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Standardisation - Enabler for Nanotechnology Innovation[1]

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Nanotechnology is an amazing field of innovation – both in terms of the materials used and of products made. However, the technology carries many risks and uncertainties: it may pose harm to people, nature, and the environment. Is an assessment of the potentially adverse impacts of nanomaterials and nanoproducts necessary before they can be brought onto the market? Many researchers see a need for legislation, but could setting standards be an alternative, either alone or in combination with legislation? This paper will argue that standards can enable innovation while also addressing the broader societal impact of nanotechnology.

This chapter will first introduce the relation between standardisation and innovation in general. Next, it will describe and discuss current activities of the International Organization for Standardization ISO in this field. Section 3 will address the possible harm – the precautionary principle, and the possible role of legislation and standards. This chapter is based on lessons from literature combined with the author's own practical experience in other fields of standardisation and innovation.

1. Standardisation to Support Innovation

The combination of standardisation and innovation is not self-evident. At first glance the two concepts ironically seem to exclude each other. Standardisation is the activity of establishing, with regard to actual or potential matching problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context (de Vries 1997). In order to establish order, standardisation 'freezes' a provision for a certain period of time. Innovation, on the other hand, involves the creation of something new. In Schumpeter's classic definition (1934), innovation is the commercialisation of all new combinations based upon the application of new materials and components, the introduction of new processes, the opening of new markets and/or the introduction of new organisational forms. The core of nanotechnology is in new materials, but the technology's development also leads to the creation of new products and requires innovation in the other categories in a manner consistent with Schumpeter's definition. If standards 'freeze' a solution, that solution cannot be changed anymore until the standard is withdrawn or revised, so in that sense it indeed hinders innovation. However, this stability is needed for interoperability: standard interfaces remain stable, providing a basis for the interconnected modules' further innovation (Lee 2010).

In addition to interoperability, the economic functions of standards also include (minimum) quality and safety, variety reduction, and information (Blind 2016). Blind and Gauch (2009) relate standards to phases in the innovation process and argue that the nanotechnology field needs these standards. Semantic standards are needed in the transition from pure basic re-search to oriented basic research, measurement

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and testing standards are needed to prepare for applied research, interface standards are needed for experimental development, and interoperability standards, quality standards, and variety-reducing standards are all needed to prepare for market entry. In nanotechnology, interoperability standards are necessary only if the technology is used in systems consisting of several interlinked components. Standards for health, safety, and the environment are needed to mitigate any potential risks of nanotechnology products. For an up-to-date overview of the current insights on the relation between standardisation and innovation consult the Handbook of Innovation and Standards (Hawkins, Blind and Page 2017).

2. ISO/TC 229 Nanotechnologies

2.1 Introduction

Meanwhile, the development of standards for nanotechnology is already underway. The International Organization for Standardization (ISO) initiated the development of international standards in 2005 by establishing Technical Committee 229 Nanotechnologies. The main topics covered by this TC are terminology and nomenclature, measurement and 'characterisation,' health, safety and the environment, and material specifications. These will be discussed in the subsequent sections of this chapter.

2.2 Terminology

Scientists working in nanotechnology come from different disciplines, backgrounds, and industries and lack common terminology (Delemarle 2017). The development of terms, definitions, units of measurement and codes, if any, is a core element in the development of any scientific field (Kuhn 1962). Whether nanotechnology is a separate field of science or a sub-field of materials science remains open for debate. Regardless of this debate, terminology is still needed to facilitate communication, reduce transaction cost, and avoid misunderstandings and any potential resulting mistakes. Terminology standardisation for nanotechnology is a basis for research itself, but also for other standards and regulation, and may also benefit practitioners in the field. Finally, sound terminology is a good basis for communicating about nanotechnology in languages other than English (Teichmann 2010).

The importance of standardising the terminology we use when discussing nanotechnology is often underestimated. Therefore, it can be difficult to find experts for standardisation committees who are willing to invest money and more importantly, time in this important work. Moreover, the specialised nature of the topic makes the involvement of nanotechnology experts a prerequisite, along with experts with an affinity for linguistics. Even if standards are available, stakeholders may be unaware of their existence, may lack financial resources to purchase them, may lack the time to become familiar with the terminology, or may even have difficulty interpreting the standard terminology (de Vries et al. 2009).

2.3 Measurements

The properties of technologies and prototypes of products made out of nanotechnology materials need to be assessed throughout the research and development (R&D) process. While different chemical, physical, electronic, and structural properties of nanomaterials create new opportunities for products, the very innovative nature of the technology entails that existing test methods for both materials and products are insufficient and new ones need to be developed in parallel to this advancing technology. Research institutes or companies may do this themselves, but establishing standards for common test methods is preferable for increased reliability and impartiality. Laying down the test methods in standards can facilitate agreement for actors across the field. Especially if such tests based on a common standard are carried out by independent third-party certification bodies with sophisticated knowledge, they make the market more transparent, and the knowledge about current characteristics may further challenge innovators to develop even better technologies and products.

2.4 Health, Safety, and the Environment

Nanomaterials are potentially risky for both people and the environment. ISO/TC 229 (2011) sees assessment of the risks posed by nanotechnology-based products throughout their life-cycle as an important priority. The development of test methods for use at nanoscale is needed in order to accomplish this. Test methods are also needed to detect and identify nanoparticles, and to characterise nanoscale materials and devices. The TC develops protocols for such assessments. Standards provide two types of legitimacy: input legitimacy originating from stakeholder involvement in the process of standard formation, and output legitimacy resulting from the effectiveness and coordinative capacity of standardisation (Botzem and Dobusch 2012).

2.5 Standardisation of Material Specifications

Nanotechnology enables the creation and use of new materials with superior performance for many applications. Standardisation of material specifications helps to define these and to create a database of materials with their known characteristics, which may also include negative side effects. Designers of products can use such a database to make use of the materials that are best fit for their purposes. A company like Philips used to have such a database internally to speed up the process of product development and to reap the benefits of better product quality while lowering the cost of purchasing, storage, and testing. At the European level, the REACH database of chemicals yields an example. The REACH information covers the intrinsic properties of around 15,000 chemical substances, and their impact on human health and the environment. In 2017 it included 21 nanomaterials, whereas the TSCA Chemical Sub-stance Inventory of the United States Environmental Protection Agency (EPA) listed approximately 160 approved nanomaterials (Sayre, Steinhäuser and van Teunenbroek 2017).

At company level, standards for materials provide a basis for communication between designers, engineers, and purchase and sales people within that company. Standards also allow for easier communication between companies. Standards provide an important basis for trade be-tween sellers and buyers, which may constitute an entire chain, from the production of raw materials via companies processing these materials and companies making semi-finished products to the manufacturers of final products and, at the end of the chain, the customers. Using standards, the customer can specify what he or she wants. This can be an exact specification of the material but it may also be a specification of the functional or manufacturing requirements for the material. In the latter case there is more choice and room for innovation. Of course, such specifications might be agreed upon within one company or between a supplier and its customer. However, increasingly companies do business with many partners world-wide and therefore there is a need for international standards for materials (van Mourik, van der Hoek and de Vries 2011).

3. Mitigating Risks

3.1 Precautionary Principle

ISO/TC 229 develops standards for nanotechnology, including standards related to the risks for health, safety, and the environment, but it remains to be determined if having such voluntary standards is sufficient to mitigate risks. Is it acceptable to bring a new technology onto the market if there is no evidence that it does not harm people, wildlife, or the environment? This ethical question relates to the precautionary principle (PP). Stewart (2002, 76) distinguishes four versions of this precautionary principle:

1. "PP1: Scientific uncertainty should not automatically preclude regulation of activities that pose a potential risk of significant harm (Non-Preclusion PP);
2. PP2: Regulatory controls should incorporate a margin of safety; activities should be limited below the level at which no adverse effect has been observed or predicted (Margin of Safety PP);
3. PP3: Activities that present an uncertain potential for significant harm should be subject to best technology available requirements to minimise the risk of harm unless the proponent of the activity shows that they present no appreciable risk of harm (BAT PP);
4. PP4: Activities that present an uncertain potential for significant harm should be prohibited unless the proponent of the activity shows that it presents no appreciable risk of harm (Prohibitory PP)."

"PP1 and PP2 are weak versions of precautionary approaches. Unlike the strong versions, PP3 and PP4, they do not mandate regulatory action and do not make uncertainty regarding risks an affirmative justification for such regulation."

The question of which version of PP is adequate is an ethical one, which needs to be reflected in the light of a societal debate. Existing legislation may also make one of them to prevail.

3.2 Legislation

Stewart (2002) defined the four versions of the precautionary principle in terms of regulation. However, governments that want to develop legislation for the field of nanotechnology face some problems:

1. They may lack the knowledge to formulate proper legislation, so they will have to rely on technical experts.

2. Developing regulation takes time and this hinders the development of the technology by extending the pay-back period of investment. Even worse, because of this delay commercial application of the technology becomes uncertain.

3. Regulation may be too rigid and as a consequence may hinder innovation.

4. The regulation, once finished, may be already outdated, which also hinders innova-tion.

Given these disadvantages of legislation, standards in combination with conformity assessment have to be considered as an alternative.

3.3 Standards and Conformity Assessment

Assessments of the risks of nanomaterials allow market actors to make informed decisions. Such an assessment requires the ability to accurately and reproducibly measure the physical and chemical characteristics of these materials (Gao and Lowry 2018). Therefore, standard-ised testing is essential for risk assessment of nanomaterials (Oomen et al. 2018). Sayre, Steinhäuser and van Teunenbroek (2017) argue that new methods are needed for testing material characterisation, hazard, exposure, fate, and risk assessment of nanomaterials. Determining environmental exposure requires modelling of flows of nanomaterials over their entire life-cycle (Nowack 2017). So, the risks that are inherent to nanotechnology create a need for agreed-upon methods of performing impact analysis. The challenge is to develop such test methods in parallel to the technology itself. This is even more difficult than developing methods for testing intended effects, because possible unintended effects need to be anticipated.

Measurement standards may help to assess impacts in an objective way, as far as objectivity is achievable in such a developing field. Different risk assessment frameworks for nanomaterials have been developed. These differ in terms of scope, advantages, and disadvantages. Most of them lack decision criteria (Oomen et al. 2018). They also point at the need for assuring quality of data. Thus, a system of conformity assessment is needed (de Vries et al. 2010). Gao and Lowry (2018) provide an incomplete overview of projects and organisations active in preparing standards but also conclude that while some methods are becoming standardised and even automated, the full range of factors influencing the reliability and reproducibility of those measurements has not yet been well documented.

3.4 Combining Legislation and Voluntary Standards

The question is to what extent stakeholders will take responsibility to make and apply rules for the nanotechnology field themselves. Companies in many other fields have done an insufficient job of this, at least in the perception of governments and societal stakeholders, such as NGOs. Therefore, governments entered those fields by imposing regulations in areas like health, safety, and the environment (de Vries, Nagtegaal and Veenstra 2017). However, as we have seen, this tends to hinder innovation in several ways. Actually, such technical regulation is the ‘Old Approach’ to product safety in the EU of some decades ago, and still common practice in China and partly also in the USA (de Vries, Nagtegaal and Veenstra 2017).

Meanwhile, the EU has had positive experiences with the so-called ‘New Approach’ (EC 2016; Hanson 2005; Hesser and Gautama 2010). In this approach, European directives set essential requirements, mostly related to product safety. These directives need to be implemented in the legal systems of the member states. They refer to European voluntary standards that provide guidance to companies in how they can meet the European directives in the case of specific product groups, and test methods to measure conformity to the essential requirements. Meeting such European standards provides a presumption of conformity to the essential requirements. Companies can declare this conformity themselves. In the case of products for which safety is a core issue, a certification body should get involved to provide an independent assessment. If they have a very innovative product for which the standards do not apply, they may demonstrate conformity to the essential requirement in another way than by meeting the standard. Because neither the regulation nor the standards prescribe a specific solution, the companies can improvise. In the United States (US) this is often different –more requirements are established through legislation and compulsory standards, and both may pre-scribe certain solutions. This hinders companies from finding better safety solutions and may thus be detrimental to innovation (de Vries, Nagtegaal and Veenstra 2017). The question is if this New Approach to product safety could also be used for the field of nanotechnology. Is it possible to formulate general performance requirements for nanotechnology?

3.5 Need for Balanced Stakeholder Involvement in Standardisation

In a longitudinal (1996?2015) case study about energy performance standards for houses in the Netherlands, de Vries and Verhagen (2016) show that a combination of a (national) governmental performance standard and a voluntary committee-based measurement standard could lead to a win-win situation in the sense of stimulating innovation and addressing the societal issue of climate change. The involvement of many stakeholders in this committee (46 stakeholder groups were represented) ensured the methods were realistic, up to date, and acceptable for most stakeholders. Government lacks the stakeholder participation, but companies may have influence via lobbying. The case shows that lobbying hindered timely tightening of the energy performance requirements in periods when the ministry had a weaker minister. Such tightening would have been beneficial not only for energy savings and reduction of CO2 emissions, but also for innovation and economic strength within the sector. Following this line of reasoning, regulation in combination with standardisation may form a realistic and up-to-date package of requirements that stimulate the nanotechnology field to innovate in a responsible way, but the risk of strong influence by certain stakeholders remains.

Gottlieb, Verheul, and de Vries (2003) conducted a case study that clearly illustrates the risk of the influence of stakeholders who stand to gain from inaccurate health and environmental safety test results. They examined a scenario involving the standard for measuring the release rate of biocides in antifouling paint. The measurement method laid down in the standard turned out to be inaccurate, allowing the paint industry to continue production of paint with a small fraction of the forbidden substance. This outcome of the standardisation process may be related to the one-sided composition of the ISO working group that developed this standard – most of its participants were employed by big paint producers. The Dieselgate case provides a more recent example of standards that are influenced by commercial interests (Skeete 2017): the standards for measuring car emissions afforded automakers the opportunity to legally sidestep strict performance standards laid out in the law and resulted in a significant performance gap in real world driving emissions. This may be an issue in the nanotechnology field as well. Apart from possible manipulations, there is the more general problem that perceptions differ between experts. Beaudrie et al. (2014) notice important differences in risk perceptions: nanoscientists and engineers at the upstream end of the nanomaterial life-cycle perceived the lowest level of risk, whereas those who are responsible for assessing and regulating risks at the downstream end perceived the greatest risks. So, in order to make standardisation an acceptable instrument for legislators, balanced stakeholder representation is needed, taking foreseeable differences in perceptions and interests into account. To achieve an accurate and unbiased picture, participation of stakeholders involved in the different subsequent stages of the nano-material lifecycle is necessary.

4. Conclusion

The field of nanotechnology needs standards developed in parallel to both fundamental and applied research. Fundamental research is necessary for developing technologies, while applied research is necessary for discovering their use in all kinds of products. These standards include terminology, specifications of materials, harmful impacts of these materials on health, safety, and the environment, as well as testing methods. Fundamental and applied research both should be used in combination with forms of conformity assessment. Because of the innovative character of the field, government regulation may hinder development. A combination of rules with voluntary standardisation is the better way to involve stakeholders and to stimulate them to take responsibility. Therefore, balanced stakeholder representation is needed, with participation of experts involved at different stages of the nanomaterial life-cycle.

Because of nanotechnology's innovative character and its promising applications, governments may stimulate further development of this new field by supporting both fundamental and applied research. As standards are important from the earliest stages of the R&D process, before granting subsidies governments should make it an extra requirement for researchers to develop standards in parallel to their investigations. This would be beneficial not only for the field, but also for the country – if these standards get accepted on an international level, it gives the country's stakeholders a competitive advantage, because for them the standards are perfectly fit for use and they know all of their ins and outs from the outset. Health, safety, and environmental risks may arise from the use of nanotechnology. Standards can ensure that technologies and products made from these do not cause harm. Societal debate may be more in-formed if such evidence is required before products based on nanotechnology are permitted to enter the market. Eventually, a publicly available database may show accepted technologies. Standards bodies should ensure balanced stakeholder representation to avoid biases in testing methods.

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