Nanotechnology

This section is meant to give readers an insight into the emerging field of nanotechnologies and risk regulation. It informs and updates readers on the latest European and international developments in nanotechnologies and risk regulation across different sectors (e.g., chemicals, food, cosmetics, pharmaceuticals) and policy areas (e.g., environmental protection, occupational health and consumer product, food and drug safety). The section analyzes how existing regulatory systems deal with new kinds of risks and reviews recent regulatory developments with a focus on how best to combine scientific freedom and technological progress with a responsible development and commercialization of nanotechnologies.

Political Spaces for Nanomaterials

*Brice Laurent**

I. Introduction

Nanomaterials have been the object of numerous public and private initiatives aiming to manage their risks and maximise their benefits. Proponents of nanotechnology programmes argue that their potential negative impacts need to be dealt with appropriately, and wish to integrate these concerns early in the industrial development of these substances. Science policy programmes do not provide a clear definition of the term "nanomaterials". Defining nanomaterials, however, has become a central concern. It is called for by manufacturers who wish to sell the "nano" quality of their products as well as by associations who wish to classify products in order to facilitate consumer choice or introduce constraints on production.

This is more than an obscure technical and legal issue for specialists. Indeed, science and technology studies has shown that technical classifications perform social order[1], and that the creation of new entities destabilises the conduct of democratic life. For instance, Sheila Jasanoff demonstrates that the "ontological uncertainty" of biotechnological objects leads to the construction of different political forms in the United States and Europe[2]. Building a legal and technical framework for biotechnology objects allocates public roles, defines expertise objectivity, and identifies public concerns – in short, it shapes political organisations at the same time as it constructs technological definitions.

This thought trend does not take for granted the separation between political decisions and scientific facts, or the likelihood that the former are based on the latter in an unproblematic way. When considering the case of nanomaterials, it incites us to reveal the political constructions enacted by the definitions of these substances. One way to do this is by comparing such constructions. Accordingly, this article considers definitions of nanomaterials proposed by the International Standardization Organization (ISO), the European institutions and a French standardisation organisation. ISO bases its definition of nanomaterials on a criterion of size, which ensures a separation between international expertise and national political choices. European institutions, on the other hand, attempt to define nanomaterials "for regulatory purposes", through a process based on arbitrage between stakeholders. Ultimately, this article describes a normative tool intended to allow manufacturers to produce nanomaterials in a responsible way through a collective reflection on industrial practices. The objective here is not to be exhaustive in the description of the proposed definitions of nanomaterials. Rather, it is to demonstrate that defining nanomaterials enacts decision-making processes, and stabilises geographic spaces characterised by a standardised approach for the collective management of chemicals.

II. International "science-based" nanomaterials

Standardisation bodies have been involved in the definition of nanomaterials. The International Standardization Organization (ISO) launched a technical committee on nanotechnology (TC229) in 2007. This committee is organised into three working groups (WG): WG1 for definition, WG2 for measurement instruments, and WG3 for environmental, health and

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1 Geoffray Bowker and Leigh Star, *Sorting things out. Classification and its consequences* (Cambridge: MIT Press, 1999).

2 Sheila Jasanoff, *Designs on Nature* (Princeton: Princeton University Press, 2005).

safety (EHS) issues. This separation is not anecdotal and reflects the science-based approach expected of TC229, under which definitions are to be crafted independently from considerations related to either instrumentation or EHS. The relevant definitions are based on the "nanoscale", defined as covering approximately sizes from 1 to 100 nm. This size range represents a scientific policy concept stated in various policy reports.[3] It is both an umbrella term that brings together the many research projects related to the exploration of properties on the atomic scale, and a technological indication characterising new properties and products. It is considered as a typical, but not exclusive, dimension.

Following the definition of the nanoscale, WG1 defined nano-objects as substances with at least one dimension within the nanoscale.[4] Nanomaterials, then, were defined as either nano-objects, or "nanostructured materials", that is, materials displaying nanoscale regularities.[5] Defining nanomaterials as such means that some existing entities are reclassified as "nano", and that differences are drawn among entities that were previously considered identical. This may be difficult to accept for companies if additional regulations are imposed on nanomaterials. But the international agreement was eventually possible at TC229 because the underlying process was "science-based", i.e. the identification criteria were used only to define the nanoscale. The linear logic of the definition of the scale, objects and nanomaterials avoids defining nanomaterials in terms of properties linked to "political" objectives – 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 are, however, other possibilities for the definition of nanomaterials in which their "nano-ness" would be characterised by properties not necessarily related to size. Researchers have, for instance, proposed to define inorganic nanoparticles "from an environment, health and safety perspective"[6]. This would lead to a definition of nanomaterials according to "size-related properties instead of size itself"[7], with potential criteria including the specific surface area, the oxidation rate or the ion release rate. The idea to define "nano-ness" according to properties other than size was introduced during the discussions within the WG1. This was consistent with TC229's mandate, which included the standardisation of "the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter"[8]. But the logic of the property-based definition could not be successful at ISO. Indeed, "nano properties" vary from one chemical to another and from one product to another, and measuring instruments for particle size, surface reaction, or crystalline states are not uniform. While the purpose of the second working group of TC229 is precisely to work on the measurement methods, it has met considerable difficulties due to the lack of standardised tools for assessing these properties. This is not just a problem of how much time is available to build technical infrastructures – if a given property were selected to define nanomaterials, then ISO members in possession of the technology necessary to manufacture the corresponding instruments would be favoured at the expense of those who would be forced to buy it. This is problematic in the context of international negotiation. But a deeper problem is to be found in the fact that property-based definitions threaten to bring into question the separation between the working groups in charge of definition, measurement and risk assessment, and eventually threaten the logic of the "science-based" process itself. They ground the definition of nanomaterials on risk management considerations, and these are precisely the "political choices" that international standardisation is expected to keep at bay. Contrary to property-based definitions, the size criterion avoids examining each material separately. 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 be applied in the standardisation body, contrary to definitions based on the physi-

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

4 Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate, ISO/TS 27687:2008.

5 Nanotechnologies – Vocabulary – Part 1: Core terms, ISO/TS 80004-1: 2010.

6 Mélanie Auffan *et al.*, "Towards a definition of inorganic nanoparticles from an environmental, health and safety perspective", 4 *Nature Nanotechnology* (2009), pp. 634 *et sqq*.

7 Auffan *et al.*, p.641

8 TC229 Business Plan.

cal and chemical properties of substances that cannot rely on pre-existing infrastructure and threaten to link the definition of nanomaterials with a "political" regulatory objective.

III. European nanomaterials for regulatory purposes

There is nothing inevitable about the impossibility to define nanomaterials based on regulatory objectives, however – initiatives within the European institutions provide a counter-example. The European Commission initially appeared reluctant to consider nanomaterials as substances deserving special regulatory treatment.[9] The European Parliament opposed the Commission on this point, however, and in November 2009 introduced an amendment to the regulation on cosmetics in which nanomaterials were specifically targeted.[10] They were defined as follows:

> "[...] an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm."[11]

This definition adds "insoluble" and "biopersistant" to the 1-100 nm size criterion, indicating that the objective is the regulation of toxicological hazards. It does not employ the term "approximately", because of legalistic constraints, and NGOs have expressed concern that a manufacturer seeking to escape regulation could use a substance larger than 100 nm (110 nm for example), but with an increased reactivity because of its size. The definition is therefore expected to be revised in parallel with advancements in the relevant research. But at any rate, the initiative of the Parliament is revealing: the European institutions may define nanomaterials according to a regulatory objective. Hence the initial opposition between the Parliament's opinion ("nanomaterials should be defined and regulated") and that of the Commission ("no specific regulation or definition is required")[12].

In 2009, the Commission asked two expert agencies to propose a definition for nanomaterials: the Joint Research Center (JRC), which is an entity of the Commission, and the Scientific Committee for Newly Identified Health Risks (SCENIHR), a committee of experts related to the Directorate for Health and Consumer Protection. JRC and SCENIHR both attempted to define nanomaterials "for regulatory purposes".[13] The difference with the "science-based" international approach is clear, as this implied forms of political interactions based on the joint formulation of nanomaterial definitions and European regulations.

Both the JRC and SCENIHR reports found that the role of the expert agencies was to identify a more effective way to connect risks and physical and chemical characteristics. The approximate 1-100 nm size limit was maintained, but considered in a more nuanced way in order to account for the potential risks of nanomaterials. Firstly, both expert groups recommended that size distribution be considered, i.e. that a given substance should be considered a nanomaterial if a certain proportion of its components falls within the nanoscale.[14] Second, both JRC and SCENIHR proposed to include in the definition of nanomaterials entities that were not considered in the ISO definitions. JRC considered that materials "in a nanoparticulate state" – that is, able to release free nanoparticles – were those that might cause risks and included them in its definition. SCENIHR was far more inclusive, and argued that all nanostructured material needed to be included, so that future development of nanomaterials would continue to be covered by the definition.

Following the two reports, in October 2010 the European Commission proposed a working definition that included a condition linked to size distribution. Following SCENIHR, it chose to refer to internal structure and surface, and, according to JRC's recommendation, used the 100 nm size limit and did not seek to introduce more complex definitions. The definition proposed by the Commission was the following:

9 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the regulatory aspects of nanomaterials, SEC(2008) 2036.

10 European Parliament resolution of 24 April 2009 on the regulatory aspects of nanomaterials (2008/2208(INI)).

11 Commission Regulation (EC) No 1223/2009 on Cosmetic Products, Art. 2, para. k.

12 For a more detailed account of the opposition between the European Commission and the European Parliament, see Diana Bowman, Joel D'Silva and Geert Van Calster, "Defining nanomaterials for the purpose of regulation within the European Union", 1 *European Journal of Risk Regulation* (2010), pp. 115 *et sqq*.

13 Joint Research Center, *Considerations on a Definition of Nanomaterials for Regulatory Purposes* (2010); Scientific Committee for Newly Identified Health Risks, "Opinion on the scientific basis for the definition of the term 'nanomaterials'" (2010).

14 SCENIHR was more inclusive than JRC in its proposition for the size distribution threshold. It also proposed an iterative approach for the definition of nanomaterial based on different thresholds of size.

"Nanomaterial: a material that meets at least one of the following criteria:
- it consists of particles with one or more external dimensions in the size range of 1 nm – 100 nm for more than 1 % of their number size distribution;
- it has internal or surface structures in one or more dimensions in the size range 1 nm– 100 nm;
- it has a specific surface area by volume greater than 60 m2/cm3, excluding materials consisting of particles with a size lower than 1 nm.[15]

Industry and NGOs were invited to comment on the proposal. [16] Thus the Nanotechnology Industry Association (NIA), a lobbying group in Brussels that defends the interests of nanotechnology businesses, voiced its concerns that the definition could include an excessive number of substances.[17] Accordingly, it argued for a higher threshold for the share of the size distribution corresponding to the 1-100 nm size range. On the contrary, the European Environmental Bureau (a federation of European NGOs) used the SCENIHR report to back the 1 % threshold for the size distribution, and announced that it would oppose any attempt to increase it.[18]

These discussions laid bare the divergence in the interests of industries (limiting the number of substances defined as nanomaterials, and therefore subject to additional and costly constraints for manufacturers) and those of environmental groups (extending the scope of substances subject to regulatory constraints). Manufacturers tend to push the European institutions to adopt the ISO definition of nanomaterials, which is not based on a regulatory objective, while NGOs defend the more inclusive SCENIHR position. In Europe, the formulation of the definition of nanomaterials for "regulatory purposes" is inseparable from an organisation of collective decision-making in which vested interests confront each other. Stakeholders comment on expert reports, and can then strategically use them to argue for an increase or decrease in the size distribution threshold. The difference with international negotiation is clear: the process of European decision-making does not rely entirely on "science" in order to achieve an international consensus that would be separate from "political" objectives. Rather, it opens the construction of expertise to negotiation among stakeholders in order to meet a regulatory objective.

IV. Nanomaterials and responsibility in the French perspective

Whether the approach is science-based or for regulatory purposes, the definitions of nanomaterials by ISO and by the European institutions draw a line between nano and non-nano. This is precisely the role of the size criteria. But there are other ways to frame the problem of the definition of nanomaterials. French delegations in international bodies, for instance, tend not to propose rigid definitions but rather seek to define the conditions under which nanomaterials can be produced in a responsible way. In ISO's TC229, France is leading a project on "control banding" which strives to develop instruments for industrial companies to manage uncertainty. In this perspective, 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 French Ministry of Health (and an active member of French delegations in international arenas), and then implemented by the French Association for Standardisation (AFNOR). The aim of this project is to develop a "nano-responsible" tool that would define the relevant principles for industries wishing to produce, use or market "responsible" nanomaterials. It is addressed to any producer of substances considered as nano based on size-related properties. The tool comprises a list of questions that producers have to answer, such as: "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, manufacturers using the tool would be prompted to

15 "[A] specific surface area by volume greater than 60 m^2/cm^3" is a condition equivalent to a specific surface area greater than that of density 1 spheres of 100 nm diameter."

16 The European Commission recently published a recommendation related to the definition of nanomaterials, which originated from this consultation. See <http://ec.europa.eu/environment/chemicals/nanotech/pdf/commission_recommendation.pdf> (last accessed on 9 November 2011).

17 Nanotechnology Industry Association, "Comments on the SCENIHR Opinion" (2010).

18 EEB position on the Commission proposition, November 2010.

adapt their practices to account for the uncertainties of their products. They would be encouraged to use methods such as containment, diffusion of information among customers, or substitution of new products by better-known substances. The tool is currently being developed through a collaborative process involving industrialists and civil society organisations. It is expected to account for technical uncertainties, as well as the expectations and concerns of civil society. Ultimately, the nano-responsible tool aims to make producers internalise the potential externalities linked to nanomaterials production. Here, science is not deployed as a resource to reach consensus (as in ISO), or subject to negotiations among vested interests (as in Europe) – rather, the project is based on the idea that responsibility can be constructed in a collective way.

For manufacturers, the nano-responsible tool aims to help assess the constraints and requirements of the development of responsible nanomaterials. As such, they consider that the project must be based on a voluntary approach without any binding provisions. On the other hand, the nano-responsible tool also represents a link between product development and the expectations and concerns of public administration, and consumers and environmental groups. It is in this connection that oppositions emerge among the advocates of the tool. They relate to issues such as certification, called for by civil society groups, but resisted by industry. Certification would give visibility to producers, distributors and users of "responsible" nanomaterials. It would link the formulation of standards to the implementation of regulations, by allowing regulators and the broader public to track industrial activities. The opposition to certification, however, highlights the ambivalence of the objectives of integrating externalities to ensure the responsible production of nanomaterials. On the one hand, "responsibility" is supposed to be a label that would allow distributors and consumers to choose among different products. On the other hand, manufacturers wish to avoid solidifying a distinction between "responsible" and "not responsible" to render possible strategic navigation in a situation where regulations are not fixed and risks are difficult to prove. As for civil society organisations, they question the potential of the nano-responsible tool to redirect the development of nanotechnology, as the tool assumes that the development of nanomaterials, however "responsible", is the ultimate objective of this collaborative project. Moreover, it is based on the internalisation of the expectations and concerns of "civil society", which then loses the possibility for external critique.

The nano-responsible tool proposes a definition of nanomaterials based on the production of concrete nano substances by industries facing an uncertain situation. The approach is experimental and ambivalent, to the extent that the participants in the project are uncertain about their engagement. The project enhances the French position in international arenas, however – the successful French application to chair the nanotechnology technical committee at the European Committee for Standardisation (CEN) in 2010 was, for instance, based on the need to develop a responsible approach to the development of nanomaterials.

V. Conclusion

Defining nanomaterials requires scientific and technical knowledge, and the organisation of collective decision-making. At ISO, the international negotiations can reach consensus to the extent that the definition is "science-based". The definition of nanomaterials according to the approximate 1 to 100 nm size criterion ensures a consensus, and a separation between international science and national sovereign politics. European institutions, in contrast, define nanomaterials according to an explicit regulatory objective. Consequently, European nanomaterials are defined by more nuanced size criteria, which take into account the size distribution of the product's components. The European discussions take the form of negotiation among industry, associations and European institutions, while the expertise of bodies such as the JRC and the SCENIHR is a resource for the production of a coherent regulatory space. Lastly, the nano-responsible tool is an experiment in the actual construction of substances, in which nanomaterials are not defined by rigid criteria, but are the concrete products of industrial processes supposed "responsible".

The political formations stabilised in parallel with the definitions of nanomaterials have a geographical extension. They are "technological zones",[19] defined by standardised ways of dealing with chemicals. The international space is not the sum, or the smallest common point of agreement between national po-

19 This expression is used by Andrew Barry in "Technological Zones", 9 *European Journal of Social Theory* (2006), pp. 239 *et sqq.*

sitions, but an original technical, political and geographical construction which must eliminate toxicological properties-based definitions to be truly stable. The European space with respect to nanomaterials is defined via the institutions of the Union that attempt to define nanomaterials for purposes of European regulation. The nano responsible tool is inseparable from the construction of France's position in international arenas. The multiplicity of nanomaterials and the difficulties in building an infrastructure capable of measuring their physical and chemical characteristics play a central role in these processes. This highlights the deep connection between the formulation of definitions for nanomaterials and the stabilisation of political and geographical orders. It also means that the public management of nanomaterials cannot be solved by a mere call for a scientific approach, as this can be defined in different ways, and differently linked to political arrangements.

Regulatory Impact Assessment

This section regularly examines Regulatory Impact Assessment (IA) at three levels: the EU, the Member States and internationally. Contributions aim to cover aspects such as the interface between IA and risk analysis, looking at methodologies as well as legal and political science-related issues. Contributions are meant to report and critically assess recent developments in the field, develop strategic thinking, and make constructive recommendations for improving performance in IA processes.

Between Effectiveness and Efficiency: The System of "In-Depth" RIAs in the Swiss Federal Decision-Making

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I. Introduction

The Swiss Federal Council (FC, the Swiss government) published a report on reducing administrative burdens on business in August 2011, in which it addressed also the performance of Regulatory Impact Analysis (RIA) at the federal level.[1] The report reviews the measures undertaken by the FC since 2007 and sketches initiatives to be launched throughout the next four years. Administrative simplification and the reduction of regulatory costs have gained on relevance in the Swiss policy and political debate in the past few months – not least as a part of the campaign for the national political elections held in October 2011, with the economic crisis as a background. A national political party has launched a popular initiative against over-bureaucratisation, and the issue is brought forward by a number of stakeholders too.

The August 2011 report also fits into a wider debate about the legitimacy of RIA systems and the right balance between their effectiveness and efficiency. This brief note draws from a comprehensive evaluation of the system of in-depth RIAs in Switzerland,[2] which supported the government's report and developed some avenues for further investigating those dimensions.[3]

II. Background: RIA in Switzerland

When RIA was introduced at the federal level towards the end of the 1990s together with two further, parallel instruments – the SME-Test and the SME Forum – the intention was to cope with slow economic growth rates and to curb regulatory inflation.[4] Since the outset, the primary goal of RIA in Switzerland has been to analyse and systematically present the economic impacts of initiatives submitted to the FC. The scope of application is relatively comprehensive, covering legislative acts as well as wide-ranging implementing acts (with significant economic impacts) and, since 2006, regulatory acts affecting more than 10,000 firms. Swiss RIAs typically cover the follow-

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1 Federal Council (2011), *Allégement administratif des entreprises: bilan 2007–2011 et perspectives 2012–2015*, Bern, available on the Internet at <http://www.evd.admin.ch/aktuell/00120/index.html?lang=fr&msg-id=40711> (German version also available) (last accessed on 28 October 2011).

2 In this note, reference is always made to the federal level.

3 L. Allio, *Évaluation des analyses d'impact approfondies et des études Standard Cost Model effectuées par la Confédération entre 2007 et 2009, Rapport final*, Etude mandatée par le Secrétariat d'Etat à l'économie, Berne, 24.8.2011, available on the Internet at <http://www.news.admin.ch/NSBSubscriber/message/attachments/23926.pdf> (last accessed on 28 October 2011).

4 Federal Council, *Bericht des Bundesrates über Massnahmen zur Deregulierung und administrativen Entlastung*, of 3 November 1999.