added amendments requiring additional risk evaluation for nanomaterials.

Hence, the EP considered that new entities were to be created within the European regulation. Thereby, it challenged the Commission by pushing an ontological argument for the existence of nano substances. By representing the

39 EP resolution: "Whereas" P.

40 EP resolution.

41 EP resolution: 9.

42 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products: Art. 2.1, alinea k.

43 In translating the 100 nm size limit into a regulatory text, the EP had also to eliminate the adverb "approximately" that was used in the ISO definition. The constraints of legal writing solidified this rigid limit. This caused NGOs to worry about the possibilities offered to companies wishing to escape the mandatory labeling to use slightly bigger than 100 nm substances (e.g., 110 nm) but nonetheless displaying enhanced properties because of their sizes. This was a reason for the EP to consider the nanomaterials amendment as a first step, which could be "adjusted and adapted" according to "technical and scientific progress and to definitions subsequently agreed on at international level" (article 2.3).

concerns of the European public through the electoral mechanism, it considers that the consultation of "lay publics" and the "scientific understanding of the public" brought forward by the Commission were not the only ways in which nanotechnology's publics were to be involved in European decision-making.

The story does not end there, as the European Commission itself released in October 2011 a recommendation "on the definition of nanomaterial".[44] The recommendation "invited Member States, the Union agencies and economic operators" to use a definition of nanomaterials based on the size distribution of the particles in a given material. It also suggested to use, when technically feasible, a specific surface area criterion. My objective is not to discuss the details of the definition eventually proposed by the Commission, but to highlight a few characteristics of the political life of nanomaterials in the European democracy. First, the initial reluctance of the Commission to regulate nanomaterials eventually resulted in a non-binding recommendation that constituted a new category of substances. As the Parliament had wished, new entities have indeed been created. But like the Commission's previous activities meant to ensure the responsible development of nanomaterials, this ontological work remains flexible and does not result in additional legal constraints. Second, the definition of nanomaterials within the European institution is tied to the connection between the public management of nanomaterials and the exercise of European values and principles. This results in attempts at crafting "policy-based approaches", translating, for instance, in definition criteria for nanomaterials that are linked to the potential toxicological properties of the substances (e.g., specific surface area, which implies a higher reactivity). The difference with ISO's "science-based" nanomaterials could not be clearer: as international nanomaterials are supposed to be independent of national policy choices, European ones are to be defined according to a "policy-based approach" consistent with European values and principles.

The European nanotechnology policy and the current debates about the definition and management of nanomaterials enact a democratic formation based on common values and principles. While the operationalization of these principles can be controversial (as the opposition between the Commsission and the Parliament shows), the public management of nanomaterials is directly connected to the moral principles that are supposed to ground the European identity. More than that, it is tied to the construction of the democratic legitimacy of the European institutions.

15.3.3 French Responsible Development

A last example I want to discuss relates to the French nanotechnology policy. The notion of the "responsible development" of nanotechnology is central in France as

[44] Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU).

in other places. But the operationalization of the "responsible development" took a different shape there than within the European institutions. While the development of nanotechnology became a priority of the French government and local administrative bodies, it also stimulated the experimentation of devices meant to ensure the collective management of nanotechnology.

The situation is contrasted though, as French actors oscillate between an ambition based on the development of nanotechnology for economic growth, and the desire to ensure the collective responsible management of nanotechnology. The best illustration of this ambivalence is certainly the case of the city of Grenoble, in the French Alps, where nanotechnology research has been a priority of the local administrative bodies.[45] This has resulted in the constant support to nanotechnology research projects, as illustrated by a research center called *Minatec*, part of the Commissariat à l'Energie Atomique (CEA, a national research institution), and proudly supported by the local public bodies. In Grenoble, the call for the responsible development of nanotechnology originated from a vocal anti-nanotechnology critique. It forced the local actors to adapt their programs to take the management public concerns into account, and stimulated the organization of public meetings devoted to the exploration of nanotechnology public concerns. This was not satisfactory for the anti-nanotechnology activists who blamed a "parody of democracy" for not questioning the objective of nanotechnology development for economic interests.

In this context, the French public bodies have appeared somewhat uncertain about how to deal with this critique and the public concerns of nanotechnology. The organization of a national debate on nanotechnology was an attempt on the part of the French government to ensure a collective discussion expected to "enlighten public choices" about nanotechnology. But many of the public meetings set up throughout the country were interrupted by anti-nanotechnology activists, and the organizers were eventually forced to cancel the final public meetings. This last example shows that the general objective of "responsibility", despite its importance for private and public actors, raises challenges for the conduct of public policy, as French actors do not attempt to ground the action on a "science-based process" independent of "political" choices, or on "principles" expected, as European principles are, to ensure the legitimacy of collective action.

Like the European Parliament, the French government introduced a definition of "nano ness" as it tried to introduce a mandatory declaration of "substances in nanoparticulate state" (*substances à l'état nanoparticulaire*),[46] defined as:

> Engineered substances characterized by one or more external dimensions, or internal structure, in the 1–100 nm size range, including under aggregates or agglomerate forms potentially bigger than 100 nm but conserving properties typical of the nanoscale.

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[45] Laurent [18].

[46] This followed a proposition originated from the "Grenelle de l'Environnement", a national consultation process about environmental regulation, launched by Nicolas Sarkozy after his election in 2007.

The draft decree asked for the declaration of substances in nanoparticulate state, and of materials that used mixtures in which "substances at the nanoparticulate state were included but not linked" (that is, "potentially extracted or rejected in normal conditions of use"). This proposition has attracted many criticisms, especially from the industrialists, who contended that operationalizing the definition was not technically feasible, because of the lack of standardized measurement instruments. They also criticized the proposed threshold for the declaration,[47] which would include, for them, far too many objects in the scope of nano products.

Other instruments could appear much more acceptable for industries than those (like mandatory declaration) that required a solidification of the boundary between "nano" and "non nano". At ISO TC229, France leads a project on "control banding", which ambitions to develop instruments for industrial companies to manage uncertainty. In this case, nanomaterials are related to known substances in order to situate industrial processes in "bands" associated with safety features (e.g., confinement, or simple protection of workers with gloves and masks within a lower risk band). "Control banding" does not draw a boundary between "nano" and "non-nano". This is also the case of a project initiated in 2008 by an official in charge of nanotechnology at the Ministry of Health (and an active member of French delegations in international arenas), and then led by the French association of normalization (AFNOR). This project aims to develop a "nano-responsible tool". This tool intends to define principles for industry wishing to produce, use, or market "responsible" nanomaterials. It is addressed to any producer of substances considered as "nano" because of size-related properties. The format is that of a list of questions that an industrial using the tool would have to answer. Questions comprise, for instance, "What are the main physical and chemicals characteristics of the substance? Is the release of nanoparticles in the atmosphere possible during the production process? In what ways is the exposition to nanoparticles possible during the product lifecycle?" Accordingly, industrialists using the tool would be prompted to adapt their practices to account for the uncertainties of their product. They would be proposed to use methods such as containment, diffusion of information for customers, or substitution of the new products in favor of better-known substances. The tool is currently being developed throughout a collaborative process involving industrialists and civil society organizations. It is expected to account for technical uncertainties, as well as expectations and concerns of civil society.

Thus, the nano responsible tool aimed to make producers internalize the potential externalities of nanomaterials. It connects the development of nanomaterial products with the expectations and concerns of public administration, and of consumers and environmental groups. It is in this connection that uncertainties about the objectives of the project might appear. They relate, for example, to certification. Certification would publicly recognize producers, distributors, and

[47] In the draft decree: "500 g for declarations before May 1st, 2013", "100 g before May 1st 2014", "10 g for later declarations".

users of “responsible” nanomaterials. It would articulate the construction of standards with the implementation of regulations, by allowing regulators and the broad public to track industrial activities. That many participants are reluctant to certification highlights the ambivalence of the objectives of integrating externalities to ensure the “responsibility” of nanomaterials. On the one hand, “responsibility” is supposed to be a label for distributors and consumers to choose among many products. On the other hand, manufacturers want to avoid solidifying the difference between “responsible” and “not responsible” to render possible a strategic navigation in a situation where regulations are not determined and risks are difficult to prove. As for civil society organizations, some of them questioned the potential of the nano-responsible tool to redirect the development of nanotechnology. Indeed, the tool assumes that the development of nanomaterials, however “responsible” they are, is the objective of this collaborative project. Moreover, it is based on the internalization of the expectations and concerns of “civil society”, which then loses the possibility for external critique.

The nano responsible tool is part of a particular democratic construction, in which the “responsible development” of nanomaterials is conducted throughout a series of experiments, some (like the national public debate) highly visible and contested, others more confined and less confrontational. While the overall objective of responsibility is widely accepted, its translation in the actual conduct of public action is uncertain. This results in the introduction of new categories (such as “substances in nanoparticulate state”) and in the experimentation of devices that are expected to deal with the situation of uncertainty regarding both the very definition of nanomaterials and the expectations and concerns of nanotechnology’s “publics”.

15.4 Conclusion. In the Democracies of Nanotechnology.

Nanomaterials have political lives, and these lives are lived in democracies. Organizing democracy with nanomaterials means organizing oppositions, allocating roles, defining public issues, and constructing publics. This is not a sole “social” matter separated from the “technical” details of the production of nanomaterials. Rather, the modalities of the democratic game shape the collective management and, ultimately, the very definition of “nanomaterials”, as much as the uncertainties about the characterization and application of nanomaterials shape the ways of organizing democracy.

In this chapter, I have argued that nanomaterials are part of global programs for the development of nanotechnology, contribute to shape public concerns, are addressed to various publics, and eventually are of an uncertain identity open for negotiation. This has led me to describe three contrasted democratic formations, characterized by their treatment of nanomaterials and the ways in which they ground the legitimacy of public and private action.

I have described an international formation, in which the separation between "international expertise" and "national policy choices" is crucial, a European one, in which the "responsibility" of European principles is ensured through their (contested) operationalization in science policy instruments, and a French experimental formation in which public actors attempt to open public policy choices and the very construction of nanomaterials to collective discussion. In these three cases, the definitions of public problems and the allocation of roles for nations, industries, and civil society organizations differ. These three formations articulate the definition of nanomaterials ("science-based", "policy-based", and experimented in various devices), expectations about future developments (left to national decision-making, tied to European values and principles, collectively experimented in public debates or the nano-responsible tool), the identification of public concerns (public perceptions to manage, safety and ethical risks to take care of, uncertainties to deal with), and the mobilization of various publics (lay public to know about, lay publics to engage, emerging concerned publics to involve). Hence, nanomaterials live different political lives in the international, European, and French spaces, and this enacts different democratic constructions.

What could then be the path for a "democratization" of nanomaterials and the associated nanotechnology programs? Rather than indicating what the "most democratic" approach could be, I have preferred to describe the democratic formations enacted by the collective management of nanomaterials. I have not attempted to evaluate initiatives according to an "ideal" of democracy. Accordingly, the analysis of the political life of nanomaterials that I have proposed here does not mobilize external criteria through which the collective management of technical issues might be evaluated. But it describes the investments needed for social orders to be stabilized, and of the possibilities for alternative constructions (e.g., the property-based definitions at ISO, or the opposition voiced by the European Parliament in Europe). Thus, the approach I have adopted proposes an empirical analysis of technical objects attached to the practicalities of the conduct of democratic life. It reintroduces oppositions and uncertainties in techno-political arrangements, and it is in this sense that it contributes to the democratization of nanotechnology.

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