Chapter 6
VSS Where Formal Regulations Are Missing: Potential Study on Example of Nanotechnologies

Joel Goebelbecker and Eike Albrecht

6.1 Introduction

This chapter aims to discuss the potential of VSS where formal regulations are missing, in this case on the example of nanotechnologies. According to the US National Nanotechnology Initiative, nanotechnologies are "... science, engineering, and technology conducted at the nanoscale, which is about 1 to 100 nanometres. Nanoscience and nanotechnology are the study and application of extremely small things and can be used across all the other science fields, such as chemistry, biology, physics, materials science, and engineering". Nanotechnology is not just a new field of science and engineering, but a new way of looking at and studying (National Nanotechnology Initiative 2012). At nanoscale, the physical, chemical and biological properties of materials may differ in essential ways from the presently known properties of the same substance(s) of macroscopic size; mostly these changes are due to the increased relative surface area or quantum effects.

Besides the remarkable and promising opportunities of nanotechnologies (e.g. potential to solve global and future key issues, such as coverage of energy supplies, conservation of natural resources and comprehensive preventive and curative medical care) they have also substantial uncertainties regarding their possible risks; nanoparticles may pose a threat due to their currently unknown properties. Hence, it seems important to standardise their effects so as to legalise them more strictly in the future. At the moment, very few rules exist for the regulation of nanotechnologies directly. For example, the provisions on fine dust or haze in European law and their transposition into the national legal systems, such

J. Goebelbecker (✉) • E. Albrecht
Department for Civil and Public Law with References to the Law of Europe and the Environment, Brandenburg University of Technology (BTU), P.O. Box 101344, 03013 Cottbus, Germany
e-mail: joel.goebelbecker@tu-cottbus.de; albrecht@tu-cottbus.de

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as the "Ordinance on Ambient Air Quality and Cleaner Air for Europe"[1] → 35th BImSchV (*Feinstaubverordnung*).[2]

In the EU regulation on chemicals REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals),[3] carbon and graphite were excluded from Annex IV (substances that are considered to cause minimum risk) because of their nanoform usage possibilities. However, besides these rare examples, no direct regulation mechanisms are observed [at least at EU level (Lohse 2011, p. 44)]. Thus, the general provisions are applicable and specific risks may be answered via voluntary regulations for now, created by the actors in the field of nanotechnologies themselves. Beyond that, international standardisation committees such as the International Organization for Standardization (ISO) and the International Electronical Commission (IEC) at present develop the basis for a standardised nomenclature and standardisation of nanoscaled objects and procedures to work towards internationally coordinated efforts and definitions in the field of nanotechnologies (CIEL 2009).

The main focus of this chapter is to reflect on the main reasons for, and benefits from, implementation of VSS as an instrument aiding sustainable development of nanotechnologies which is highly linked with the question of precautionary assessment of risks to human health and the environment. In this context, this chapter supplements and continues the previous chapter (Chap. 5), giving a practical example on the connection points between law and standardisation, showing the possibilities of complementing one another in practise. The chapter starts following this introduction by exploring the technical potential of nanotechnologies themselves and discussing their need for standardisation (Sect. 6.2). The following Sect. 6.3 describes what voluntary standards might do better than compulsory regulation and Sect. 6.4 highlights the potentials of standardising nanomaterials in three different ways: First the social benefits will be discussed, secondly an economic outlook will be developed and thirdly it will be shown which potential for the environment can be expected in the sector of standards of nanotechnologies.

[1] Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on Ambient Air Quality and Cleaner Air for Europe (OJ L 152, p. 1).

[2] Ordinance on marking vehicles with low share of the pollutant load (Verordnung zur Kennzeichnung der Kraftfahrzeuge mit geringem Beitrag zur Schadstoffbelastung) of 10 October 2006 (Fed. Law Gazette I p. 2218), last amended 05.12.2007 (Fed. Law Gazette I p. 2793).

[3] Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, p. 1) last amended by Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006 (OJ L 353, p. 1).

In addition, based on an example of the ISO 31000:2009,[4] a risk management system able to handle nanotechnologies will be addressed in Sect. 6.5. Section 6.6 gives some recommendations on the standardisation process of nanotechnologies highlighting similarly which objectives standardisation cannot deliver. In this context, an answer to the question of the need for nano-specific laws will be approached. The chapter ends with conclusions in Sect. 6.7.

6.2 Current Trends

The experience with previous emerging technologies has prompted a growing demand for an approach to governance where the technological innovation has to be part of a unique process aiming to benefit society. Hence, sustainable growth has become a vital objective for many governments globally. However, the ethical, legal and societal aspects (ELSA) potentially connected to nanotechnologies are becoming ever more relevant and will progressively affect their governance approach (Mantovani et al. 2011).

At the same time, the technological development in the case of nanotechnologies is evolving rapidly in various directions. The following two sections consider the importance of nanotechnologies and their need for standardisation.

6.2.1 Why Is Nano Important?

Nanotechnologies as 'enabling technology' apply early on in the value chain, being used to design smaller, lighter, more durable and smarter materials resulting in products with significantly improved and in some cases entirely new functionalities. Yet, products and materials based on nanotechnologies are available to consumers in some countries already, and many more additional products and applications are currently in the research and development stage.

The 'new' properties of current and future applications of nanotechnologies are seen to have the potential to improve greatly the quality of life in nearly every sector and it is reasonable to predict that nanotechnologies will be the next disruptive technology because of the projected ability to impact and change so many areas of materials, applications and sciences. The innovation potential of nanotechnologies is still reaching much further ahead: Thus important contributions to solve global and future key issues (Federal Ministry of Education and Research 2009) such as medical care, coverage of energy supplies, and the

[4] ISO 31000:2009, Risk management—Principles and guidelines, ed. 1, published 15.11.2009, ISO copyright office, Geneva, Switzerland.

conservation of natural resources (resource savings) through the application of nanotechnological discoveries are expected (Tucker 2009).

In the field of nanotechnologies, both large corporations and small businesses are (and will be) involved (Federal Ministry of Education and Research 2010). Beyond that, many applications affect not only the industrial use, but especially contribute to the everyday life of consumers. In view of such progress, it is predictable that products derived out of nanotechnologies will be increasingly available to consumers worldwide in the coming years (Luther and Malanowski 2004). However, already today, products that can be realised only with the help of nanotechnologies have made significant sales. The global market for nanotechnologies (e.g. used in sun cream, colouring, even in food, as antibacterial coverage or medicine) was valued at nearly $20.1 billion in 2011 and should reach $20.7 billion in 2012 (BCC Research 2012). These numbers will after the increasing economic breakthrough even rise strongly. Total sales are expected to reach $48.9 billion in 2017 after increasing at a 5-year compound annual growth rate (CAGR) of 18.7 % (BCC Research 2012).

6.2.2 Why Standardisation of Nanotechnologies?

Although, nanoparticles have been present for a long time naturally in the environment (e.g. volcanic eruptions, fires, and sea salt aerosols) or produced anthropogenically (e.g. burning wood or petrol, welding), it probably becomes generally problematic that the environment and those inhabiting it are faced with an unprecedented and ever-growing volume and diversity of nanoparticles (Mae-Wan 2010; Mantovani et al. 2010). So far, little is known about the exposure of nanoparticles with respect to human health and environment and their potential impact on them. However, concrete evidence is available, that there are interactions of nanoparticles with biological systems (Monica et al. 2006). In a recent study, researchers examined whether gold nanorods could readily pass from water to the marine food web. Their findings suggest that nanoparticles move easily into the marine food cycle and are absorbed in marsh grasses, trapped in biofilms and consumed by filter feeders, such as clams (Ferry et al. 2009). Moreover, a number of publications show that nanoparticles may pose special risks because of their unique properties. In terms of small size, it is important to note that the tiny nanoparticles are able to overcome especially those (biological and physical) barriers that usually remain unconquerable for larger particles (Führ et al. 2006).

Due to this exceptional nature of nanomaterials, the current methodologies employed to conduct risk assessments, toxicological assessments and life cycle analysis of products containing or consist of nanotechnologies may be ineffective or may not currently exist. There are presently almost no standard test methods for measurement of human or environmental exposure to nanoparticles (Hatto 2007). In further consequence, the effects of many nanomaterials are not yet sufficiently evaluated. Initial investigations show that the environmental risks should receive

special attention; the studies have speculated that an increased hazard can at least not be excluded (NanoKommission der deutschen Bundesregierung 2008).

To solve these problems, the use of specific hard regulation is advocated by some parties, but so far, the strategies from authorities worldwide have been essentially on probing the extendibility of existing regulatory schemes for nanotechnologies. In the last few years, voluntary measures have been endorsed by public bodies and industry to build confidence and trust, promote safety or gather data. To support the regulatory efforts, an intense activity to increase the knowledge base and to develop standards, methods and protocols is also going on (formally since 2005) involving acknowledged bodies, such as International Organization for Standardization (ISO), European Committee for Standardization (CEN), Organization for Economic Co-operation and Development (OECD) and, recently, World Health Organization (WHO) (Mantovani et al. 2011).

As progress accelerates in the manufacture and characterisation of nanoscale materials and nano-enabled products, it will become increasingly important to researchers, manufacturers, regulators, and other stakeholders to have agreed upon nano standards. Such standards will include definitions with which to communicate; testing and characterisation methods to compare results; and materials properties to facilitate commercialisation of the many and varied applications and uses of nanomaterials (Secretariat of CEN/TC 352 2007).

6.3 Voluntary Nano Standards

The OECD and the ISO have set up special committee groups on nanotechnologies to monitor and address their challenges (IRGC 2009). These organisations are currently working on the standardisation of methods to identify and measure potential risks derived from nanomaterials and their applications and have already published guidelines on health and safety practices for nanomaterials in the workplace, and terminology used for nanotechnologies and nanosciences. They are currently developing standards on a range of other nano-related topics, such as nanoparticle measurement methods, and the safe handling and disposal of nanomaterials. In addition, several nano-specific risk strategies have also been designed to help companies assess, monitor and manage the possible impacts of nano-based products and processes (CENELEC 2012). What these (and other) voluntary standards can deliver is outlined in the following sections.

6.3.1 Stricter than Law?

Private standards have a much larger role in human society than just agreed measures. Put simply, a standard is an agreed, repeatable way of doing something (BSI 2012). However, in the standard-developing process, many stakeholders have

to be heard and included, which might lead to the consequence that a 'middle way' will be developed, 'more-or-less' satisfying all attendees; by comparison a legislator would not have these problems. Alternatively, legal standards are created usually in a formalised procedure which is time consuming and in particular in such fields where the innovation speed is high, not fast enough to keep up pace with the scientific progress. However, standard initiatives usually aim to complement existing regulation (or prepare the ground for new ones), in this case, helping to gather detailed information on the introduction and use of nanomaterials and nano-related products to the market. However, their voluntary nature has some drawbacks, when endorsed by public/government bodies they received a moderate response, so that it was suggested, for example in the case of reporting schemes, to make them mandatory. On the other hand, when promoted by private companies, these measures are treated by some stakeholders with suspicion and of little value in their opinion (Mantovani et al. 2011). Nevertheless, even with their relative lack of force when compared to legal standards, voluntary standards can play an important, constructive role in the present state of nano-specific regulation, to build a knowledge base to support policy and regulatory decisions (Mantovani et al. 2011). They might also be used by companies as a strategic tool to reduce their regulatory burden, when handling nanomaterials.

To summarise, a private standard usually should (at minimum) respect the law, and even be tighter (e.g. more specific) but there may be cases, in which there are sometimes stricter laws than what is agreed internationally as a standard. Indeed, private standards are usually voluntary; however, they can become obligatory if they progress to becoming legally-binding (e.g. by contract) or their thresholds are used as guidance values, e.g. for undefined legal terms (Albrecht 2008).

6.3.2 Faster than Law?

In the case of nanotechnologies the above question can clearly be answered with a 'yes', as till now only very few laws try to address nanotechnologies. For example, in the EU there will be, among others, labelling requirements for cosmetics[5] (perhaps soon: novel foods[6]) and the obligation to carry out studies[7] for food

[5] Regulation 1223/09/EC of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, p. 59).

[6] See Regulation 258/97/EC of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 043, p. 1) last amendment Regulation 596/2009 of 18 June 2007 (OJ L 188, p. 14) and the Commission staff working document—Accompanying document to the Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No. xxx/xxxx [common procedure]—Summary of the impact assessment [COM(2007) 872 final] [SEC(2008) 12] (SEC/2008/0013 final, 14.1.2008).

[7] Art. 4 and Art. 6 of Regulation 258/97/EC of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 043, p. 1) last amendment Regulation 596/2009 of 18 June 2007 (OJ L 188, p. 14).

additives.[8] In contrast, the process to standardise these technologies seems to be proliferating and indeed availability of appropriate standards seems to be pivotal to implementing an appropriate regulation for nano-related products (Mantovani et al. 2010). The law in this case (maybe true for every innovative technology) has a problem with 'knowing' and 'defining' new technologies and procedures. So it might be right to say, that the standardisation-committees have and had the advantage of (broader) knowledge regarding nanotechnologies.

Added to this, most of the international standard organisations indeed have become very efficient in coordinating the associated consensus processes in such matters. Thus, they gather information relatively quickly and are able to come to an inclusive agreement within a short timeframe.

However, the speed of the process of standardisation cannot move quicker than the information that can be generated out of the research and development and in many cases to come to consensus, cultural changes often are needed in some sectors. The pace of standardisation will always be dependent on the acceptance and pace of implementation of the policies which the standards support. However, there may be some different redundant standards with the same regulative topic. Hence, there might be a time following the publication of (a) standard(s), in which a leading standard (adopted by the majority of involved stakeholders) will have to win through, and such a process could take a long time. The lawmaker again does not have such 'problems'. Hence, at least in theory, the law could be faster than the standard-maker(s), because here only one party within a formalised procedure can decide which way to go. Indeed, in this case, the process of standardisation is clearly leading the legislative one.

6.3.3 Laws Following Standardisation?

As addressed in the previous sections, there are efforts underway to elaborate a regulatory framework to address many of the aspects related to the use of nano-technologies, but it is largely acknowledged that there is the need to improve technical guidance documents used for the application and implementation of existing regulatory frameworks, as well as to develop new ones. The availability of appropriate standards is pivotal to implementing an applicable regulation for nano-related products (Mantovani et al. 2011).

Until now, the standardisation-initiative's aim has been to complement existing regulation, helping to gather detailed information on the introduction and use of nanomaterials and nano-related products on the market (e.g. type, use, quantity, and safety aspects of the material or related product). Thus, voluntary measures can play an important, constructive role in the present state of regulation: For

[8] Regulation 1333/08/EC of 16 December 2008 of the European Parliament and of the Council on food additives (OJ L 354, p. 16).

nanotechnologies it seems special, that for the more risk attached to the issue, the more government involvement is likely (Lohse 2011, pp. 58f.). Currently, it seems that most governments have a preference for the possibility of self-regulation of the industry. However, with the further development of nanotechnologies, it is likely that with its expanding technical possibilities, the risks of the applications will rise, and would make a governmental legal approach more likely; which then will possibly follow, or at least take into account some approaches of standards.

The legislature is able to take over private standards, indeed: Like in almost all fields of the German environmental law the use of standards and thresholds is commonly practiced and is necessary for its systematic and reasonable execution, to make it applicable and functional by defining legal terms or giving thresholds to users. However, the German Federal Constitutional Court has set some requirements to allow the takeover of private standards (BVerfGE 49, 89—Kalkar I).[9]

6.4 Potentials on Standardising Nanomaterials

Nanotechnologies encompass different research fields and find their way into a large variety of sectors and markets. However, that makes a standard based and uniform definition complex and difficult. Nevertheless, standardisation-processes play an important role in the short and medium term in dealing especially with the current uncertainties about the regulatory situation of nanotechnologies. Standards can support disclosure and sharing of information, definition and dissemination of guidelines and best practices, provide common principles and values and facilitate trust between different current and potential stakeholders. Thus, they do not primarily intend to replace regulation or any other legislative requirement but instead aim to help complement those (e.g. definitions or thresholds) or help during the redefinition of existing hard regulation (Mantovani et al. 2010).

Current focus (Secretariat of CEN/TC 352 2007) of standardisation efforts of nanotechnologies is centred in the four broad areas of:

- Terminology and nomenclature (providing a common framework for communications about nanotechnologies for commercial, scientific, and legal purposes);
- Nanomaterials (characterising physical and chemical properties of nanomaterials for various applications);
- Safety and risk assessment (developing evaluation methods to prove suitability, toxicity, health and potential environment effects on human body);
- Nanometrology (developing methods, equipment and systems to measure basic characteristics of nanoproducts).

[9] Federal Constitutional Court's Decisions (BVerfGE) Vol. 49, p. 89—Kalkar I, decision 2 BvL no. 8/77 from 08.08.1978.

6.4.1 Social Potential

Standards and compliance are the keys ensuring the quality and consistency of physical, chemical and biological measurements throughout society (BSI 2012). Standards exist at different levels and with different scopes: National standards such as ANSI (American National Standards Institute) in the United States or DIN (German Institute for Standardization) in Germany, regional standards such as the standards set by the Pan American Standards Commission or the EN standards in the European Union, and international standards such as the IEC or ISO that are recognised in most of the states worldwide.

Standards generally create above all comparability. For nanotechnologies this is applicable, however, very detailed chemical, physical, pharmaceutical, technical or biological information may not be understandable in detail, at least by the (private) end users and therefore might be more beneficial for the business to business (B2B) communication (e.g. producer to processor). Here, standards for nanotechnologies can provide the essential framework for industries and governments to maintain domestic and foreign confidence in goods and services and are also the key to enhancing global competitiveness, attracting investment and encouraging and supporting innovation, benefiting from committees of manufacturers, users, research organisations, government departments and consumers working together to meet the demands of society and technology (Standards Australia 2012).

On 08.04.2006, an article published by the Washington Post entitled "Nanotech Raises Worker Safety Questions", lamented that no state or federal occupational safety regulations relate to the specific risks of nanomaterials, even though many laboratory and animal studies have shown that nanoparticles are or at least some could be problematic for health (of workers) and environment (Weiss 2006). Additionally, downstream users in the supply chain need security and so, in the matter of social recognition, one facet of standardisation might become vital: The labelling of nanoproducts to protect consumer health and ensuring fair practices. Consequently, future standards or labels should give end users confidence that products are safe and reliable, and that they will perform as they are intended. Here, standards could establish consistent expectations and help generally ensure those expected properties or features are met by the products.

For end-users, a label refers to mainly product features and also serves declaration and security purposes, in justified cases it also includes information on safe handling and disposal of products, and hence, a nano label seems appropriate when the consumer should be informed in regard to a product on the inherent quality or environmental, health and safety properties. Thus, labelling is a key management tool in risk regulation, meeting generally different objectives: On the one hand it marks and enables the mature consumers purchasing decisions and protects them from misleading information, on the other hand it should enable and promote innovative product development. Consumers are thus included in the risk management of various product groups. Nano-specific labelling requirements are for

example increasingly used in EU law, initially in the areas of cosmetics, foods and biocidal[10] products.

As opposed to this, voluntary labelling could not yet penetrate the market significantly (Mantovani et al. 2012). Moreover, it would be most beneficial, that information about the nature of the processing and use of nanomaterials would also get back to their manufacturers and suppliers, as a bi-directional transfer of information allows on each stage of the supply chain the optimal estimation of potential risks, thus helping to use the whole potential of nanotechnologies and cutting their risks to the lowest possible level. Art. 34/38 of the European REACH Regulation already demands such a procedure, which establishes the flow of information between manufacturers and users; but this is up to now mainly linked to chemical, not nanotechnological (e.g. quantum physical) effects.

6.4.2 Economic Potential

The economic potential of standardisation of nanotechnologies is enormous. Not only can trade barriers be reduced; standards as mentioned also create a common language that manufacturers and end users can utilise to communicate on issues like quality and safety. Thus, standards help in promoting product compatibility and interoperability, overcoming trade barriers for global markets and fostering the diffusion and adoption of new technologies in general. In addition, they give participants of the development process (e.g. scientist, producers, traders, authorities or consumer protectors) early access to technological knowhow. Moreover, the participants may be able to influence how certain test or measurement guidelines are documented, thereby affecting the content of the standard, in the case of a pending or an already developed standard.

International standardisation is a way to overcome technical barriers of inter-local or inter-regional commerce caused by differences among technical regulations and standards developed independently. These technical barriers mostly arise when different groups come together, each with a large user base, doing some well-established practice that between them is mutually incompatible. Establishing standards, preferably at the earliest opportunity, is one way of preventing or overcoming this problem. However, typically for any new dynamic area at the beginning is that there is a mixture of vocabulary and terminology causing confusion and retarding the adoption of new developments. The early publication of standards provides a relatively consistent set of terms that will address these issues.

Furthermore, standards, particularly open standards, contribute to the standardisation of interfaces and products, leading to larger markets due to lower market segmentation. Larger markets induce more competition between suppliers.

[10] Regulation 528/12/EC of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, p. 1).

This in turn causes falling prices, higher unit sales of products, more research and development and more technical progress for a better balance of supply and demand (e.g. weaker fluctuations in the price fluctuations of supply or demand), and lower transaction costs by simplified contract negotiations and contracts (Smith 1776; Buxmann and König 1998; Morasch 2006). But moreover, the cost of standardisation will enter into decisions about when, where, and if product or process standards are used (David and Thompson 2008). Here, the standpoints could be one of both; that process standards are harder to monitor and would therefore be more costly, especially in a third party auditing situation, or that they are an investment where at least the economic benefits will outweigh the expenses.

It is likely that standards will vary according to the specific nanotechnology in question. However, global integration will require cooperation among competing institutions. But typically, the tension that results from competition limits cooperation on regulation. Additionally, who integrates with whom becomes a point of contention (IFAS 2007). For some enterprises, the use of standards is a strategic tool to raise competitiveness; others might see standardisation only as an added cost of doing business.

In recent years 'nano' has often been used as an effective sales slogan, presumably for conventional products that have nothing to do with nanotechnologies (Eisenberger et al. 2012). This is not only unpleasant for consumers but also for producers of actual nanoproducts, as they invest considerable research and development work in their products. Therefore, there were isolated cases in several countries of voluntary labelling applied to nanotechnology in the form of a so-called private label and seal, but which has not yet significantly penetrated the market. To date, there is no established negative labelling in the form of special 'nano free' labels, but in the future enterprises may try occasionally to inform consumers about products that contain no nanoparticles (Eisenberger et al. 2012).

In 2004, the reinsurer Swiss Re expressed among other concerns that nanotubes could have similar effects on human health, such as in the case of asbestos, and therefore recommended insurers to limit the liability for nanotechnologies (Swiss Re 2004). Likewise, the insurer Allianz sees conceivable risks that could have not only health related, but also far-reaching economic consequences if not handled professionally (Allianz SE 2005). Regarding this, for any assurance-seeking company it should be conclusive to gain an advantage, if it has a standardised risk management system implemented. Beyond that, a compliance with standards could be a reason for an insurer to make a contract with an enterprise handling nanomaterials; at least it is very likely, that a company without standards and risk management would not find insurance, or get relatively hard contracts in any case. This might predominantly be true for the matter of environmental harms, especially harms threatening biodiversity (Knopp 1995).

And one question remains to be explored: How does the risk profile of a company change, if it works with nanomaterials? Possibly a standardised risk management system is required which takes into account the specific characteristics of nanotechnologies. This can ultimately affect the overall assessment of the value of a company. Here it will be interesting to watch whether future nanotechnologies

receive good valuations from society, or such as genetic engineering and nuclear technology have slipped into the negative, which then could be fatal for due diligence.

6.4.3 Ecological Potential

As already mentioned, the labelling could play an increasing role for the risk-and technology-regulation where traditional instruments are limited. As a result, the states and the authorities may observe voluntary labelling by the industry carefully and will force it into compulsory labelling when the voluntary approach fails. The Royal Society and The Royal Academy of Engineering (UK) already recommended that given the emerging evidence of serious toxicity risks, nano-ingredients should be subject to new safety assessments and face mandatory product labelling (RS and RAE 2004).

Besides, unlabelled and unstandardised nanomaterials might be very risky when in the processing, use or disposal of any sanitary or environmentally hazardous substance is handled unknowingly. Hence, by passing information down the value chain by using standardised labels, sustainability is highly promoted by standardisation. In the subject of 'best practices' and similar matters it helps to bring all the developers, manufacturers, distributors, users, and firms on the reuse or disposal side to a table and discuss an integrated view. Standardisation brought to end-users could also help to strengthen their involvement in sustainable development of nanoproducts, by enabling the users to compare the products.

By harmonising standards at a global level, there seems to be the agreement that the main focus needs to be on public health and environmental impacts (IFAS 2007), and if nano standards evolve from current standards, there will be a combination of national and international standards. It might be possible to begin by agreeing on principles for standards rather than on specifics. Indeed, international standards have more potential to become politicised while national standards can be developed in a manner that is relevant to local conditions (IFAS 2007). For nano applications, if there are environmental consequences, they must be related to local and national situations. However, nanotechnologies exhibit unique features and do not have national boundaries. Some nanoproducts, if persistent, e.g. some inorganic or carbon nanoparticles (Reijnders 2012), could have international implications if they are released into the atmosphere or water cycle. Therefore, the question of the right of a country to refuse to be in contact with the product needs to be addressed. There also is the issue of the right of a government to reject exposure of its citizens to certain materials (IFAS 2007).

One of the other many challenges that must be overcome is how to prioritise which standards to develop next, based on measurement best practices and characterisation processes. It has to become clear to understand whether the measurement tools available today are the right tools from an international perspective, taking into account current technical developments and those of the foreseeable future. However, standards could provide clear guidance regarding the currently

questionable disposal of manufactured nanomaterials and could support manufacturers and others in making decisions as to the most appropriate way to dispose of their process waste. As increasing numbers of products incorporating nanomaterials are made, the need for manufacturers to safely dispose of the process waste also increases. This will not only be useful to manufacturers, but also to those involved in waste disposal, research and development on nanomaterials and the regulation or monitoring of waste and waste disposal.

Deliberately manufactured nanoparticles are important technological materials with many benefits but also attendant risks and hazards; certain standards should also help in their assessment and management.

6.5 ISO 31000:2009 – A Brief Introduction

In the capital market, for example, risk management is known as an obligation due to changes in the German Stock Corporation Act[11] since 1998. There is a worldwide standard on risk management: The international standard ISO 31000:2009.[12] In conjunction with the revised ISO IEC Guide 73:2009[13] "Risk management – Vocabulary" the documents were published in late 2009.

ISO 31000:2009 provides principles and general guidelines on risk management (risk being defined here as the "effect of uncertainty on objectives") and is not specific to any industry or sector. The design and implementation of risk management plans and frameworks will need to take into account the varying needs of a specific organisation, its particular objectives, context, structure, operations, processes, functions, projects, products, services, or assets and specific practices employed (ISO s. a.). The familiar 'top-down' approach in the standard offers generally a basis to deal with emerging risks, such as those associated with nanotechnologies or related processes and is above that able to take into account all the different risk conditions in an organisation. However, it will not automatically deliver thresholds or values to deal with nano-related risks. A schematic view of the standards framework is shown in Fig. 6.1 below.

As depicted, ISO 31000:2009 offers continuous stages: Establishing context is about setting the parameters or boundaries around the organisations risk appetite and risk management activities. It requires consideration of the external factors and the alignment with internal factors such as strategy, resources and capabilities (AIRMIC et al. 2010). It involves defining the location and extent of the system

[11] Art. 91 para 2 Stock Corporation Act (Aktiengesetz) of 06.09.1965, Fed. Law Gazette I, p. 1089, last amended 20.12.2012, Fed. Law Gazette I, p. 2751.

[12] ISO 31000:2009, Risk management—Principles and guidelines, ed. 1, published 15.11.2009, ISO copyright office, Geneva, Switzerland.

[13] ISO IEC Guide 73:2009, Risk management—Vocabulary, ed. 1, published 2009, ISO copyright office, Geneva, Switzerland.

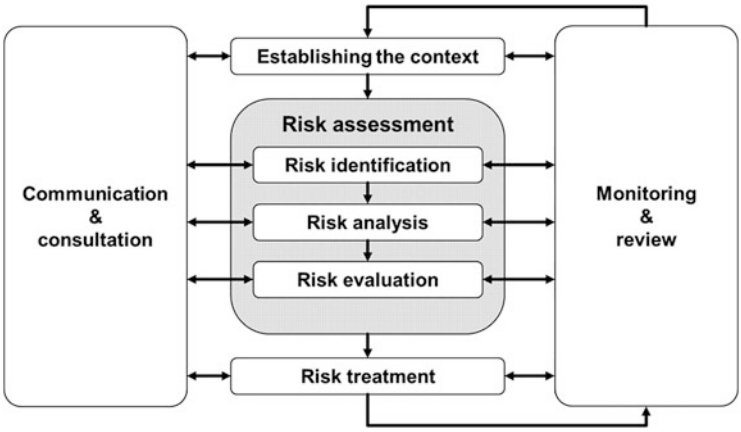

Fig. 6.1 Risk management process of ISO (adapted from ISO 31000:2009, Clause 5)

and the processes operating in its area that may generate risks. It is important to decide which subgroups (e.g. site producing nanomaterials) the risk management plan shall address. The subsequent risk assessment aims to explore (1) the potential impact (i.e. high level of damage) on (2) a particular value (e.g. environment) from (3) a hazardous process (e.g. production of nanoparticles). Thus, as part of establishing the context, the economic, social, political and environmental values where the plan applies should also be described. In addition, there must be defined risk criteria for the risk assessment, including the preparation of likelihood and consequence scales and their combination into a risk matrix, to be able to determine the level of risk. It is also important to define the level at which a single risk is considered acceptable, tolerable or intolerable; here, it is wise to modify the acceptance level for local conditions in consultation with all stakeholders (e.g. providing relevant data and research findings on nanomaterials). The importance of the process of establishing context must not be underestimated. Setting the wrong context is a risk in itself, because all of the steps in the subsequent process of the standard are dependent upon it (Krause and Borens 2009).

Risk assessment: Comprises the single processes of identifying, analysing and evaluating risks. Concerning nanotechnologies it is expected that there will be risks mostly in the product and its processes, but as well as in an uncertain legal environment or standard which is prone to development and change. Hence, an operator should utilise a range of risk identification techniques, e.g. set up a process of how scientific studies on effects of nanomaterials may be followed.

At this point, the ISO/IEC 31010 provides further guidance on how to select and apply systematic methods for risk assessment. As far as nanotechnologies are concerned, it must be assumed that there will be scarce available data to estimate a reliable level of risk. However, the risk analysis considers possible causes, sources, likelihood and consequences to establish the inherent risk. Existing management controls should also be identified and effectiveness assessed to determine

the level of residual risk (AIRMIC et al. 2010). The risk assessment process inherently requires that uncertainty is transparently described, but also, provides for a scale of likelihood or consequence to be ascribed to what may possibly occur. Finally, risk evaluation, as defined in ISO 31000:2009 involves comparing the results of the risk analysis with risk criteria, to determine whether the level of risk is acceptable, tolerable or intolerable. Concluding the three steps of risk assessment in a short overview (Krause 2009):

1. Risk identification, e.g. emission of a substance; short and long term exposure;
2. Risk analysis, e.g. likelihood and the consequence associated with each risk; finally the overall level of risk (e.g. high, medium, low);
3. Risk evaluation, e.g. the intolerable and tolerable level of risk and residual risk; execution and effect of controls or mitigating actions.

Next step, risk treatment: The risk owner in general is able to treat risks by avoiding them completely, modifying their likelihood or influencing the extent of their consequences. First and foremost the process of developing management options as part of the risk management plan should aim to reduce, avoid or eliminate intolerable risks as a first priority. Management options considering nanotechnologies could be designed to reduce the likelihood of their risks (e.g. implement work practise guidelines to reduce the probability of an emission of nanoparticles) or their consequences (e.g. implement an emergency management plan to reduce the result of possible emission), or both. To decide which of the management options to choose from, a cost benefit analysis could determine which of the possible risk treatments will provide the best benefit, relative to cost; however treating the highest risks first should always take priority (Krause and Borens 2009).

Monitoring and review: This process enables tracking of all risks, to ensure they remain within an acceptable range. The monitoring and review process is interwoven throughout the entire risk management procedure proposal of the ISO 31000:2009 and could be particularly beneficial if the changing environment (e.g. social or political, legal and regulatory climate) of nanotechnologies is taken into consideration. Any modification here should be a trigger for the user of the standard to review the risks in light of those changes. Alternatively as part of the monitoring and review, if the risk profile of a certain indefinable or uncertain risk source has, as under some circumstances single nanotechnologies or materials, not changed, it may be wise to extend delaying the handling (e.g. of unknown nanomaterials) until such time as the likelihood and consequences of the distribution risk can be better defined. On the matter of some nanotechnologies, it seems this could be especially appropriate at the present stage of development and knowledge level (Krause and Borens 2009).

6.6 The V in VSS

As shown, standards are powerful instruments to support the development of new technologies like nanotechnologies and help to make them sustainable in many ways. However, standards *per se* are not legally binding, but they can become that

by laws and regulations of the legislature or by contracts in which compliance is agreed to be binding. Here standards are often being used to fill undefined legal terms, for example, the term 'state-of-the-art' or 'best available technology' used for instance in the Integrated Pollution Prevention And Control Directive (IPPC),[14] and retrieving legal significance.

However, a few functions may not be deliverable by standards: In this section the need for laws should become clear. Today, several regulatory agencies worldwide focus essentially on the following actions (Mantovani et al. 2010):

1. Provide or improve technical guidelines and procedures to support safety assessment for specific types of nanomaterials or nano-related products.
2. Adapt or strengthen pre-market notification procedures to ensure nanomaterials are reviewed before entering the market, including options for mandatory reporting schemes.
3. Introduce amendments and changes into existing legislation to ensure inclusion of nanomaterials and nano-related products (e.g. specific definitions, risk management procedures, labelling, restrictions, or the exclusion of carbon and graphite of the Annex IV of the REACH regulation, etc.).

The availability of suitable standards therefore is pivotal to implement an appropriate regulation for nano-related products (Mantovani et al. 2011). However, due to the innovative production processes enabled by nanotechnologies and the peculiar behaviour of the matter at the nanoscale, the system of written and physical standards established for the macroscopic and microscopic world, cannot easily be scaled down to the nanoscopic world (Mantovani et al. 2010).

6.6.1 Standards Are Not Laws

Standards in general, especially voluntary ones, all share a weakness—obvious as it might be: As long as they are not agreed on the basis of private law agreements, e.g. B2B-contracts, they are voluntary! Hence, whenever it becomes too difficult for joining enterprises, it might be unsurprising that the participant simply withdraws from the standard. Indeed, standards are in general lacking the power of force to sanction violations. However, if a voluntary standard (or a fragment of it) becomes part of an agreement (e.g. as described above) with sanctions included, it may lead to a different outcome.

Nevertheless, a future evolution of nanotechnologies regulation(s) could influence the path of the entire development of nano-related products and processes. However, even if an enterprise would comply with all standards, especially international ones, this would still not be a guarantee of legality within single states of its

[14] Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control (OJ L 24, p. 8).

processes or products. In addition, the existence of a published standard does not imply that it is always useful or correct. For example, if an item complies with a certain standard, there is no assurance at all that it is fit for any particular use; therefore validation of suitability thus becomes necessary.

Certain countries around the world are making it a primary part of their own research plans to guide or fertilise the process of standardisation to benefit from the following development of the standardisation. For instance, the Chinese Ministry of Science and Technology has made the drafting of nanotechnologies research standards part of its national basic research plan (MOST s. a.).

Other countries (e.g. Canada, Japan, and USA) are striving for leadership positions within standard organisations (ANSI s. a.), too, so that they can help shape the standards to which everyone must adhere later on. It so happens that numerous different standard setting organisations globally are highly active in defining standards (Tucker 2009). So the main question might be: Which one will manage to become dominant (e.g. most common)?

6.6.2 Limitations of Standards: Need for Laws?

As shown, standards in general help make life simpler and increase the reliability and the effectiveness of many goods, services, and processes. They are intended to be aspirational—a summary of good and best practice rather than general practice. And standards are designed for voluntary use and do not impose any regulations (BSI 2012). However, private standards are one tool in the regulatory spectrum of the legislator to provide a solution to a problem (possible risks of nanotechnologies). The disadvantage of an industry standard is that the establishment and development generally is driven by economic interests and hence the published standards may be controlled, or at least be influenced, by interest groups along this process (SRU 2011). Here, there is also a high potential for laws and legislation to handle the risks of nanotechnologies and to assure sustainable development in every way by selecting the correct standard to be adopted or enforced (SRU 2011).

In terms of nanomaterials, as a special form of substances, their properties and effects still leave many knowledge gaps in the analysis of the regulatory framework, which makes a continuous precaution-oriented handling of those materials impossible. These shortcomings are partly due to the peculiarities of nanomaterials (SRU 2011). Accordingly, the need for nano laws is in demand. Though, the above mentioned shows that a proper regulation might not be possible without the utilisation of standardisation: In the first stage, it should be build knowledge about regulatory procedures and gaps and in parallel develop standards for self-regulation. Then enforced self-regulation in the medium term should be made possible followed finally by strict legislation in the long term. Here, there even might be an independent ‘nano-law’ possible (Mantovani et al. 2010).

6.7 Conclusions and Recommendations

Self-regulation initiatives, such as standards, play an important role in the short and medium term to deal with the current uncertainties and ambiguity about the regulatory situation for nanotechnologies. They can support disclosure and sharing of information, definition and dissemination of guidelines and best practices, provide common principles and values and facilitate trust between different current and potential stakeholders. As clearly stated in the general objectives of most of these initiatives, their aim is not to replace regulation or any other legislative requirement but instead to help complement those (Mantovani et al. 2010).

Private standards offer the possibility to regulate necessary issues where the state is not able to regulate or to execute. For example, Peine (2011) stated on the example of the Equipment Safety Act[15] which serves as transposition of the European Directive on General Product Safety[16] transformed into German law, that difficulty, complexity, and dynamics (Breuer 1976) of technology makes a reference to technical regulations necessary and legitimate to gain control over the complexity of the future. Here, the German Constitution is the framework for political action which does not omit the technological future (Peine 2011).

Indeed, in the case of nanotechnologies, at least, law and private standardisation could and should go well together. Both take into account human and cultural factors, and undeniably, nano risks are eventually managed by people, not processes or tools. There will be the need to respect different perceptions, but also different settings and positions: There might be no 'one-size-fits-all' approach; the law as well as those responsible for crafting standards should respect that.

However, finding the suitable standards or laws, trying to understand them and to obey them, one could be forgiven for becoming lost; nonetheless there is still one more item to consider: There might be one thing that strict legislation cannot force and voluntary standards cannot deliver either. The best way to be truly "sustainable" is to form individual opinions, run research independently, collect expertise and finally be transparent and open: Inform stakeholders and decision makers—even if the message is not a good one; create a forum for communication, e.g. as it is regulated in the European REACH-approach. This would potentially be more appropriate instead of uncritically investing "only" on private standards and laws and hoping everything will work out well. Similarly the risk management, at least, must stay dynamic, iterative and responsive to change. Likewise this is true for respective standards and laws and might especially be true on the matter in question of nanotechnologies. Nevertheless it is also true for every other possible issue.

[15] Art. 1 of the German Equipment Safety Act (*Gesetz zur Neuordnung der Sicherheit von technischen Arbeitsmitteln und Verbraucherprodukten*) Fed. Law Gazette I pp. 2 and 219, last amendment on 07.07.2005, Fed. Law Gazette I p. 1970.

[16] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, p. 4).

Hence, it is imperative to get away from mere blind compliance with mandatory or voluntary rules (passive risk mitigation) and come to a lively integration, following the depicted change of mindset to active and preventive risk defence.

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