International Handbook on Regulating Nanotechnologies

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20 Voluntary measures in nanotechnology risk governance: the difficulty of holding the wolf by the ears

Christoph Meili and Markus Widmer[1]

20.1 MANDATORY GOES VOLUNTARY – AND VICE VERSA

The regulation of manufactured nanomaterials has been a matter of discussion among government representatives, scientists, environmental and consumer advocates and politicians since the beginning of the commercial rise of consumer products containing or claiming to contain manufactured nanomaterials. However, manufactured nanomaterials, until very recently, were not required to be explicitly labelled or registered, and due to the current lack of reliable data about their release into the environment, governments and authorities worldwide have manifested difficulties in estimating prevalent types, amounts and uses of nanomaterials on the market. This means that it has also been difficult to derive estimations of potential exposure to manufactured nanomaterials to both humans and the environment.

Further, a conclusive database does not exist which lists all products containing manufactured nanomaterials in a given country or of a given sector of application. In the absence of official statistical data on the use of nanomaterials in the industry and in consumer products, the best approach to gain such overview to date is probably to visit the Project on Emerging Nanotechnologies' (PEN) (2009) web-based database on consumer products, which is based on continuous worldwide internet research. As of August 2009, more than 1000 products were included in the inventory.

Much the same as with the current knowledge on information regarding nanomaterials in trade, in the early phase of technology development, regulators and others are often unable to base potential regulatory decisions on an accredited state of science and technology that describes the expected impacts of manufactured nanomaterials on human health and the environment upon certain levels of exposure. This may particularly be attributed due to a lack of practical long-term experiences with manufactured nanomaterials, and the only slowly increasing scientific evidence which is reached through a process of unifying conflicting research findings. Unsurprisingly, at this stage of technology development, regulators

often face considerable pressure to become active through a growing number of early-adopting industry players which engage in the new technology, and various NGOs which call for adequate control of any potential hazards. In this context, it has been the non-governmental ETC Group, which, in 2003, for the first time issued a call for a global moratorium on nanotechnology lab research and a recall of consumer products containing engineered nanoparticles (ETC Group, 2003a, 2003b, 2006).

Due to a lack of commonly agreed definitions and nomenclature, standardized reference materials, testing strategies and representative endpoints, scientists have not yet been able to determine absolute no-effect levels of manufactured nanomaterials under normal human exposure. Rather than sticking to a strictly precautionary approach by eliminating any potential exposure, it is very difficult to establish quantitative relationships between a certain level of exposure and an expected consequence, to derive measures which will be equally or more effective in the case of nanoscale materials, or to define a level of tolerable risks. As a consequence, in the debate about the regulation of manufactured nanomaterials, it is commonly agreed that early regulatory decisions would lack key scientific and methodological fundamentals, which would otherwise be relied on for sensible regulation.

In addition to such uncertainties and depending on the regulatory framework and the political environment of individual countries, government agencies, such as the US EPA, obviously face considerable hurdles when trying to require companies to notify, register or undertake testing to develop additional information on manufactured nanomaterials (Denison, 2008; Davies, 2010; and Widmer and Meili, 2010), and they are confronted with considerable resistance when considering to implement new regulations. Traditional command and control regulation has been criticized as having inadequate enforcement, as leading to an adversarial culture of compliance, as well as being reactive, slow, inflexible, and overly formal (Webb, 2004). It has been argued, therefore, that in a political climate of de-regulation, combined with a lack of sufficient government agency funding and based on positive experiences with previous voluntary programs, voluntary measures seemed attractive to governments as an alternative to conventional regulation, and that they would represent a sensible and feasible response (Bullis, 2005). In the case of the European Union, the situation is slightly different, because, with the recent entry into force of REACH in mid 2007, chemical legislation has been subject to major changes and practical experience is still missing in wide parts.

Nevertheless, since 2006, several administrative bodies in the US and, to a lesser extent, in Europe have moved toward using non-regulatory (voluntary) measures in context of manufactured nanomaterials. However, not all voluntary measures fulfil the same purpose; there can be identified

differences in terms of their primary purposes and the number and kind of stakeholders addressed and involved.

Regarding the case of nanotechnologies, voluntary measures have been identified in the following areas:

- voluntary reporting schemes
- voluntary risk management systems
- codes of conduct, and
- guidelines and auxiliaries.

In the following sections, we will briefly outline the characteristics and the scope of each group of voluntary measures and present representative examples for each group. As the classifications above are not exhaustive, other initiatives and approaches exist which may not be clearly attributed to only one group. Following the discussion on the various approaches, an assessment of their governance of nanomaterials will be made.

20.2 VOLUNTARY APPROACHES IN RISK GOVERNANCE OF NANOMATERIALS

Voluntary Reporting Schemes

Voluntary reporting schemes in the context of nanotechnologies can be characterized as government-funded programs designed to provide authorities with information and statistical data on use, handling procedures and safety measures in place for manufactured nanomaterials. Such programs may therefore be issued by governments or authorities in light of a lack of reliable data on the extent of manufactured nanomaterials in production and on the market, or in light of a lack of sufficient information to enforce mandatory legislation. They may also provide authorities with a first overview on potential exposures and the safety measures that are currently in place in the industry, in order to allow prioritization of further measures. Voluntary reporting schemes have been implemented in the early phase of discussion about potential regulation of manufactured nanomaterials both in Europe and in the US.

The most prominent examples in the area of nanomaterials are the UK Department for Environment, Food and Rural Affairs' (Defra) Voluntary Reporting Scheme (VRS), which was launched in September 2006 and concluded in September 2008, and the EPA's Nanoscale Materials Stewardship Program (NMSP) (since January 2008) in the US. Both Defra and the EPA launched their voluntary reporting schemes with

the intention to collect information from companies on a voluntary basis that would otherwise not have been covered by existing mandatory reporting requirements, including to:

- collect information from companies on the types and extent of nanomaterials being manufactured, handled and marketed
- gather information on current risk management practices
- build evidence on potential exposures, hazards and risks, and
- inform considerations of the appropriateness of existing controls of manufactured nanomaterials.

While Defra's VRS explicitly discouraged organizations from generating new data solely for the purpose of the scheme, the EPA's NMSP is divided into a basic and in-depth phase; under the former, companies are invited to submit existing data, while during the in-depth phase, companies would voluntarily develop new data on a set of representative nanomaterials.

The success of these voluntary reporting schemes has been controversial. Although the UK Department of Trade and Industry estimated that there are over 350 organizations involved in micro- and nanomanufacturing in the UK, after the closure of the two-year program Defra had only received 11 submissions (Defra, 2008). The EPA NMSP program, which is still running, has received considerably more feedback, with submissions under the basic program from 29 organizations on more than 123 nanomaterials (EPA, 2009).

However, due to its voluntary character, the data collected may not be representative for all manufacturers or for the whole market, and it must be expected that exemplary companies with a strong awareness of the concerning safety issues or other subgroups of the entirety of companies will be more likely to participate in such voluntary programs. According to an Interim Report on the EPA NMSP one year after launch, nearly two-thirds of the chemical substances from which commercially available nanoscale materials are based were not reported under the Basic Program (EPA, 2009). Nevertheless, 12 of the 14 major nanoscale materials subject to testing in the OECD Working Party on Manufactured Nanomaterials (WPMN) sponsorship program were also reported under the EPA NMSP, a fact which supports the assumption that the NMSP basic program has at least captured some nanoscale materials of global significance (OECD, 2008). However, with only four companies that agreed to participate in the in-depth program as of December 2008, the low rate of engagement in the in-depth program suggests that most companies are not inclined to voluntarily develop and provide new data on their nanoscale materials (EPA, 2009).

While, according to the EPA, the NMSP can overall be considered

successful, some data gaps have not been addressed by data submissions, and the 'EPA is considering how to best use testing and information gathering authorities under the Toxic Substances Control Act to help address those gaps' (EPA, 2009: 3) (see also Widmer and Meili, 2010). Ultimately, the information provided to the authorities under voluntary reporting schemes, such as the NMSP, will also serve to prioritize decisions and shape future mandatory regulations.

Reporting schemes and information collection initiatives have also been under consideration on a state level in the US. Much like in the case of voluntary reporting schemes, such oversight programs or nanomaterial registries are intended to enable local authorities to gain a more current, precise and comprehensive picture of the actual production, processing and handling of manufactured nanomaterials in reach.

The municipality of Berkeley, California, may serve as a representative example for such mandatory oversight initiatives. As early as in December 2006, Berkeley adopted the first municipal regulation specifically referring to manufactured nanomaterials. The Berkeley City Council amended Title 15 of its Municipal Code to require that:

> All facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases, and mitigate such materials (Section 15.12.040, Subsection I).

Cambridge, Massachusetts is at least one other locality that has expressed interest in the Berkeley model; however, while supporting the implementation of an inventory on facilities that manufacture, handle, process, or store engineered nanoscale materials in the city, the Cambridge Public Health Department did not recommend that the City Council enact a new ordinance regulating nanotechnology in July 2008 (Cambridge Nanomaterials Advisory Committee and Cambridge Public Health Department, 2008).

In the absence of nanotechnology-specific federal regulations, there is plenty of room for states and municipalities to regulate nanotechnology on their own, often in a more stringent way than the existing federal chemical regulations are able to regulate nanotechnology. However, by fostering or tolerating such local approaches, it is feared that the emergence of a patchwork of individual provisions and requirements are both costly and in a later phase, if federal regulations emerge, will need to be harmonized (Keiner, 2009).

Nevertheless, the existence of mandatory and voluntary reporting schemes for manufactured nanomaterials from the municipal to the federal level is a result of the poor availability of nanospecific data to

authorities, and the intention of governments and authorities to claim such information from businesses as the first step potentially leading to further regulatory decisions.

Voluntary Risk Management Systems

The responsibility to safely handle manufactured nanomaterials during production, processing and disposal lies with industry and trade, and the existing uncertainties about potential risks and the regulation of nanomaterials raise the need for proactive risk assessment and monitoring activities by industry. Voluntary risk management systems (VRMS) with a focus on nanomaterials therefore provide appropriate tools, procedures and guidance on how to appropriately and responsibly handle manufactured nanomaterials and also on how to identify, assess and minimize potential risks under circumstances of high uncertainty.

Such VRMS are commonly unilateral commitments which usually go beyond existing legal obligations and complement existing risk management approaches in a company. In the specific case of nanomaterials, such tools must be able to deal with the existing uncertainties regarding risk assessment and the high dynamics in the development of the state of science and technology.

Prominent examples of nanospecific VRMS are, for example TÜV SÜD's CENARIOS®[2] standard or Environmental Defense/DuPont's NanoRisk Framework. In the following section, the CENARIOS approach will be further elucidated.

CENARIOS is a voluntary risk management and monitoring system that describes systematic structures and processes to identify, assess, document, update and manage any potential risks resulting from the manufacturing and handling of nanomaterials.

CENARIOS relies on existing standards and guidelines for risk assessment and risk management, but it also includes new tools and procedures that have been developed to comply with complex technology risks with high uncertainty and high technology and market dynamics (TÜV SÜD Industrie Service, 2008).

To compensate for the incomplete risk data on manufactured nanomaterials (the consequences), while still being able to conduct risk analyses, CENARIOS uses semi-quantitative state-of-the-art estimations to replace the 'consequences' variable. Regarding the consequences of an event, only very limited information is available to date. For example, there are hardly any reliable long-term experiences that show how permanent exposure to nanoparticles will affect human health or the environment. Unlike fully quantitative methods, semi-quantitative methods explicitly take this

into account and allow subjective assessments to be linked to objective experience.

Nanomaterials and products which contain nanomaterials form part of an interdisciplinary technology which is characterized by short cycles of scientific and technological innovation and is very much subject to the impact of social trends and regulatory measures. The emerging state of science and technology plays a major role in the case of nanotechnologies, and a risk management system in the area of nanotechnologies should be able to closely monitor these dynamics, make the information available for risk reassessment in a timely manner and allow companies to pro-actively respond to these changes. Under CENARIOS, a risk monitoring system aims to prospectively identify and analyse risks. Unlike other risk management systems, however, which exclusively consider health, safety and environmental risks, CENARIOS also includes 'soft risks' such as societal risks (public perception, development of the debate on risks), regulatory risks (dynamics of regulation, risk of change) and liability risks (product liability, liability risks along the value chain). Through continuous risk monitoring, the risk assessment process is continuously supplied with current findings from science and technology, society and regulation.

Regarding transparency of the system, all requirements are disclosed in the CENARIOS Certification Standard (TÜV SÜD Industrie Service, 2008). The standard describes the requirements that companies must fulfil in order to certify their nanospecific risk management system according to this standard. This enables potential users to determine which requirements are already fulfilled by existing risk management systems (for example, ISO 9000, ISO 14000) and which elements are yet to be established. The certification procedure is performed by the independent certifying body of TÜV SÜD, and re-certification needs to be done regularly. In this process, the documentation of the risk management system is reviewed and the overall risk management processes within the company are assessed. As CENARIOS is not a product certificate, certification exclusively refers to the risk management system.

Codes of Conduct

Codes of conduct are common instruments that document and communicate a set of rules outlining the responsibilities of proper practices for an individual or organization where no mandatory rules are present. Such commitments might also define a general attitude towards the engagement in a new or controversial sector or technology such as nanotechnologies. As a widespread type of voluntary engagement, several codes of conduct have been used in the context of manufactured nanomaterials.

Specifically for the area of nanotechnologies in research, the European Commission (2008b) in 2008 published a recommendation for a code of conduct for responsible nanosciences and nanotechnology research. According to the Commission, the code is complementary to legislation and provides Member States, employers, research funders, researchers and more generally all individuals and civil society organizations involved or interested in nanosciences and nanotechnologies research with guidelines favouring a responsible and open approach to nanosciences and nanotechnologies research in the Community (European Commission, 2008a). The code is based on seven general principles and gives guidance to the members for their research actions in the field of nanotechnology.

For the area of businesses and industries engaged in nanotechnologies, in 2008 the UK Royal Society, in partnership with several other organizations, launched a code of conduct named Responsible NanoCode (Royal Society et al., 2008). It is aimed at encouraging these organizations to consider all aspects of their involvement with nanotechnologies, including broader social and ethical issues. Other codes of conduct have been developed by BASF with a focus on defining principles on how to responsibly engage in nanotechnologies, or by the Swiss Retailer Association (IG DHS, 2008). In the latter, the signing members commit to the highest possible transparency for consumers and to the precautionary principle in the light of a lack of regulations.[3]

It has been argued that the development and implementation of civil regulation, such as codes of conduct, is less resource intensive and are more time effective than traditional state-based regulation (Bowman and Hodge, 2009). However, voluntary codes of conduct are also subject to criticism. One key argument concerns the unilateral character of the commitment that is made through a code. Usually, this approach lacks both a mechanism to independently evaluate its effectiveness and sanction poor compliance, and the public, to which the commitment of the code are often primarily addressed to, is left in the dark regarding compliance or noncompliance (Bowman and Hodge, 2009). Commonly, in contrast to (voluntary) risk management systems, as codes of conduct usually lack explicit standards, such commitments deal with the concerning topic on a rather abstract level, and it has therefore been argued that codes of conduct are used by industry to delay or weaken rigorous regulation and forestall public involvement; on the other hand, however, they may well be regarded as a clear statement that certain issues are a priority topic in the corresponding company. The overall value of such voluntary codes depends on the transparency of the process and, of course, on the specific commitments and their implementation in the individual case.

Guidelines and Auxiliaries

Principally, any non-mandatory guideline or tool to support companies in identifying, assessing and managing risk related to manufactured nanomaterials may be classified as a voluntary measure in risk governance, and several authorities have already published such documents (see for example, NIOSH, 2009; Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, 2007). Such guidelines help trade and industry organizations to identify possible sources for risks in the production, use and disposal of manufactured nanomaterials, and usually suggest precautions and measures to minimize exposure.

As an innovative approach, the Swiss Government introduced in December 2008 an auxiliary for businesses called the Precautionary Matrix for manufactured nanomaterials (Höck et al., 2008). The matrix has been developed as a key element under the Swiss Action Plan for Synthetic Nanomaterials (Eidgenössisches Departement des Innern (EDI), 2008).

Rather than establishing regulations, the Precautionary Matrix approach aims to provide structured guidance to industries and trade organizations involved in nanotechnologies to get an estimation of the risk potential of the concerning application related to one step in the production or processing of the nanomaterial. Upon entering a limited selection of nanomaterial-specific and application-specific parameters into an electronic form, the matrix provides a simple hazard classification of the nanomaterial considered, being either in 'class A' (risks specific to nanomaterials are low, no further clarification necessary) or 'class B' (possible risks, further clarification and/or risk reduction needed).

If further measures are necessary, however, to assess and manage potential risks in the area that the Matrix has identified to be critical, it does not provide further assistance on this task. Consequently, the Precautionary Matrix may be regarded as an instrument that supports companies in engaging with the risk issue and provides a framework to make them ask the right questions. The tool is especially suited to be used in the context of duty of care and industry self-supervision, both principles which are essential in the regulatory approach of Switzerland.

20.3 SUCCESS AND FAILURE OF VOLUNTARY MEASURES IN NANO RISK GOVERNANCE

Different types of voluntary measures have been introduced in the context of nanotechnologies in recent years by diverse stakeholders and with varying purposes. We have seen the use of voluntary reporting schemes,

codes of conduct, voluntary approaches to risk management and other guidelines and auxiliaries.

Prominent examples of private enterprises engaging in voluntary measures of risk governance in nanotechnologies include BASF in Germany (Responsible Nano Code – code of conduct), Bühler Partec in Switzerland (CENARIOS – risk management system), DuPont in the US (NanoRisk Framework – risk management system), or the Swiss retailer's association (IG DHS – code of conduct). On the other hand, a series of government agencies have also invested considerable efforts in non-mandatory approaches, such as the European Commission (Code of Conduct on Research), Defra in the UK (voluntary reporting scheme), EPA in the US with the Nanoscale Materials Stewardship Program (voluntary reporting scheme), or the Federal Offices of Public Health (FOPH) and the Federal Office for the Environment (FOEN) in Switzerland (Precautionary Matrix – guidelines and auxiliaries).

Under the prevailing circumstances, voluntary measures have been broadly welcomed by governments, authorities and various other interest groups as suitable tools to bridge the current uncertainties preventing an early implementation of mandatory regulations. The immanent gaps in the scientific knowledge and the missing data on toxicity, eco-toxicity and possible exposure pathways of manufactured nanomaterials, and the corresponding lack of scientifically validated standards and methodologies have essentially forced both companies and government agencies to appeal to voluntary, aspirational commitments for a responsible development of nanotechnologies as opposed to prescriptive and stringent standards (Bowman and Hodge, 2009).

While some of the recently implemented voluntary initiatives in the risk governance of nanotechnologies and manufactured nanomaterials have clearly been shown to fulfil the objectives set, others have been deemed less effective. From experiences with previous voluntary measures, predominantly in the sector of environmental protection, and by analysing the underlying conditions and the structure of individual programs in the case of nanotechnologies, a series of important preconditions, key elements and requirements which contribute to the success or failure of such voluntary approaches have been identified (see, for example, Hansen and Tickner, 2007).

One key driver in favour of voluntary measures as opposed to a mandatory approach is arguably their potential of quick implementation, by avoiding lengthy political discussions and laborious negotiating of the details of a regulation with all stakeholders involved. This factor plays an important role in the case of manufactured nanomaterials particularly, since commercial exploitation of these technologies is way ahead of their

inclusion in the regulatory system – as regulators, politicians and scientists are discussing possible forms of regulation and control, an increasing variety of consumer products is hitting the market and many more are expected to emerge across all industries and application sectors.

Apart from that, however, the (alleged lengthy) process of stakeholder inclusion and public consultation can also be regarded as an important element in the development of a sound governance approach, which is broadly accepted and appears trustworthy to the ones it is directed towards. Transparency in design, reporting and evaluation is a key precondition to enable and foster such stakeholder inclusion. While, across all categories, some voluntary measures in risk governance of nanomaterials have undergone some kind of consultative process in either design or evaluation (for example, there was a consultative process in the DuPont and Environmental Defense's NanoRisk Framework, the EC Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, the Royal Society's Responsible Nano Code and the Swiss Federal Office's Precautionary Matrix), others have been developed and implemented completely unilaterally with no opportunity for third parties to influence or comment the respective approach during their development. In general, government-funded initiatives underlie certain statutory requirements to consider public engagement and involvement. The European Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, for example, includes the element of 'inclusiveness', which provides that, regarding the governance of nano research, all stakeholders should be allowed to participate in the decision-making process in an open and transparent manner.

By intuition, it may seem obvious that voluntary measures will fail to fulfil any goal of providing a certain level of safety and creating public trust if there are no incentive mechanisms to ensure participation of most, if not all, and if there are no ways provided to benchmark the measure's performance and, if necessary, to sanction noncompliance.

Incentives to participate or disincentives not to participate play an important role to convince non-participants or laggard firms. As long as a voluntary measure is only committed to by a minority of the possible addressees, there is room for rogue firms and free riders, and the measure will probably fail to guarantee an agreed level of safety which would make mandatory regulation obsolete. Other voluntary programs, however, such as reporting schemes, may depend less on complete participation, and the results from limited participation may very well fulfil their goals. This may be achieved by either positive or negative incentives, for example, through an imminent threat of (mandatory) regulation, or by rewarding participating organizations in some form (incentives may include reduced costs, publicity or technical support).

The issue of benchmarking, control and sanctioning has been controversially discussed. From a regulator's point of view, there is a clear need to assess the effectiveness of voluntary approaches in order to assess the necessity of mandatory action.

Depending on the voluntary measure under consideration, however, different goals are pursued, with different benchmark criteria being applied. Further, due to the voluntary measure's rather unspecific character and the missing knowledge about the risks, there are often no quantitative standards to benchmark a voluntary measure against. In this case, regulators, the public and other involved parties have to rely on the trustworthiness and the probity of the committing company. On the other hand, it may nevertheless be naive to assume that broad compliance will be reached when it is essentially dependent on the ongoing commitment, motivation, and goodwill of the individual organizations alone (Bowman and Hodge, 2009). In this context, signed commitments and requirements regarding periodical reporting have been identified to contribute to meeting a voluntary measure's overall goal (Hansen and Tickner, 2007).

The inability to benchmark compliance or hold signatories accountable for noncompliance means that voluntary measures undermine the credibility of both the committing party and the measure itself. While in the case of conventional command and control regulations, sanctioning of noncompliance is ensured through laws and regulations, control authorities, fines and, ultimately, courts. It may also be argued that in times of globalization, with the internet as a medium through which various interest groups can reach and mobilize large parts of the broad public and create considerable pressure, there might come other and new mechanisms of sanctioning noncompliance into play. In fact, these means should not be underestimated and may be regarded as an important element in the control-and-sanction process of voluntary measures: the public watchdog never sleeps.

20.4 CONCLUSIONS AND OUTLOOK

In conclusion, it can be observed that in the debate about the definition of an appropriate governance model for nanotechnologies, voluntary measures have recently played an important role. Some companies have implemented measures such as codes of conduct or voluntary risk management systems, or they have participated in voluntary reporting schemes implemented by governments.

Despite this interest in voluntary measures in nanotechnology risk governance in recent years, incentives to (or disincentives not to) engage

in activities going beyond existing mandatory regulations for companies seemed to be rather small. While some companies have exploited their voluntary engagement to demonstrate responsibility and build trust (mainly among customers), not many companies have followed them yet. Furthermore, there are no clear tendencies yet that some measures will prevail on a more broad basis, for example, as some kind of voluntary industry-wide standard.

Considerable uncertainties persist as to how effectively existing regulatory frameworks will be able to handle manufactured nanomaterials and the corresponding issues arising from commercially exploiting their unique properties (see Widmer and Meili, 2010). In the case of the US and EU chemicals legislations a series of issues are identifiable which might prevent appropriate handling of manufactured nanomaterials within existing regulatory frameworks. Further, there is internationally still little consensus concerning the nature and form which regulatory frameworks for nanotechnologies should take (Bowman and Hodge, 2009).

In this climate of uncertainty, voluntary measures in nanotechnology risk governance may be regarded as attractive to businesses, since they offer an opportunity to demonstrate responsible engagement, create public trust, ameliorate their reputation, develop novel approaches to handle new risks, and anticipate potential future regulations. Most importantly, voluntary measures in risk governance support companies in recognizing, assessing and minimizing risks associated with the use of nanomaterials, thereby obtaining specific know-how and minimizing potential liability risk.

Complementing the voluntary approach, the latest trends in the regulation of nanotechnologies show the rise of the first mandatory regulations which will explicitly establish rules for manufactured nanomaterials. More or less in time with the overwhelming adoption of the European Parliament's report on regulatory aspects of nanomaterials in April 2009 (European Parliament, 2009), in which the Commission is called to consider manufactured nanomaterials more explicitly within existing regulatory frameworks, the European Parliament will adopt changes with specific reference to nanomaterials, for example, in the recast of the Cosmetics Directive and the amendment of the Novel Food Regulation.[4]

It seems, therefore, safe to say that voluntary measures in nanotechnology risk governance will not completely replace explicit and mandatory forms of regulation of nanomaterials. Ideally, the coexistence of both mandatory and voluntary approaches will prove to be a fruitful and effective mixture on the balancing act between safety considerations and public trust. Nevertheless, in the context of the prevalent uncertainties rendering the design and enforcement of mandatory forms of regulations

very difficult at this time, voluntary measures in nanotechnology risk governance often represent practical and quickly implementable options to bridge the period of data gathering, political decision-making and regulatory orientation. Or, in order to take reference to the wolf quote in the title, it might be better to hold the wolf by the ears and thereby keeping him at a rather small and dangerous distance than letting him go and being wolfed by the beast.

NOTES

1. The Innovation Society is a leading international nanotech consulting firm. Its experts have a broad business and technical background and provide management and business information services to clients from business, industry and governmental bodies. The company has developed several risk management tools for emerging technologies. As an example the company and TÜV SÜD launched CENARIOS®, the first certifiable nanospecific risk management system (RMS) which is already applied in the market.
2. CENARIOS® is the legally protected name of the risk management system jointly developed by TÜV SÜD Industry Service (Munich) and the Innovation Society (St. Gallen). TÜV SÜD is one of the world's largest certification bodies and the Innovation Society is an international technology consulting company with broad experience in the area of nanotechnologies. CENARIOS® refers to 'Certifiable Nanospecific Risk Management and Monitoring System'.
3. A more comprehensive analysis of advantages and disadvantages can be found elsewhere (Bowman and Hodge, 2009).
4. See: *Council Directive (EC) 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products* [1976] OJ L262; Commission Regulation (EC) No. 258/97 [1997] OJ L043.

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