Chapter 5
Technology Assessment Beyond Toxicology – The Case of Nanomaterials

Torsten Fleischer, Jutta Jahnel, and Stefanie B. Seitz

5.1 Introduction

Although the term technology assessment (TA) is generic for non-uniform, partly even contradictory approaches and activities, it can be defined as 'a *scientific, interactive and communicative process which aims to contribute to the formation of public and political opinion on societal aspects of science and technology*' (Decker and Ladikas 2004). Regarding responsibility in nanotechnology development TA activities aim to provide knowledge which politics and society can use as a basis for action and decision-making in the governance process of nanotechnology. Within this process the focus was put on manufactured particulate nanomaterials (MPNs), a group of substances – inseparably linked to nanotechnology – that are only commonly characterized by their nano-size. The peculiarity of MPNs is that their properties differ significantly from those of lager particles of the same material. This makes them suitable for new or improved applications which are expected to be a major opportunity for the economic and sustainable development of many countries. However, these new properties deriving from the nano-size are just the same as those which concern scientists, in particular, but also policy makers, a number of stakeholders and parts of the general public.

Experiences of the past, e.g. with chemicals, asbestos or ultrafine particles, showed that new materials may be a source of new threats for human health and the environment (Oberdörster et al. 2005). The scientific community – in particular the toxicologists – was and is still expected to answer the question of whether MPNs pose environmental, health and safety (EHS) risks or not, and to provide policy makers with the appropriate knowledge to perform risk assessment as a prerequisite for science-based risk management. Beside the problem that the (nano)toxicology

T. Fleischer (✉) • J. Jahnel • S.B. Seitz
Institute for Technology Assessment and Systems Analysis (ITAS), Karlsruhe Institute of Technology (KIT), Karlsruhe, Germany
e-mail: torsten.fleischer@kit.edu

S. Arnaldi et al. (eds.), *Responsibility in Nanotechnology Development*, The International Library of Ethics, Law and Technology 13, DOI 10.1007/978-94-017-9103-8_5,

research agenda is not only driven by the aim to produce systematically knowledge for decision-making of politics and society, the current concept for assessing nano-specific risks is the conventional expert-based chemical risk assessment procedure (SCENIHR 2007, 2009). This concept is limited to a narrow toxicological perspective defining risk itself as a hazard multiplied by exposure. The toxicological risk assessment paradigm is based on confidence in the knowledge used despite serious methodological uncertainties in the case of nanotechnology. Accordingly, a wider concept is needed which allows for a plurality in perspective, actors and different kinds of knowledge adequately considering societal impacts for understanding risk in a broader sense than simply experts. In addition, regulation based on quantitative risk assessment is an inherently slow governance process. This leads to alternative more adaptive governance frameworks, such as those suggested by the Environmental Defense Fund and Dupont (Nano Risk Framework, Environmental Defense Fund and Dupont 2007) or the International Risk Governance Council (IRGC 2006). The IRGC framework combines the scientific risk-benefit assessment with an assessment of risk perception and the societal context of risk, called concern assessment. Here we deal with the outcomes of the different methods for concern assessment. We will discuss the possible support for an inclusive understanding of risk appraisal as a precondition for responsible risk management and risk governance.

5.2 Why Beyond Toxicology?

5.2.1 Limitations of the Classical Risk Assessment

Toxicology as discipline aims to study the adverse effects of chemicals on living organisms, especially humans. Thus, it also provides knowledge for decision-making during risk management. Moreover, toxicologists were among the first who expressed concerns regarding potential risks of MPNs towards health and the environment. Subsequent, nanotoxicology emerged from the classical toxicology, and studies in particular the biological effects of engineered nanomaterials on living organisms and in ecosystems (Oberdörster 2010a). In general, (nano)toxicology is the justification for risk governance according the precautionary principle. Thus, nanotoxicology research is incorporated into risk assessment as a part of the governance of MPN-risks.

The classical risk assessment is a well-established and formalized process intended to

> calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system (OECD 2003).

The risk assessment process consists of four steps: hazard identification, hazard characterization (usually summarized as hazard assessment), exposure assessment, and risk characterization.

According to the Risk Commission (2003), a scientific risk assessment process primarily deals with consequences of the effects of noxious agents to human health. Risk assessment resembles a process in which the probability of a harmful effect on individuals or populations is quantified. The framework was developed for conventional chemicals as an information and decision-supporting tool for possible regulations. Associated uncertainty in the progress is managed by the application of safety factors. There is a consensus that the classical measures of toxicology are in principle applicable to nanomaterials, but standard procedures of risk assessment have to be modified (e.g. Rocks et al. 2008).

The EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) stated already in their 2007 opinion that the current methodologies are generally likely to be able to identify the hazards associated with the use of nanomaterials. However, they see the need for modifications for the guidance on the assessment of risks (SCENIHR 2007, 2009). Moreover, assessing risks of nanomaterials using conventional paradigms may not be sufficient to capture all the dimensions of risk of an active nano-bio material, as risk may arise not only from its inherent material toxicity but also from its interactions with complex biological systems (Maynard et al. 2006).

The main limitations for current procedures to assess the risks of nanomaterials are:

- The question of the identification and definition of the term 'nanomaterial' poses a challenge for framing a 'substance class' with a high diversity for risk assessment.
- Equipment and methods for characterization and detection of nanomaterials are often not appropriate and need further optimization (Maynard et al. 2006; Tiede et al. 2008; Marquis et al. 2009; Leach et al. 2011). It is still impossible to detect nanomaterials in biological matrixes.
- A definition or concept for dose/concentration is still missing.
- High quality exposure and dosimetry data is also still missing. Many exposure-related studies are published on occupational scenarios while many fewer studies are published on environmental and consumer exposure as well as about both acute and chronic exposures (ENRHES 2010; Aschberger et al. 2011).
- Standardized methods including appropriate controls are largely still missing. Exacerbating factors – such as surface functionalization, dispersing behaviour in biological media or the use of solvents in the case of non-dispersing nanoparticles (e.g. fullerenes) in aqueous media – that may e.g. produce testing artefacts (Henry et al. 2007) – are not addressed sufficiently in many studies (ENRHES 2010; Aschberger et al. 2011).
- Studies that showed no significant (hazardous) effects are usually not published, even though they are crucial to relieve MPNs from the suspicion of hazard (Krug and Wick 2011).

- There is an ongoing debate on the significance of high-dose *in vitro* or *in vivo* studies conducted so far and whether or not the used methods are suitable for hazard characterization (e.g. Oberdörster 2010b).
- For eco-toxicological studies it is, in general, difficult to simulate real environmental scenarios since the dose is quite unknown and the extrapolation of data is very limited (ENRHES 2010; Aschberger et al. 2011).

Limitations within the classical risk assessment processes concerning uncertainties and knowledge gaps that also occur with other chemical substances become even more overt in the case of MPNs. Moreover, one overarching difficulty will most probable always remain: In contrast to the vast majority of substance classes of hazardous chemicals that need to undergo risk assessment, MPNs share no common characteristics apart from the fact that the primary particles are in nano-scale. Although there are a number of approaches to categorize MPNs in a kind of 'hazard classes' or develop EHS risk prediction systems (e.g. Foss Hansen et al. 2007; Xia et al. 2009, 2010; Burello and Worth 2011; Puzyn et al. 2011), it is the consensus in the nanotoxicology community that due to the knowledge gaps and intrinsic limitations of characterization of MPNs, today only a 'case-by-case' assessment is responsible and sound. Thus, risk assessment of MPNs requires the full dataset for each and every kind of MPN. This makes the progress of gathering the relevant data for this case-by-case approach extremely slow – although the literature body is increasing constantly. Therefore also today, a complete risk assessment is only possible for a small selection of highly abundant MPNs, like nano-silver, carbon nanotubes and fullerenes, or titanium dioxide nanoparticles (e.g. Krug and Wick 2011; Aschberger et al. 2011).

Additionally classical risk assessment favours scientific knowledge that can be measured, weighted and monitored. This ignores the importance of values, ethics and tacit forms of knowledge when judging risks. There are several inherent value judgements in risk assessment and value-based decisions should be left to the political decision-makers (Senjen and Hansen 2011).

5.2.2 *On the IRGC Risk Management Framework*

Facing these limitations of the risk assessment there was the request for a more holistic approach beyond the expert-based chemical risk assessment procedure. In order to consider societal impacts and societal needs for understanding risk in a broader sense than experts, the classical toxicological-driven risk assessment paradigm should be widened.

In its white paper published in 2006, the International Risk Governance Council tackled this problem and introduced a new conceptual framework for the risk governance of nanotechnology (IRGC 2006). Risk Governance, according to the IRGC

> includes the totality of actors, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken. Encompassing the combined risk-relevant decisions and actions of both governmental and private actors, risk governance is of particular importance in, but not restricted to, situations where there is no single authority to take a binding risk management decision but where instead the nature of the risk requires the collaboration and co-ordination between a range of different stakeholders. Risk governance, however, not only includes a multifaceted, multi-actor risk process but also calls for the consideration of contextual factors such as institutional arrangements (e.g. the regulatory and legal framework that determines the relationship, roles and responsibilities of the actors and co-ordination mechanisms such as markets, incentives or self-imposed norms) and political culture including different perceptions of risk (Renn 2008).

Concerning the responsibility in nanotechnology development, the IRGC framework is a sophisticated risk management model. It involves a multitude of different actors in a dynamic process with various iterations and feedbacks. It acknowledges that risk governance decisions have to be taken in instances of complexity, uncertainty and ambiguity. Therefore, strategies should be based on a corrective and adaptive approach and take into account the level and extent of available knowledge and a societal balancing of the predicted risks and benefits. The framework includes two innovative concepts for the governance of (potential) risks arising from the use of MPNs:

- It integrates a scientific risk-benefit assessment (including environment, health, and safety (EHS) and ethical, legal, and other social issues (ELSI)), with an assessment of risk perception and the societal context of risk (referred to in the white paper as concern assessment).
- Inherent is the need for all interested parties to be effectively engaged, for risk to be suitably and efficiently communicated by and to the different actors and for decision-makers to be open to public concerns.

The IRGC Framework is a cyclical process and consists of four phases: The 'Pre-Assessment' which can be seen as the trigger or initiator of the whole assessment and management process is the first phase. Subsequent, 'Risk Appraisal' as the second phase of the IRGC risk governance framework follows and comprises two elements: risk assessment (see Sect. 5.2.1.) and concern assessment (see Sect. 5.2.3.). This is followed by the third phase called 'Tolerability and Acceptability Judgment' which brings together the classic risk characterization and risk evaluation as a new element. Finally, 'Risk Management' (Phase 4) has to react not only to new scientific results regarding a hazard or an exposure to it. It also reacts to changing societal or cultural factors like altering expectations on risk reduction procedures, new judgments about tolerability and acceptability of risks, developing value systems or shifting risk perceptions of different actors.

Some authors criticised this framework because public participation is still perceived as a factual input, as part of an expert-driven process, rather than empowerment of citizens (Senjen and Hansen 2011).

5.2.3 *The Role of Concern Assessment*

During the risk management phase, one has to address what the concerns of the general public and the stakeholders are, when it comes to a widespread market introduction and usage of MPNs. In short: within a risk governance process that considers the political and institutional conditions in modern societies, risk assessment has to be complemented by a concern assessment.

In a book article that addresses conceptual issues of the IRGC framework raised by external experts in a round of formal comments, the lead authors define concern assessment as

> a social science activity aimed at providing sound insights and a comprehensive diagnosis of concerns, expectations and perceptions that individuals, groups or different cultures may link to the hazard (Renn and Walker 2008).

Understanding these different concerns, expectations and perceptions is an important factor in getting to know better how individuals and groups perceive and assess risks and what actions (or non-actions) are perceived as being risky for what reasons. In addition, it helps to comprehend how the different actors are expected to develop and implement adequate measures in risk management and risk communication. Investigations of the evolving socio-cultural and political context in which research at the nano-scale is conducted, the societal needs that nanotechnology may satisfy and the popular images that experts, politicians and representatives of the various publics associate with nano-science and nanotechnology are additional elements in improving the societal knowledge about adequate risk management procedures (IRGC 2006).

Fundamental for the comprehensive diagnosis of concerns is the meaning of risk. According to IRGC (2005) and Renn and Walker (2008), risk is characterized in general as a '*mental construction*', which means that risk is

> not a real phenomena but originates in the human mind. Actors, however, creatively arrange and reassemble signals that they get from the 'real world' providing structure and guidance to an ongoing process of reality enactment. So risks represent what people observe in reality and what they experience.

Generally speaking, the perception of technological risks depends on two sets of factors. The first consists of psychological factors such as perceived threat, familiarity, personal control options and positive risk-benefit ratio. The second set includes political and cultural factors such as perceived equity and justice, visions about future developments and effects on personal interests and values. While the first set of components can be predicted to some degree on the basis of the properties of the technology itself and the situation of its introduction, the second set is almost impossible to predict (IRGC 2006).

While conventional chemical risk assessment can build upon a long tradition of scientific discussion, methodological development and established organizational and institutional practices, concern assessment is still in its early stages. That notwithstanding, what is needed is a systematic assessment of the concerns and preferences of the various actor groups and the public at large, together with a systematic feedback of its results to the related regulatory and legislative processes. These are necessary prerequisites to improve our understanding of the likely societal responses to the developments in nanomaterials and nanotechnology. This is also important for the implementation of risk governance structures that are accepted as socially responsible and to avoid public controversies and potential conflicts.

5.3 How to Translate Concern Assessment into Praxis?

5.3.1 Methodological Challenges

In the IRGC framework, risk communication has a central role and several functions. First of all, this should enable an information flow between the different players (policy makers, scientists of the different disciplines, stakeholders and representatives of the general public) as well as the different phases of the process. Moreover, risk communication is the key to building trust for the risk management process and improving the performance of the management system significantly (IRGC 2006). Concerning the communication between persons that are professionally involved in the process (scientists, policy makers) and 'the outside world', another principal function of risk communication is to enable concerned citizens to make their own balanced risk-judgment. This means that any person or social group affected by risks should be sufficiently well-informed to make a personal judgment of the risks, which meets their own criteria.

Thus, the aim of dialogues, engagement and participation events engaged in concern assessment and/or risk communication should be to address fundamental issues and characteristics of the risk problem, such as the degree of complexity, the nature of uncertainty and ambiguity. High levels of ambiguity require the most inclusive strategy for participation since not only directly affected groups but also those indirectly affected have something to contribute to a debate. To translate these rather abstract requirements into actual political action remains a demanding task.

One of the key problems in developing formats for public participation is that the general public – by definition – is neither organized, nor can it be represented adequately by self-appointed representatives. To address this problem, a number of innovative tools such as consensus conferences, citizens' juries, focus groups, scenario workshops, etc. which are more dialogue-oriented than the classic forms (like exhibiting documents for inspection and providing opportunities to submit comments) and made for more effective participation by non-organized citizens have been developed and tested, and numerous experiences regarding the design of participatory procedures have been acquired (e.g. Gavelin et al. 2007; Hullmann 2008; Bonazzi 2010).

Among a set of well-established methods that social science used and uses to study perceptions of nanotechnology's benefits and risks within individuals, groups or the society as a whole are quantitative and qualitative methods. Each of them has its own pros and cons. Quantitative methods – including surveys which are designed to ascertain large and therefore representative datasets as well as experimental studies using non-probability samples – for example, allow for testing and revising existing hypotheses, and making statements about defined groups of people. Typical examples are large, standardized polls within a representative sample of a population. In contrast, qualitative methods are rather designed to gain insights into individual arguments, ideas or values and to explore new aspects of an issue. Thus, they are designed rather open (not standardized) to capture even unexpected facts. Beside in-depth interviews, focus groups are typical examples of qualitative methods (Fleischer and Quendt 2007; Fleischer et al. 2012a).

Generally speaking, the landscape of research into perceptions of nanotechnology and nanomaterials – and the related concerns – among European citizens is somewhat patchy. To our knowledge, representative studies about the familiarity with, attitudes towards and perceptions of nanotechnology covering all member states have only been performed within three Special Eurobarometer surveys in 2002, 2005 and 2010. This research has been complemented with a number of country studies over the last few years (e.g. BMRB 2004; BfR 2008). Since these surveys have used various methodologies and mostly different questions or different question wordings, their results are hard to compare with each other and with the Eurobarometer findings. In the following chapters the quantitative and qualitative results are discussed separately.

5.3.2 Quantitative Results: Eurobarometer Survey 2010

The most recent – and most reliable – representative data on the awareness, expectations and attitudes of the general public towards nanotechnology in Europe can be taken from a 2010 Special Eurobarometer survey on biotechnology (Eurobarometer 2010). This survey covers a representative sample of the population of the respective nationalities of the European Union Member States (plus Iceland, Norway, Switzerland, Croatia and Turkey), resident in each of the Member States and aged 15 years and over. The survey was carried out between the 29th of January and the 17th of February 2010. All respondents were interviewed face-to-face in people's homes and in the appropriate national language. The sample size (usually around 1,000 respondents per country) permits accuracy (confidence interval) of ca. ±3 percent points. The Eurobarometer study allows for comparing public opinions in different EU Member and Associated States. It gives some indications of what effects public dialogue and engagement exercises may have had on public opinion in a particular country prior to the opinion poll (ObservatoryNano 2012).

Regarding nanotechnology, respondents had been asked first if they had ever heard of nanotechnology before. Forty-six percent of Europeans had heard of nanotechnology, while 54 % had never heard of it. Looking at the socio-demographic data, they show that gender, education and age are factors. Fifty-four percent of men (compared to 39 % of women) had heard of nanotechnology. Most likely to have heard of nanotechnology were managers (76 %), students (60 %) or self-employed people (57 %) as well as persons who left full-time education age 20+ (68 %) and everyday users of the internet (62 %). Least familiar with nanotechnology were house persons (30 %), retired (35 %) or unemployed (38 %) people as well as those who left school at age 15 or below (22 %) and non-users of the internet (25 %). Forty-one percent of Europeans expected a positive impact of nanotechnology on their way of life in the next 20 years, 40 % did not know, 10 % expected a negative effect and 9 % thought that nanotechnology would have no effect.

In order to tap into perceptions of, expectations of and concerns about nanotechnology, respondents were presented ten statements about nanotechnology and asked whether they totally agreed, tended to agree, tended to disagree or totally disagreed. The statements covered four clusters: perceived benefit, perceived safety/risk, perceived fairness/unfairness with regard to distributional equity and worries related to unnaturalness.

As a general impression at the European level, one third of the respondents believed that nanotechnology may do harm to the environment, is not safe to human health and is not safe to future generations, respectively. One third expressed an opposite view and one third did not know. A more regional perspective showed interesting differences: The higher the number of respondents in a certain region that had already heard about nanotechnology, the higher the number of respondents that didn't agree that nanotechnology is safe to their health and agreed that nanotechnology would do harm to the environment (Fleischer et al. 2012a). On this highly aggregated level, there seems to be a positive correlation between perceived knowledge about and perceived risk of nanotechnology, an observation that has to be confirmed by future in-depth research.

Surprisingly, in a number of countries, the percentage of respondents who express an opinion about perceived safety/risk of nanotechnology is even higher (statistically significant) than the percentage of respondents that have already heard about nanotechnology. In other words, the perceptions of some respondents appear to be based on factors other than factual knowledge about nanotechnology.

A more detailed analysis was provided by Gaskell et al. in an accompanying report to the Eurobarometer survey, presenting research from the FP7 project 'Sensitive Technologies and European Public Ethics' (STEPE). They found that, across the European public

> the balance of opinion is that nanotechnology is somewhat more likely to be beneficial than not, to be unsafe rather than safe, to be inequitable rather than equitable, and not particularly worrying (though, equally, not particularly unworrying) (Gaskell et al. 2010).

They also showed that perceived safety is by far the most influential variable on overall support of or opposition to nanotechnology, followed by benefit, worries related to unnaturalness and lastly inequity.

5.3.3 Qualitative Results: Observations in Public Engagement Exercises and in Dedicated Focus Group Studies

Additional insights for studying perceptions and concerns related to nanoparticles can be gained from the results of qualitative methods. Various participatory projects – like *NANOBIO-RAISE*, *DEEPEN*, *TIME for Nano*, German *NanoCare*, Austrian *Risiko:dialog*, Danish Survey of 2004, UK *Nanotechnology, Risk and Sustainability*, Dutch *Nanopodium*, or Swiss *Publifocus*) have included qualitative methods such as interviews or focus groups.

Only one of the projects that was using qualitative methods was focused explicitly on conceptions and concerns regarding MPNs: the focus groups that were conducted within the German 'NanoCare' project (Fleischer and Quendt 2007), while the remainder were dealing with nanotechnology in general. Two further focus group discussions dealing with MPNs were performed within the NanoSafety project (Fleischer et al. 2012a). Both events focused on getting insights into ideas, concepts and associations that citizens had of nanoparticles and nanoproducts. A second part of the discussions addressed the participants' expectations regarding political action.

During focus group discussions the citizens talked with each other using statements, narratives, comparisons, analogies, metaphors and stories. With these verbal tools they expressed only indirectly accessible mental and cognitive constructs like concerns, perceptions, opinions and expectations. Furthermore, underlying reasons, rationalities but also individual emotional reactions and feelings were expressed.

The vast majority of people still have little or no idea of what nanotechnology is or about its possible implications. Despite this, members of the public have already expressed similar concerns to those associated with other technologies perceived as being risky, particularly around governance structures and corporate transparency. Many citizens were astonished about the broad scope, spectrum and extent of 'nanoproducts' already available. Many discussants arbitrarily mixed their terminology and used nanoparticles, nanotechnology and sometimes also 'nanoproducts' quasi synonymously.

The different concerns and expectations of the participants were motivated by special individual contexts and could be linked to concrete needs and intentions. The statements during the events of different qualitative methods were grouped according to the following main dimensions.

Regarding *human health*, improvements in disease prevention, early disease detection or medical treatment were expected. The participants hoped to benefit from improved medicinal applications (nanomedicine). Thereby, they were concerned about potentially adverse health effects (mainly due to inhalation) of MPNs, the entry of MPNs into the human body due to their very small size and scientific uncertainty regarding the behaviour of nanoparticles in the human body as well as uncertainties with regard to risk assessment.

Improvements due to MPN applications were expected for the *environment*, such as effects on pollution prevention and remediation, also energy conservation, efficiency gains in production due to miniaturization effects, cleaner manufacture with fewer emissions and less waste. Nanotechnology-based environmental technology applications like devices for waste water treatment were expected to bring benefits as well as the substitution of classical hazardous chemicals. However, the participants were concerned about uncontrolled release of MPNs into the environment, their possible occurrence in ground water, in air and their possible enrichment in the food chain. They worried about life-cycle impacts like energy and resource intensive manufacturing, problems in the recycling and disposal phases, especially considering disposal and behaviour in wastewater treatment.

Asked for their *acceptance* of MPNs, the citizens were less reluctant to the use in medical applications, cosmetics and other sectors. They appreciated consumer and household ‘nanoproducts’ increasing convenience in daily lives. The contribution to the progress of medical applications and the possible substitution of chemicals of concern was stated as an advantage, too. Nevertheless, they argued that due to the lack of knowledge, a reasonable balancing of opportunities versus risks is not possible. Citizens were concerned about the transparency of communication, credibility and trust in companies that bring ‘nanoproducts’ into the market. They refused the application of nanoparticles in the food sector. In general, every manipulation and deviation from natural growth was met with scepticism and even suspicion.

Moreover, the participants stated that *research* on MPNs and their risks should be organized and performed by international, independent authorities, by universities, or state-run institutions. They voted for an increase of funding for safety research.

Concerning *ethical and social aspects*, the participants were worried about the expensiveness of nanotechnology and thus limiting access for those who could benefit the most (unequal access), widening the divide between the industrialized and the developing world. Concerning privacy issues, they stated that the collection of increasingly sensitive data in medical diagnostics is likely to raise serious questions about information provenance and distribution, and that convergence with information and communication technology could result in possible threats to civil liberties from increasingly advanced surveillance capabilities, enabled by nanotechnologies. Moreover, the participants were concerned about subsequent developments that may be as much in the hands of users as the innovators and could be used in ways not originally intended. The complexity of the product life-cycle of nanotechnology applications may make it difficult to establish a causal relationship between actions of a company and any resulting impact. Thus, questions about sufficient liability frameworks were raised.

Regarding *regulation and control* issues, the participants were concerned whether existing regulatory regimes are robust enough to deal with nanomaterials, or whether new regulation is required. The right balance between a responsible development and safe use of nanomaterials were important for them. Like other emerging technologies that are closely linked to basic scientific research, nanotechnology generates intellectual property that is perceived as valuable and thus should be protected by patents. There is an obvious trade-off between the various laws, regulations, and treaties that govern the relationship between the public good and the protection offered by patents, they felt. The most important measure suggested by the participants in focus groups was the labelling of ‘nanoproducts’, which serves as a basis for deliberation and choice as well as to obtain additional information on their use, risk and appropriate disposal. But they also agreed that the consumer needs information ahead of a purchase decision: information about the (potentially) hazardous nature of a nano-ingredient enables the consumer to interpret the label and allows a risk-benefit consideration. Several participants were worried about the safety of consumer products and the lack of concrete regulations. Few citizens explicitly demanded a definitive ban (moratorium) of all ‘nanoproducts’. Other participants thought of the possibility to subject ‘nanoproducts’ to a (governmental) authorisation after they were proven to be harmless. They concluded that an authorisation process and the obligation of long term studies would make a moratorium unnecessary.

The various aspects of concerns and perceptions found in our analysis of the outcomes of qualitative methods support, deepen, and refine the findings of quantitative surveys (like in the Eurobarometer survey), especially with regard to the possible harm to health and the environment and safety aspects. Further concerns deal with the trustworthiness and credibility of information and measures and desired communication requests. In connection with quantitative results they allow for an improved assessment of the concerns – and their basis – within the general public. They also support the findings of Gavelin et al. (2007) who analysed and discussed the results of dialogue projects dealing with nanotechnology in general, like *Nanologue* or *SmallTalk*. Gaining and maintaining public trust under conditions of scientific uncertainty seems to be the key element of the debate on perception and acceptance of nanomaterials. Openness and transparency are factors that have proven to be helpful in achieving this objective. Gavelin et al. found that the general public supports nanotechnologies that are linked to a wider social good and that it is concerned about known and unknown risks as well as the ability of the government and private sector to manage those risks. The public calls for more open decision-making about nanotechnologies. Risk communication strategies should enable a two-way communication. A transparent discussion should make available to the public informed opinions about scientific aspects, including risks and benefits, provide clear and transparent descriptions of the regulatory and funding approaches, furnish information on who has the responsibility to regulate and support nanotechnology (Gavelin et al. 2007).

5.3.4 Positions and Concerns Expressed by Stakeholders

Besides the necessity of taking into account public perception and social concerns also the interests and concerns of organized stakeholders have to be considered. The various stakeholders that have taken a position in the negotiation around ‘nano’ could be divided into the main groups of civil society organisations (CSO), industry and academia. CSO themselves include consumer groups, trade unions and environmental groups. In publications, stakeholder dialogues and presentations pick up

Table 5.1 Summary of the most prominent positions of different stakeholder groups on the main issues in the 'nanodebate'

CSO	Academia	Industry
Call for an increase of safety research and (partial) moratorium for the marketing of certain products.	Call for an increase of research funding.	Development of risk assessment approaches and safe handling guidelines.
Call for mandatory measures including a general labelling obligation and a harmonized traceability system. Some even call for a (temporary) moratorium.	Support for definition that is based on a defined narrow size scope with conditional exceptions (inclusion of aggregates and agglomerates).	
Call for a broader scoped definition with regard to size, also including aggregates and agglomerates.		Support voluntary measures like codes of conduct and guidelines for safe handling. Case by case decisions and assessment by scientific agencies that consider e.g. application conditions may be appropriate instruments.
Foster dialogues involving all stakeholders for equity of decision-making and public participation.	Support dialogues involving all stakeholders.	Foster stakeholder dialogues – but public 'participation' only with an informative character.

the main concerns expressed by members of the groups they represent, and cluster the various aspects. They formulate requests and recommendations for further handling of risk and improvement of governance procedures, considering the concerns raised. The main focus of stakeholder dialogues is the risk governance of engineered nanomaterials including their regulation. For consumer products, there is most discussion on nano-ingredients in food, cosmetics and other household products. Labelling and transparency are core issues next to safety. Stakeholder involvements tend to be on an invitation based on expertise and representativity (ObservatoryNano 2012). In Table 5.1, we have attempted to summarize the positions of the three stakeholder groups.

5.4 Contributions of Concern Assessment to Risk Governance

Finally, the question remains how the results of concern assessment, which bear controversies and potential conflicts, could be intertwined with the procedures of political decision-making and risk governance.

The first step is to choose a suitable and adequate method and to interpret the outcome and the gathered data carefully and with caution.

Large surveys – like this Eurobarometer study – usually ask about statements regarding nanotechnology in general. It remains unclear to which part of the multifaceted concept of nanotechnology the respondents in these surveys refer and how these answers can be related to the more specific perceptions and concerns with regard to MPNs. On the other side, research using qualitative methods shows that most laypeople do not clearly discriminate between nanotechnology and nanomaterials. More often than not, they link risks of nanotechnology to the application of nanomaterials in various products and areas, therefore 'nanotechnology' could be read as a synonym for 'nanomaterials' within this context. In general, quantitative methods ask for existing and already formed opinions and attitudes, which are simply considered as static cognitive entities already located in individuals. Depending on personal priorities with respect to each application the responses to general questions vary from survey to survey and it is still unclear how attitudes on a single application influence the appraisal of nanotechnologies in general (Renn and Grobe 2010). In addition the responses vary with the concrete wording of the questions. For example defining the subject can prime the survey respondents.

Interpreting the results of qualitative concern assessment methods – such as focus group discussions – is also challenged by a complex system of dependent and influencing factors like concerns, perceptions, trust, acceptability, attitudes and opinions. Furthermore, some of these factors like attitudes and opinions tend to be fragile and volatile. The participants' statements about the acceptability of 'nanoproducts' in the focus group discussions indicated that attitudes and acceptance are difficult to be achieved and depend on the individual case. Experience shows that it would be overly optimistic to expect people to report insightfully on what is truly important to them or to assess what the factors are that influence their judgments and decisions. In addition, most of the qualitative methods are dynamic processes and events. People's talks, the exchange of information, hearing the perceptions and expectations of others led some participants to rethink their initially voiced positions, to formulate other, alternative statements and expectations. It became obvious to the observers that opinions cannot simply be considered as static cognitive entities already formed and located in individuals waiting to be 'excavated' by smart moderators. Many of them were formed no earlier than in the processes of interaction with other participants during the discussion (Myers 2005). This may be part of the explanation why the outcomes of focus groups on nanotechnologies have, so far, led to divergent findings. The drawbacks are based on answers, sensibilities and interactions at a point in time and challenge the interpretation of the results (Berube et al. 2011).

Thus, methods for concern assessment, especially qualitative methods, can provide no more – and no less – than first insights into people's perceptions, conceptualizations, associations and expectations regarding future technologies. With regard to risk governance their value is informational rather than instrumental. Their results can broaden the perspective of the various actors, but they do not allow for a simple delineation of governance strategies. In spite of these limitations, a number of observations can be considered for further risk governance issues (Fleischer et al. 2012b).

One example is the diffuse terminology of 'nano', which could not only be observed among laymen, but can also be consistently found among scientists, science communicators and regulators. Participants in focus group discussions used a number of metaphors in trying to better understand the content and the implications of nanotechnology (Davies 2011). In addition, a number of participants used mental short cuts or heuristics to conceptualize the unknown 'nano' terminology. For example they connected it to the more familiar natural-artificial dichotomy. When participants interpreted 'nano' as something new, artificial, they were much more sceptical about the implications of its production and use. Heuristics serve as a kind of information filter and are influenced for example by affect, values and beliefs. These kinds of 'qualitative' judgments differ from expert judgements using empirical assessment data, logical rules or probability aspects. Thus, they might shape discussion processes and their outcome differently from expert discussions. This finding may support the observation that the public's struggle with understanding science and new technologies does not necessarily emerge from a science knowledge deficit or a lack of technological literacy but rather emanates from existing personal belief predispositions and value systems that new technologies may change (Berube et al. 2011).

The second step for including concern assessment into the entire risk governance process is the 'translation' of the results into recommendations and concrete measures.

For many laymen, the concept of risk was related to the context of the application of nanoparticles rather than to the nanoparticles themselves. While people were sceptical about using nanoparticles in food, they were less critical about using them in controlled industrial environments and articulated a certain hope for using them in medicine as tools for new therapies. This could also mean that risk governance should not predominantly address nanoparticles as such but their application in different contexts – both regulatory approaches and risk communication have to address the context dependence of risk perception more specifically.

The participants of the focus group event within the STOA-project deliberated, discussed and assessed various regulatory instruments that the organizers considered to be potentially useful for risk governance of nanomaterials. Most of them were not discussed separately but rather as a combination of different measures that complement one another. In the discussion, broad consensus developed that labelling of products containing nanoparticles serves as a basis for deliberation and choice. Many participants appeared to have a 'coupled expectation' on risk governance actors. They saw the government and the consumer organizations in the role to oversee developments in products containing nanoparticles. At the same time, participants expected to be sufficiently informed about the potential risks of nanoparticles and about products containing them in order to make informed choices. Although or even because the participants in focus group discussions knew very little about nanotechnology, their claims became very clear. Independently from their different attitudes, their request as citizens and customers for clear and unbiased information coming from actors involved in risk governance was common. There was almost no trust in research results from industry. One might argue that oversight and building trust on the one hand and information and labelling on the other, are not alternatives, but merely complementary strategies for risk governance (Fleischer et al. 2012a, b).

A variety of participation events attempted to develop new forms of direct democracy in decision-making on science and technology. These upstream or midstream public engagement projects had only temporary success, but had so far not led to noticeable change and impacts on decision-making. On the other hand, public engagement in priority-setting on funding projects is widely regarded as a successful application (ObservatoryNano 2012).

In addition to public participation, stakeholder dialogues too can offer knowledge that is valuable for assessing risks and the possible approaches to managing them. But it is important that it is not the task of stakeholders at the appraisal stage to deal with normative questions like the tolerability of the risk or risk management options. By gathering information on the potential for public scepticism or social conflict in addition to experiential and practical stakeholder knowledge, concern assessment could help to identify social impacts and distinguish areas that require a more detailed analysis. In this context, concern assessment is an important part of an explicit interdisciplinary process of knowledge production.

The inclusion of scientific risk-based assessment and concern assessment in one framework could be seen as a new paradigm in the debate about the roles of sound science and precaution in decision making. By building into conventional risk analysis soft issues such as societal values, concerns and risk perceptions, as well as by looking into the interactions between various actors, such an integrated framework can lead to a better-balanced risk governance.

References

Aschberger, K., C. Micheletti, B. Sokull-Klüttgen, and F.M. Christensen. 2011. Analysis of currently available data for characterising the risk of engineered nanomaterials to the environment and human health – Lessons learned from four case studies. *Environment International* 37(6): 1143–1156.

Berube, D.M., C.L. Cummings, J.H. Frith, A.R. Binder, and R. Oldendick. 2011. Comparing nanoparticle risk perceptions to other known EHS risks. *Journal of Nanoparticle Research* 13(8): 3089–3099.

Bonazzi, M. 2010. *ANNEX – Communicating nanotechnology – Why, to whom, saying what and how? An action-packed roadmap towards a brand new dialogue*. European Commission, Unit 'Nano- and Converging Sciences and Technologies'. http://cordis.europa.eu/nanotechnology/src/publication_events.htm.

British Market Research Bureau (BMRB). 2004. *Nanotechnology: Views of the general public. Quantitative and qualitative research carried out as part of the nanotechnology study*. BMRB Social Research 2004. London: The Royal Society and Royal Academy of Engineering Nanotechnology Working Group.

Bundesinstitut für Risikobewertung (BfR). 2008. *Wahrnehmung der Nanotechnologie in der Bevölkerung. Repräsentativerhebung und morphologisch-psychologische Grundlagenstudie*. BfR-Wissenschaft 05/2008. Berlin: BfR.

Burello, E., and A.P. Worth. 2011. QSAR modeling of nanomaterials. *Wiley Interdisciplinary Reviews. Nanomedicine and Nanobiotechnology* 3(3): 298–306.

Davies, S.R. 2011. How we talk when we talk about nano: The future in laypeople's talk. *Futures* 43(3): 317–326.

Decker, M., and M. Ladikas (eds.). 2004. *Bridges between science, society and policy. Technology assessment – Methods and impacts*. Dordrecht: Springer.
Engineered Nanoparticles: Review of Health and Environmental Safety (ENRHES). 2010. Project report. http://www.nanowerk.com/nanotechnology/reports/reportpdf/report133.pdf. Accessed 20 Oct 2012.
Environmental Defense, DuPont. 2007. *Nano risk framework*. http://www.environmentaldefense.org/documents/6496_Nano%20Risk%20Framework.pdf. Accessed 20 Oct 2012.
Eurobarometer. 2010. *Eurobarometer wave 73.1*. Special Eurobarometer 341. Biotechnology. Bruxelles: European Commission.
Fleischer, T., and C. Quendt. 2007. *'Unsichtbar und unendlich'. Bürgerperspektiven auf Nanopartikel. Ergebnisse zweier Fokusgruppen-Veranstaltungen in Karlsruhe*. Wissenschaftliche Berichte FZKA 7337. Karlsruhe: Forschungszentrum Karlsruhe.
Fleischer, T., J. Jahnel, and S.B. Seitz. 2012a. *NanoSafety – Risk governance of manufactured nanoparticles* (Final report). Brussels: European Parliament, STOA.
Fleischer, T., J. Haslinger, J. Jahnel, and S.B. Seitz. 2012b. Focus group discussions inform concern assessment and support scientific policy advice for the risk governance of nanomaterials. *International Journal of Emerging Technologies and Society* 10: 79–95.
Foss Hansen, S., B.H. Larsen, S.I. Olsen, and A. Baun. 2007. Categorisation framework to aid hazard identification of nanomaterials. *Nanotoxicology* 1(3): 243–250.
Gaskell, G., S. Stares, A. Allansdottir, N. Allum, P. Castro, Y. Esmer, and et al. 2010. *Europeans and biotechnology in 2010: Winds of change? A report to the European Commission's Directorate-General for Research*. Luxembourg: Publications Office of the European Union.
Gavelin, K., R. Wilson, and R. Doubleday. 2007. *Democratic technologies? The final report of the Nanotechnology Engagement Group (NEG)*. Involve: London.
Henry, T.B., F.M. Menn, J.T. Fleming, J. Wilgus, R.N. Compton, and G.S. Sayler. 2007. Attributing effects of aqueous C60 nano-aggregates to tetrahydrofuran decomposition products in larval zebrafish by assessment of gene expression. *Environmental Health Perspectives* 115(7): 1059–1065.
Hullmann, A. 2008. *European activities in the field of ethical, legal and social aspects (ELSA) and governance of nanotechnology*. European Commission. ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/elsa_governance_nano.pdf. Accessed 25 Oct 2012.
International Risk Governance Council (IRGC). 2005. *White paper no. 1 on risk governance: Towards an integrative approach*. Geneva: International Risk Governance Council.
International Risk Governance Council (IRGC). 2006. *White paper no. 2 on nanotechnology risk governance*. Geneva: International Risk Governance Council.
Krug, H.F., and P. Wick. 2011. Nanotoxicology: An interdisciplinary challenge. *Angewandte Chemie International Edition* 50(6): 1260–1278.
Leach, R.K., R. Boyd, T. Burke, H.-U. Danzebrink, K. Dirscherl, T. Dziomba, M. Gee, L. Koenders, V. Morazzani, A. Pidduck, et al. 2011. The European nanometrology landscape. *Nanotechnology* 22(6): 062001.
Marquis, B.J., S.A. Love, K.L. Braun, and C.L. Haynes. 2009. Analytical methods to assess nanoparticle toxicity. *Analyst* 134(3): 425–439.
Maynard, A.D., R.J. Aitken, T. Butz, V. Colvin, K. Donaldson, G. Oberdörster, M.A. Philbert, J. Ryan, A. Seaton, and V. Stone. 2006. Safe handling of nanotechnology. *Nature* 444(7117): 267–269.
Myers, G. 2005. Applied linguistics and institutions of opinion. *Applied Linguistics* 26(4): 527–544.
Oberdörster, G. 2010a. Safety assessment for nanotechnology and nanomedicine: Concepts of nanotoxicology. *Journal of Internal Medicine* 267(1): 89–105.
Oberdörster, G. 2010b. *Concepts of nanotoxicology*. NanoAgri 2010 conference. http://www.nanoagri2010.com/fao_mini_papers_extra_files.pdf. Accessed 20 Oct 2012.
Oberdörster, G., E. Oberdörster, and J. Oberdörster. 2005. Nanotoxicology: An emerging discipline evolving from studies of ultrafine particles. *Environmental Health Perspectives* 113(7): 823–839.

ObservatoryNano. 2012 Annual report 4 on ethical and societal aspects. In *Communicating nanoethics*, ed. I. Malsch, A. Grinbaum, V. Bontems, and A.M.F. Anderson. Maerz 2012. Brussels: EU.

Organization for Economic Cooperation and Development, Environment Directorate. 2003. *Description of selected key generic terms used in chemical/hazard assessment*, OECD series on testing and assessment number 44. ENV/JM/MONO(2003)15. Paris: OECD.

Puzyn, T., B. Rasulev, A. Gajewicz, X. Hu, T.P. Dasari, A. Michalkova, et al. 2011. Using nano-QSAR to predict the cytotoxicity of metal oxide nanoparticles. *Nature Nanotechnology* 6(3): 175–178.

Renn, O. 2008. White paper on risk governance: Toward an integrative framework. In *Global risk governance: Concept and practice using the IRGC framework*, ed. O. Renn and K. Walker, 3–73. Dordrecht: Springer.

Renn, O., and A. Grobe. 2010. Risk governance in the field of nanotechnologies: core challenges of an integrative approach. In *International handbook on regulating nanotechnologies*, ed. G.A. Hodge, D.M. Bowman, and A.D. Maynard, 484–507. Cheltenham: Edward Elgar.

Renn, O., and K. Walker. 2008. Lessons learned: A re-assessment of the IRGC framework on risk governance. In *Global risk governance: Concept and practice using the IRGC framework*, ed. O. Renn and K. Walker, 331–360. Dordrecht: Springer.

Risk Commission. 2003. *Ad hoc Commission on 'Revision of risk analysis procedures and structures as well as of standard setting in the field of environmental health in the Federal Republic of Germany' final report*. Berlin: Risk Commission.

Rocks, S., S. Pollard, R. Dorey, L. Levy, P. Harrison, and R. Handy. 2008. *Comparison of RA approaches for manufactured nanomaterials*. London: Defra.

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). 2007. *The appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of nanomaterials*. Brussels: European Commission.

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). 2009. *Risk assessment of products of nanotechnologies*. Brussels: European Commission.

Senjen, R., and S.F. Hansen. 2011. Towards a nanorisk appraisal framework. *Comptes Rendus Physique* 12(7): 637–647.

Tiede, K., A.B. Boxall, S.P. Tear, J. Lewis, H. David, and M. Hassellov. 2008. Detection and characterisation of engineered nanoparticles in food and the environment. *Food Additives and Contaminants: Part A, Chemistry, Analysis, Control, Exposure and Risk Assessment* 25(7): 795–821.

Xia, T., N. Li, and A.E. Nel. 2009. Potential health impact of nanoparticles. *Annual Review of Public Health* 30: 137–150.

Xia, X.R., N.A. Monteiro-Riviere, and J.E. Riviere. 2010. An index for characterisation of nanomaterials in biological systems. *Nature Nanotechnology* 5(9): 671–675.