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.

“One to Rule Them All”? – The Standardisation of Nanotechnologies

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1. Introduction

Nanosciences and nanotechnologies are a field of blooming technological applications, developed or manufactured at the nanoscale (a billionth of a meter). At this scale, matter shows new and unexpected properties1. These may significantly differ from one case to the other, which results in a great diversity of different industrial applications, and eventually in very heterogeneous end-user products. As a matter of fact, the generic dimension of nanotechnologies, understood as a platform or enabling technology, drives their diversity, and potentially affects almost every industrial sector.

In this respect, nanotechnologies are expected to bring about the “next industrial revolution”, according to the widely spread formula borrowed to the former National Nanotechnology Initiative (NNI, 2001). Symmetrically, from the very beginning of nanotechnologies’ development, calls have been raised for appropriate governance and social embedding of these new and complex technologies2. The European Commission, for instance, pays careful scrutiny to societal dimensions as well as public health, safety and due protection of the environment3. However, it remains unclear how precisely to govern such a diverse and flourishing field of end-user applications, since that it is acknowledged there is no one-size-fits-all solution4.

The development of international standards or technical norms is part of the solution to bridge that gap, and indeed contributes to the actual governance schemes that apply to nanotechnologies5. The literature in social science generally acknowledges that such norms do matter. They help to shape the trajectories industrial developments are following. For instance, Star and Bowker state that “Each standard and each category valorises some point of view and silences another.” (…) These are “long-term, collective forms of choice [that] are morally weighted”6. Accordingly, standards do have consequences, even (or especially) in the technological realm. Standards are both “ubiquitous but underappreciated tools for regulating and organizing social life in modernity”7.

On a formal basis, standards are or are not adopted by industrial partners on a purely voluntary basis, even though they are developed in close relationship

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1 ISO uses the following working definition in the Business Plan of its technical committee TC229 (p. 3): “Nanotechnology is the application of scientific knowledge to control and utilize matter at the nanoscale, where size-related properties and phenomena can emerge. The nanoscale is the size range from approximately 1nm to 100 nm”.


II. Standards as a means of regulation

ISO sets the tone when it comes to standards. It gathers and coordinates, in a global arena, multiple National Standards Bodies (NSBs) that provide a great deal of the work which is being mobilized by ISO, while it develops its technical norms. However, beyond this role of coordination, ISO does also perform its own specific expertise and helps shaping the outcomes of its “Technical Committees” (TCs).

In general, standards are useful to determine, or contribute to clarify, a common nomenclature, including specific methodologies or terminologies. Their main focus is on end-of-the-pipe consumer products. The business plan of ISO’s Technical Committee on nanotechnologies, TC229, states: “the foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.” The expansion of global trade provided an “impetus” for standards’ development, as a result of the increase of good exchanges and “the resultant compatibility problems due to outsourcing of components in different countries”.

ISO thus works in close partnership with NSBs and, through its Technical Committees, provides different kind of deliverables, most notably International Standards. The adoption of these technical norms by the actors of innovation is voluntary. However, the process of standardization itself provides strong incentives to comply with a standard, for different reasons.

The first one is economic. Innovation actors would avoid being marginalised on a specialised market they are competing on, which could eventually end up by their exclusion from this market. Secondly, standards are useful for scientific or technical purposes, as they offer common technical grounds to harmonize and level some different approaches, so that it has a scientific relevance if actors agree upon these common standardised grounds. Obviously, economic and scientific incentives to standardisation are driven by the same need for compatibility mentioned above.

Lastly, standards also contribute to shape the rules regarding innovation and should therefore be considered as a regulatory tool. Not only are innovators urged to use technical norms, but they may turn out to have to, if that norm is directly endorsed and/or legally enforced by public authorities, either at the national or European levels. So, depending on the cases and to a variable extent, standards do matter when it comes to the regulation of science and technology.

The European institutions frequently use International Standards to develop their own policies
and regulation and, even further, happened to recommend the adoption of standards as a privileged means for regulation. In the case of nanotechnologies, the European Commission expresses a “continued commitment to regulatory and standardisation activities” (p. 5).

In this respect, standards can be thought of as yet another manifestation of a trend towards the development of “soft law” to regulate new and emerging technologies. Such an evolution encompasses, for instance, voluntary codes of conduct or ethical review in funding allocation. In the case of nanotechnologies, the work on standards will operate hand-in-hand with tools such as, most notably, the Code of Conduct for Responsible Nanosciences and Nanotechnologies, or the ethical provision required from applicants, i.e. scientists and innovators who apply for European public funding and therefore need to include an ethical statement, as a result of the Science in Society programme of the European Commission. More generally, the Commission envisions the work on standards with nanotechnologies as favouring the “inclusiveness” of the approach.

So, for all these reasons, standards actively contribute to the regulation of nanotechnologies. According to Bowman and Van Calster, the purpose here is eventually to “alter behaviours” through the use of a set of complementary yet distinct regulatory tools. This report will now address more specifically how standards are being developed and issued for nanotechnologies, and shortly question their legitimacy.

III. Standardisation of nanotechnologies

Many difficulties arise when it comes to tentatively standardise a field that is still in its infancy. As a matter of fact, nanotechnology, as a political initiative, took momentum no more than a decade ago, with the National Nanotechnology Initiative (NNI). Ten years later, in February 2011, the NNI renewed its strategic plan and offers a rear overview on a decade of nanotechnology funding. This report stresses that, if “the NNI has dramatically expanded scientific understanding of nanoscale phenomena and enabled the engineering of applications”, however “the tremendous potential anticipated from nanoscale R&D is still far from full realization”. Ensuring this potential is the key mission ISO assigns to itself, through its approach to nanotechnology and standardisation. However, ISO has to deal with manifold complexities that result from the state of affairs at the nanoscale and its eventual R&D applications, which still goes in very heterogeneous directions.

So, many uncertainties result from this situation and need to be dealt with, and ISO intends to take up this challenge. Beforehand, it is important to underline that strong incentives are supporting standardisation, as it were. Despite this relative youth of nanotechnology as a field, there are strong incentives to stabilise the nanotechnology realm and map, delineate and circumscribe its iterative developments (see above). In this respect, many international fora are working to provide such clarifications, for instance on the terminology of nanotechnology. The European Commission also installed a Technical Committee on nanotechnologies at the “European Committee for Standardization” (CEN – Comité Européen de Normalisation), TC352. The Commission mandated CEN to present a standardisation programme and a list of proposed standards projects has been developed. This is currently being followed up by a specific stand-

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19 European Commission, “Communication on the role of European standardisation in the framework of European policies and legislation”, COM(2004)674 final. It states that “Standardisation is an integral part of the Council’s and the Commission’s policies to carry out “better regulation”, to increase competitiveness of enterprises and to remove barriers to trade at international level”.


21 Diana Bowman and Graeme Hodge, supra note 6, p. 12.


28 The International Electrotechnical Commission’s Technical Committee 113 (IEC/TC113), ASTM International’s Committee E56, or the OECD’s Working Party on Manufactured Nanomaterials.

ardisation mandate focusing on terminology, characterisation of nanomaterials, and methods to assess and simulate exposure. With nanotechnologies, in the EU, standardisation also operates together with other regulatory initiatives, such as the definition of nanomaterials or the issue of labelling.

Apart from European initiatives, the leading role on standardisation of nanotechnologies undoubtedly belongs to ISO. For instance, CEN/TC352 acknowledges its work on nanotechnologies to be “closely related” to that of ISO. However, on the one hand, it intends to avoid “any duplication of efforts” with ISO, and on the other hand, it expects “that the pace and timing of some projects will depend upon progress in ISO”. Therefore, CEN appears willing to hold back some of its work, while awaiting ISO’s critical insights. Keeping in mind this complementary approach that prioritises ISO, the report now focuses on this latter.

ISO’s willingness to standardise nanotechnology’s development definitely interplays with all these initiatives. However, from the inside, ISO develops a more tentative approach that suits the inner contested dimensions of nanotechnology. ISO develops a twofold strategy to tackle its inner diversity and complexity. Their approach to nanotechnology spans over different TCs, which address nano-related issues incidentally. But it is complemented by a nano-specific approach, which targets nanotechnology generically for all the potential research and application that may result, in general, from nanotechnology’s development.

First of all, several technical committees (TC) are dealing with the issue of nanoscience and nanotechnologies such as, obviously, TC34 (food products) and TC217 (cosmetics). These committees, as a matter of fact, do have a different focus than only nanotechnologies. Nevertheless, within the work provided by these TCs, nanotechnology is addressed, more or less peripherally, on the basis of actual nano-enabled applications, whenever it is relevant to the work of the TC.

The second strategy is to address nanotechnology specifically. One of ISO’s TCs is fully devoted to this issue: TC229 on Nanotechnologies. ISO/TC229 was created in 2005 and equipped with a “business plan”, which has the status of a guiding informal document. However it is frequently revised, it does not appear that significant shifts are noticeable in the general orientations. As for any of ISO’s TCs, TC229 operates within ISO’s core mission which is directed towards end-products (consumer products). It does engage in partnerships outside ISO. For instance, TC229 develops “a key liaison” with TC113 at the International Electrotechnical Commission, which finds its translation for example in the organization of Joint Working Groups.

In the Business plan of this TC, ISO tackles the manifold uncertainties of nanotechnology’s development. It states that “many of the documents produced by ISO/TC229 will be anticipatory (developed ahead of the technology that act as a “change agents” and guide the market) and horizontal (provide underlying support to a technology or a range of technologies but are not themselves application specific). This horizontal necessity necessarily means than first standards, as they aim to apply to the whole field of nanotechnology, will be large enough to encompass the very heterogeneity of nanotechnologies’ development, at least in a first stage. In this respect, they regard mainly “terminology and nomenclature, measurement and characterisation”, which ISO estimates to be a very priority.
The rationale for acting this way precisely relates to the youthfulness of nanotechnology as a field of R&D. Such a “tentative” approach is not really new to ISO’s work and is increasingly on the agenda, due to the inner complexities and uncertainties of most technological developments.

In general, TC229 is fully devoted to develop standards alongside an overall process of standardisation that “will play a critical role in ensuring that the full potential of nanotechnology is realised and that nanotechnology is safely integrated into society” (business plan, p. 1). More specifically, ISO follows four key objectives with respect to nanotechnologies: support sustainability and responsibility, facilitate global trade, support improvement of protection in HES issues and, lastly promote good practices.

The expected outputs of TC229 are of different kind. "Four categories of standards are being developed; terminology and nomenclature standards provide a common language for scientific, technical, commercial and regulatory processes; measurement and characterisation standards provide an internationally accepted basis for quantitative scientific, commercial and regulatory activities; health, safety and environmental standards will improve occupational safety, and consumer and environmental protection [...] ; and materials specification standards will specify the relevant characteristics of manufactured nanoscale materials for use in specific applications". Interestingly enough, the two first categories use the present form (provide), as if these outputs were immediately reachable, whereas the two latter categories use the future (will improve; will specify), as if they were targeting long term, expected yet uncertain outcomes.

So far, ISO already released an overall total of 11 standards, most of them in 2010. Among them, the most important are technical specifications which define the vocabulary tied with nanotechnology issues.

IV. Some issues of legitimacy

ISO is one of the key players that together perform the earliest forms of a global governance of new & emerging technologies, including nanotechnologies. It takes place in a larger context of international cooperation, as also do for instance the Working parties near the OECD, or these more or less informal committees that span over EU and US. Such platforms have far-reaching outcomes but are also fairly recent, both in scope and spread. Therefore, just like every kind of emerging industry and entrepreneurship, one may argue it needs to achieve a proper degree of recognition and legitimacy.

The fundamental working principles of ISO are democracy and consensus. Most notably, each member country, no matter its size and economic strength, gets one vote. ISO and its TCs take decision by means of consensus shaping. According to Forsberg, raising the issue of legitimacy is relevant to ISO, given the worldwide recognition of ISO’s standards and the ambitious role it intends to play in the regulation of nanotechnology.

Forsberg argues that ISO’s legitimacy depends on inputs, throughputs and outputs improvements. Inputs require that more attention is paid to the actual participation of a broader array of societal actors, especially stakeholders. Throughput legitimacy arises from procedural rules, most notably the respect of transparency all along the process of standard shap-

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44 In extenso: “1. Support the sustainable and responsible development and global dissemination of these emerging technologies; 2. Facilitate global trade in nanotechnologies, nanotechnology products and nanotechnology enabled systems and products; 3. Support improvement in quality, safety, security, consumers and environmental protection, together with the rational use of natural resources in the context of nanotechnologies; 4. Promote good practice in the production, use and disposal of nanomaterials, nanotechnology products and nanotechnology enabled systems and products”. ISO/TC229 Business Plan, p. 7.


46 Released standards are available on the Internet at <http://bit.ly/tc229publ> (last accessed on 8 July 2011).

47 Most important is ISO/TS 27687:2008 on Terminology and definitions for nano-objects: Nanoparticle, nanofibre and nanoplate, see also ISO/TS 80004-1:2010 on Vocabulary (Part 1: Core terms).


49 Geert Van Calster, “The regulation of nanotechnologies in the EU”, Symposium The Governance of Nanotechnologies in Belgian and European contexts, Université Catholique de Louvain, held in Louvain-la-Neuve, March 18th, 2011.


51 However, it is unclear how ISO defines and applies democracy.


53 A complete list of participants is available on the Internet at <http://bit.ly/tc229members> (last accessed on 8 July 2011).

54 Ellen-Marie Forsberg, “Standatisation in the Field of Nanotechnology”, supra note 52.

55 In his classical study, Scharpf distinguishes input and output legitimacy, to which Forsberg adds “throughput”; see Fritz Scharpf, Governing in Europe: effective and democratic? (Oxford: Oxford University Press, 1999).
ing. Lastly, output legitimacy would consist in means to validate the actual technical norms as they are eventually adopted. Yet another issue there would certainly be the actual access to these, since fees are required in order to access the actual standards. Forsberg concludes with the necessity to broaden up the debate, for instance through improved stakeholders participation.

To these concerns, we add the contested issue of repartition of members of the TC229. ISO itself analyses this composition as problematic. It states that the "Committee will take steps to encourage additional members from Africa and the Middle East". To this, we could add that Europe is notably over-represented, as compared to any other continent, including Americas. This relates to two big issues with political representativeness. ISO does not tie the weight of a member with the funding it provides and favours this principle of "one country, one vote". However, one may argue that discrimination occurs when unequal countries, e.g. in terms of population, are treated equally. The second issue regards the weak representativeness of Africa and the Middle East, which results either from a lack of interest or, more likely, from a lack of allocated resources.

V. Conclusion

Standards do matter, as they seek to shape alignments among innovators and contribute to shape the actual outcomes of R&D processes. In a sense, they can be thought of as slowly ordering a chaotic field, the field of nanotechnology, which is very heterogeneous and complex. Step by step, standards could help stabilise the situation, clarify ambiguities while unpacking and dealing with other ones. It does so in the alleged interest of economic, scientific and regulatory stakes. In this view, the more nanotechnology would be understood and framed through standards, thus refraining from a "largely uncontrolled growth", the more precise and technical the standards could go, undoubtedly creating "locks-in" effects in nanotechnology's development.

ISO acknowledges this challenging role and entertains rather high ambitions with respect to nanotechnologies. It focuses on consumer products and the facilitation of global trade. However, it eventually reaches far beyond and potentially regards every industrial or R&D actor concerned with nanotechnologies' development, in most sectors of activity. Such kind of effects is not only consented but also actively promoted by a great deal of public authorities, most notably the European Commission. Standardisation is expected to contribute to a regulatory agenda, which encompasses a wide plurality of tools and approaches that, all together, would help to frame nanotechnologies' development. For this reason, precisely, organizations like ISO need to ensure their legitimacy, which has not to be taken-for-granted.

This is where a fine-grained understanding of the dynamics of standardisation is more needed than ever, especially to unfold the left-asides of this "standard world". "Just as the choice of one standard over another signals a preference for a specific logic and set of priorities, so the choice of standards of any sort implies one way of regulating and coordinating social life at the expense of alternative modes."