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Regulating Nanoparticles: The Problem of Uncertainty

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Abstract

This article describes unresolved challenges of regulation of nanoparticles, mainly from a European perspective. The authors shall argue that the presently dominant strategy, which in this article will be called 'filling in the regulatory gaps', is unsatisfactory with respect to the management of uncertainty and ignorance associated with development and use of nanoparticles. Its shortcomings resemble those of 'the modern model' and 'the precautionary model' described by Funtowicz (2006) and Funtowicz and Strand (2007). Possible future alternative strategies to enable a *truly precautionary* approach are discussed.

1. Introduction: Nanoparticles and Nanomaterials - New Types of Regulatory Objects

This article discusses principles for the regulation of nanoparticles, which - by contested definition (Von Schomberg 2010) - are engineered particles with at least one dimension less than 100 nanometers. While human activity has led to the creation of nanoparticles for many years already, mainly as the result of combustion of fossil fuels (Park 2007), the matter of concern here are the engineered nanoparticles that are now increasingly being designed and manufactured as the result of increased interest and available funding for nanoscience and nanotechnology all over the world. The scientific interest in nanoparticles (and indeed other nanomaterials [3]) stems from the fact that properties of materials often change when the size is reduced to the nanoscale, due to increased surface to mass ratio, as well as quantum effects that start to manifest themselves at this scale (Park 2007). Accordingly, there is considerable concern among scientific and regulatory authorities that novel properties thus exhibited may cause unintended and unforeseen effects on human health and the environment (see e.g. Royal Commission on Environmental Pollution 2008, SCENIHR 2009). Even with extensive experience with a given material in bulk form, one does not know what might happen when nanoparticles of that same material are introduced into the natural environment and to humans (see for instance Donaldson and Stone 2007). As more nanoparticles are engineered and manufactured, the more unknown and potentially hazardous encounters there will be between them and the environment, including animals and humans (Colvin 2003). During the first decade of the 21st century, one has witnessed a gradually intensified debate on how to address the potential hazard in scientific and regulatory terms (see for example Royal Commission on Environmental Pollution 2008, Craye 2009).

In Europe, Van Calster (2006) predicted early that the European Commission did not view nanotechnology as requiring the development of new legislation. In the action plan implementation report (European Commission 2007a), the Commission stated that the current strategy is to regulate by '...improving the implementation of the current regulation' (p. 8, paragraph 6.1). The judgement of the Commission was, in other words, that nanoparticles will be sufficiently covered by laws and legislation areas already in place, or by extending the application of existing laws. This strategy of 'filling in the regulatory gaps' was reiterated by the Commission in its 2008 statement to the European Parliament (European Commission 2008b). The Parliament did, however, question the adequacy of the strategy in light of the paucity of scientific evidence on the potential negative effects (or rather 'risks') of nanomaterials. The issue is unsettled at the time of writing (August 2011); a time at which the main issue under debate appears to be whether 'nanomaterials' can or should be defined by a precise scientific definition (Lövestam et al. 2010, SCENIHR 2010, Maynard 2011). This article will not address the 'definition' debate *per se* but rather present a theoretical argument against the general regulatory strategy of 'filling in the gaps'. A strategy defined here as follows:

1.Establish an overview over existing regulations for different aspects of nanoparticles (development, use, storage, transport etc), and how and to what extent they may apply,
2.Identify 'gaps' in this regulatory patchwork, and
3.Extend the regulatory domain of one or more regulatory instruments in order to 'cover' the field, in which gaps are to be filled in.

There are several regulatory areas that should be considered relevant for possible nanoparticles regulation (for instance cosmetics, novel foods, product liability, packaging and labelling, occupational safety). It is not within the scope of this chapter to go into detail on laws and regulations (see instead Van Calster 2006; 2008 as well as Van Calster and Bowman 2010). A European directive of particular importance, however, is the one called '*Registration, Evaluation, Authorization, and restriction of Chemicals*' (REACH), which applies broadly to many different substances at the nanoscale (although nanoparticles are not mentioned explicitly) (Bowman & Van Calster 2007; European Commission 2008c). The article will return to REACH below.

Several European countries such as France and the UK, have run a number of different 'policy activities' for nanotechnology (Dorbeck-Jung 2007, Delgado et al 2010). These are activities focused for instance on public engagement and regulatory evaluation, and aimed at arriving upon a regulation which is proactive and integrative, including soft regulation mechanisms. One interesting question, the myriad of details about national regulation apart, is what effect these activities have had on processes in the EU. Van Calster (2008) specifically discusses this question, and his interpretation is briefly as follows: One has to understand current regulatory trends in the EU in part as the result of lessons from perceived regulatory failures in the Member States (he mentions GMO and BSE), causing risk aversion in the population. In combination with diverging regulatory policies between the Member States, this has been seen as a justification for an expansion of EU regulatory power. At the same time, there is a strong drive for regulatory integration and harmonisation, with the main aim of enhanced market integration. The strategies that now are developing in the EU, in other words, have to be seen as trying to balance public risk aversion against and the emerging international market potential for nanotechnology. Particularly, the stricter division between risk-assessment and risk management has to be seen as part of this, enabling a strict management while at the same time being able to defend risk assessment on grounds of sound science against technologically more liberal trade partners (Van Calster 2008).

The appropriateness of existing regulatory principles or nanoparticles has received some public attention, notably from non-governmental environmental organisations such as the Action Group on Erosion, Technology and Concentration (ETC group) and Friends of the Earth (FoE). A main worry has been that the special features of nanoparticles, as well as the lack of knowledge of how they may interact with the human body and the environment, is not adequately dealt with by the current legislation. This issue has also been raised with respect to REACH. One issue of concern was that the lower mass limit for the REACH legislation to enter into force (1 metric ton) ought to be lowered for nanoparticles due to their higher chemical reactivity per volume. In the report from the FoE on Nanofood (FoE 2008) the issue of lack of regulation of nanoparticles in the area of food and food-related items was put on the agenda. A major concern in this report is the definition of nanoparticles as *particles less than 100nm*. According to FoE, there are indications that particles up to the diameter of 300nm pose similar health risks as those under the size of 100nm. The FoE therefore called for a change where all particles up to 300nm in size must be considered to be 'nanomaterials' for purposes of health and environment assessment (FoE 2008).

The mentioned examples of debate show a characteristic feature, namely that the issues revolve not only around a regulatory gap, but also stress the lack of knowledge (Maynard et al 2006). This is expressed as follows by Beaudrie and Kandlikar (2011):

> 'There is a paucity of data available on the current production and use of nanomaterials and extreme scientific uncertainty on most aspects of the risk assessment 'causal chain.' (p. 1477).

So far, the response from the EU authorities, consistent with other jurisdictions, has been to aim at 'filling in the knowledge gaps'. This strategy is based upon the assumption that there are identifiable sets of information that one needs to, and can, gather in order to perform the risk assessments necessary to decide which nanoparticles should be allowed and how they should be regulated. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) was given the task, by the European Commission, to state its opinion on the appropriateness of current risk assessment methodology for nanoparticles. In their repeated reports on the issue they have gone through the scientific practises and knowledge and conclude that there are knowledge gaps, which should be addressed by further research and to be managed by the application of the precautionary principle. For instance, the SCENIHR (2006, p. 6) concluded that the data that is needed to perform the risk analysis within the current risk analysis methodology was lacking in most instances. This resulted in the recommendation of a precautionary approach (p 54):

> 'In the absence of suitable hazard data, a precautionary approach may need to be adopted for those nanoparticles that are likely to be biopersistent in humans and/or in environmental species'.

Simultaneously, research into impacts of nanoparticles on human health and the environment has been funded to fill these gaps in our knowledge, so as to be able to perform the required risk assessments:

> 'The purpose of [the EU's] strategy is to reinforce the Union's leading position in N&N research, development

> and innovation, while addressing any environmental, health, safety and societal concerns upfront.' (Aguar and Murcia Nicolás, 2008, p. 5).

REACH - which, in the absence of specific regulation for nanomaterials, is the main regulatory instrument for chemicals on the EU level, in general and accordingly also for nanomaterials - also explicitly advice that a precautionary approach is adopted. In its article 1 (3) it is stated that REACH

> 'is based on the principle that it is for manufacturers, importers and downstream users to ensure that they [...] do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle'.

The question, however, is if and how one may ensure that there will be no adverse effects, given the unknowns about nanoparticles - a challenge they share with other novel and potentially potent inventions. This does unfortunately not make the issue less acute. The examples above have that in common that they do not go beyond conventional regulatory wisdom in believing that knowledge gaps should - and can - be addressed by better (more accurate) risk assessment. With this mindset safety is something that should - and can - be ensured by better (tighter) risk management. Within the literature on environmental governance, it has been argued for years that such approaches (even when supplemented by the precautionary principle) may neither be sufficient nor the proper focus under conditions of uncertainty and ignorance (Wynne 1992, Funtowicz and Ravetz 1990), or in the words of Tyshenko et al. (2010): 'the almost inevitable certainty that there would be new or additional issues outside the scope of the initial assessment of risk' (p. 259). This is not, however, all there is to it; for instance, the European Commission issued a Code of Conduct for nanoresearch (European Commission 2008). This issue will be revisited in the final part of the article. However, the official main regulatory frame is that of risk assessment and risk management, the latter strengthened with the precautionary principle. The article shall now turn to the problem of uncertainty.

2. The Problem of Uncertainty: Filling in a Gap or an Ocean?

In principle, not all uncertainty can be reduced to risk. This insight was intellectually established a long time ago (Knight 1921). In the context of technological and environmental risk, it has been with us for two decades (Funtowicz & Ravetz, 1990; Wynne, 1992). The philosophical implication is that the modern model is not a valid justification for acting solely upon scientific advice, for instance in the form of a risk assessment:

> '[...] risk assessment seems inadequate to timely inform policy makers about the health and environmental risks of nanomaterials, if not in the short term, then most definitely, in the long term, and risk assessment does not seem feasible for the purpose of dealing with the complex emerging risks of nanomaterials.' (Hansen 2010, p. 445)

Still, even though many experienced practitioners and decision-makers have a profound understanding of uncertainty, risk maintains its position as the dominant frame of mind for assessment and management of hazard. One of the reasons for this is, of course, that for many foreseeable and identifiable hazards, this approach works. A risk assessment is a systematic way of evaluating evidence; of assessing the probability and consequences of anticipated hazards; and of doing a systematic effort to anticipate hazards. Risk assessments accordingly may make the world a safer place, everything else kept constant. Indeed, in the case of issues and problems of low complexity, they may even keep the involved hazard under quantitative control, that is, allow a rigorous risk management. Moreover, when the stakes are not too high, the risk approach may be cost-efficient, in the sense that the occasional unanticipated adverse effect that escapes the risk assessment, is tolerable.

The latter perspective shows that in the absence of scientific truth, the pragmatic choice of a risk-cost-benefit approach is in itself in need of a justification that may have a risk-cost-benefit character. Such a justification would have to state that the long-term, over-all performance of the risk approach to hazards, will lead to a better cost-benefit ratio than the alternatives. Specifically, it would have to be assumed that rapid technological innovation, development and introduction - facilitated by the efficient instruments of risk assessment and management - will be beneficial to humanity, and perhaps crucial for maintaining economical growth. Secondly, only minor unanticipated harm would have to be expected, in the sense that it would not cancel out the benefits in the over-all societal calculation.

This speculative calculation is perhaps unavoidable. However, it needs to be performed with an eye for the context. In the case of engineered nanoparticles, they are not only new introductions into the world. They are actually engineered with the specific purpose of having different properties and being more potent than conventional materials. The questions of how different, and how devastating a hypothetical hazards might be, are crucial to one's position on the appropriateness of a risk approach. For instance, the position of Friends of the Earth is that a moratorium is needed 'until nanotechnology-specific safety laws are established [...]' (FoE 2008, p. 46). If one believes, on the other hand, that there

may be serious hazards that are not foreseeable, the logical implication is a permanent moratorium/full stop in R&D, rather than more sophisticated risk assessment and more precautionary risk management.

There is of course no consensus in terms of the science of hazards, but serious, irreversible harm to human health and ecosystem is imaginable. Foss Hansen et al (2008) suggest five warning signs (novel, readily dispersed, biopersistent, bioaccumulative and irreversible action) for when one may agree that nanomaterials are more likely to cause harm and the precautionary principle should be applied. Facts exist, preliminary or consolidated, but a comment needs to be made about the uncertainty that remains after testing. Testing methodologies envisioned in REACH will be used as an example in what follows.

Testing methodologies always carry an assumption of universality. For instance, the validity of tests of particles depends upon the sample of tested particles being identical, or similar in all relevant aspects, to other production lots. Since the present authors do not have specific expertise on this technical issue, let us for the sake of argument assume that it does not constitute a problem. Testing for effects on human health or in ecosystems, however, is a more complex issue. In reality, one has to specify a simplified model system in which to perform the test - a defined habitat instead of an ecosystem; animal models (e.g. rodents) instead of humans; cell cultures, or similar. One always knows the in vitro testing conditions to be different from the real in vivo systems of interest. The difference, however, eludes quantitative description, exactly because of the variability and complexity of the in vivo systems. This is why in vitro tests always introduce uncertainty (Strand et al 1996; Strand 2000). One epistemological point regarding in vitro tests, however, is that they are asymmetrical in the sense that it is logically more straight-forward to justify an in vivo claim of presence of danger than one of its absence, since negative in vitro results also can be due to noise or failing sensitivity (Strand et al, 1996). This is reflected in the main clause on in vitro methods in REACH:

> 'Results obtained from suitable in vitro methods may indicate the presence of a certain dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment.' (p. 375)

However, in the text subsequent to this quote (p. 376) the asymmetry gets muddled by a doubly circular argument: That in vitro tests may be taken to indicate absence of danger if the method has been validated and the results are adequate. The problem is, of course, that the only safe criterion of method validation and adequacy of results is to know the in vivo effects, the unavailability of which was the reason for doing the in vitro test in the first place. This epistemological asymmetry - that the absence of evidence of harm does not imply absence of harm - is supposed to be managed in REACH by employing QSAR - quantitative structure-activity relationship studies. The reason why this does not solve the problem is further explained in a separate text box.

> Let us for a moment look at the strategy of using QSAR - quantitative structure-activity relationship studies in REACH:
>
> > 1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR) Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:
> >
> > - results are derived from a (Q)SAR model whose scientific validity has been established,
> > - the substance falls within the applicability domain of the (Q)SAR model,
> > - results are adequate for the purpose of classification and labelling and/or risk assessment, and
> > - adequate and reliable documentation of the applied method is provided. (p. 375)
>
> It should be noted that QSAR is given a privileged position in relation to in vitro tests: QSAR results, positive as well as negative, are sufficient in the sense that they may replace testing. The epistemological asymmetry is not maintained. This expresses a belief in the validity and reliability of QSAR, which calls for a comment.

There are different types of QSAR methods and techniques. What is common to them all, is that a typically large set, X, of physico-chemical measurement data of various compounds (the 'structure') are correlated with a measured effect, Y, of each compound (the 'activity'). The activity may in principle be any kind of measurable property of interest, for instance toxicity, carcinogenity or mobility. The 'correlation' consists in the design of a mathematical model Y = F(X) in which parameters of F are varied so as to allow for the best 'prediction' of the Y; typically the best fit of the measured Y in terms of least sum of squares. Often the model is simply a multiple linear regression of some kind, for instance a regression on principal components or other forms of latent variable regressions reducing the dimensionality of the data space. The resulting model with estimated parameters is then used to predict the unknown property Y of new compounds on the basis of physico-chemical measurements of these compounds, X.

> There are at least three interesting aspects with QSARs of the kind just described. First, it should be admitted that they have produced impressive results and envoked quite a lot of enthusiasm. Secondly, the QSAR experts are the first to insist on the limitations of these methods and the need for sober validation and definition of their domain of validity (Tropsha et al, 2003) Eriksson et al. (2003) concludes: 'Provided that QSARs are applied with care and common sense and are developed by fulfilling the basic acceptability criteria outlined here, they constitute an important and powerful tool definitely deserving a slot [sic!] in the risk assessor's toolbox.' (p. 1374). Third, from an epistemological perspective, they are hardly the natural choice when faced with novel and poorly characterised classes of compounds, because these models - especially the latent variable regressions - are explicitly instrumental, non-realist modelling techniques. Latent variables do not necessarily have any physico-chemical interpretation. The models are also explicitly linear or, if nonlinear, otherwise heavily constrained by mathematical design. Basically, they work when they can interpolate between known data points. Complex, nonlinear, extreme, surprising effects are not to be seen in QSARs, that is, unless they have been programmed into the model. Drawing upon Eriksson et al (2003) in their call for common sense, we find it hard to see it as common sense if REACH will result in QSAR of novel classes of nanoparticles being seen as sufficient for risk assessment.

These are examples of specific sources of uncertainty and ignorance within the risk assessment methodologies. The metaphor of 'filling in the gaps' implies an image of regulation as something that surrounds and encapsulates its object which is mostly covered, but with certain holes and cracks of definite, limited, knowable and measurable size. In the presence of strict uncertainty and ignorance, this metaphor is seriously misleading as the 'gaps' might be indefinite, unpredictable and perhaps only recognizable post hoc, if at all.

This means in effect that the precautionary model, defined by the so-called double-negative formulation of the precautionary principle, cannot provide the desirable level of protection against surprising harmful effects. Basically, one is then forced to conclude that there is no control to be had or safety to be ensured (Funtowicz & Strand 2011). If one takes this position, the purpose of the regulation may need to change, and this cannot be seen independent of other fields of policy, such as innovation policies and the desire to unilaterally protect the competitiveness of the European industry.

3. Truly Precautionary Approaches

This section will indicate some directions in which to search in beginning to overcome the above described challenge for regulation and governance of nanoparticles, essentially that the strict uncertainty involved implies that the situation is not under control. In other words; the insight that there is uncertainty at a level where we do not even know the right questions to ask, in consequence means that even though no adverse effect has been documented so far, the possibility for one to manifest tomorrow will always exist.

First, however, it will be useful to mention main currents in academic debates on the issue. Regulation and governance of nanotechnology is currently the focus of much attention from the emerging research field called SEIN (social and ethical interactions of nano) or ELSA (ethical, legal and social aspects) of nano (Doubleday 2007, Kjølberg and Wickson 2007, Von Schomberg 2010). A lot of the discussion revolves around questions about the appropriate objects, as well as the appropriate mode and level of regulation. Regarding the objects, there is the issue of life cycle, and where, in the line from invention to shelf life and waste disposal, the focus ought to be placed. Furthermore, among 'objects' of regulation there are also processes and actions - such as invention, development, production, use, transport, destruction, and intellectual or physical property rights of nanoparticles. Complicating the issue even more, there are challenges of specificity of regulation, because nanotechnology is so entangled with other fields of science and technology.

Next, there are challenges of mode and level of regulation. Among modes, one may imagine anything from prohibition to conditional permission, placement of responsibility and liability, and taxation. Notably, there is also the mode of 'self-regulation', through encouragement or enforcement of 'responsible practice'. As noted above, the European Commission launched a recommendation on a 'Code of conduct for responsible nanoscience and nanotechnology research' (European Commission 2008). It states that

> 'Researchers and research organisations should remain accountable for the social, environmental and human health impacts that their N&N research may impose in present and future generations (Article 3.7)',

while Article 4.1.13 reads

> '[...] priority should be given to research aiming to protect the public and the environment, consumers or workers and aiming to reduce, refine or replace animal experimentation' (.

This document is not binding, and exactly how it is supposed to be implemented remains unclear, not the least how it can be 'enforced' onto a world of science and technology that largely is governed by its own norms and values (Kjølberg & Strand 2011). However, although it is difficult to implement directly, it may still be important as a statement of an ideal,

and as an expression of societal values. This kind of rationale is also heard as an argument in favour of unilateral national regulation, even in the absence of international consensus or any hope of an effective international regulation. The authors' own country, Norway, has some tradition in this respect. For instance, the Norwegian Committee for Research Ethics in Science and Technology (NENT) demands in its guidelines that Norwegian research must be in accordance with sustainable development and must promote peace and global equity. These guidelines apply to research e.g. at the present authors' university by a university board decision. There is little promise, however, of resolving the challenge posed by strict uncertainty as long as implementations of such guidelines remain absent and the expectations and demands of being 'accountable' are construed in terms of having performed a proper risk assessment.

So far, the article has focussed on these concerns in the context of current academic debates. The main argument has been that development of nanoparticles (and indeed other technologies) creates hazards that are unforeseeable in such a way that the risk assessment may be rendered post hoc as de facto having been useless. In addition to the theoretical arguments made above, suggestive cases such as thalidomide and DDT may add to the visualisation of the problem. If society is to learn from these experiences, the learning might consist in becoming more sensitive to early signs of later disasters (European Environmental Agency, 2001). Translated into the present context, the challenge is to identify properties of a decision, or of an artefact, that could or should trigger a different strategy than a cost-benefit approach and a conventional risk assessment (possibly modified with the precautionary principle). In the language of post normal science, the strategy should change when the stakes are high, and uncertainty and ignorance are or might be high (Funtowicz and Ravetz 1993). Technological development is a primary example of such situations, because it effectively produces uncertainty and ignorance by changing the world.

Candidate properties for artefacts that need other strategies would be those that appear likely to lead to uncontrollability, unknown, surprising and disastrous consequences, and irreversibility. For us it seems as though engineered nanoparticles are particularly interesting in this respect. Nanoparticles are engineered precisely to have different properties and be more potent than conventional materials with which we have long experience. Smallness in itself may be such a property, as it may entail problems of detection, invasiveness and uncontrollable transport. Self-assembly, if that ever becomes a 'real potentiality', would of course be a strong candidate for alternative, non-risk-based regulation.

Whereas governments regulate for a variety of reasons and with a number of purposes, this article focuses on the prevention of unintended harm, potentially disastrous harm, to health and the environment. Does the European Union - or other authorities - regulate nanoparticles primarily to control the hazards and the risks and to keep its citizens safe, or to facilitate innovation, trade and economic growth, or does one hope that both purposes are possible? Fisher (2006) writes that the purpose of environmental regulation is to reduce risks (p. 102). If the situation is characterised by strict uncertainty, and the purpose of regulation is to reduce risk, the regulation can be argued to miss the point. When the regulation is constructed to reduce the expected risks and controlling the anticipated harms, but the innovation that is regulated have surprising and devastating effects that are left unregulated, then one may argue that the regulation (even if it fills the defined purpose) is missing the target. It might therefore be worth opening up a discussion of the desired purpose of regulation (Craye 2009). Another issue, touched upon above, is the conflict between the apparently risk adverse public and the harmonisation of regulation in order to not put obstacles for trade and the economic potential of nanotechnology. A regulation that in vain intends to avoid hazard by controlling risk, might be more dangerous than a regulation without ambitions of control. European citizens are told that:

> 'The European Union is committed to ensuring the health and safety of all citizens residing in its territory. This means not only making sure that the products circulating in the EU market are safe, but also being able to take action against possible threats to health, such as for example infectious diseases. This is ensured by carrying out thorough risk assessments before any important decision is taken.' (EC, Risk assessment system, Practices 2011).

Intentions apart, it is difficult to see how such statements can avoid discouraging public awareness about the problem of unanticipated hazards.

Alternative, 'truly precautionary' approaches to regulation do not abound. A stepwise, perhaps weak but not necessarily unhelpful alternative is that of replacing risk assessment with a broader approach to knowledge inputs and going from a frame of risk assessment to one of impact assessment (Strand 2001). This alternative needs to be discussed in conjunction with the so-called case-by-case-principle. It might be that a truly precautionary approach would have to specify classes of nanoparticles as its regulatory objects rather than the individual chemical compound. Indeed, Maynard (2011) has proposed a 'list of trigger points' as an alternative approach, whereas Canady (2010) reported on the idea of identifying and managing 'nanospecific uncertainty factors'. In Helland's (2009) concept of 'inherency risk analysis' the search for alternative technological solutions is built into the risk assessment procedure. These are all examples of interesting complementary approaches.

It is by now widely recognised that in addition to broaden the knowledge input to include more types of scientific expertise, one can broaden it to also include members of the public. Since the 1990s, public participation has emerged as a key response to the problem of uncertainty in decision-making, with the aspiration of a more precautionary approach. However, the resulting deliberation will hardly be more precautionary than the involved members of the public. This is an obvious weakness that does not receive enough attention. The implication of this is that the design of facilitated public participation processes becomes crucial. More public participation per se does not solve the problem of

uncertainty (Delgado et al 2010), above all not if the question brought to the public is a narrow one, framed in terms of risk. This may limit the response and output of the deliberation. In the worst case it may distract people from asking other sort of questions about the direction of societal change brought about by the development in question, which perhaps was the key idea in the original arguments in favour of shifting the focus upstream from regulation of hazards (the end product) to handling the creation of hazards (innovation) (Wynne 1992). This idea has grown in recognition ever since, as testified by the report 'Taking European Knowledge society seriously' (European Commission 2007b). The report uses the phrase 'From Risk-Governance to Innovation-Governance' to describe the move upstream in the process. From a similar perspective, Lee (2010) argues that EU regulation of nanotechnology will fail to take the broad range of social and ethical issues into account as long as it is narrowly construed around risk.

For what such surveys are worth, Scheufele et al (2007) found that at least their sample of the US public expressed less concern than experts did about the risks of nanotechnology. They concluded by quoting Curall et al (2006) who argue that 'now is the time to educate the public aggressively with facts about the risks and benefits of nanotechnology' (p 154). What is not exposed by these surveys is whether the public instead worry about uncertainties or about whether the benefits and costs of nanotechnologies are distributed fairly. If the idea is to educate the public about 'how to worry' about nanotechnology, or if indeed the experts have to tell the public when the right time is to participate with what sort of worries, public participation is probably not what is needed in order to meet the challenges of uncertainty in decision-making. This said, these doubts and weakness do not imply that there is no value in public participation.

A theoretically less problematic alternative is to put a ban on their development and use. This alternative may be justified if one concludes that engineered nanoparticles satisfy the criteria for being potentially too dangerous and too embedded in uncertainty and ignorance to justify a risk-cost-benefit approach. This alternative deserves attention. Often, it is discussed in the form of a moratorium for a specified period of time, for instance 10 years, to learn more about the risks. In other words, the proponents of the moratorium argue along the lines of the 'filling in the knowledge gap' paradigm and seem to assume that a given period of time and research will reduce the ignorance and uncertainty to a safe level. This assumption, as well as its negation, is of course impossible to demonstrate now, at the time of the decision.

4. Conclusion

If the ultimate purpose of nanoparticles regulation is to keep the citizens safe (no matter the costs), the eternal ban appears to be the only alternative. The fact that such a ban is mostly considered unrealistic or unacceptable indicates that the purpose of regulation is composite as well as infused with a hope that disasters will not happen. We would welcome a discussion on why it is unrealistic or unacceptable, and why it is perceived as quite normal when, say, Hansen (2010) asks in a subheading: 'How to Protect Human Health and the Environment Without Hindering Innovation'. If uncertainty means that there is no way of ensuring safety while accelerating innovation, why do scientists, regulators and policy-makers apparently accept the political and ethical position that one should not protect human health and the environment to a larger extent than what is possible without hindering innovation?

What are the prospects, then, of arriving at truly precautionary approaches to the regulation of nanoparticles? Perhaps bleak, it is to be admitted. In the case of serious harmful events, the political climate may change radically, but in that case, for that particular event, it will be too late for precaution. Still, we believe efforts to imagine different regulation at the level of its purpose can be useful in at least two ways: as parts of a plan of contingency measures for the long-term post-disaster regulatory era; and, with luck, as part of actively producing the road forward and hopefully around and away from some of these disasters in the on-going construction of present and future societies.

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[3] Most of our discussion may apply to other nanomaterials or other novel materials than nanoparticles. However, we will use the term 'nanoparticles' throughout the paper as this is at least somewhat less ill-defined than the category of 'nanomaterials'.

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