Standardisation in the Field of Nanotechnology: Some Issues of Legitimacy

Abstract
Nanotechnology will allegedly have a revolutionary impact in a wide range of fields, but has also created novel concerns about health, safety and the environment (HSE). Nanotechnology regulation has nevertheless lagged behind nanotechnology development. In 2004 the International Organization for Standardization (ISO) established a technical committee for producing nanotechnology standards for terminology, measurements, HSE issues and product specifications. These standards are meant to play a role in nanotechnology development, as well as in national and international nanotechnology regulation, and will therefore have consequences for consumers, workers and the environment. This paper gives an overview of the work in the technical committee on nanotechnology and discusses some challenges with regard to legitimacy in such work. The paper focuses particularly on stakeholder involvement and the potential problems of scientific robustness when standardising in such early stages of the scientific development. The intention of the paper is to raise some important issues rather than to draw strong conclusions. However, the paper will be concluded with some suggestions for improving legitimacy in the TC 229 and a call for increased public awareness about standardisation in the field of nanotechnology.

Key words
Nanotechnology, voluntary standards, governance, legitimacy

Introduction
Nanotechnology holds great promise for improved applications in fields such as medicine, energy efficiency, defence, materials technology, food and agriculture, cosmetics, and so forth. In fact, nanotechnology might allegedly have a revolutionary impact on these fields, due to our new ability to manipulate properties at the nano level, making materials stronger, thinner, more elastic, antibacterial, and so forth. However, when creating novel properties at the nano level, we also create novel risks and concerns about health, safety and environment (see e.g. Stern and McNeil 2008), especially related to toxicity (Fernandez and Pilar 2008). Other ethical concerns also arise, related to e.g. social justice, human enhancement, invasion of privacy and the creation of transhumans (see Ebbesen et al. 2006). It is important for industry, government and society that these technologies are developed in line with societal needs and with a strong commitment to safety and societal approval. Different means of technology governance are therefore being developed (see for instance Hullmann 2008). Regulation of nanotechnology is being developed by national and international public authorities. At the same time, voluntary standards, as developed for instance by the International Organization for Standardization (ISO), will also be important for governance, and will likely be referred to in regulations. The European Commission states in its new approach to regulation that technical harmonisation is a prerequisite for establishing an inner market based on the free movement of goods. This technical harmonisation is to be achieved by ISO and CEN (the European Committee for Standardization). Through the Vienna Agreement, ISO and CEN have agreed to cooperate in standardisation projects where they have common interests, such as in nanotechnology. ISO's work in developing nanotechnology standards will therefore be important for European nanotechnology regulation. When ISO's standards impact on regulation, they will influence risk management and therefore how nanotechnology may affect consumers, workers and the environment. With this potentially important role, issues of legitimacy and proper procedure crop up, making it necessary to ensure that the standards are good for everyone.

This paper is based on a research project that took place from September 2009 to June 2010. The project was carried out with the secretary of the nanotechnology committee of Standards Norway and involved document and literature studies, interviews and participant observation. The document and literature studies were focused on two 'clusters' of issues: a) ethics and governance of nanotechnology, and b) voluntary standards, governance and legitimacy. The focus was on standardisation in nanotechnology, but literature from other areas of standardisation and on other discussions of nanotechnology governance was also included. Semi-structured interviews were conducted in person and on the telephone with participants in TC 229, technical standardisation officers and representatives of stakeholder organisations. I participated in two ISO meetings where I was registered for one working group and two task groups. I engaged in a number of informal conversations with TC 229 experts during the meetings. I also participated in the national mirror committee for nanotechnology. The participant observation was documented by field notes. The project was concluded by a one-day workshop including 24 participants, consisting mainly of members of ISO's nanotechnology committee and ELSA[1] scholars. Detailed minutes were recorded from the workshop. A final project report was distributed to all the people who had been involved in the project.

The project focused on the current and potential role of ISO standards in nanotechnology governance, and included a discussion of the new ISO guidance on Social Responsibility (ISO 26 000). In this paper the focus is exclusively on the work in ISO's technical committee on nanotechnology (TC 229) and the legitimacy challenges that arise due to its potential impact on science, innovation and regulation. The paper first briefly presents ISO and its nanotechnology standardisation work. Then it introduces the notion of legitimacy, and discusses ISO's nanotechnology standardisation initiative in light of input, throughput and output legitimacy. Particular attention is paid to stakeholder involvement and scientific robustness in the context of uncertainty. Finally, the paper concludes with some general considerations and recommendations. Because of the limited timeframe and resources in the project this paper should be read as a scoping paper identifying important issues for further research, rather than as providing strong conclusions.

ISO's work on nanotechnology standards

ISO is the world's largest developer and publisher of voluntary international standards. It is a non-governmental organisation, with national standardisation agencies as its member bodies. ISO consists of a general assembly and Technical Committees (TCs) that produce standards in their fields. These TCs consist of representatives from national authorities, private companies, research institutes and other delegates from the national member bodies and liaison organisations. ISO's work relies on market principles, and ISO only develops standards that have a market. According to ISO, their standards make the development, manufacturing and supply of products and services more efficient, safer and cleaner; they facilitate trade between countries and make it fairer; and they provide governments with a technical base for health, safety and environmental legislation and conformity assessment[2].

Two fundamental principles for ISO are democracy and consensus. Every full member country[3] of ISO has the right to take part in the development of any standard: 'No matter what the size or strength of that economy, each participating member in ISO has one vote. Each country is on an equal footing to influence the direction of ISO's work at the strategic level, as well as the technical content of its individual standards.'[4] Consensus is the working method in the TCs. In general, the work in the TC is carried out in working groups, at semi-annual meetings and in electronic communication between the meetings. The production of an International Standard is validated by the national member bodies in several steps:

> *Step 1 – New work item proposal*: For a new work item to be accepted at least 5 countries must be prepared to contribute actively in the work.
> *Step 2 – Committee draft*: A first draft developed by the committee. The participant National Member Bodies (NMBs) vote yes, no or abstain to the draft and submit their comments.
> *Step 3 – Draft International Standard (DIS)*: A second draft submitted for voting and comments by the participating NMBs.
> *Step 4 – Final Draft Standard (FDIS)*: The final draft before the official publishing of the standard submitted for voting and (usually) minor editorial comments.

ISO publishes not only International Standards, but also Publicly Available Specifications (PAS), Technical Specifications (TS) and Technical Reports (TR). These other documents represent lower levels of consensus.

1 ELSA stands for Ethical, Legal and Social Aspects (of Emerging Technologies).

2 In addition they share technological advances and good management practice, disseminate innovation, safeguard consumers and users, and make life simpler by providing solutions to common problems. See http://www.iso.org/iso/about/discover-iso_what-standards-do.htm. Accessed 21 January 2011.

3 A full member country is an ISO member country with an established national standardisation body. See http://www.iso.org/iso/about/iso_members.htm. Accessed 21 January 2011.

4 http://www.iso.org/iso/about/discover-iso_the-iso-brand.htm. Accessed 22 January 2010.

The national member bodies are crucial in ISO's work. They submit experts to the working groups and validate the work in the groups. The composition of the ISO TC's national 'mirror committees' is therefore important: they should consist of experts who have the competence to take part in or at least validate the work in the working groups. In order to ensure that the standards also benefit consumers, the environment and other relevant stakeholders, such organisations should also be represented. However, participation in ISO work (including work in the national member bodies' mirror committees) is not compensated, so all costs must be taken by the participants themselves.

In 2004 ISO decided to establish a technical committee for standardisation in the field of nanotechnology (TC 229). This TC consists of a Chairman's Advisory Group (CAG), four working groups (WGs) and three task groups. There are 36 participating (actively contributing and voting) member countries, 8 observing countries (who follow the development of a standard, and may make contributions to the work, but who do not commit themselves to active participation), and 8 liaison organisations (the EU, the OECD, and other projects and organisations)[5]. TC 229 explains in its business plan that '[i]nternational standardization will play a critical role in ensuring that the full potential of nanotechnology is realized and that nanotechnology is safely integrated into society. Standards will help create a smooth transition from the laboratory to the marketplace, promote progress along the nanotechnology value chain – from nanoscale materials that form the building blocks for components and devices to the integration of these devices into functional systems – and facilitate global trade.'

Nanotechnology standardisation is special since this field is in such an early stage, scientifically, commercially and with regard to regulation. In this situation ISO is in reality building a conceptual foundation for science and technology development. The first working groups (WGs) to be established were therefore on terminology and nomenclature (JWG 1) and measurement and characterisation (JWG 2). A working group on Health, Safety and Environmental Aspects (WG 3) was also established. These working groups were in the business plan justified as follows: 'The development of standards for terminology, nomenclature, metrology and characterization will support research, commercialization and trade in materials and products at the nanoscale, stimulating growth through the commonality of metrics and terminology. These standards will also support the development of appropriate national and international regulatory regimes, including guidance documents, in the fields of occupational and environmental health and safety. These regimes will provide certainty and confidence for workers, consumers, manufacturers and users alike.' A working group on material specifications (WG 4) was subsequently established. In addition to the four working groups, there is the Chairman's Advisory Group (CAG) and three task groups:

- Task Group on Nanotechnologies and Sustainability
- Task Group on Consumer and Societal Dimensions of Nanotechnologies
- TG 1 Measurement and Characterization for EHS[6]

At present one international standard has been published (ISO 2970:2010: Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test), in addition to four technical specifications and two technical reports. 36 publications are under development[7].

The task groups are not supposed to develop standards, but to identify and discuss relevant issues and advise the TC. The task group on Consumer and Societal Dimensions is to advise the TC on priorities for standards development and ensure that TC 299 has mechanisms for receiving input from relevant consumer and other societal communities. The task group on Nanotechnologies and Sustainability advises the TC 229 on how to include sustainability as a strategic priority for TC229 and how standards might help implement sustainability solutions.

We have so far looked at ISO's ambitions and work structure. Many organisations, not least ISO itself, foster great expectations to what ISO can achieve. However, as I want to discuss not only ISO's potential role in nanotechnology governance, but also the prerequisites for justifying such a role, we must examine how these

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5 'Liaison membership provides a way for international and broadly based regional organizations to participate in and be informed about the development of standards, and thus to ensure wider acceptance of the final result and to ensure coordination of parallell standardization activities in different bodies.' (ISO 2008c: 19).

6 No longer operative.

7 http://www.iso.org/iso/iso_technical_committee?commid=381983 .Accessed 14 Oct 2010.

standards are developed in practice. There is clearly a distance between ideals and practice in TC 229, as there is in all parts of ISO, and probably in all human affairs in general. This is also recognised by the TC itself, as I will return to below. But first we will look at certain challenges facing ISO related to societal and scientific legitimacy.

The relevance of legitimacy in standardisation

In political philosophy, legitimacy has traditionally been discussed in the context of governments. It is a status that the people confer on the government's officials, acts and institutions, through their belief that the government's actions are an appropriate use of power by a legally constituted governmental authority following correct decisions on making policies[8]. ISO is a non-governmental organisation (NGO) and does as such not need such political legitimacy. However, legitimacy can also be defined in a broader sense. Suchman (1995) seminally defined organisational legitimacy as 'a generalized perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions.' (574). In this respect, legitimacy is important to any organisation and one should expect that ISO would want legitimacy in the eyes of national governments, international organisations, industry, the scientific community, the public, consumers and other stakeholders. Anyone can make standards in any field; there are no particular requirements to this kind of work. In order to have an impact in a field, however, the standard maker, or at least, the standards, must be perceived as legitimate; if not, the standards will fail to become widely adopted. Especially in new and controversial fields like nanotechnology, the standards' legitimacy is crucial, but legitimacy is discussed with regard to many kinds of standards.[9] In fact, it seems hard to avoid legitimacy issues when speaking about ISO as a governance player. According to Risse (2004: 1), 'Governance beyond the nation-state provides an excellent laboratory for probing a host of issues related to concepts of concern to political scientists, such as legitimacy, accountability, and the participatory quality of various governance arrangements.'

With the issue of legitimacy come also procedural questions of transparency, participation and quality. Franck (1999: 1) defines legitimacy as 'the aspect of governance that validates institutional decisions as emanating from right process'. Van den Berghe (2006: 6) adds: 'In secularized, democratic societies, the primary source of legitimacy lies in the involvement of those impacted by a decision in the decision-making process leading to it.' In the remainder of the paper I will apply a model of legitimacy distinguishing between *input legitimacy* (i.e. how legitimate is the participation in the development process?), *throughput legitimacy* (i.e. how legitimate is the design of the development process?) and *output* legitimacy (i.e. what is the outcome of the development process?). This model has successfully been used by Werle and Iversen (2006) on ICT standardisation and by Hahn and Weidtmann (2010) in an analysis of the ISO 26 000 guidance on social responsibility. Input legitimacy and throughput legitimacy are related to an inclusive and democratic development process of the standard, while output legitimacy focuses on the results of the procedures. In the case of making nanotechnology standards, the quality of the standards will be crucial for their output legitimacy and one may distinguish between how the scientific environment evaluates the standards (scientific legitimacy) and how stakeholders evaluate the standards (stakeholder legitimacy).

As we have seen, ISO has ambitious visions for its role in society and in the governance of nanotechnology. In this context, and with the globally recognised position of ISO, the standards developed are expected to significantly impact the development of nanotechnology and nano regulations. From a normative point of view, the more societal influence and impact an organisation, a decision, or – in this case – a standard may have, the more societal legitimacy it should have and the more procedural requirements follow. On the other hand, the voluntariness of ISO's standards seems to reduce ISO's responsibility for the impact of its standards, perhaps even to the extent that questions of legitimacy are irrelevant for ISO. It may be argued that no societal decisions are made by ISO; it is those who decide to adopt the ISO standards (in which case they may be forceful recommendations, if not mandatory) that are responsible for their consequences. If the decision makers think the standards are unsatisfactory, they should simply not adopt them. But, on the contrary, it may be questioned whether decision makers do not perceive the situation the other way around: Are ISO/CEN standards adopted

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8 From http://en.wikipedia.org/wiki/Legitimacy_(political). Accessed April 2010.

9 For accounting and ISO 9000, cf. Tamm Hallström (2004); for accounting, cf. e.g. Johnson and Solomon (1984); for ISO 26 000, cf. e.g. Ruwet (2009) and Hahn & Weidtmann (2010); for ICT, cf. Werle and Iversen (2006); for ISO 14 001, cf. Raines (2003).

because they seem to have an *a priori* legitimacy by the very fact that they are made by these institutions? In a Norwegian context, at least, there is no evidence that decision makers see it as their responsibility to double-check the standards' substantive validity. An important reason for accepting ISO's standards without scrutiny is that since nanotechnology is a global industry, it is in practice difficult to operate with national standards. The WTO may consider specific national regulations as technical barriers to trade, and nations will avoid accusations from the WTO by adopting ISO standards. This makes it relevant to distinguish between institutional legitimacy and the legitimacy of the institution's products. The legitimacy of ISO as an institution gives their standards an *a priori* legitimacy. However, this only focuses on the throughput legitimacy of the standards (i.e. the design of the standardisation procedures), and neglects the crucial input and output legitimacy issues. This may be perceived as a responsibility gap with regard to individual standards, where the source of the standards' input and output legitimacy is unclear. Therefore it is reasonable to propose that *both* ISO and the adopters (at least when they are public decision makers) are responsible for the legitimacy of the standards that will set the framework in the market and in regulation. In this perspective the authority of ISO is not negligible, even if its standards are in theory voluntary. Thus, even if ISO repeatedly refers to the claim that ISO standards are voluntary and that users may choose to follow other standards (or develop their own standards), this claim must be modified strongly, and the question of legitimacy becomes critical.[10]

In the following I would therefore like to discuss the work in TC 229 in relation to the concepts of input, throughput and output legitimacy.

Input legitimacy and participation

Ensuring appropriate participation in the standard making is the most important issue of input legitimacy. However, achieving balanced participation is a well-known problem in ISO.[11] ISO is an organisation that intends to facilitate trade (see for instance ISO 2010), and the TC 229 Business Plan makes it clear that the standardisation work is meant to facilitate commercialisation of nanotech products. From a global ISO perspective, participation is dominated by industrialised countries (such as the US, China, Japan and the UK). As Blind and Gauch (2009) show, it is important for countries with large national nanotech interests (like the US and China) to significantly influence the work.[12] Blind and Gauch also report on the problems of recruiting non-industrial researchers to nanotech standardisation in Germany. The factors they identify are likely to be present also in other industrialised countries. It is therefore reasonable to expect that the representatives from the industrialised countries often (though not exclusively) represent industrial interests. Werle and Iversen (2006) and Jakobs (2010) similarly report on problems with recruiting other non-industrial participants to ICT standardisation, and the barriers they identify are not specific to this sector.

Blind and Gauch (2009) present different motivations for nanotech industries to be part of their national delegations and take part in the ISO working groups. From studies of ICT standardisation Jakobs (2010) shows that participants with industrial interests in some circumstances favour solutions, decisions and strategies that benefit their particular industry. One may suspect that this is also the case in nanotechnology standardisation. Industrial interests may of course also include protecting consumers and the environment, because of concern for the long-term economic sustainability of the industry and because of genuine moral commitments; this, however, cannot simply be assumed. There is therefore a need for representatives from consumer, worker and environment organisations to ensure that these concerns are taken adequately into account. Raines (2003) shows in a paper on ISO 14 001 that stakeholder absence impacts on both the legitimacy and the efficacy of the standards.

There are three options for participating in standard making: in the ISO technical committee, in national mirror committees, or through public hearings. Anyone can submit comments in the hearing rounds, but (at least in Norway) few seem to take this opportunity. Only members can take part in the national mirror committe and be appointed experts to ISO. In Norway at the moment, any interested person can become a member of the committee and be appointed to ISO TC working groups. However, since participation is not compensated (unless the participant is funded by his own organisation or other sponsors), there are few active members of the

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10 For a critical discussion of how voluntary such voluntary standards in fact are, see Tamm Hallström 2004b.

11 See e.g. ISO/IEC/GEN 2001.

12 There are few participants from developing countries, perhaps because they do not have nanotechnology research and industry. However, also developing countries will import nanoproducts and will experience the potential consequences in the same way as more developed countries, so that participation is therefore relevant for such countries as well.

committee who take part in national and ISO meetings. Active participation is dominated by people from industry and research.

As ISO no longer simply harmonises the market, but has larger societal ambitions[13], it has sought wider legitimacy through wider participation. From a market perspective, the inclusion of consumers is the most important, and in 1978 ISO established a committee on consumer policy (COPOLCO), which among other things provides recommendations for how to include consumers in standardisation processes.[14] In Norway and in other countries, consumer representatives can get their travel expenses covered by the standardisation organisation. However, as consumer representatives should be included in all standardisation projects, the pressure on consumer organisations is quite high. Moreover, ISO meetings are time-consuming, running over a week twice a year, all around the world. In addition, time is needed for proper preparation. Employees in consumer organisations also need their work hours financed and cannot take part in all kinds of standardisation processes. In reality, consumer participation is therefore limited. This holds true at a national level, at least in Norway, and it also holds true at an international level. For instance, even if ANEC (the European Consumer Voice in Standardisation) has nanotechnology as one of its priority areas, they lack the funding to engage actively in the TC 229 work.

When consumer participation is so difficult, even when actively supported by ISO and others, it is even harder to get participation from other NGOs. The International NGO Network on ISO (INNI) is working for increased NGO participation in standardisation processes and states that[15]

> […] ISO's quiet transformation from creating technical engineering standards to developing standards related to environmental and social policy has gone virtually unnoticed and unchecked by environmental and social justice organizations. Like the World Trade Organization (WTO), the rules established by ISO will have a major impact on national and local environmental issues – from the environmental management standards deployed by major multinational corporations to eco-labeling, water privatization, global warming and corporate social responsibility. Environmentalists and social justice advocates cannot continue to ignore ISO; we must get involved in shaping these standards and guiding the direction of their implementation.

A number of European environmental NGOs have created a consortium called the European Environmental Citizens Organisation for Standardisation (ECOS) to enhance the voice of environmental protection in standardisation work. ECOS aims at 'increasing the ecological performance of products, ensuring sound measurement methods for pollutants, greening management systems in businesses and improving consumer information towards sustainable consumption'[16]. ECOS recognises the importance of standardisation in the nanotechnology field and has made a list of recommendations to the EC (ECOS 2008). Because of a lack of funding, however, they have been unable to follow the work in TC 229 as closely as desired. ECOS has a liaison relationship with TC 229, which means that they can take part in the working groups but without a vote (only national delegations can vote). Therefore, ECOS encourages national environmental NGOs to participate in their national mirror committees. In this way, they can become part of the national delegations to ISO meetings and influence national votes. ECOS' problem in this respect is that the national environmental NGOs lack funding and already have a heavy work load.

It is hard to determine the exact number of stakeholder representatives taking active part in TC 229, because delegates are registered by name, e-mail address and country only, and not with information about the organisation they work for. From taking part in the meetings, however, the experience is that there are few consumer representatives and even fewer representatives from other societal stakeholder groups. This is to be expected taking the above mentioned barriers to participation into account, but there is a need to confirm this by establishing the facts about participation structures in TC 229. If this really is the case, TC 229 consists

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13 See for instance ISO' strategic plan for 2011 – 2015 'Solutions to Global Challenges', where it is stressed that ISO contributes to all three dimensions of sustainable development: economic, environmental and social. http://www.iso.org/iso/iso_strategic_plan_2011-2015.pdf. Accessed 02 February 2011.

14 http://www.iso.org/iso/resources/resources_consumers.htm. Accessed 20 January 2011.

15 From their webpage http://inni.pacinst.org/inni/. Accessed 2 April 2010.

16http://www.ecostandard.org/. Accessed 15 January 2010.

predominantly of technology *enactors* (i.e. scientists, as well as technology developers and technology promoters like business managers and governmental agencies in charge of technological development); conversely, there is insufficient involvement of technology *selectors*, typically (i) regulatory agencies responsible for safety, environmental protection, etc., (ii) new stakeholders, such as consumer groups and environmental groups, and (iii) spokespersons for society (see for instance Rip and te Kulve 2008).

In addition to the obstacles to participation, there is also a question of what impact these kinds of organisations have when they do in fact participate. An environmental NGO member who has been partly involved calls the TC 229 work 'a farce'. This refers to the experience of not having any impact on the discussions, even with apparently well-founded arguments. A Danish report by an environmental NGO in other standardising processes also testifies to having merely a moderate effect (Danmarks Naturfredningsforening 2004). Werle and Iversen (2006) show from ICT standardisation that participants who are only able to participate on an ad hoc basis may remain outsiders whose suggestions can easily be dismissed by the committee (2006: 35). Organisations that feel excluded from meaningful participation should perhaps consider withdrawing from the process in order to avoid being nothing but an alibi. It is interesting to compare their experience with the position of another group of non-scientific experts, namely *lawyers*, who in some cases wish to assess the technology legislation consequences of concepts or models before a proposition can be agreed on. These are a powerful group of non-scientific participants and illustrate the difference between more and less powerful stakeholders (cf. Mitchell, Agle and Wood 1997): whereas environmental NGOs feel ignored in the scientific discussions, lawyers may halt the process.[17]

This brings us to another aspect of participation in standard making, namely how the participation takes place. One needs to question how democracy and consensus is secured in practice. Certainly, the principle 'one country, one vote' holds true in ISO; however, the national member committees are not democratically organised, so there is no mechanism of substantial democracy in ISO. ISO could also be interpreted as a forum for democratic deliberation (this is also implied by its consensus principle) where the best arguments and the best solutions are supposed to win and where all the participants might exercise equal influence. However, this discounts language difficulties and misunderstandings. Moreover, anecdotes from the working groups suggest that consensus on output does not necessarily reflect a rational process of argumentative deliberation alone, but can be based just as much on negotiations and politics. This is shown to happen in other areas of standardisation. For instance, Jakobs (2010) shows that negotiations and informal agreements take place outside of the official meetings in ICT standardisation. Lee (2009), when discussing the role of scientific experts with regard to establishing food safety standards in the Codex Alimentarius Commission, criticises an 'idyllic' description of the work of experts. One may argue that all global organisations experience that cultural differences and power politics – and the negotiations between different interests – may be just as important as 'the best argument'. But even if these are well-known features in such international fora, they simply cannot be ignored when discussing democracy and legitimacy of the institutions, also in the case of TC 229. At some point the gap between ideals and practice has consequences for quality and legitimacy. Systematic interviews with the working group experts or recordings and analysis of the deliberative processes in the working groups would be needed to establish how decisions are made in the case of TC 229.

One could argue that broad participation is not necessary – or even feasible – in an area of such scientific complexity as nanotechnology. Indeed, Hatto argued in the project workshop that only specialists should enter the process: 'Experts nominated must have appropriate knowledge – not just a general interest in the area.' However, this seemingly discounts that some of the most apparently purely technical standardisation decisions involve value choices.[18] This is the case not only for standards for health, safety and environment, but also for basic terminological issues. For instance: Should we speak about nano objects, nano substances or nanomaterials? What are the legal, regulatory, labelling – and ethical – consequences of one of these terms versus the other? And what are the consequences of this terminological choice upon metrology in WG 2 and the HSE recommendations to be produced in WG 3? Friends of the Earth Australia (2008: 1-2) shows how the terminological stage is an important arena for conflicts of interests:

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17 They also illustrate the point that the broader the participation, the harder and slower the process.

18 As Werle and Iversen say: 'Technical standards are never purely technical' (2006: 23).

> The size range within which the ISO has defined nanoparticles will have significant implications for health and safety regulation at a national level. […] [T]he use of an arbitrarily defined size range to act as an index of novel properties is problematic. Particles that fall outside the size range deemed to encompass nanoparticles – even if they are not much bigger and also exhibit novel, nano-specific behaviour – will not be assessed as new chemicals. These particles will not trigger new health and safety assessments where substances have previously been approved for use in larger particle form.[19]

This is an ethical implication of choice of terminology in the sense that consumers, workers and the environment may not be equally well protected against harm from particles that exhibit nano characteristics as they would have been with a more encompassing definition of the nano range.[20] The same concern is at stake with regard to measurement: 'It is hoped that exposure and commercial use will be measured using nanoparticle-appropriate metrics (e.g. number of particles or particle surface area) rather than mass as per conventional materials' (ibid. p. 1). This is a value question in so far as one of the methods is thought to give more precise information and thus a better basis for e.g. risk assessments, than the other. One may claim that using nanoparticles-appropriate metrics simply is a question of getting the science right. However, getting the science right has been a main concern with regard to nanotechnology. Friends of the Earth (2006) reports: 'One of the primary concerns about nanoparticles is that there is increasing evidence that nanotoxicity will not be detected by the testing methods currently available for bulk chemicals (e.g. computer simulations such as QSARs (Qualitative Structure-Activity Relationships).' Controlling risk of harm because of nanotoxic effects is of great concern and TC 229 metrology choices should ensure that such effects are brought out in risk assessments. In this way value questions crop up even at a terminological and measurement level and have consequences throughout the TC 229 work. Scientists and lawyers are not more competent than others in determining whether the ethical consequences of a choice of terminology are acceptable. Thus, even though TC 229 involves technical competencies, there is also a need for broad engagement. Even if it was not intended this way, encouraging only experts to participate may be seen as a power mechanism that excludes voices that are not on the 'inside'. In the workshop, Hatto's position was countered by an environmental NGO representative who claimed that it is indeed possible to understand the crucial issues with a general understanding of science and nanotechnology.

At the project workshop, Fern Wickson highlighted the tension that exists in TC 229 between nanosciences and nanotechnology. Although the purpose of standardising is to help develop nanotechnology, this is at this point in time mainly done by standardising nanoscience. On the one hand, broad participation is apparently not possible because only specialists can understand the science; on the other hand, when science is mainly a means for developing technology, broad participation is important in order to influence this development in a socially approved direction. Broad participation is therefore both important (in light of the upcoming commercialisation that will result from today's scientific premises) and difficult (since most of the current work is scientific).

Some may claim that input legitimacy, participation and the pragmatics of the process is not a problem if the processes are transparent. In this way one can take an informed stance on the development of the standards and reject standards one perceives to be lacking in legitimacy. However, first, this assumes real voluntariness of the standards (which we have seen is an assumption to be doubted). Second, in our project we experienced several transparency related problems and ambiguities. It was hard to access information about the TC 229 participants (names, affiliations, etc.). It was also difficult to access documents related to the working groups and task groups with which we were registered. The documents we did access were summaries and did not seem to reflect a wider argumentation in the group. These problems might be due to unfortunate technical errors, accidental shortcomings or even misunderstandings on behalf of this researcher, and a more thorough assessment of the actual transparency of the TC work should be carried out. However, these problems indicate that transparency can be improved and that information should be made more readily accessible. It should also be noted that the problems presented above were problems for *registered experts*. It is even harder to access information for the *general public*. In order to access any information (except the drafts that are out on public

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[19] It should be noted that TC 229 uses a somewhat open-ended definition that takes this into account. In the technical specification on terminology and definitions for nano-objects, they define the nanoscale as the size range approximately from 1 nm to 100 nm (ISO/TS 27687).

[20] As long as there is no other regulation in place addressing this size range.

hearing) you must become a member of the committee. However, at that point you are no longer a member of the general public. Moreover, one of the TC 299 participants reported in a meeting that she had had problems being accepted as a member of her mirror committee. It is tempting to interpret these problems in light of an hypothesis that ISO is somewhat ambivalent on the issue of transparency: finding it necessary to balance transparency with the need for creating a protected space where the experts may work in peace. One may fear that opening up the processes may make them even less efficient. The need for a protected space has therefore perhaps been given more weight than transparency. This trade-off should be further explored in future research. Until then we may tentatively conclude that these transparency and access issues make it difficult to determine the real quality control and broad, inter-disciplinary participation in the development of the standards (input legitimacy). If it really is the case that it is difficult to monitor the work from the outside, there is not sufficient transparency for disregarding issues of input legitimacy.

Finally, it should be noted that the national mirror committees have a role in the development of the standards, halfway between the working groups and the public. The national mirror committees vote on, and provide comments to, the working groups at several points in their development of the standards. In this sense, the input to the work is broader than the contributions from the experts in the working groups, potentially enhancing input legitimacy. Moreover, the voting can also be seen as a test of the acceptability of the standards, potentially contributing to securing output legitimacy. However, again, there might be a gap between ideals and practice in the ISO system. Due to nanotechnology's broad and interdisciplinary nature one would expect it to be hard to recruit enough experts - with a sufficiently broad scope of expertise (including experts from societal stakeholder groups) - to the national mirror committees. At least in Norway so far, the knowledge about this standardisation work seems limited, entailing that a number of relevant experts and NGO representatives are never recruited. And again, this is unfunded work. In Norway, for instance, this makes it difficult to arrange committee meetings because travel costs (which may be substantial) are not covered. Committee members may of course give their comments by e-mail, but this also involves allocating unfunded working hours to this task. In the future, research should be conducted that systematically studies the participation in the national mirror committees of TC 229, the extent of review of the ISO documents, and how the extent of review varies with, for instance, the available expertise in the committee related to the document in question. Another problem with the review in the national mirror committees is that some national standardisation agencies (like the Norwegian committee) have a policy to vote 'yes' to a proposal unless there are specific counterarguments, even when the mirror committee lacks the expertise to adequately assess the proposal.[21] Standards may therefore appear to be more thoroughly validated than what they really are. On this note, we shall proceed to discussing issues of output legitimacy in more detail.

Output legitimacy, scientific uncertainty and scientific robustness

It is hard to mend the problems connected to participation and input legitimacy because of a lack of incentives and/or resources for non-industrial stakeholders to take part in the processes. Werle and Iversen (2006) claim that taking the problems of input legitimacy into account is a reason for focussing more on output legitimacy. Werle and Iversen define output legitimacy as making the 'good standard' from all stakeholders' perspectives, and explain: 'Developing a 'good' standard requires facilitating access to SDO [Standardization Organizations] of as many diverse interests and values as necessary to assure that all relevant technical, commercial, socio-economic and socio-political aspects are appropriately taken into account. But it does not require that they are directly and proportionally represented in the standardization process by advocates and other representatives of these interests and values.' (2006: 32). Werle and Iversen suggest that pressure groups should try and influence the routines and mental frames of the standardisers, so that they are stimulated 'to consider potential non-market and non-technical impacts of standards' (2006: 37) in their work in the working groups. They mention guidelines and special external or internal review committees as options for such broadening of the frames or cognitive scope. This resonates in fact with current work in the TC 229 Task Group for Consumer and Societal Issues and the Task Group on Sustainability. It might be a promising way to ensure broad societal and stakeholder acceptability of the resulting standards, i.e. what was termed stakeholder output legitimacy above. However, output legitimacy will also be a matter of the reception of the standards by the scientific environments, and to this issue I will now turn.

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21 The alternative is to vote 'abstain'.

The main scientific challenge to the TC 229 work is the current status of scientific knowledge. The safe and socially robust development of nanotechnology requires first and foremost research, and the above quote from the business plan shows that TC 229 intends to take a lead in developing science. With such high scientific ambitions, TC 229 may be an important tool for addressing the most crucial concerns surrounding nanotechnology at the moment, namely a lack of a common terminological and metrological framework and HSE assessment tools. The question, then, is what role TC 229 can play in building the requisite knowledge base for the governance of nanotechnology. A central issue here is how standards can achieve output legitimacy – in the sense of scientific legitimacy – in light of the current scientific diversity and uncertainty. The standards need to be robust, in the sense of not being vulnerable to the progress in science and not assuming a particular approach to nanoscience and technology. Robustness is thus related to how comprehensive the internal discussions have been, because even if TC 229 can make its experts agree, there is a much larger scientific community that has not been involved in the process. Scientific diversity and the lack of scientific knowledge is both the justification of TC 229's work and also its problem: there is a need for standards precisely because there is little scientific consensus. TC 229 takes it upon itself to lead where others hesitate, but this raises some questions: Why is ISO an appropriate forum for producing scientific consensus? Can ISO really do this – or will TC 229 only succeed at the expense of scientific quality and broad scientific legitimacy and robustness of its output? I will therefore now discuss the issues of scientific uncertainty and diversity related to the work in TC 229.

Anecdotal evidence suggests that the lack of scientific knowledge is a practical problem in some of the working groups (this is also confirmed by Delamarle and Throne-Holst 2012). WG1 leader Clive Willis stated in the project workshop that although the 'Holy Grail' would be a 'single, 'bright-line' description for the nanoscale', 'variation in dimensional dependence poses difficult challenges in creating terminology that is both accurate (i.e. reflecting physical reality) and precise (i.e. not being so vague or general as to encompass such a potentially broad range of materials so as to be relatively useless)'. By October 2010 seven documents were published: one international standard, two technical reports and four technical specifications. *Technical reports* are issued when a technical committee or subcommittee has collected data, such as references and explanations, that are of a different kind from that which is normally published as an international standard. *Technical specifications* can be produced when the given subject is still under development or when there is the future but not immediate possibility of an agreement to publish an international standard. These are thus guidance documents that represent lower levels of consensus.

Generic challenges to the scientific work in the working groups are

- ambiguity in the field
- a lack of relevant knowledge
- a lack of relevant expertise available at all (for some areas)
- a lack of relevant expertise willing to engage in such work
- a lack of sponsors willing to fund expert contributions
- a lack of consensus among the experts
- the diversity of disciplines impacted by and contributing to nanotechnologies, making it hard to communicate and agree in the process.

The lack of knowledge is mentioned in TC 229 publications. Is this admission sufficient, or does the scientific uncertainty affect standard making in nanotechnology more fundamentally? The technical report on health and safety practices in occupational settings (ISO 2008a: 42) states that the 'existing structure of risk assessment framework is flexible enough to be adapted to nanomaterials'. This is a controversial issue, however, and TC 229 has here taken a value stance on the issue without appropriately discussing whether the situation really is characterised by risk, uncertainty, ambiguity or even ignorance (see Wynne 1992 and Wickson et al. 2010).[22] Even if the documents are not very substantial, it is debatable whether standards should be published at all at this point in time. Publishing standards may lead people to believe that this knowledge is more established and well-explored than what it actually is. If it is true that this field is characterised by massive ignorance and ambiguity (as e.g. Wickson 2009 argues), then this hardly seems the proper climate for standardising. In a

22 Please note that it was beyond the scope of the project to critically assess the adequacy of TC 229's treatment of uncertainty.

workshop on nanotechnology standardisation, ISO, IEC, NIST and OECD (2008: 2) recognise that – at least in some areas of nanomaterials characterisation – 'there is perhaps a greater need for new measuring instruments and techniques than for new documentary standards, though the former, once developed, will need validation and verification and ultimately the preparation and delivery of standards covering the techniques and principles used. In the specific case of nanoparticles, it is not generally realized that particle size distribution is not a fundamental property of the material being studied, but a temporary state of dynamic equilibrium between dispersion and agglomeration in suspensions or aerosols. This, and numerous other differences between perception and reality, present tremendous challenges in such a high-profile subject area.'

The bottom-line dilemma is this: On the one hand, obtaining scientific knowledge and adequate nanotechnology regulation requires a common framework of e.g. terminology and measurement methods. In that respect ISO's initiative is to be applauded. On the other hand, standardising terminology, measurement methods, etc. at this point in time may prematurely fix concepts and practices that should remain open and dynamic until more knowledge is gained. A pluralist approach focussing on best practices rather than fixed standards might create better methods and solutions, as compared to narrowing the explorative approach at this early stage of nanoscience and technology. Admittedly, ISO's standards are open for revision, and will be revised as knowledge develops. Still, it is ethically debatable whether ISO should publish standards at this early point. As a thought experiment one may ask what the limit is for when the scientific knowledge of a field would seem to be too uncertain to warrant standardisation. With regard to nanotechnology, if the field actually is characterised by risk, then standardisation is possible. If it is characterised by large ignorance, it would probably not be seen as eligible for standardisation, but maybe for a general moratorium. This is perhaps the most fundamental ethical issue concerning standardisation of nanotechnology. The question is thus where on the scale between known risks and large ignorance nanotechnology is placed. Wickson claimed at the project workshop that the uncertainties grow as more research is being undertaken (i.e. new areas of uncertainty are being uncovered). Can we imagine a situation where the ISO process is put on hold because of a recognition of increased uncertainty? With increasing uncertainty the precautionary principle will at some point be relevant, also in the context of standardising. Moreover, ISO does in fact have general recommendations for including the precautionary principle. For instance, ISO 2008b (section 3.2.5.1) says that: 'Standards writers should take into account the precautionary principle when developing provisions in standards.' The precautionary principle is also included in ISO 26 000 on social responsibility, where it is defined in line with the Rio Declaration on Environment and Development (pp. 40-41). One option for showing genuine respect for the precautionary principle would be to address this in all relevant standards and stress that products should not be put on the market until there is sufficient knowledge about HSE consequences of using the product (in a life cycle perspective). This does not entail waiting until there is 'perfect knowledge' (whatever that would mean); it rather entails engaging with HSE and ELSA researchers, as well as other stakeholders, about when marketing seems warranted. If the precautionary principle is held to apply for nanotechnology this would be an extra incentive for broad stakeholder inclusion in TC 229.[23]

Finally, with regard to standard making and scientific issues we should consider the relation between TC 229 and the wider scientific community. TC 229 organises about 350 experts, which is a small part of the nanoscience community. This again is a reason why ISO is able to produce consensus at all, but it also makes the output vulnerable to criticism. Standards developed in a wider scientific process would (in addition to having better input legitimacy) likely be more robust to criticism and therefore considered to have better output legitimacy from a scientific perspective.

In order to determine the strengths of developing standards within ISO and to predict how acceptable such standards might be to a wider scientific community, there is a need to study the dynamics of the discussions in the working groups with regard to understanding the scope of arguments considered and the nature of possible disagreements. In areas of scientific controversy there is often a recommendation to include counter-expertise in order to achieve nuanced discussions (see Conrad 1982 for a literature review). Counter-expertise would seem to be needed in order to balance discussions that otherwise would not reflect the real width of knowledge or scientific positions in the area. Determining whether there is sufficient width of expertise is important for identifying any need for additional (counter-) expertise. There is also a need for analysing whether any potential

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[23] For an account of the relation between the precautionary principle and stakeholder involvement cf. e.g. Stirling et al. (2006).

disagreements can be due to reasons other than scientific convictions. Jakobs (2010) shows that several kinds of motivations influence the actions of experts in the working groups. Analysing the discussions in the working groups will give important input to predicting how widely acceptable the output standards will be.

There are of course relations between ISO and scientific fora, because TC 229 participants are active in the scientific world and disseminate the TC 229 work there (cf. e.g. Murashov and Howard 2008). One might also imagine TC 229 engaging even more proactively in the scientific community – as TC 229 also acknowledges in its Strategy Statement – in order to rationalise the TC 229 work and facilitate a wider scientific discussion about the specific topics for standardisation. For instance, public research funding institutions might conceivably take into account knowledge needs related to specific standardisation activities when designing their nanotechnology research programs and calls. This might also have the benefit of more concerted efforts in building a knowledge platform for nanoscience and technology.

Given the current level of knowledge, there are all in all considerable scientific challenges with making standards in the nanoscience and nanotechnology field. Actually producing normative documents is challenging. The robustness of the output is also a challenge; there is a risk that the output will be controversial and that its scientific quality will be criticised by the experts who were not part of the process. This will also be a risk to the standards' perceived legitimacy and their adoption. In order to reduce this risk, a possible strategy would be to embed the TC 229 work even more deeply in a comprehensive scientific discourse. However, this may reduce efficiency so much that TC 229 may lose its momentum and participants may become less willing to invest the necessary amount of time.

As more and more substantial standards are produced, it will be possible for the wider scientific community to assess the scientific quality of the standards. Until then, a judgement on the scientific quality and output legitimacy must be put on hold. As with wider stakeholder legitimacy, the scientific legitimacy can so far best be assessed by appraising the experts who take part in the processes: their academic background, areas of expertise, current affiliation, etc. Such an assessment would be an important topic for further research.

Conclusion

This paper has highlighted important challenges with regard to input and output legitimacy in TC 229. We have seen that thorough input legitimacy, in the sense of broad participation on equal terms, is still not achieved. We have also seen that Werle and Iversen have recommended a focus on output legitimacy (in the ICT standardisation context). This is a promising strategy also for TC 229, and a strategy that is actually being followed. However, enhancing output legitimacy in this way should not substitute independent validation of the standards. We do not yet know how the standards' output legitimacy will be perceived from a scientific perspective. With regard to stakeholder validation of the output the problem is that such validation requires specialised knowledge. Many stakeholders are likely to find it hard to assess the quality simply by looking at the output. This means that relying entirely on output legitimacy also seems hard. Stakeholders need to be reassured that the actual procedures for making the standards are good enough. Transparency of the work – with regard to who participates in the development and how decisions are made – is therefore important. The TC 229 Chairman's Advisory Group (CAG) has undoubtedly considered the issues discussed above, and one response has been to establish the Task Group on Consumer and Societal Dimensions and the Task Group on Sustainability. So far, however, the legitimacy issues have not been effectively tackled.

It should be clear that ISO should not shoulder all the responsibility. The national standardisation bodies are at least equally responsible for ensuring adequate participation in the standardisation work, and perhaps even more so. This is a responsibility for both the secretary and the leader of the mirror committee. Experts come from national delegations, and ISO and the national member bodies must cooperate in order to strengthen participation and scientific input by creating awareness and funding will among national authorities, as well as awareness and interest among relevant national experts and stakeholders. However, with regard to transparency, the national member bodies are constrained by ISO rules and directives, so that increasing transparency is primarily an ISO responsibility.

ISO standards have been criticised before. For instance, ISO 9 000 on quality management has been criticised on several points as being inferior to best practice (Murphy and Yates, 2009: 71). Still, ISO 9 000 was perhaps the best compromise possible, considering all the member countries' interests, and the 9 000 standards are among the most widely used ISO standards. But there must be a lower limit on how much compromise can be made before the quality of the standard is so low that it loses its legitimacy. This limit is of course hard to define, but – taking the problems of input legitimacy into account – standards should be thoroughly assessed prior to their recommendation in order to ensure that the compromises have not detracted from our best knowledge and basic values. Standardisation involves value issues, and when these issues are solved in negotiations – especially in negotiations where technology enactors are strong – compromises may be made that are not optimal from a societal point of view. Recognising that nanotechnology standardisation is complex and challenging, the TC 229 standards should be duly scrutinized before being accepted. Decision makers should critically and realistically appraise what can be achieved by voluntary standards. It should not be the case that ISO's standards are accepted simply because they are produced by ISO, rather than because of their quality.

The project reported on here was limited both in time and resources, and the work in TC 229 is developing continuously. Many of the claims in this paper should therefore be followed up by further studies. Still, I would like to draw some tentative conclusions. I believe that ISO standards may contribute positively to the governance of nanotechnology if the challenges related to input and output legitimacy are tackled more effectively. Moreover, all TC 229 publications should refer to the comprehensive uncertainty surrounding nanotechnology and make their value choices transparent. They should also recommend the application of practical means for ensuring social responsibility in nanotechnology development, for instance the new ISO 26 000 guidance. ISO should more proactively make the necessary organisational changes for the societal role they are now taking, especially regarding increased participation and transparency. The Task Group on Consumer and Societal Dimensions seems to have a well justified agenda, but its work should be given higher priority. There is a risk that this task group (and the Task Group on Nanotechnology and Sustainability) will be seen as pure window dressing if they do not create concrete results or have visible impact on the TC and CAG. Finally, the two task groups, the CAG and the working groups should interact more in order to ensure that ethical and legitimacy issues are not simply "outsourced" to advisory task groups, but will be integrated in the discussion in the whole organisation, including the national mirror committees. Consciousness about issues such as those presented in this paper must penetrate the organisation, from strategic decisions in the CAG to concrete formulations in standards.

The impact of TC 229's work may in fact be substantial, making the quality of the standards an important issue. Both ISO and the countries participating in TC 229 should therefore debate the organisation of the standardisation work, incentive structures, communication and awareness issues, and standardisation funding. This debate should also address the fundamental objections to the whole initiative of making nanotechnology standards, for instance that standardising may conceal the fact that some experts consider the nanotechnology field to be so uncertain that standardisation of procedures like risk assessment currently is entirely unsuitable. The appropriate legislative context for nanotechnology standards is therefore an important issue. Finally, it should be discussed whether ISO is the right place for handling such an important and difficult scientific task as making a scientific basis for the development of nanosciences and nanotechnology.

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