Rüdiger Haum, Ulrich Petschow, Michael Steinfeldt, Arnim von Gleich

Nanotechnology and Regulation within the Framework of the Precautionary Principle

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Rüdiger Haum, Ulrich Petschow, Michael Steinfeldt, Arnim von Gleich

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Institut für ökologische Wirtschaftsforschung (IÖW) gGmbH

Potsdamer Straße 105
D-10785 Berlin
www.ioew.de

Tel.: +49.(0)30.884 59 40
Fax: +49.(0)30.882 54 39
mailbox@ioew.de

Zusammenfassung

Die vorliegende Schriftenreihe gibt einen Überblick über das Thema Regulierung und Nanotechnologie. Die Regulierung von Nanotechnologie umfasst mehrere Themenfelder. Die normativen Aspekte der Entwicklung von Regulierung unter Unsicherheit und der Technologiebewertung sind ebenso wichtig wie eine Bestimmung der möglichen Wirkungen nanotechnologischer Anwendungen und bereits existierende Regulierungen. Die Schriftenreihe bietet eine Schritt für Schritt Einführung in alle relevanten Themen. Als erstes wird das Vorsorgeprinzip als Konzept für Entwicklung politischer Maßnahmen unter Unsicherheit eingeführt. Danach werden anhand des Ansatzes „Charakterisierung von Technologie“ erste Hinweise auf mögliche negative Effekte von Nanotechnologie auf Umwelt und menschliche Gesundheit identifiziert. Anschließend fasst die Schriftenreihe den Stand der Forschung in Bezug auf mögliche gefährliche Effekte von Nanotechnologie zusammen. Zuletzt werden die Regulierungen für Chemie und Kosmetika sowie allgemeine regulatorische Maßnahmen von Nanotechnologie untersucht sowie eine Reihe von Vorschlägen zur zukünftigen Politikgestaltung gemacht.

Abstract

This report gives an overview on the subject of regulating nanotechnology. Such regulating nanotechnology touches a number of issues. Normative aspects of designing regulation under uncertainty and technology assessment are equally important as an evaluation of the potential effects and the existing regulations as such. This report is concerned with a detailed step-by-step introduction to all relevant issues. Firstly, it introduces the Precautionary Principle as a concept to take action under the uncertainty in policy-making. Secondly, traces first hints regarding possible adverse effects by assessing nanotechnology with the approach of "characterisation of technology". Thirdly, the report presents the latest research results on the possible hazardous effects of nanotechnology applications. Finally, areas of regulatory concern with the focus on chemicals and cosmetics are discussed with regard to nanotechnology. The last part presents a number of recommendations for future policy design.

The Authors

Rüdiger Haum, M.A., M.Sc., is research fellow in the IÖW-Department of Environmental Economics and Policy.
Dipl.-Ing. Michael Steinfeldt is research fellow in the IÖW-Department of Corporate Environmental Management.
Dipl.-Volksw. Ulrich Petschow is head of the IÖW-Department of Environmental Economics and Policy.
Dr. Arnim von Gleich is professor of production technology at the University of Bremen
Kontakt: *Rüdiger Haum, Tel. +49-(0)30-884594-0, E-Mail: ruediger.haum@ioew.de*

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1 Introduction

The assessment of environmental impacts of nanotechnologies has so far been viewed primarily in terms of opportunities. Risks have been mainly associated with the development in the far future of "self-replicating nanorobots". Only more recently, partly in connection with the transition to industrial production (especially of nanoparticles and nanomaterials), reservations have been voiced with regard to certain aspects arising from the intrinsic nature of this technology.

The following report gives an overview on the subject of regulating nanotechnology. Such regulating nanotechnology touches a number of issues. Normative aspects of designing regulation under uncertainty and technology assessment are equally important as an evaluation of the potential effects and the existing regulations as such. This report is concerned with a detailed step-by-step introduction to all relevant issues. Firstly, it introduces the Precautionary Principle as a concept to take action under the uncertainty in policy-making. Secondly, it presents a way of assessing a new technology like nanotechnology called "characterisation of technology". Thirdly, the report presents the latest research results on the possible hazardous effects of nanotechnology applications. Finally, areas of regulatory concern are discussed with regard to nanotechnology. The last part presents a number of recommendations for future policy design.

1.1 The scope of study

This study is not aimed at developing an overall appraisal of nanotechnologies. The main focus is on nanoparticles and the potential environmental and health effects of

their release since they are one of the few nanoapplications already in production and use.
Outside this scope are therefore those applications which are sometimes described as wet nanotechnologies and which may be interpreted as the convergence of nano- and biotechnologies along with their specific problems. Furthermore, the study does not focus on the possible contributions of nanotechnologies to environmental soundness. Other studies of the IÖW indicate that nanotechnologies may have a positive environmental impact. In addition, we are not investigating the wider societal implications of nanotechnologies nor the question of innovation and possible distributional effects.

The main concerns of this study are nanoparticles and their potential adverse effects on the environment and health as well as the question of what might be an appropriate way of handling nanotechnologies (nanoparticles) against the background of the Precautionary Principle in general as well as that developed specifically by the European Union. Another concern of this study is the regulatory framework and the need to develop this against the background of the emerging nanotechnologies.

1.2 The issue of nanotechnologies

Nanotechnology is defined as the production and application of structures, devices and systems by controlling their shape and size on a nanometer scale. In its broadest sense, it includes all technologies and processes that also operate on the nanometer scale. Nanotechnology embraces a wide variety of sectors and we can expect a number of different technologies to become integrated under the term of nanotechnology.

The simple handling of materials at a nanoscale is not a fundamentally new phenomenon. Particles of nanosize, for example, have long been used in tyre manufacture. What is new, however, are the basic "aspirations" of nanotechnology: actively controlling and shaping molecular architecture. Production on the molecular scale "atom by atom" could, in principle, lead to substantial improvements in the efficiency of resource use (for example, a large reduction in waste materials).
Notions of how nanotechnologies may develop have sparked a great deal of controversy, although it should be noted that most concerns relate to possible long-term trends (e.g. towards self-replicating nanorobots) not expected to take place before 2040.
Rocco (2002: 5) gives the following time frames for industrial prototypes and marketing in the field of nanotechnology:

Table 1: Time frames for the development of nanotechnology

- Nanotechnology has – in the form of carbon black, for example – been used "inadvertently" for centuries

- There have been isolated applications (catalytic converters, composites, etc) since the 1950s and, after more became known about nanostructures, since the beginning of the 1990s

- First generation: passive nanostructures (around 2001)
  Fields of application: coatings, nanoparticles, bulk materials (nanostructured metals,
  polymers, ceramics and ink-jet products)

- Second generation: active nanostructures (around 2005)
  Transistors, amplifiers, adaptive structures, etc.

- Third generation: 3D nanosystems (around 2010)
  With heterogeneous nanocomponents and different assembling techniques

- Fourth generation: molecular nanosystems (around 2020)
  With heterogeneous molecules, based on biomimetics and new design

Source: Rocco 2002

The distinction between the technology itself and the various contexts in which it can be applied means that a host of different questions, involving different time scales, arises with regard to ecological sustainability assessment. For actual or short-term developments, conventional assessment tools like life-cycle analysis and (eco-)toxicological assessment can be applied. More difficult are attempts to assess the possible consequences arising from the subsequent generations of nanotechnology applications. One main focus should be at the ecological sustainability of these conceived paths of development, and on the unintended side-effects. Further expected advances in nanotechnology, however, could entail risks similar to those of genetic engineering. These risks are typified by those inherent in the so-called "wet nanotechnologies", which are involved mainly with cells (termed "nanomachines" in the jargon of nanotechnology). This also applies to the so-called self-replicating nanorobots – the feasibility of which has been called into question – and are, in terms of the problems generated, the inorganic equivalent of genetic engineering. At the same time, it becomes evident that risk management and the assessment of opportunities and threats are approaches that need to be examined within different time frames.

2 The Precautionary Principle and the European Union

In this section we look first at some general discussions about the Precautionary Principle, a highly-debated issue in international politics. Already a superficial glance at the Principle can provide indications concerning the application of the Principle in different policy arenas. The more detailed summary of the Communication of the Commission about the application of the Precautionary Principle involves ways to focus our understanding of the Precautionary Principle of the European Union. Though it is thought of as an input for ongoing discussion, some crucial element may also be identified. The aim of this study is to take the Precautionary Principle into account and, using an approach of "characterisation of technology", to give advice on further action. By using both concepts, some steps can be taken to identify potential technology-related adverse effects even before identifying possible adverse effects on targets such as the environment and/or health. Following this approach, an emphasis is taken on the early stages of innovations (especially the R&D as well as the design stage) in which these adverse effects may be excluded or at least reduced.

It has to be pointed out that there is not just one interpretation of the Precautionary Principle. For example Steward systemizes the different approaches to the PP and finds out that there are at least four interpretations of the PP. In his systematization, he distinguishes between weak and strong types:
1. *Nonpreclusion Precautionary Principle*. Regulation should not be precluded by the absence of scientific uncertainty about activities that pose a risk of substantial harm.
2. *Margin of Safety Precautionary Principle*. Regulation should include a margin of safety, limiting activities to the level at which no adverse effects have been found or predicted.
3. *Best Available Technology Precautionary Principle*. Best available technology requirements should be imposed on activities that pose an uncertain potential to create substantial harm, unless those in favour of those activities can show that they present no appreciable risk.
4. *Prohibitory Precautionary Principle*. Prohibitions should be imposed on activities that have an uncertain potential to impose substantial harm, unless those in favour of those activities can show that they present no appreciable risk.

According to Steward the first two approaches might be interpreted as weak approaches while the last two as strong interpretations of the PP. His own interpretation is that the weak versions are those which are based on scientific reasoning

while the strong versions are more based on critics of the environmental effects of technology (Stewart 2002).

The discussions on the strong version of PP are furthermore developed with hindsight to the increasing complexity of cotemporary environmental risks, the limitations of the current practice of science for policy as well as the limitations in the Policy structures incorporation environmental science (Tickner 2003: 5ff.).
Against this background the proponents of a strong interpretation of the PP point out that there is a need for a "broad lens through which to view problems, to get an understanding of the interactions of systems and parts of the system, to look at interactions and cumulative effects and the need for a broader definition of disease and effects" (Tickner 2003: 5ff.).

It has to be stated that the Precautionary Principle is far from being a not contested concept. It has been pointed out that that the nature of scientific uncertainty is changing and international organisations exert ever-increasing pressure to base governmental action on more "rational" schemes such as cost-benefit analysis and quantitative risk assessment instead of the Precautionary Principle. This Precautionary Principle is criticised as being both too vague and too arbitrary to form a basis for rational decision-making. The assumption underlying this criticism is that any scheme not based on cost-benefit analysis and formal risk assessment is irrational and without a secure foundation in either science or economics (Ashford 2002). The critics´ claim that traditional risk analysis provides sufficient information for an effect-based regulation while other approaches are more or less arbitrary and reject scientific assessments (Majone 2002, Sandin 2002).
Contrary to this, proponents of precautionary regulation point out that the Precautionary Principle will not mean that there will be a ban on substances but that there is a need for a cautious step-by-step diffusion of risk-related activities or technologies until more knowledge and experience is accumulated (Bennet 2000) and a risk-based regulations may have shortcomings against a background of scientific uncertainty.

Taking a strong interpretation of the PP some key features of scientific inquiry might be an integral part when operationalising the PP:
It should be delineated (Tickner 2003:10 ff.)

- What is known and the certainty with which it is known
- What is not known
- What is suspected
- The limits of science
- Probable outcomes of different policy options
- Key areas where new information is needed
- Recommend mechanisms for obtaining high-priority information.

With this there is a need for

- cross-disciplinary approaches and multiple lines of evidence,
- Fuller and more explicit discussion of uncertainty
- The for the qualitative and quantitative knowledge
- Iterative approaches to scientific knowledge
- Monitoring, surveillance and mappig for feed back and early warnings

Going further in taking a strong interpretation of the PP, the following aspects become relevant for discussion:

1. Precautionary actions should not be postponed if the evidence is not yet conclusive.

This regulatory action might set in motion actions to avoid irreversible and especially long-term damage. While not having scientific certainty, precautionary regulations about dose-response relationships may be set in place.

2. Precautionary Principle and the problem of coping with insufficient data and system boundaries in assessing and evaluating risks.

Regulatory actions may be required if specific criteria of potential irreversibility and the extent of potential damages are met. "Regulation is based on the characteristics of hazards without considering exposure or effects. The major claim here is that specific characteristics of risk may serve as early warning signs for potential hazards, even if the pathways leading to damage are yet unknown or unexplored. The most popular examples here are the CFCs, which were designed to be chemically stable (as a means of avoiding toxic effects) but turned out to be destructive to the ozone layer" (Precaupri 2003).

3. A central concept in this context is the shift of the burden of proof.

While the regulatory agency in most legal concepts has to prove that a new substance or activity poses an unacceptable risk to the public, this understanding of precaution places the burden of proof on the shoulders of the agency proposing such a move. This agency has to demonstrate that the planned activity or release of a substance will not harm the environment or human health.

4. The Precautionary Principle may urge an exploration of a wide range of alternatives to possibly harmful actions.

5. For reasons of legitimacy there must be public participation in the decision-making.

All these elements of the Precautionary Principle mentioned are not mutually exclusive and may not always be appropriate to the specific situation; nevertheless they provide some indication concerning action and inaction, for example, in the field of nanotechnology.
It must be pointed out that elements of the Precautionary Principle are common in all national and international regulations but the degree of the use of this Principle may be different in different regulatory regimes as well as in specific circumstances. It must also be mentioned that there is no general rule concerning the application of the Precautionary Principle in different countries. Even the case of shifting the burden of proof to the proposing body may not lead to effective results as there may not be any proof that an action is harmful or beneficial to the environment and human health. Drawing on the Precautionary Principle is, in most cases, a question of weighing up the advantages and disadvantages. There is no test for possible unknown damage. Nevertheless, the burden of proof may be placed on the proposing body to at least close information gaps. This shifting of the burden of proof is more or less an approach which is used in several regulatory activities, especially in the drug and chemical sectors.

Furthermore, in our case with nanotechnologies, further questions must be raised regarding the question of how to deal with the new technologies and innovations. These always contain uncertainty and a lack of knowledge and it is quite obvious that even with foresight, activities may not help to identify possible risks such as the consequences of lack of data and system boundaries, for example, as in the case of CFCs. We believe that substantial knowledge exists (especially in the field of chemical regulation). This knowledge should be used to examine new technologies on the basis of the characteristics of hazards without considering exposure or effects.

2.1 PrecauPri

The EU funded project PrecauPri developed some criteria for interpreting and applying the Precautionary Principle within the European Union. The project defined "precaution as a prudent and sound choice of response in the face of uncertainty" and uncertainty as "a situation in which well-founded hypotheses of potential negative impacts are available, yet final empirical evidence of harm is missing". Furthermore, "prudent and sound choices" are characterised by using "substantive and procedural steps to evaluate potentials for harm". This appraisal aims at identifying specific characteristics of threats (including inherent hazards or social mobilisation poten-

tial) and does not focus merely on the likelihood of consequences and damage potential (Precaupri 2003).

The Precaupri project developed a general model to deal with the four central challenges of contemporary risks: seriousness, uncertainty, complexity, and ambiguity.

While not using this model in detail, we believe that our approach should be based on these ideas: "Seriousness describes especially the inherent potential of a risk-related agent to cause harm to the environment or to human health, e.g. exposure-based hazard criteria such as ubiquity, persistency, bio-accumulation or cause-effect related criteria such as carcinogenicity, mutagenicity and reprotoxicity. Criteria of seriousness may be an excellent guide for setting up an early warning system, if effects are still unknown or ignorance about potential impacts prevails" (Precaupri 2003)

At this point of development of nanotechnologies the other factors as uncertainty and complexity as well as ambiguity are equally important. The approach of "characterisation of technology" takes this as a starting point for a precautionary approach to nanotechnologies and, along with this, the potential effects of the handling of nanoparticles.

EU and the Precautionary Principle

The Maastricht Treaty added the Precautionary Principle to Article 174 (ex Art. 130r) EC. This Principle was not mentioned in any of the EC environmental action programmes prior to 1991. Krämer (2003) points out that the clause was proposed by Belgium and adopted without much discussion. As EC law is autonomous it cannot be interpreted by referring to national notions or concepts.
According to Krämer, prior to the insertion of the Precautionary Principle in the EC Treaty, all cases of scientific uncertainty, which are now subsumed under this principle, were subsumed under the notion of prevention (Krämer 2003). The best illustration for precaution is the landmark judgement of the Court of Justice in the BSE case. In that judgement, the Court upheld an export ban on British beef because of the risk that British beef was infected with BSE and stated:

"Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks becomes fully apparent. That approach is borne out by Article 130r(1) of the EC Treaty, according to which Community policy on the environment is to pursue the objective inter alia of human health. Article 130r(2) provides that that policy is to be based, in particular, on the principles that preventive action should be taken and that environmental protection requirements must be

integrated into the definition and implementation of other Community policies." The same approach is adopted in Directive 2001/18 on the deliberate release of genetically modified organisms where considerant four mentions the prevention and considerant eight the Precautionary Principle.

The Precautionary Principle is still open to broad interpretation. While usually the wording of the Rio Declaration (1992) is cited, "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damages, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation", the European Union refers to the definition of the Convention on the protection of the marine environment in the North-East Atlantic (OSPAR 1992): (The Precautionary Principle is a principle) by virtue of which measures are taken when there are reasonable grounds for concern that substances or energy introduced directly or indirectly into the environment may bring about damage to human health, harm living resources, even where there is no conclusive evidence of a causal relationship between the inputs and effects".

EU - Communication

In 2000, the Commission issued a communication on the Precautionary Principle in which it outlines the Commission's approach to using the Precautionary Principle, establish guidelines for applying the Precautionary Principle, tries to develop a common understanding of the principle as well as points out that there should be no misuse of the principle as a "disguised form of protectionism". The Precautionary Principle should come into use "specifically where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community." (EU 2000: 2). This part of the study is mainly based on the EU Communication.

This pointed out that the application of the Precautionary Principle is an eminent political task based, on the one hand, on the definition of what may be an "acceptable level" of risk for the society and, on the other hand, on the existing scientific information especially that concerning scientific uncertainty and possible "unacceptable risk". The Commission further points out that there is a rather broad range of possible actions which range from legal binding measures to "a research project or a recommendation". Furthermore, the Commission points out that, when action is deemed necessary, measures based on the Precautionary Principle should be:

- appropriate to the chosen level of protection,
- non-discriminatory in their application,

- consistent with similar measures already taken,
- based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- subject to review, in the light of new scientific data, and
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

With these elements, the Commission emphasises that, before taking action, there is a need for weighing up the risks, the use of a rather broad range of measures – from a total ban to more differentiated measures – as well as the costs and benefits involved (not only in economic terms).
Furthermore, the application of the Precautionary Principle should not be unlimited but there should be some periodical review about the available scientific information and especially about the completeness and inclusiveness.

In addition, the Commission points out that the responsibility for producing scientific evidence is a common consequence of these measures (reversal of the burden of proof). These substances are to be treated as dangerous until commercial interests demonstrate that the substances are safe (compare this to the regulation of chemicals). Objections were raised and pointed to cases where there is no prior authorisation procedure and the burden of proof is shifted to the producer and/or importer. However, this cannot be made a general rule.

Dimensions of the Precautionary Principle

The communication of the Commission points out that the "The dimension of the Precautionary Principle goes beyond the problems associated with a short or medium-term approach to risks. It also concerns the longer run and the well-being of future generations." With this approach the focus of the Precautionary Principle resembles the aim of sustainable development and points out that the well-being of future generations depends on decisions taken today. This approach widens the perspective in the sense that well-being not only depends on the environmental and health effects but also on future economic and social conditions, which may also be affected what action is taken today. Against the background of the lack of knowledge concerning the preferences of future generations, this is also a rather difficult problem of balancing present actions or inactions. This is especially so because the well-being of future generations cannot be evaluated or predicted by scientific knowledge but by "world views" of prime-movers today.

Aim: Political level of protection

The approach of the Commission in pointing out that there is one main aim: the political level of protection which should not be put into question. There is a need for evaluating technological developments and its positive or negative contribution towards the level of protection. With this there is a need for methods to identify the risks and/or benefits of new technologies, for example. The main point is therefore how to asses these risks against a background of usually limited knowledge.

Scientific knowledge and the need for taking measures

The Precautionary Principle, as interpreted by the Commission, points out that there may be a need for taking measures even in the absence of "all the necessary scientific knowledge".

Nevertheless, the Commission takes into account that the Precautionary Principle should not be used arbitrarily but used in balancing in a "proportionate, non-discriminatory, transparent and coherent" way so that "decisions require a structured decision-making process with detailed scientific and other objective information especially using the three elements of risk analysis: the assessment of risk, the choice of risk management strategy and the communication of the risk".

Any assessment of risk that is made should be based on the existing body of scientific and statistical data. Most decisions are taken where there is sufficient information available for appropriate preventive measures to be taken but in other circumstances, these data may be wanting in some respects.

The Precautionary Principle is a decision exercised where

- scientific information is insufficient,
- inconclusive,
- uncertain and
- where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and
- inconsistent with the chosen level of protection.

The constituent parts of the Precautionary Principle

The communication points out that the Precautionary Principle reveals two quite distinct aspects:

(i) the political decision to act or not to act as such, which is linked to the factors triggering recourse to the Precautionary Principle;

(ii) in the affirmative, how to act, i.e. the measures resulting from application of the Precautionary Principle.

The Commission differentiates between a prudent approach and the application of the Precautionary Principle within a risk analysis study (risk assessment and risk management) and the role of scientific uncertainty in this risk analysis. According to

the Commission, the prudent approach is part of risk assessment and therefore part of scientific opinion produced by risk evaluators, while the application of the Precautionary Principle is part of risk management. This is when a full assessment of the risks is not possible because of scientific uncertainty and decision-makers must consider whether the chosen level of protection may be in jeopardised.

Factors triggering recourse to the Precautionary Principle

The use of the Precautionary Principle

The Precautionary Principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data.

Identification of potentially negative effects

Firstly, a potentially negative effect of a phenomenon has to be identified. Secondly, the relevant scientific data have to be evaluated and therefore a scientific examination carried out.

Scientific evaluation

The scientific evaluation of the potential adverse effects should be undertaken, based on the available data when considering whether measures are necessary to protect the environment etc. The risk assessment should be considered when deciding whether or not to invoke the Precautionary Principle. The result of this assessment should express the possibility of occurrence and the severity of a hazard's impact, the extent of possible damage, persistency, reversibility and possible delayed effects. While it may not be possible to carry out a comprehensive risk assessment, nevertheless, the available scientific information has to be evaluated. Where possible, a report should be made, which indicates the assessment of existing knowledge and the available information, stating the views of the scientists on the reliability of the assessment as well as on the remaining uncertainties. If necessary, it should also identify those topics for further scientific research.

The limits of scientific knowledge may affect each of these components, influencing the overall level of attendant uncertainty and ultimately affecting the foundation for protective or preventive action. An attempt to complete these four steps should be made before a decision to act is taken.

Scientific uncertainty

Scientific uncertainty usually results from five characteristics of scientific methodology: the variable chosen, the measurements made, the samples drawn, the models used and the causal relationship employed. Scientific uncertainty may also arise from a controversy about existing data or lack of some relevant data. This uncertainty may also relate to qualitative or quantitative elements of the analysis.
Risk managers should be fully aware of these uncertainty factors when adopting measures based on the scientific opinion supplied by the evaluators. However, in some situations the scientific data are not sufficient to enable these prudent aspects to be applied in practice, i.e. in cases where extrapolations cannot be made due to a lack of parameter modelling and where cause-effect relationships are suspected but have not been demonstrated. It is in situations such as these that decision-makers face the dilemma of having to act or not.

The triggering factor

Once the scientific evaluation has been carried out to the best possible degree, it may provide a basis for triggering a decision to invoke the Precautionary Principle.
The evaluation should identify if the "desired level of protection" should be jeopardised, include an assessment of the scientific uncertainties, a description of the hypotheses, which are used to compensate the lack of the scientific or statistical data.
Furthermore, an assessment of the potential consequences of inaction should be considered.
Consequently, the decision to wait or not to wait for new data and to act or not to act should be taken with a maximum of transparency.

Lack of scientific data should not be used to justify inaction.

According to the communication of the Commission "even if scientific advice is supported only by a minority fraction of the scientific community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognised".

The Precautionary Principle and the burden of proof

The application of the Precautionary Principle in different regulatory regimes is done by positive lists (principle of prior approval) before bringing products or substances into the market. This is done to different degrees in chemical, drugs, cosmetics and other products. In these cases there is a shifting of the responsibility for producing scientific evidence. This applies in particular to substances deemed "a priori" hazardous or which are potentially hazardous at a certain level of absorption.
Where such a prior approval procedure does not exist, it may be necessary for the user, a private individual, a consumer association, citizens or the public authorities

to demonstrate the nature of a danger and the level of risk posed by a product or process. Action taken under the name of the Precautionary Principle must in certain cases include a clause reversing the burden of proof and placing it on the producer, manufacturer or importer, but such an obligation cannot be systematically entertained as a general principle. This possibility should be examined on a case-by-case basis when a measure is adopted under the Precautionary Principle, pending supplementary scientific data. This gives commercial interests, who have an economic interest in the production and/or marketing of the procedure or product in question, the opportunity to finance the necessary research on a voluntary basis.

In summary, the Precautionary Principle is not really a new approach. There are several approaches which may be at least first steps in the application of the Precautionary Principle within the environmental and health regulation procedures in the EU and elsewhere.

2.2 Nanotechnology and regulation and the Precautionary Principle

If technologies are to be designed and developed with a view towards both safety and sustainability, it is essential to carry out technology assessment at an early stage and to understand the different types of innovation process involved. The aim of this contribution is to help answer the following questions that are important in the assessment, promotion and shaping of nanotechnology:

- What can we know? And what can we do?
- What methodology should we follow? How can the prospective assessment of an emerging technology be more than blind, haphazard guesswork?
- Is there a technology-specific reason for explicitly focusing on nanotechnology? Why is so much attention directed to the potential beneficial and/or detrimental effects of this form of technology? Just how potent and/or versatile is it, and does it qualify as a "power technology" and/or "key technology"?
- Which aspects require special careful consideration in the development and design of this line of technology? In particular, what role can guiding principles play in helping us adopt a precautionary approach in steering the course of nanotechnology?

3 New technologies and technology assessment

It is not the aim of this project to facilitate comprehensive sustainability assessment. The focus is on ecological and health effects, i.e. both on the intended opportunities and the unintended risks and side-effects; more on easily identifiable short-term effects and less on easily anticipated long-term consequences. Scientifically endorsed technology assessment is based on reasonably well-established and formalised assessment procedures, methods and criteria.
The procedures include not only political discussion forums involving the public, consensus conferences, hearings and e.g. Enquete Commissions set up by the German government, but also environmental impact assessments, approval procedures and legal proceedings. The key methods employed include risk assessment, ecotoxicological and toxicological testing, cost-benefit analysis and life-cycle analysis. Examples of assessment criteria are resource consumption, greenhouse potential, impact on habitats and biodiversity, water pollution class, and acute and chronic toxicity. Ultimately, the assessment methods used should - in conjunction with assessment criteria - provide rigorous (i.e. for the most part scientifically sound) arguments for economical, political and public debates about choices of technologies, processes and products. Our knowledge of the potential effects of substances, techniques and application systems is limited by:

- The as-yet-unknown concept

This is knowledge that is basically attainable but not yet available, perhaps because certain tests have not yet been carried out or because experience is still lacking in particular areas. There may be many reasons for this, such as lack of awareness of the potential problem (as with the ozone-depleting effects of CFCs) or lack of resources (e.g. time, money, and manpower). A typical example is the specific effects for which chemical substances not registered before 1982 have yet to be tested (e.g. acute toxicity, CMR, biodegradability, bioaccumulation, etc.).

- The unknowable concept

For fundamental reasons, the ways in which unstable, complex and dynamic systems respond to intervention cannot be predicted. The reasons for this "unknowability" lie primarily in the system's intrinsic "architecture", that is to say the unstable condition of the systems within which the intervention takes place. However, the "intensity" of the intervention, in terms of both quality and quantity, also plays an important role.
Examples include the unforeseeable response of ecosystems to the existence of "gaps" in their food chains or the unpredictability of the isolated, spatially and temporally limited effects of climate changes (e.g. when and how will the Gulf Stream react?).

3.1 Managing the unknown

When predicting the impact of an emerging technology, the inescapable problem of predicting uncertainty becomes acute. Nevertheless, there is a need to create information about the potential behaviour of nanotechnologies and to reduce the "as yet unknown". Furthermore, neither the "novelty" of a technology nor lack of knowledge about its potentially problematic consequences constitute good or sufficient grounds for "great concern" or for even a comprehensive "moratorium". Newness and insufficient experience justify "circumspect behaviour" – which is true for any non-routine activity in everyday life.
In order to warrant such "great concern", and, in turn, taking comprehensive measures in accordance with the Precautionary Principle, further reasons are required. These reasons are generally intrinsic to the technology itself (e.g. extremely high power and potential impact, considerable depth of intervention) or the specific application contexts (intervention within an especially vulnerable, unstable and important supporting system). The level of potential risks is usually determined by:

i) the quality of the intervention (identification of high-risk technologies);
ii) the quantity of the intervention (identification of cumulative effects); and
iii) the quality of the system subjected to the intervention.

The development of sensible (rational and value-oriented) ways of managing uncertainty, and especially "dealing with the unknown", is among the core tasks of "reflexive modernisation". Important prerequisites are:

i) analysis and characterisation of the technology (i.e. of the type of intervention); and
ii) analysis and characterisation of the systems subjected to the intervention. Here, the systems directly affected are the technical application systems, with human health and/or ecosystems affected only indirectly.

3.2 The "characterisation of technologies" approach to technology assessment

In response to the opinion – still frequently voiced – that technology itself is neutral, and only its various applications can be subjected to value judgements, we can say that technology is always a "way of dealing" or "form of interaction" with something. It cannot, in consequence, be neutral. At the same time, however, the question "what is it used for?" is important in terms of its assessment.

Knowledge about the impact of a technology (the central prerequisite of technology assessment) requires familiarity with three basic elements:

i) An agent (the technology, substance etc. whose possible effects are to be assessed);
ii) An impact model (i.e. a scientifically verifiable theory on how the agent acts on a potential target); and
iii) A target upon which the agent acts (e.g. climate, ecosystem, organism, or organ).

In the case of nanotechnology, it is the impact model and/or the target system that are the actual unknowns. The proposed approach to problem-solving in technology assessment is to change the focus by changing the view from the potential target systems towards a closer look at the agent, in our case nanotechnology, which is going to act upon them. The emphasis is therefore on the characterisation of the agent. We have to address the question of what (potential) effects can be expected or deduced simply by virtue of the "nanoscale" of the interventions.

3.3 Technology-specific effects

"Size does matter!"

Let us now take a look at what makes nanotechnology so interesting:

i) Its potency and depth of intervention (the possibility of controlling the smallest building blocks of matter or – conceivably – of living things). To what extent is nanotechnology a "power technology" and/or a "high-risk technology"?
ii) The "new effects" achievable through its use. Where does nanotechnology merely I mprove and enhance existing possibilities and effects – and where does it bring about qualities that are truly new and unprecedented?
iii) Its versatility in both possible effects and applications. To what extent is nanotech nology a key technology and/or a fundamental innovation?

The following list gives some immediately obvious nanospecific aspects and effects, together with some of the possible (or expected) properties and effects arising from them.

Nanospecific aspects/effects

- Small size: Mobility and perceptibility/detectability
- Specific surface area-volume ratio: adhesion, cohesion, agglomeration; => altered chemical reactivity and selectivity; catalytic effects, quantum effects
- Self-organisation: uncontrollable, autonomous developments, replication

- Precision of the specification and substance quality: chemical purity, defined particle size; "rare", and perhaps problematic, elements and groups of substances

The following table lists some immediately obvious nanospecific aspects and effects, together with some of the possible (or expected) properties and effects based thereon.

Table 2: Nanoqualities and derived problematic "nanospecific" effects

Nanoquality	Potential effects/problems	Non-nano examples
Well defined particle size and purity	Material and energy streams, resource consumption recycling	Technical ceramics
Material quality	Health and environmental hazards, problematic (rare) elements or groups of materials in open use	Gallium-arsenide in semiconductors Heavy metals in catalysts
Smallness and mobility of particles	Dust, air mobility, remaining suspended, entering the lungs and even the alveoli passing through cell membranes, the blood-brain barrier	CFCs (mobility and persistence) Ultra fine particles from diesel engines
Adhesion, cohesion, agglomeration	Fate of emitted nanoparticles or fibres in environment, "intrinsic safety" with a tendency to adhesion, cohesion and agglomeration?	Metal ions in soil with mobilising and piggyback effects
Changing chemical reactivity and selectivity	Altered ratio between surface and content leads to massive changes in catalytic reactivity, unexpected toxic and ecotoxic effects are highly inferred	Problematic effects of ultra fine particles seem to be strongly dependent on size, and surface of the particle, perhaps less on the (main) substance
Changing and intensified catalytic effects	Altered ratio between surface and content leads to massive changes in catalytic reactivity, unexpected toxic and ecotoxic effects are highly inferred, also photocatalytic effects in inorganic (atmosphere) and organic areas	
Quantum effects	Mostly depending on well-defined and purified conditions, where impurities are a source of technical failure. In the environment, side effects in organisms or ecosystems are generally unlikely	

Self-organisation	On one hand, highly promising for resource efficient technology, consistent with natural processes, on the other hand, hazard of uncontrollable developments (self-replicating nanobots)	Self assembled Monolayers, biomimetic materials

Source: IÖW

4 Characterisation of nanotechnologies

Taking into account our present-day knowledge, there is, with regard to nanospecific effects (excluding self-organisation effects and cumulative effects of mass production), no reason for particularly great concern about global and irreversible effects of the specific technology "per se", with it being on a par with the justifiable apprehension concerning nuclear technology and genetic engineering.
The nature and level of risk of nanotechnologies that can be anticipated is perhaps most akin to that associated with (synthetic) chemistry. If we are to avoid making the many mistakes seen in the field of chemistry, then it is necessary to assess and consciously shape technologies – and to adopt precautionary measures – at an early stage. The REACH system outlined in the current EU White Paper on Chemicals Policy prescribes risk analysis and management procedures which are probably also adequate for most nanotechnological applications. With regard to risk management, too, much can be learned from the chemical industry and from the handling of chemicals. However, the risk management of chemicals still has shortcomings with regard to implementing the Precautionary Principle which is developed especially for chemistry but may be applicable to other circumstances ("inherently safe substances, techniques and application systems"). This includes the still widespread failure to incorporate available precautionary measures in the development of substances and technologies, and therefore the neglect of guiding principles as "instruments" of influence and design.

Thus a double-track approach may be the most promising concept for the "sustainable nanotechnology" project:

- Identify the technology-specific impact mechanisms of nanotechnology. It is especially important to establish more firmly the appropriateness of, and soundness of reasoning behind, the "characterisation of technologies" approach and to improve its (differentiating) power to predict possible effects.
- Choose and justify particularly "interesting" application contexts, which may include:

  Those with a particularly high degree of intrinsic sensitivity (in terms of the quality and architecture of the affected systems). Here, risk assessment would be the method of choice.

Those which exhibit a considerable social dynamic in any case (because of potential intensification, mass and cumulative effects, and level of input). The preferred instrument here is life-cycle analysis.

4.1 Environmental and health effects of nanotechnologies – overview of recent research

Diversity of materials

Engineered nanomaterials must not be considered as a uniform group of substances. Instead, there is (or will be) an extraordinary breadth of nanoscale designed materials, in which

- there are many different types,
- they can be of many possible sizes and possess different surface coatings,
- there is not one "most important" class of materials to focus on,
- nanomaterials are diverse and will be used in many forms and sizes.

Because of the sheer diversity of nanomaterials, it is virtually certain that some examples will cause problems to our environment and human health with respect to the whole life-cycle. "Nanoengineered particles" are a vast class of materials. They span sizes from 1 to 100 nm, with diverse compositions (ZnO to gold) and shapes. Moreover, the core inorganic species is only half or less of the major part of these materials – namely their surface. To consider only the core composition without concern for its surface chemistry and stabilisation will surely lead to problems interpreting any data. There is not likely to be one simple answer when it comes to whether or not nanoparticles are 'safe'. Differences in size, shape, surface area, chemical composition and bio persistence require that the possible environmental and health impact be assessed for each type of nanomaterial in its own right: closely similar compounds may induce substantially different health effects (Colvin 2003, Hoet et al 2004).

Furthermore, engineered nanoparticles present high surface areas in solution and can adsorb molecular contaminants. This coupled with their small size can provide such species access to areas of the body and cellular organelles not normally exposed. Facilitated transport of such impurities, exogenous or endogenous in nature, could be an even larger problem in biological systems than the nanoparticles themselves.

4.2 Possible effects on the environment and health

Translocation

When inhaled, nanoparticles translocate within the body and may be found in the liver, brain and even the foetus. Nothing is known about the effects of these translocations. At the Nanotox 2004 conference, Vyvyan Howard described possible translocations of nanoparticles to the foetus. While not having finished this research at that time, he seemed to be convinced that he would be able to prove this hypothesis. Against the background of several studies Howard mentions that "once ultrafine particles have been internalised there appears to be a natural 'passageway' for them to travel around the body" (Wootlife 2004) Günter Oberdörster (University of Rochester, New York) tracked the progress of carbon particles that were only 35 manometers in diameter and had been inhaled by rats. Nanoparticles were detected in the olfactory bulb a day after deposition in the nasal mucosa, and levels continued to rise until the experiment ended after seven days. Nevertheless, little is known about what effect nanoparticles will have when they reach the brain (Oberdörster 2004).

Smallness

Potential problems may arise from increased reactivity through the relatively larger surface area of nanoparticles. Also, nanoparticles entering the human lung via inhalation may not be filtered out due to their small size and be transferred into the blood stream causing problems and negative health effects. Oberdörster mentions that agglomerated nanoparticles may not be a problem (or not more a problem than other PMs) individual nanoparticles may cause severe problems. Conventional compounds which are normally considered to be harmless may therefore prove to be dangerous on a nanometer scale.

Adverse effects of new materials

Current research suggests that, for example, nanotubes may damage the lungs when inhaled. The related studies are, however, contradictory in their results. One study suggests that inhaled clumps of tangled carbon nanotubes caused the same effect to the lung as ordinary dust. With another study, the exposure to individual carbon nanofibres caused lesions in the lungs and intestines of test animals (mice) (Brumfiel 2003).

Effects of nanotubes – different studies with different nanotubes and different results:

Nanotubes trigger the formation of granulomas (a combination of dead and live tissue surrounding the material) which is a significant sign of toxicity. Nevertheless different studies come to different conclusions regarding the seriousness of granulomas: While Lam (NASA) reports that the granulomas remain a problem, the study

of Warheit (Du Pont) mentions that granuloma formation may be observed but that the inflammation trails off after three months. It has to be pointed out that both researchers used different nanotubes. The Warheit study used laser-evaporated nanotubes in rats. Lam used HiPco and carbon arc NTs in mice (Lam 2003)

Same material; different reaction

The same materials may behave in different ways. Carbon black as well as nanotubes consist of carbon. While carbon black produces no reaction in toxicological tests, carbon in the form of nanotubes (here single-walled nanotubes SWNT), produce granulomas in the lungs. The main reason may be the different forms of carbon: individual tubes are ~ 1.5 nm in diameter and several microns long, as bundles, nanotubes are packed tightly and in parallel to form rods. Nanotubes are structured as fibres while carbon black is amorphous. The surface chemistry between SWNTs and carbon black is also different (Lam 2003).

Environmental effects

There are some worries about the ability of nanoparticles and microparticles to control heavy metal and radionuclide mobility in the environment. Brumfiel (2003) reports that researchers at Rice University investigated the behaviour of buckyballs. They suspended buckyballs in water and then poured them through a soil-like material. The behaviour of these structures changed with extremely different consequences. Where the buckyballs clumped together and formed particles of some micrometers, these were absorbed into the soil (as any other organic material). However, where the buckyballs were dispersed it was observed that water formed a protective sheath around each of them with the consequence that they were able to move through the soil without being absorbed and therefore posing a risk to the groundwater. In addition, there are indications that this material could enter the food chain. Brumfiel also reports that nanoparticles may be absorbed by earthworms (Colvin 2003).

Since nanoparticle research is still in its infancy, only general recommendations can be made regarding research and treatment:

- Differences in size, shape, surface area, chemical composition and persistence require that possible environmental and health impact be assessed for each type of nanomaterial
- There is a need to classify nanoparticles because not all of them seem to cause (the same degree of) inflammation
- A general proposal concerning nanoapplications in medicine is that they should be water soluble to avoid potential problems in the body.

- Avoidance of the open use of nanoparticles, as long as there is limited knowledge concerning the behaviour (for example rapid agglomeration into bigger particles etc.)

In general the environmental fate of nanomaterials has to taken into account. The behaviour of nanomaterials in different environmental mediums has to be observed. Research at Rice University tries to identify the effects of nanomaterials in soil (biopersistency, dissolution, biodegradation, aggregation (adsorption to an environmental matrix) in an aquatic environment (dissolution and suspension in aqueous media, sedimentation) and also raises the question about bioaccumulation (earthworms and aquatic animals) (Tomson et al 2003).
The preliminary findings of this research are

- States of aggregation of nanoparticles may change in various aqueous environments
- Adsorption of contaminants to the surfaces of nanoparticles is very strong
- Adsorption/desorption of organic compounds to nanoparticles may be hysteretic
- Adsorption/desorption of heavy metals onto/from nanoparticles are predictable, based on a normalised surface area sorption isotherm
- Nanomaterials in natural aqueous environments may substantially affect the fate and transport of contaminants.

4.3 Ultrafine Particles and nanoparticles

The limited assumptions on behaviour and effects of nanoparticles are mainly based on knowledge of ultrafine particles. Research in this field made enormous advancement in the 90s and showed that the success in reducing air pollution through more efficient combustion processes may have unintended consequences as the proportion of ultrafine particles is increasing. Ultrafine particles are thought to have adverse effects on the human body and the environment. Unlike nanoparticles, these particles are the result of combustion processes. The comparability of the two particle types is therefore limited and nanoparticles may pose other, additional problems (Kreyling 2004, Colvin 2003).

Nanoparticles are only a fraction of future nanotechnology applications. They are the most tangible sources for possible negative threats since numerous applications are close to commercial production. In the long run, possible risks from self-organisation and self-replication have also to be considered in research, assessment and development of technologies.

4.4 A life-cycle approach to nanomaterials

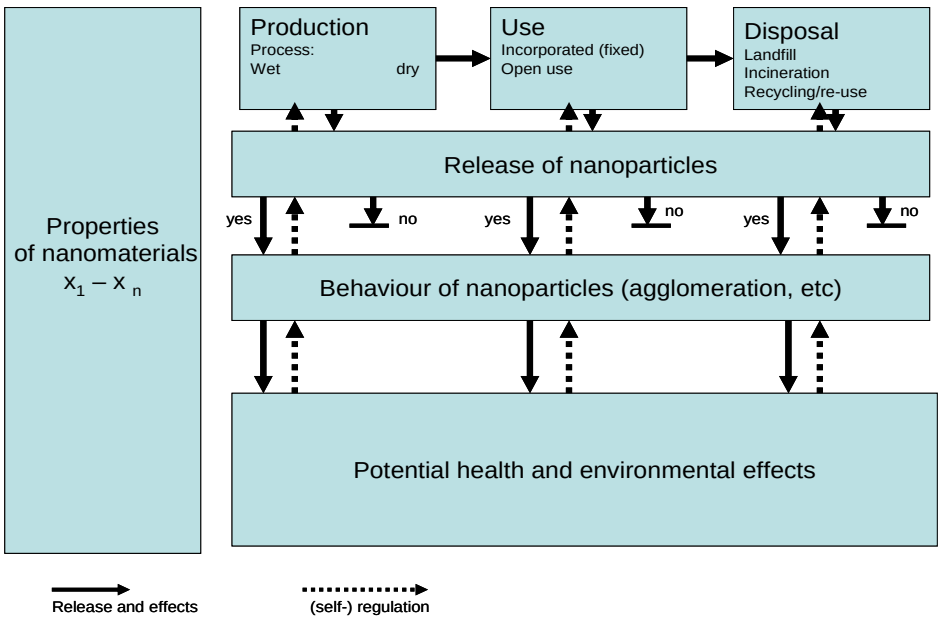
As pointed out in the previous sections nanoparticles may cause problems especially in open use. A glance at the life-cycle of nanomaterials shows:

1. Production processes of nanomaterials differ significantly. Engineered nanomaterials are not necessarily produced by combustion processes (except CVD/DVD and Flame Assisted Deposition) but mainly in liquid or closed gas phase reactors. Therefore direct exposure to engineered nanoparticles is limited.

2. Products: Most nanoparticles are enclosed or fixed in products, for example nanotubes in screens, particles in surfaces and coatings. The chance of nanoparticles being released is limited.

3. The behaviour in disposal and recycling is not yet well researched, but we think that the possibility of a release of individual nanoparticles is negligible. It has to be borne in mind that very limited and preliminary knowledge concerning the questions above is available.

Graphic 1: Possible release paths of nanoparticles



Source: IÖW

In general, we believe that the main focus of research should ask questions such as: Will there be an open use or a release of nanoparticles. If this is the case, precautionary measures should be undertaken as long as there is a limited knowledge base concerning the behaviour of nanoparticles (Do they agglomerate? What are the potential environmental and health effects?).

Manufacturing processes of nanomaterials

The following section gives a summary of production processes for nanomaterials, especially nanoparticles. The list focuses on processes, which may release nanoparticles and through which adverse effects may occur. In addition, we look at some products containing nanomaterials as well as nanoparticles themselves. No information is currently available concerning the disposal of products containing nanoparticles. We emphasise that these findings are only preliminary and based mainly on assumptions. Sound knowledge concerning the effective release of nanoparticles is not yet available[1].

1. Vapour Phase Deposition (CVD, PVD)

A very important procedure for the production of nanoscaled powders and thin layers from vapour-phase base materials is the vapour phase deposition, which is divided roughly into chemical (CVD) and physical (PVD) vapour phase deposition.

In the case of PVD, solid raw material in a vacuum environment is converted into the vapour phase by physical effects (e.g. thermal energy). The particles condense on a nearby substrate and thus build up into a thin film. The different processes of the PVD differ in the method of vapour deposition, i.e. the way the material is heated to evaporation. The conventional method for heating is thermal evaporation, further methods are sputtering, arc evaporation, molecular beam epitaxy (MBE) and ion plating.
CVD covers all processes, which lead to a separation of solid products by means of a chemical reaction of the gaseous base material on or near the substrate. The gaseous material is then led into a reactor and chemically split by an input of energy. This takes place either thermally, via stimulation of the reactants in plasma or via electromagnetic radiation. A part of the intermediate products is adsorbed on the substrate, where a film is built up by a heterogeneous reaction. Important CVD processes are: thermal CVD, plasma-activated CVD (PACVD), photo-CVD as well as catalytic CVD, which is increasingly used in the production of carbon nanotubes.

2. Flame-Assisted Deposition

[1] The description of the production processes follows Paschen/ Coenen/ Fleischer et al. 2003

Nanoparticles can be synthesised by the decomposition of liquid or gaseous starting substances in a flame. Among the most well-known procedures are flame spray pyrolysis, flame hydrolysis (aerosil process) and flame synthesis. Hydrogen diluted with argon or hydrocarbons serve as fuels. A substantial advantage of these processes can be seen in the fact that the flame already has the necessary energy. Thus fine-grained powders can be produced without complex preprocessing or postprocessing. Furthermore, complex vacuum plants or reactors are not required with the production of oxides. Particle size and crystal structure can be affected by varying the concentration of the reagents, flame temperature and retention time of the materials in the flame. However, particle size can only be inaccurately defined for these parameters. Nevertheless, these processes are already used extensively in industrial applications, due to their simple applicability.

3. Sol-Gel Processes

The sol-gel process represents an extraordinarily important wet-chemical process in the production of the most diverse nanotechnological products such as powders, thin layers, aerogels or fibres. In the first step, nanoparticles are synthesised in a solution by the reaction of the liquid components producing the "sol" state. Subsequently, the sol is converted into the gel state. The molecules formed in the sol can grow together either through chemical reaction until they represent one space-filling macromolecule, or individual sols thicken until a gel is formed that is stabilised by electrostatic repulsive forces. Destabilising sols and/or gels can precipitate nanoparticles of a defined size. One of the most promising possibilities offered by the sol-gel process is to produce organically-modified products by combining organic and inorganic components.

4. Precipitation

Precipitation is a chemical procedure to synthesise nanoparticles from solutions. Adding suitable substances activates the precipitation procedure. Thus, either a change in the composition of the solvent occurs, so that the precipitating material becomes slightly soluble and/or insoluble, or a new compound is formed, whose solubility is clearly lower than that of the concentration in the solution. The formation of nanoparticles runs gradually through a spectrum ranging from crystalline germs or amorphous primary particles right up to particle agglomerates. However, germ formation and nucleation rate must be larger than the growth rate of the particles. In the case of a continuous precipitation, particle size distribution and structure of the agglomerates can be procedurally adjusted by the correct choice of flow conditions and reciprocal effects between particles.

5. Self-assembled monolayers (SAM)

Long-chained organic molecules form closely-packed monolayer structures by adsorption on oxidic and metallic surfaces. Ultra-thin layers can thus be manufactured, whose structure is given by the arrangement of the substrate atoms. Accumulated molecules form a chemical bond with these substrate atoms and the emerging layers are called self-assembled monolayers. If the molecules separated in the monolayer have a further functionality, besides that of the functional group for the bonding to the substrate, then this can be used, for example, as a template for the selective separation of inorganic materials.

6. Molecular imprinting

Molecular imprinting is a procedure that allows the manufacture of highly-interlaced polymers in the presence of a template molecule. A template can be understood to be a molecule that controls structure and arrangement of the system synthesised upon it, by its defined geometry growth. Functional groups of the monomer are spatially fixed with those of the template and thus the outside form of the template is copied. The template molecules are subsequently removed by extraction. In this way cavities with binding sites with a well-defined spatial arrangement remain in the polymer network. In order to select the appropriate molecule, the template is either identical to it or strongly resembles it in structure so that it can be recognised and bound to it molecularly.

7. Lithography

Lithography processes used for the production of nanostructures can be divided into two categories: parallel methods that write the entire surface simultaneously, or serial methods that write the structure gradually. Parallel processes are optical lithography, electron beam and ion beam projection processes atomic lithography as well as X-ray lithography. Serial processes are electron beam writing and ion beam writing, as well as scanning probe lithography.
Optical lithography is the most commonly used process for the production of nanostructures. The semiconductor structures produced with this process ultimately generated the basis for the entire electronic industry. In optical lithography, a beam of light or X-rays is projected through masks with a certain structure which hits a sample surface covered with photoresist. After the resist has been formed, the mapped structure is usually transferred to the substrate by an etching process. The smallest size that the structure can be depends on the wavelength of the light applied.

There are two ways of writing with electron beam lithography: directly with a focused beam on the substrate (electron beam writing), or the structure can be produced using a mask (electron beam projection process). Ion beam lithography is very similar to electron beam lithography; however, with this process, direct structuring of a component is possible without photoresist and etching.

Application phase

Much less knowledge is available concerning the application phase and the emission of nanoparticles. Particles are often fixed in products and therefore the release of nanoparticles is generally limited. There is, however, an explicit use of non-fixed particles, for example, in the case of sunscreen and the emission of nanoparticles for remediation. Finally, the special effects of nanoparticles are central to their economic value. They may have adverse effects in other than their intended applications such as, for example, catalytic converters. Taking into account the limited knowledge of the behaviour of nanoparticles, our basic advice is to avoid open use until their safety is proven. However, the main hazards of nanoparticles may be limited to their main industrial applications. A summary of some of the main products and related production processes as well as the potential risk of release of particles is given in table 3.

Summary

It must be stated that the production processes of nanomaterials and/or nanoparticles are diverse and so are the possible risks of nanoparticle release. While the main processes are based on wet procedures, others are based on gaseous processes. Although gaseous processes may cause problems related to the release of particles, the present data point out that containment measures could be improved and that emissions are relatively low compared to those emissions related to combustion processes especially those from traffic. Nevertheless, the specificity of engineered nanoparticles should be taken into account. It has to be pointed out that there may be major problems in reducing the potential risk of releasing nanoparticles. Consequently, the main problem may remain. The problems can be identified using the concept of "characterisation of nanotechnologies". This, however, must be put into action.

Table 3: Overview of production processes in nanotechnology

Nanotechnology-based products	Nanostructure	Manufacturing process	Potential hazards	Industrial sector
Applications: New Surface Functionalities and Finishing				
Tribological layers: e.g. superhard surfaces	ultrathin layers; nanocrystallites; nanoparticles in an amorphous matrix	vapour phase deposition, PECVD	PVD/CVD production process: risk of disposal of nanoparticles is small (process is running in a vacuum environment) use stage: low scale disposal of nanoparticles possible	engineering, automotive
Thermal and chemical protection layers	ultrathin layers; organic/inorganic hybrid-polymers; nanocomposites	vapour phase deposition; sol-gel		aerospace, automotive, ICT, food
Self-cleaning and antibacterial surfaces	ultrathin (polymer) layers, nanocrystallites in an amorphous matrix	vapour phase deposition, sol-gel, soft lithography		textile, ICT, food, building, medicine...
Scratch-resistant and anti-adhesive surfaces	ultrathin layers; organic/inorganic hybrid-polymers	Sol-gel; SAM	use stage: low scale disposal of nanoparticles possible	building, automotive, textile, consumer goods
Products with "nanoparticle effects" : e.g. colour effects in lacquers	nanoparticles, ultrathin layers	flame assisted deposition, flame hydrolysis, sol-gel	production: deposition possible; use stage: low scale disposal possible	building, automotive, consumer goods, textile
Applications: Catalysis, Chemistry, Advanced Materials				
Catalysts	nanoporous oxides, polymers or zeoliths; ultrathin layers	precipitation, sol-gel, SAM, molecular imprinting	not known	chemistry, automotive, environmental, biotech
Sieves and filtration	sintered nanoparticles, nanoporous polymers	self assembly, colloid chemistry		chemistry, environmental
Applications: Energy Conversion and Utilisation				
Fuel cells	ceramics from sintered nanoparticles	div.	not known	energy, automotive
Supercapacitors	nanotubes, nanoporous carbon aerogels	div.	nanotubes possibly toxic when inhaled	energy
Superconductors	ultrathin layers	e.g. vapour phase deposition	production: risk of disposal is small	energy, medicine
Applications: Construction				
nanoscale additives: e.g. carbon black in car tires	nanocrystals and particles	flame assisted deposition, flame spray pyrolysis	production process: disposal of nanoparticles possible, danger of	building, automotive

nanoparticle-reinforced products: e.g. temperature resistant components	(amorphous) nanoparticles	flame assisted deposition, flame hydrolysis	inhaling for workers; use stage: low scale disposal of nanoparticles possible	automotive, ICT, consumer goods, medicine, aerospace
Application Area: Information Processing and Transmission				
Nanoelectronic components	ultrathin lateral nanostructured semiconductor	PVD, CVD, lithography	PVD/CVD production process: risk of disposal of nanoparticles is small	ICT
Displays	utrathin layers	PVD, spin-coating		ICT, automotive
Application Area: Nanosensors and Nanoactuators				
Sensors: e.g. GMR sensors	metallic ultrathin layers; ultrafine tips	CVD/PVD/MBE; etching, SAM	PVD/CVD production process: risk of disposal of nanoparticles is small	automotive, engineering, ICT, analytics
Probes e.g. for scanning tunnelling microscope	utrathin layers, ultrafine tips and molecules	PVD, etching, SAM		analytics
Application Area: Life Sciences				
Active agent carrier: e.g. drug carriers	organic molecules, nanoporous oxides	self assembly, anodic treatment	flame hydrolysis production process: disposal of nanoparticles possible; use: particles may be absorbed dermally; very small TiO_2 particles possibly toxic	Pharma, medicine
Cosmetics: e.g. pigments	utrathin layers from nanoparticles, (amorphous) nanoparticles	wet-chemical separation; colloid chemistry		cosmetics
Sunscreen	nanocrystalline titanium dioxide (TiO_2)	flame hydrolysis		cosmetics

Source: IÖW after Paschen/ Coenen/ Fleischer et al. 200

5 Present and future regulatory frameworks for nanotechnology

We have seen so far that the Precautionary Principle, as understood by the European Commission, advises policy makers to take specific action on two levels regarding the regulation of nanotechnology. The first relates to a better understanding of the technology and its effects. We have, therefore, presented an approach to assess technology and also discussed potential hazardous effects of nanotechnology. We have seen that serious concerns regarding toxic effects of nanoparticles exist. They are, however, not grave enough to require immediate regulatory action. The Precautionary Principle, however, suggests a two-fold strategy to further investigate subject matter. On the one hand, the toxic effects of nano-particles should be better understood. On the other hand, the present regulatory regimes should be investigated to assess whether they are appropriate for future nanotechnology applications. This second aspect is the focus of this study and we will pursue this aspect in this report.

As stated before, specific regulations relating to nanotechnology or its applications do not yet exist. Different opinions exist whether new, specific regulations are/will be required or whether existing regulatory frameworks are adequate. The debate about nanotechnology and regulation will intensify when more nanotechnology applications are available and some form of regulatory action is inevitable. A reasonable basis for this has to be laid out in order to establish the necessary framework. This basis consists for the most part of a better understanding of the nanotechnology effects on human health and the environment and on the suitability of existing regulatory frameworks. The following areas of regulation may be affected by future developments in nanotechnology.

- Emissions
- Chemicals
- Occupational safety
- Drugs/ pharmaceuticals
- Cosmetics
- Food and newly-developed foods

The main present concerns relate to:

- Particle size
- Form of nanoparticles
- New properties of nanoparticles

The main scientific difficulties in judging toxic effects of nanoparticles related to measurement problems and determining the full contribution of nanoparticles to the overall amount of toxic emission.

5.1 Examples: chemistry and cosmetics regulation

The legal system of the EU has not yet produced any specific regulation regarding nanotechnology or its application. A discussion about the possible need of such regulation, however, has been started within specialist interest groups. In the following, two regulatory frameworks, chemicals and cosmetics, are presented and discussed with regard to their adequacy for nanotechnology applications. The area of chemicals was chosen because this shows the highest number substances subject to obligatory registration. Cosmetics regulation deserves closer scrutiny because a number of cosmetic products like suntan lotion or toothpaste already contain nanosized substances.

Chemicals

The registration and admission of new chemical substances is laid down in the regulations governing chemicals. The registration and admission of known and established substances is regulated by Council Regulation (EEC) No 793/ 93 of 23.03. 1993 on the evaluation and control of the risks of existing substances.

Importers and producers of new chemical substances are required to register their substances. New chemical substances are those substances that are not listed in the European Inventory of Existing Chemical Substances. Whether a substance is declared and treated as a new substance depends solely on its chemical formula. A new size or new physical property does not qualify a substance as a new one if the corresponding formula is already listed.

For the registration process, producers and importers in Germany have to provide information to the Federal Institute for Occupational Health and Safety (BAUA) on the physical, chemical, toxicological, and eco-toxicological properties as well as the use of the substance in question. The depth of information depends on the intended production volumes of the substance. Basic toxicity, testing for mutagenic activity, etc. is required from a production volume of one tonne upwards. The rule of thumb is: the higher the production volume, the higher the information requirements. The requirement to submit test results is based purely on production volume, not on particle size. If the particular information does not yet exist the producer is obliged to undertake the relevant testing to fulfil all information requirements.

The registration sheets are then distributed to several different evaluation authorities (occupational safety, environment, health) who evaluate the substances according to their properties. All information sheets are subjected to the authorities' evaluation. If they suspect any hazardous effects from the new substance, the authority is required to undertake a risk assessment. The result of the risk assessment then determines further action which ranges from inaction to requiring further testing from the producer right up to classification or prohibition of the substance.

According to the evaluation of the authorities' representatives, the existing regulatory framework is adequate to deal with the introduction of new substances in the nanotechnology sector. A producer wishing to produce nanotubes would, in the opinion of the expert interviewed, for example, be required to undertake inhalation testing. If there were any indication of hazardous effects, the authorities would carry out a risk analysis. New testing methods and procedures may eventually be required to detect hazardous effects of nanosubstances.

There is, however, one area of concern that relates to the declaration. The producer is not required to declare the particle size of the substance. In the opinion of the Federal Institute for Occupational Health and Safety (BAUA), the producer may be obliged to declare particle size when describing the use of the substance. However, it is presently unclear if the existing regulation definitely obliges the producer to do so.

All substances listed within the European Inventory of Existing Chemical Substances do not have to undergo registration and can be produced and traded according to the rules found within the register. Existing substances which are re-manufactured to nanosize are not classified as such during registration but as micro-pedants to the original substance, if they are registered at all. According to the statements of a representative from the Federal Institute for Occupational Health and Safety BAUA, monitoring of existing substances which are re-manufactured to nanosize is difficult since a producer would not have to register them. Regulators are, however, aware of this problem and have started internal discussions to consider it.

Problems of current chemical regulation:

- Testing based on production volume, not on particle size
- Testing measures not adapted to small sizes
- Remanufactured substances fall through testing although they may be toxic (e.g. due to particle size).

Cosmetics

The production and commercialisation of cosmetics is regulated within the cosmetics regulation in accordance with Directive 76/768/ EEC on cosmetic products. Following this directive there is no registration or admission procedure for cosmetics. Producers or importers are liable to due diligence and have to ensure that the ingredients of their products are harmless. A producer is also required to keep a record of the documents on which the innocuousness is based. The cosmetics regulation lists substances which are prohibited for using for production, which are only to be used within certain limitations and which are suspected to be hazardous and need further testing to be declared harmless. In addition, a producer must submit specific data about the contents of its cosmetics to a number of public agencies, which test the substances for their harmlessness.

The controversial case of the use of titanium dioxide illustrated problems of using nanoscale substances in cosmetic products. As an inorganic UV-filter, nanoscale titanium dioxide belongs to a category of substances, which are suspected of having hazardous properties and have to be reviewed by the scientific committee of the EU Commission to ensure that no possible negative effects are present. The nanoscale substance has been added to suntan cream since the mid-nineties. Because its properties were considered equivalent to the well-established macro version of titanium dioxide and admission was based on its chemical formula and not on particle size, no separate scientific review of nano titanium dioxide was undertaken. Macro titanium dioxide was allowed as an additive to suntan cream up to concentration of 25 per cent.

Public concern about the risks of nanoparticles and nanoscale titanium dioxide made the Scientific Committee for Cosmetic and Non-Food Products (SCCNFP) of the EU Commission test the substance for toxic effects. The SCCNFP concluded that nanoscale titanium dioxide was safe to use within the existing limitation of a 25 per cent maximum concentration. This decision is, however, questionable since the review by the SCCNFP was based purely on industry studies and doubts about the safety of the substance are still raised within the scientific community (Christ 2003, Royal Society 2003). The increased surface area in general may damage skin by free radicals as these materials are active photocatalysts. The US National Nanotechnology Initiative is planning currently planning further research on the uptake of Titanium Dioxide into the skin, underlining scientific doubts in the substance's safety (Teague 2004). There are, however, ways to overcome this problem. One, for example, is to coat the nanoparticles (Royal Society 2003: 10). Furthermore, Colvin reports that research on the effects of free radicals is based on micronised titanium. Information on particle sizes below 100 nm is not yet available. One other important issue is the stability of the organic components in sunscreens that contain nanoscale titanium and zinc oxide particles. These materials are active photocatalysts and the free radical species they generate under light can degrade sunscreen for-

mulations. These processes can also damage biological molecules which may pose some risk to consumers. Nevertheless, the risks of sun exposure are more severe (Colvin 2003).

A number of other cases of comparing macro- and nanoscale substances can be observed, although reservations regarding the safety of the nanoversion of the substance persist. The US Food and Drug Administration took the same stance regarding nanoscale titanium dioxide. In a dispute over the approval of a production facility for nanobased materials, a German administration court concluded that the emissions of the facility could be treated as emissions containing ultrafine particles. Existing emission regulation was, therefore, in the eyes of the court, adequate to protect against hazards and no further warrants were imposed.

Problems of current cosmetics regulation

One problem with the regulation of cosmetics is the comparison of nanoscale substances with their macro pedants. Micro substances might be either not tested at all, because they are considered just as safe as the same substance on a macro scale, or they are subjected to tests designed for known hazardous effects leaving hazards intrinsic to nanosized substances unconsidered.

6 OECD Principles of good laboratory Practice and nanomaterials and applications

The OECD Principles of Good Laboratory Practice (GLP) were adopted by the OECD Council in 1981 as an annex to the Council decision on the Mutual Acceptance of Data in the Assessment in Chemicals. The background of this decision was that government and industry were concerned about the quality of non-clinical and environmental safety studies upon which hazards assessments are based. In addition, different schemes of implementation in different countries were developed which may result in obstacles to trade as each country insists that its own practice in testing standards is the pre-condition for market entry.
By having a variety of laboratory standards, two problems arose. Firstly, similar tests have to be carried out several times to comply with different standards. Secondly, testing is costly and time consuming and may, furthermore, be used as an instrument for market protection. To overcome these obstacles the OECD Principles were developed with the aim of promoting quality test data. Comparable quality of test data forms the basis for mutual acceptance of data between countries.

According to the OECD, the scope of the Principles of Good Practice should be applied to the non-clinical safety testing of test items found among pharmaceutical products, pesticides, cosmetics and veterinary drugs as well as food additives, feed

additives and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some cases, may be living organisms. The purpose of testing these items is to obtain data on their properties and/or their safety with respect to human health and/or the environment. The European Union integrated these principles in a Directive (1999/11/EC of 8 March 1999) which now have to be harmonised (and integrated) into the national law of member states.

Test Guidelines and Principles of Good Laboratory Practice should ensure data quality. In this way, the mutual acceptance of data should be guaranteed. While the test guidelines prescribe the way the tests should be carried out, Good Laboratory Practice is a kind of quality assurance referring to the quality of the institution carrying out the test. The Principles of Good Laboratory Practice are mainly a managerial approach to develop transparency concerning the results of testing, which is the main point concerning the mutual acceptance of data as well as the pre-condition for avoiding non-tariff barriers.
The main point of testing nanotechnology (products) may not be the question concerning Good Laboratory Practice but instead the test guidelines, which may have to adapted to the possible unique effects of these new technologies.

For example, new knowledge about environmental and health problems has to be followed by new testing guidelines: The OECD has set up a task force on endocrine disrupters, whose main task is to develop new test guidelines:

- Enhancements and modifications of existing test guidelines
- Development of new test guidelines
- Management of validation work, as appropriate
- Development of a harmonised strategy for the screening and testing of endocrine disrupters
- Sharing test procedures and assessments

This approach is used for newly-identified environmental and health problems. In the case of nanoparticles, potential adverse environmental and health effects have been identified (for which at least for macromaterials there are several test guidelines). Testing procedures are obviously not conceivable for currently unknown adverse effects. On the other hand, however, are problems concerning the adequate testing of nanoparticles, such as those for measurement (for example particle number vs. mass). Some of the newly-identified effects of nanoparticles may only be possible in special research institutions.

This shows the need for developing a metrology for nanoparticles and the standardisation of testing. The example here shows that new developments have conse-

quences for test guidelines as well as for their assessment and validation. This may not only be a task for national authorities but also for the EU and especially international organisations in this field. Therefore, it may be a major task in the future to place the focus on nanotechnology and its products and procedures. We believe that there is an urgent need for an international effort to comply with the ever-accelerating changes in nanotechnologies.

There is a need for

- Grouping of nanoparticles
- Tools for screening and testing
- Co-ordination of testing
- Sharing hazard/risk assessment reports

The question concerning the testing of nanomaterials and products and GLP standards are actually not answered: as our research reveals, there is actually no procedure for legislative handling of nanomaterials and products and there has been actually no registration of nanomaterials and products with the competent authorities to be labelled as nanomaterial.

The needs and new tools for sustainable chemistry as developed by the OECD are, for example:

- Collection and generation of data
  (e.g. release estimation methodologies; product registers) and also
- Risk assessments
  (e.g. life-cycle assessment; toxicogenomics/proteomics, transgenic animals)
- Risk management
  (e.g. sustainable chemistry; green procurement; socio-economic analysis).

We also believe that these aspects will cover the problems of nanotechnology.

7 The Toxic Substances Control Act and nanotechnology

The following section illustrates the limits of existing regulatory frameworks regarding nanotechnology by summarising how the U.S. Toxic Substances Control Act applies to nanotubes.

The Toxic Substances Control Act

The Toxic Substances Control Act (TSCA) is the US regulatory act for chemical substances. It was passed in 1976 and is administered by the Environmental Protection Agency (EPA). Its aim is to regulate chemicals in commercial use with risk or potential risk to the environment. Chemicals can be produced and traded freely. If a

chemical has to be admitted through the TSCA, the enforcing agency EPA has to demonstrate that the new chemical substance may entail harm to health and the environment. The TSCA provides six different regulatory mechanisms to be used by the EPA:

- Inventory of chemical substances
- New chemical review
- Testing of existing chemicals
- Direct regulation of chemicals
- Reporting/ record-keeping requirements
- Import/export requirements

The TSCA Chemical Substance inventory is a list of all chemical substances met in U.S. commerce. New chemicals are reviewed within the pre-manufacture notice process (PMN). The testing of existing chemicals is guided by rules outlined to industry by the EPA. Direct regulation means that the EPA has the power to prohibit or limit the manufacture of chemicals based on risk assessments. Manufacturers must keep records and reports of potential adverse effects. Finally, TSCA and the Treasury Department define import and export requirements (Wardak 2003).
The TSCA defines a chemical substance as "any organic or inorganic substance of a particular molecular identity, including any combination of such substance occurring in a whole or in part as a result of a chemical reaction or occurring in nature and any element or uncombined radical". This definition excludes mixtures, articles, pesticides, tobacco products, nuclear material, food, cosmetics, and drugs.

The TSCA Chemical Substance Inventory is a database of about 80.000 chemical substances in commercial use. All existing chemical substances, around thirty million (which mainly exist within research laboratories), are listed in the Chemical Abstract Service (CAS) database, run by the American Chemical Society. Of the 80.000 chemical substances held in the TSCA database, only 50.000 have been reviewed and only 5.000 have been subjected to rigorous testing. The TSCA database provides information on the existence but to a much lesser extend on the risk of chemical substances (Wardak 2003).

The TSCA and the Precautionary Principle

The TSCA differentiates generally between existing and new chemicals. Within the regulations regarding existing chemical substances, no aspects of the Precautionary Principle were included while designing the regulation. If a chemical is already on the market, the EPA has to provide evidence that the substance may be hazardous. Regulatory action can only be taken, if most scientific uncertainty about the effects of a chemical substance has been resolved (Wagner 2000). This contradicts an understanding of the Precautionary Principle which suggests regulatory action in any

form if the degree of uncertainty is high. Manufactures on the other hand have little incentives to gather information on the toxicity of their existing products apart from possible reputation damage if harmful effects of the substance materialise.

Regarding new chemicals, some of the TSCA elements have been designed in accordance with the Precautionary Principle. If a producer wants to market a new chemical substance, in most cases he has to file a pre-manufacturing notice (PMN) to the EPA. From the information reported in the PMN, the EPA then has to determine whether the new substance may have hazardous effects. If any indicators for potential hazards are found in the PMS, the EPA can demand that the producer carries out further testing of the substance. The burden of proof is, in this case, in accordance with the Precautionary Principle, partly shifted to the manufacturer. If the new chemical belongs to a certain product class known for its hazardous effects, even more stringent testing requirements are prescribed by TSCA regulation.

The first conceptual, non-precautionary gap in the TSCA model of regulating existing and most new substances is that they do not get tested if they are not regarded as suspicious. In addition, the information requirements within the PMN relate generally to the identity and the future use of the chemical rather its possible effects. The producer is not required to include health- or safety-related information on the new substance (Döhmann 2003). Health and safety information is only required if the new substance includes components which have already been subjected to safety testing as components or if the substance belongs to one of 45 categories of known hazardous substances. Different regulations apply if the chemical is to be produced in very high quantities or its use will expose it to a high number of persons. In those two cases, the EPA has to provide evidence that the substance may pose some risk of substantial human exposure or release into the environment in order that further testing is carried out by the manufacturer. In other words, the threshold for the EPA to be authorised to require further investigation from the producer is lower. The second conceptual and non-precautionary gap is that the agency has to provide all proof for possible hazards if the substance is already on the market.

The weaknesses of the TSCA outlined in the preceding paragraphs are related to all types of chemical substances. In the following section, the TSCA will be reviewed with regard to nanotechnology applications.

Applying the TSCA to nanotubes

Nanotubes are an already commercialised nanotechnology application, produced mainly by sixteen firms of which eight are located in the United States. The companies produce over 2.5 tons of nanotubes every day. Carbon nanotubes are used in

semiconductor and metal applications and will possibly replace the use of silicon in semiconductors within the next fifteen years (Wardak 2003). If a chemical is manufactured in or imported into the US, it has to undergo the TSCA procedure. The following steps describe the application of a new substance from the point of view of the producer.

If the new substance falls within the TSCA definition of a chemical, the first step of the producer is to determine whether the substance is already listed in the TSCA Chemical Substance Inventory. The TSCA inventory as such indicates general classification problems of new chemicals, which will become more stringent with nanotechnology applications. Firstly, some current types of nanotubes are not listed in the TSCA inventory although there are commercial products. Secondly, some nanotubes are not listed in the categories where a chemical expert would expect them to be listed according to their formula.

If the substance is already listed and no guideline or order regulates the substance, it may be manufactured immediately. The most important rule regarding existing chemicals in this context is the newly-adopted regulation which will be discussed below. If the substance is not listed, the producer faces two options:

1. Under the TSCA the producer can report and apply for an exemption from the regular pre-manufacturing reporting
2. Under the TSCA, the producer can report and not apply for an exemption and enter the pre-manufacturing reporting

Exemptions

In order to manufacture a new substance without being subject TSCA regulations, the producer may apply for three different forms of exemption. They are the Low Volume Exemption (LVE), Low Release and Exposure (LoREx), and the Test Marketing Exemption (TME). The LVE is probably the most important exemption in relation to nanotechnology. It exempts a manufacturer from full PMN reporting if less then 10 tonnes of a particular chemical are produced per year. It is likely that many nanochemicals will meet this exemption due to their relatively small production volume.

The second exemption is the Low Release and Exposure Exemption (LoREx). It states that the chemical must have no dermal or inhalation exposure to workers and consumers, must meet the low-volume exemption, and must not be released to groundwater and landfills. It is hard to meet this exemption and it is even harder to think of nanoapplications that qualify for this exemption.

The Test Marketing Exemption (TME) can be applied for if only small amounts of the chemical substance are produced in order to explore its market potential before go-

ing into full production and distribution. It is also likely that nanochemicals will qualify for this exemption since the number of nano products is expected to grow enormously in the following years.

If the exemptions are denied or the producer does not originally apply for exemption, a pre-manufacture notice (PMN) must then be filed. The PMN must be filed 90 days before start of production. In this part of the process, the problems of providing information and further testing for potential hazards will re-appear. If the chemical is not subjected to further testing, it will enter the chemical substance inventory and production may proceed (Wardak 2003).

New Use Rule

An additional problem of the existing TSCA regulation is the Significant New Use Rule (SNUR). A producer may wish to market a chemical substance, which already exists but which has a significant new use. In this case, the producer must file a Significant New Use Notice (SNUN) which allows the EPA to consider and evaluate the new use of the chemical. Establishing and evaluating new uses may be difficult given to the property changing ability of nanoengineering. Establishing a "new use" is therefore a foreseeable problem. In addition, new substances may comply to TSCA regulation but may also have significant new uses entailing potentially new hazards.

The aspects outlined above highlight the problems of the TSCA regarding nanotechnology. This rather superficial view on the complex TSCA process has focused on a number of problems and it is likely that more will arise if the process is reviewed in depth and new commercial applications hit the market. There are already foreseeable problems relating to classification, exemptions from regulation, and the establishment of new rules (Wardak 2003).

8 Implementing the Precautionary Principle

There is no life without risks. There is no way towards a sustainable economy and society without innovation since innovation and risk are inextricably linked.
The fact that a certain technology, procedure or substance is new is not reason enough for far-reaching measures to be justified by the Precautionary Principle. Additional causes for concern are required. In many cases, there will be no other choice than to give things a try. However, the method of "trial and error" has its limitations. It is only appropriate for small and generally reversible steps.
The method of trial and error is simply irresponsible if we reasonably expect global and irreversible effects of certain projects, technologies or interventions to be possible. The production and deliberate release of CFCs was such a case. The precau-

tionary principle has to be applied in cases of high technological potential and efficacy, i.e. either extremely large steps by a single innovation (high depth of intervention) or high volumes and growth rates of small single steps (cumulative effects).
Thus caution, with regard to the quality and quantity (dynamics) of the innovative steps we make, is the guideline to follow for the implementation of the Precautionary Principle. Information about the quality of the steps can be obtained by "characterising the technology" and information about the quantities and dynamics of application can be obtained by surveying the production process.

8.1 Implementing the Precautionary Principle in REACH

The future regulatory framework for chemicals within the European Union, REACH, may serve as an example for implementing the Precautionary Principle within a regulatory framework. REACH stands for Registration, Evaluation and Authorisation of Chemicals and will be the future standard chemicals regulatory body within EU member states. REACH will regulate the commercial admission of new chemical substances and the testing of around 30.000 existing commercial chemicals which have not yet been subjected to systematic testing regarding their toxic effects on the environment and human health. The aim of the REACH framework is greater protection of human health and the environment without threatening the competitiveness and the innovative capacity of the EU chemical industry. It is highly likely that the REACH system contains a number of similar weak points regarding the regulation of nanotechnology applications within the TASC, as stated above.

The core of REACH is an integrated system for registration, evaluation and admission of chemical substances that will replace around 40 existing, separate directives and orders. REACH has however not reached its final legislative stage. All following conclusions regarding the relation of REACH to nanotechnology are based on the revised proposal of the EU-Commission and are therefore tentative. A step-by-step review, as undertaken in relation to TSCA, is only possible to a more limited extent.

The first step of the REACH system already includes the most obvious problematic similarity to the TSCA. Generally, all new and already existing chemicals must be registered in a central database of a future European Chemicals Agency. However, if less then one tonne of the chemical is produced per year then they do not need to be registered with the chemicals agency. The producer is only obliged to pass on existing safety information to clients.

The registration threshold required is only one tenth of the TCSA threshold. However, due to the minimum weight of nanoapplications and their yet unknown properties, even one tonne of a hazardous nanoapplication may pose serious health or

environmental risks. Also exempted from registration are special materials groups such as intermediates, polymers, and products, which are included in other European regulations. This form of exemption may also turn out to be problematic due to the classification problems already indicated. New nanoapplications may be classified and regulated under the wrong procedure or may or may not be classified or regulated at all.

Within the registration phase, the producer must provide the agency with a prescribed set of information and provisional evaluations on the intrinsic properties and hazards of the substance. The producer/importer must also provide information on the users and uses of the new substance. If the imported/manufactured volume exceeds 10 tonnes, information on risks with identified uses for human health and the environment, and how those risks are adequately controlled must be provided in the form of a report. For lower volumes, safety information produced for the safety data sheets will be submitted as part of the technical dossiers. If the production volume of the chemical exceeds 100 tons then more detailed information requirements have to be met.

Testing by the manufacturer is already required for registration if present knowledge on the substance cannot meet the information requirements for registration. It is not yet known whether the information requested also includes particle size. In addition, the REACH system does not include a routine for significant new uses of existing chemicals.

Once the chemical is registered, the evaluation process then commences. Central to evaluation is that the producer has to demonstrate that his new substance is innocuous. The evaluation process is carried out by various agencies of member states and includes a dossier and substance evaluation. Dossier evaluation means that the dossiers submitted will be reviewed for animal testing. They may also be reviewed for compliance with information requirements.
A substance evaluation may be undertaken if there are reasons to believe that a substance is hazardous to human health or the environment. Dossiers submitted on new chemicals will only optionally be reviewed for indications of potential hazards. As a result of the evaluation process, the producer may be asked to provide more information on the substance in order to bring the registration dossier into compliance or to clarify risks.

From a nanotechnology perspective, the type of information requested by a future European Chemicals Agency is crucial to adequately evaluate potential health and environmental risks. Similar to the TSCA, the likelihood of a new or established substance being subjected to further testing on potential negative effects increases with

the level of certainty about its potential harm. The more specific the type of information provided by the producer, the higher the chances of tracing the negative effects. The EU Commission declared: "It is expected that substance evaluations will focus on those substances that may pose the greatest risk to human health and the environment" (EU 2003). Information requirements for the producer should be adequately tailored to avoid the conceptual "no suspicion – no testing" gap.

All substances of concern will enter the authorisation process. Authorisations apply to particular uses of the substance in question and will only be granted if the producer demonstrates the adequate control of the substance or socio-economic benefit outweigh the risks. Examples of substances that will be subject to authorisation are: carcinogenic, mutagenic or toxic to reproduction, persistent, bioaccumulative and toxic, very persistent and very bioaccumulative properties.

Registration and testing of existing substances under REACH

Chemical substances already in production or imported in volumes of 1 tonne or more per year, per manufacturer/importer, must be registered in REACH. This means that around 30 000 marketed substances will need to be registered. Of these 30 000, around 20 000 are produced or imported in volumes of between 1 and 10 tonnes. Substances that are already on the market will be gradually phased into REACH. Substances produced in high volumes and known to be toxic will have to be registered first. Registration deadlines will be calculated from the year the legislation enters into force so that the new obligations will apply from:

- Year 3 for high production volume chemicals (1,000 tonnes or more/year/ manufacturer or importer) and highly toxic chemicals in volumes of 1 tonne or more

- Year 6 for production volumes in the range of 100 – 1,000 tonnes

- Year 11 for low production volume chemicals (1 – 100 tonnes)

Within REACH (Registration, Evaluation and Authorisation of Chemicals) – the concept for a new kind of regulation of chemicals and their associated risks – we can find both approaches towards the implementation of the Precautionary Principle. On the one hand, the quantities coming along with the introduction of an innovation (substance and/or application context) determine the risk analysis. The stringency of the tests, or the amount of required data, respectively, is determined by production volumes. For high volumes, the most detailed data are required. For smaller volumes remarkably less, and for volumes common in research and development nearly no data at all are required.

On the other hand, qualitative aspects of innovations and substances (in the sense of the depth of intervention) play an important role in this new approach to regulate chemicals. To a large extent, certain properties of chemicals like carcinogenicity, mutagenicity or reproduction toxicity (CMR) determine the requirements of risk management. This applies even without an analysis of exposure, which is an equally important step within a complete risk analysis procedure. An extremely interesting example of implementing the Precautionary Principle is the planned handling of very persistent and very bioaccumulative (vpvb) chemicals. These characteristics stand for a high probability of an irreversible exposure (and with also the additional characteristics of mobility for a global exposure). This alone is reason enough for chemicals with these characteristics have to undergo certification, even without concrete indications of the probable occurrence of adverse effects. Measures of risk management are in this case direct consequences of a "characterisation" of the technology or substance, even without any scientific model of cause and effect!

8.2 Learning from REACH for regulating nanotechnology

The current structure of the REACH system is focused on gradually testing all known chemical substances. New substances will only be reviewed optionally. This is a reversal of existing regulation aims and is based on the fact that new substances make only around one per cent of all chemicals in commercial use. Evaluating the hazardous effects of existing chemical substances is, in the eyes of the EU commission, therefore more urgent then reviewing all new substances. This has a number of implications for nanotechnology applications. The gaps in existing regulation regarding the re-manufacturing of existing substances to nanosize may now be closed. This supposes that manufacturers will not start declaring the remanufactured existing substances as new substances. Under the REACH system, such substances will only be optionally reviewed. This is an area of concern, since new substances in the nanodomain may have toxic effects of yet unknown dimensions, which may not be discovered through registration. In addition, as stated beforehand, whether the toxic effects of a new substance under review will be identified depends mainly on information requirements. Including particle size in these requirements should be considered.

The two ways of applying the Precautionary Principle mentioned in the preceding subsection are transferable to any approach of regulating nanotechnology within REACH or within an independent form of legislation.
Gradually adjusted requirements for (eco)toxicological data are highly recommended with regard to production volumes of nanoparticles . Furthermore, the requirements of risk analysis and risk management are dependent on the probability of exposure

within the factories or, in case of release, dependent on the potentially global and irreversible range of exposure (requirement of containment, inherent safety, etc.).
Special attention is recommended For qualitative and quantitative aspects concerning the fate and possible adverse effects of nanoparticles due to their smallness, their mobility, their ability to reach the alveoli within the lungs, and due to the changing reactivity (compared to macroscopic particles) and catalytic effects.
On a larger time scale special attention is also recommended concerning the possibilities of self-replication and self-reproduction. There is a possibility of a shift from molecular self-organisation, already used in many cases in nanotechnology, towards these more problematic dynamics.

8.3 Possible measures

There is actually a task to prove whether the procedures which are proposed for CMR and vpvb substances in REACH should be also applied to nanoparticles. We do not know enough about such particles, but they do seem to share a high probability of adverse effects with CMR substances (yet not equally specified). They also seem to share with vpvb substances a high probability of unexpected inner exposure (lungs, blood/brain barrier) and outer exposure (mobility, remaining suspended in air, piggyback effects). But here, too, more knowledge is necessary on the properties and the fate of nanoparticles in the human body and in the environment – in terms of technology characterisation.
Furthermore, with regard to long time trends, it is essential to look at developments in the field of the self-organisation, self-replication and self-reproduction of nanomolecules, organelles, assemblers, or robots. The attitude, present in many debates, that self-replication and self-reproduction of nanotechnological objects is simply science fiction and will never happen is neither adequate nor responsible. In addition, there will be a loss of credibility if those involved do not impose these same limits on their hopes and expectations with regard to the "positive" effects of nanotechnology in future.

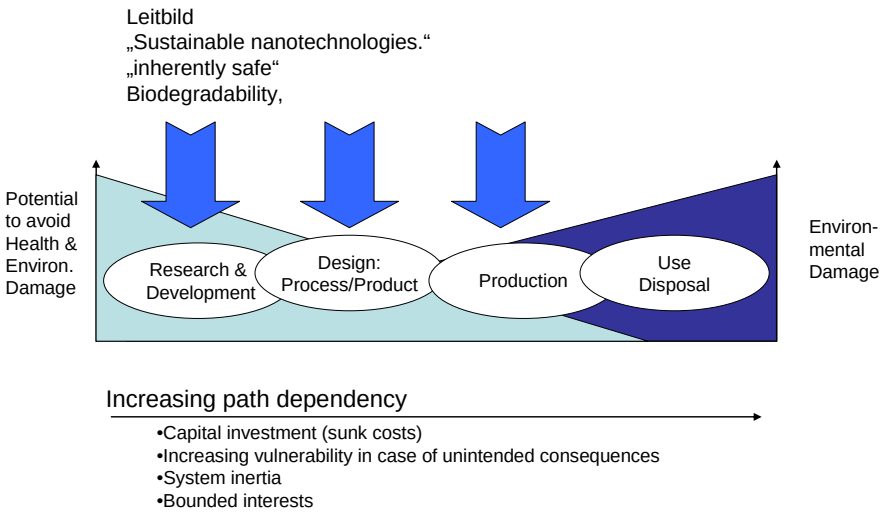
Finally, we have to mention two additional possibilities of implementing the Precautionary Principle far beyond the regulative approach of REACH. Firstly, there is the development and design of technologies following guiding principles such as "inherently safe nanotechnology" or "sustainable nanotechnology'. A second approach is the integration of safety, health and environmental (SHE) aspects into the intra-enterprise quality management and also the supply-chain management system. Risk minimisation and risk management is not only the task of the authorities. Especially scientists and developers (not to forget funding of R&D) and also the economic actors (the enterprises) have the duty to tap their full potential.

Innovation and risk are inextricably linked. Innovation needs freedom. These socially granted liberties have to be applied in a very responsible way.

9 Innovation, the Precautionary Principle and intervention

One major question, especially in the case of innovations, is the question of when and where is precautionary action to be taken? Our proposal is that as in the case of nanotechnologies, which is still in their infancy, the Precautionary Principle should be taken into account at a very early stage. This is because of the idea that, at the beginning of the shaping of technologies, action should be taken to avoid future problems and, with this, the Precautionary Principle in this stage of nanotechnology development may be the leitbild or "model" for inherently safe nanotechnologies. However, the R&D stage is obviously just one stage and may be complemented by product use and the disposal stage where an inherently-safe handling has to be considered the leitbild. In an ideal case, the inherently safe nanotechnology would avoid the common known problem of end of pipe regulations.

Graphic 2: R&D, Production, life-cycle and potential effects to avoid EHS threats



Source: adapted from Rejeski (2003)

Diagram 2 shows the important stage of R&D as well as product design concerning the potential adverse effects of nanotechnologies. Ideally, most of the potential adverse effects should be avoided in these early stages. The knowledge derived from the characterisation of technologies approach may give important leads for design processes. As already explained, the characterisation of technologies approach is shown against a background of experience in chemical regulation so that there may be some unintentional consequences of nanotechnologies. Bearing this in mind, the design processes should avoid these obvious problems and make nanotechnologies

inherently safe. In this way problems in the production, use and disposal stages may be avoided otherwise adverse effects may be the consequence. The ways to reduce these adverse effects in later stages may be characterised as add-on strategies, usually connected with high costs.
Of course, even in the later stages inherent safety may be a strategy as, for example, used in high risk chemicals.

However, other points must be mentioned: technological developments usually are path-dependent. Once a particular path is successful, other potential paths are no longer developed. They may, however, be preferable from an environmental point of view. Thus, by creating the path, the exit options become expensive, while the financial livelihoods of many people may be involved. This is not only a problem of environment but a problem of producers and users of nanotechnologies if adverse effects are identified with their concomitant financial problems to producers.
The main idea is that, at an early stage of development, main issues are considered and some guiding principles such as "inherently-safe nanotechnology" are used as one way to overcome certain problems. While it is not necessarily clear if this will lead to some form of "sustainable nanotechnologies" it is at least a major step in this direction. We believe that some preliminary problems may be identified and some consultation programme developed for possible action (regulation as well as self-regulation).

10 Regulation approaches in selected EU member countries and the US

The following section gives an overview about the regulatory activities regarding nanotechnology in the United Kingdom, Sweden, Denmark and the US. Several representatives of regulatory bodies, mainly in charge of the admission of chemical substances, were contacted and a number of interviews held. The aim of the interviews was to gather information on current activity regarding the regulation of nanotechnology and to identify problems that representatives of public authorities associate with the regulation of nanotechnology. The countries were selected according to their traditional role as leading countries in environmental and health regulation (Sweden, Denmark) or because of an advanced public discussion of nanotechnology within the particular country (US, UK).
In general, one can distinguish a number of different regulatory approaches to the problem of nanotechnology and regulation.

- Self-regulation before scientific results.

Cosmetics producer L'Oréal, for instance, dropped its research on the characteristics of buckyballs after outside researchers raised questions about toxicity. Rice Univer-

sity found nanoparticles from nanotubes on the skin of members of the research staff. Consequently, an enclosed area was set up and nanotubes were converted into powder form, which was easier to contain.

- Changes in regulations according to nanospecific requirements.

From our enquiries with representatives of national regulatory bodies, the main conclusion is that, in general, the existing regulation has the capacity to handle present and future nanotechnology products and substances. In addition, no specific form of nanotechnology regulation has yet been issued. However, existing regulation may need to undergo some change with regard to guidance and application as well as to some nanospecific extensions. This conclusion is only preliminary. Our research has shown that existing regulation has not yet been applied to nanotechnology applications and in rare cases nanotechnology is only a part of the regulatory body's agenda. There is also limited awareness that future nanotechnology has implications for health and safety regulations.

It must be pointed out in this context that regulation is not the only measure used to react against possible adverse effects from emerging technologies and their applications. Other measures of sustainable governance of technology include the creation of an informed, critical public, the creation of guiding principles for the development of new technologies and the integration of health and safety aspects into the quality management chain.

United States

The United States is by far the most advanced country regarding the development of nanotechnology and the debate between government and industry on possible regulatory implications resulting from nanotechnology. That is not to say that the US debate has produced any substantial results or specific regulatory action. The awareness of potential problems is bigger than in the other countries that were investigated, and possibly matched only by the awareness in the United Kingdom.

Awareness In the US is, for example, expressed in the initiation of dialogues between representatives of the nanotechnology business community and concerned regulatory bodies and workshops on the subject matter. The workshops, for example, transcend the subjects of effects of nanotechnology on the environment or health and explicitly address societal implications.

The main regulatory task on the problem of emerging nanotechnologies within the US Food and Drug administration is to communicate with industry on the one hand and to hold internal discussions about the nature of nanotechnology applications on

the other. Regulatory steps can now be taken if a manufacturer produces such substances without a statement or declaration. Industry now has a strong incentive, in their opinion, to indicate the new contents of products. New regulation or a change of existing regulation is not necessary, following the judgements of representatives of the Food and Drug Administration.

At most, the use and the guidance of existing regulation and some toxicity tests may have to be changed. The most important step is in the eyes of the experts to engage in dialogue with manufacturers and decide on a product-by-product basis how to proceed further. This regulatory approach assumes willingness from the manufacturers´ viewpoint to share information and to cooperate as well as to be conscious of potential hazards. It also assumes at least a superficial understanding of the risks of a new product containing nanomaterials and to identify and evaluate risks. The approach, from the viewpoint of the regulators, is aimed at a more intense cooperation by interchanging information provided by commercial interests concerning the possibility of hazardous effects on the one hand and information about existing regulations to safeguard against these effect provided by the regulators.

A particular gap in safety regulations is identified regarding the use of nanomaterials. In the US, material safety data sheets (MSDS) list the properties and restrictions for most nanomaterials that are identical to those given for macroscale bulk material. Workers using microscale substances therefore have no formal requirement for safety precautions beyond those adopted for bulk solids of identical composition.

United Kingdom

The UK shows a similar public discourse on the relationship between nanotechnology and regulation. The last report of the Better Regulation Task Force, an independent institution advising the British government on regulatory issues, for example, has included a section on the subject. In addition, comprehensive studies on nanotechnology currently carried out by the Royal Society with results due to be published in spring this year prominently including the aspect of regulation.

The approach towards nanotechnology taken within the Health and Safety Executive, the authority responsible for the regulation of chemicals on the workplace and within industrial areas, resembles the FDA position of the US. Their main activity regarding nanotechnology is currently to gain a deeper understanding of the technology's effects and to persuade companies and researchers to undertake more research into hazardous effects. The agency's representative emphasised that the agency is still in an early phase of horizon scanning while being aware of potential implications from future nanoapplications for regulation. The representative interviewed did not express the opinion that the British Chemical Agents directive may

have to undergo change. However, guidance may have to be changed. He expressed concern regarding the size of particles but concluded that international standards of measuring particle size were needed before steps to deal with the subject could be taken. He also expressed concern regarding the re-manufacturing of existing chemical substances on a nanoscale. Whether those products should be treated as new materials should be decided on an EU-level.

A public stakeholder debate carried out by the Royal Society yielded the following statements by representatives of industry, science, and government regarding the regulation of nanotechnology:

- Strong pleas for more research on the toxic effects of various nanoparticle groups and classification of these groups
- The view that existing regulation and legislation will cover all potential problems until self-replicating machines have become reality
- Toxic effects are expected to be similar to effects of existing substances and products
- Concern was expressed regarding size and reactivity of nanoparticles
- Participants expressed the need for open debate about risks, risk assessment and risk governance
- Representatives of industry stated the need of self-regulation for industry to avoid risk
- A generically new danger deriving from nanotechnology was not expected since all applications derive from simply a collection of technologies. Nanosciences may have individual risks, but these should be dealt with separately, not collectively.
- Also, the fear was expressed of over-regulation before enough research was carried out to understand the harmful effects of nanotechnology.

Sweden

The public debate on nanotechnology and regulation seems to be much smaller then in the US and UK. Swedish authorities have not yet looked into the subject of nanotechnology and regulation. The cosmetics control department has not yet discussed the subject and no manufacturer in Sweden has so far approached the department with a nanoproduct. It is, however, perceived as a problem within the department that cosmetics regulation covers the formulas of substances but not their size. The National Chemicals Inspectorate has not yet analysed the issue of hazards/risks from nanotechnology and nanosize particles/molecules and was therefore unable to consider the question of the implications from regulation.

Denmark

As in Sweden, a public debate on nanotechnology and regulation does not seem to exist in Denmark. Public bodies do not currently address the issue. No relevant environmental or chemical regulation exists and the Danish Environmental Protection Agency considers the domain as a problem for the future. Questions on the implications of nanotechnology development on regulation could therefore not be addressed. The agency has, however, commissioned a report on future environmentally-sound design which includes nanotechnology due in spring 2005.

General comments on the regulation of nanotechnology

- Awareness of possible implications of nanotechnology development for existing regulatory regimes is still limited
- No specific type of regulation has yet been issued within EU member states
- USA and England and Germany lead in public discussion of the subject, Sweden and Denmark show much less awareness or take less action
- The actual regulation of chemicals in the European Union is not adequate to cope with nano specifics, a new form of declaration may solve a number of problems
- Within the future REACH system, detecting hazardous effects depends partly on the design of information requirements and may not be able to cope with nanospecifics
- Most experts consider existing regulatory frameworks as adequate for nanotechnology. Possible changes may be introduced regarding guidance of regulation, introduction of new tests tailored to nanoscale substances and the stronger considerations of particle size
- The example of the TSCA shows that substantial gaps regarding the classification and registration of nanotechnology applications already exist.
- Our preliminary findings point to the fact that the situation within the EU may not be so different
- Existing substances, which are remanufactured to nanosize, do not have to be registered.

With regard to the potential risks and hazards which may be caused by nanotechnologies, the following question must be raised: what is the appropriate reaction towards this technology in light of the limited scientific knowledge concerning the environmental and health effects of these technologies and their applications? This relates to the question of the level of precautionary action that should be taken: reaching from a total ban, a moratorium, strict regulation, any regulation or by enforcing scientific knowledge.

Representatives of regulatory bodies and academia are in the majority opinion that problems potentially caused by nanotechnology are not so different to problems which already exist and are covered by the regulation of chemicals as well as genetically-modified organisms.

The case of nanoparticles on which the emphasise is put in this study, the regulation of chemicals and especially of hazardous chemicals, may be appropriate not least because there is some understanding of the problems of hazardous substances as well as of dust and other potential hazards from the materials. Especially interesting in this regard is the necessity of authorisation within the REACH system for chemicals that are very persistent and very bioaccumulative even without any specific model of (eco)toxicological effects.

In general, registration and approval procedures for new substances and products are a good mechanism to evaluate the degree of hazard of new products. Routines to examine existing substances, such as those within the REACH system, increase protection levels against potential harm. In the near future, nanotechnology will be confronting regulations that cover emission, chemicals, occupational safety, pharmaceutical, and food regulation.

Approval procedures exist for the main fields of nanotechnology applications. Nevertheless it has to be pointed out that there is a need to adapt these regulations with regard to the potentially unique effects of nanotechnologies and what may be even more important, to initiate discussion processes within the regulatory community. These may give rise to adequate legislation concerning the potential effects of nanotechnologies especially those of nanoparticles. Current regulation of particles is based on particle mass per unit. This is no longer adequate since toxic effects also result from the (small) size of the particles. Our survey has shown that the regulators in different member states of the European Union have taken no action at all. In some member states discussions have been initiated, but in general the perception of the problem seems to still be very low.

11 International Discussions on the regulation on nanotechnology

At the international level, initial discussions concerning the regulation of nanotechnologies have only just started. In general, three approaches can be identified

- Foresight Guidelines, with the focus on molecular nanotechnologies and the aim to avoid the release of self-replicating nanobots by measures to reduce the possibility of uncontrolled behaviour of these nanobots
- The ETC group pointing out that nanotechnologies are inherently unsafe and on the one hand pose a risk to the environment and on the other had for society as a whole. This has resulted in a call for a moratorium (etc group 2002)

- Pacific Research Institute, which discusses at least three options; a moratorium, use only for military applications and some form of self regulation (Pacific Research Institute 2002)

All these proposals seem in one form or other not really applicable to the real world problems of nanotechnologies or of nanoparticles. While, of course, there are the dark sides of nanotechnologies, the main points have not really developed so far. On the one hand, these proposals do not reflect the possibilities of the shaping of technologies and on the other hand they are only concerned with the technologies as such.
With our focus on nanotechnologies and especially on nanoparticles, the question becomes more complicated: while we propose the possibility of shaping technologies (in this case nanotechnologies) with some guiding principles, there is also the question of regulation not only being focused on the technology as such, but is there a need for the development and adaption of the whole regulatory framework to deal with the specifics of nanotechnologies.

With this, there will be no discussion if there is a need to develop a regulatory framework which fits the specifics of nanotechnologies, while much may be derived from existing regulations in the field of chemicals as well of genetically-modified organisms.
Taking this in account, there is still an urgent need for some form of self-regulation in the industry, not least in the interest of the industry itself since a lot of commercial capital is at stake.

The question must be raised as to what is the adequate level of the regulatory action against a background of the great diversity of nanotechnologies: Is there a need for general regulation of nanotechnologies or is more appropriate to regulate it at a more individual level as for example with chemicals, foodstuffs, etc.

Some of these actions have started in the United States and may be considered as a cooperative effort to identify environmental and health problems and to find adequate solutions. In the following section we give an overview of one aspect in describing the research needs and possible action required.

11.1 Need for research by the chemical industry – as seen by industry, regulatory authorities and researchers

In 2002 a workshop entitled "Nanomaterials and the Chemical Industry – R&D Roadmap Workshop" was held (Vision 2020 2002). Its main aim was to identify the technical objectives and difficulties in the application and marketability of nanoma-

terials within the chemical industry and the key requirements for R&D were also derived. Further aspects – pertaining to safety, the environment and health – were also identified. It should be pointed out that discussions in these three areas were restricted solely to problems directly related to them that could result from use of nanoparticles and nanomaterials. Longer-term problem areas were barely touched upon in this respect.
These other areas are referred to below, since these fundamental questions are of importance for further research efforts, in that they basically constitute a research agenda for nanotechnology.

There are many possible impediments to market development that result from a lack of knowledge about the safety, environmental and health impact of nanomaterials. They include:

- A lack of knowledge about the airborne dispersal of nanoparticles
- A lack of knowledge about environmental concentrations of nanoparticles (problem: measurement and quantification)
- Great uncertainty concerning the upscaling of production, as no environmental standards exist
- Insufficient knowledge about health risks of nanomaterials
- A lack of data on toxicity
- Insufficient experience with regard to the safe handling of nanoparticles
- Largely inadequate knowledge about the impact on health, safety and the environment

This led to the following research priorities being drawn up:

- Development of models to enhance understanding of the inhalation and uptake of nanoparticles and their transfer to the blood circulation or tissue
- Investigation of the short- and long-term effects of health risks caused by nanoparticles
- Investigation of the breakdown of nanocomposites / the release of nanoparticles into the environment

R&D requirements:

- Studies on the toxicological properties of nanomaterials which are adsorbed by microparticles, and on the aggregation of nanomaterials
- Compilation of health, safety and environmental data on nanoparticles in various composites
- Toxicity testing and studies
- Interaction of nanoparticles with human physiology
- Life-cycle aspects of nanoparticles
- Modelling aimed at designing environmentally-friendly nanomaterials

- Development of rapid screening processes
- Methods and criteria for measuring the toxic effects of nanomaterials under conditions of use
- Recycling / immobilisation
- Commissioning of environmental impact studies and life-cycle analyses (LCA)

Main output of this high-priority R&D work

- Comprehensive understanding of human toxicity as caused by nanomaterials
- Rapid results for new materials
- Adequate understanding of the environmental impact and the indirect effects on health

In general, it can be noted that we currently have only minimal knowledge of the impact of nanotechnologies on safety, the environment and health, and that this – especially from the point of view of industry – may hinder the development and marketing of these technologies. It must be stressed, however, that the problems mentioned are not fundamentally new ones; the main problem surrounds the methods of assessment that need to be applied in, for example, the chemical industry. As far as our knowledge is complete, these efforts are not so well developed but this may be a starting point for further action to develop this field.

12 Recommendations

On the basis of this study, the IÖW recommends the following regulatory steps to be taken by the EU administration

- Release of nanoparticles should be restricted due to the potential effects on environment and human health
- A ban of the production of nanoparticles does not seem to be justified, not at least because the emission in production, use and disposal of nanoparticles may be limited if open use is avoided
- There is a need for guidance of nanotechnology for example by developing the leitbild or "model" of inherently safe nanotechnologies
- Nevertheless there is an urgent need for further research on the potential adverse effects of nanoparticles
- There is a need for the development knowledge concerning the behaviour of nanoparticles, this is a need for industry in general as well for medical applications and potential health effects
- There is a need for transparency and open public discussion of the light as well as he dark sides of nanotechnologies

- The discussion concerning sustainable chemistry may give some main indications concerning potential adverse effects and at least ways to avoid known problems
- Industry should undertake some form of self-regulation to ensure safe production and safe nanotechnology applications
- New regulatory regimes are not yet necessary. The EU should encourage and support the examination of existing regulation for its adequacy

13 Summary and main conclusions

Scope of the study

This study has focused on nanotechnologies and especially on nanoparticles. Further developments like nanobiotechnology are not covered. The structure of the study is as follows: First, we have a look at the precautionary principle with a focus in on how it is laid down in the communication of the EU. Second, we use the approach "characterisation of technologies" to identify potentially problematic features of nanoparticles. Third, we gathered the existing information about environmental and health effects of nanoparticles. We finally screened the existing regulatory framework, esp. chemical regulations in the US and Europe concerning their adequateness concerning nanoparticles.

The beneficial effects of nanotechnologies and especially nanoparticles do not fall within the range of this study. But against the background of life cycle analysis, which the IOEW applied to several applications of nanotechnology in previous studies, even in the early phase of development of these technologies potentials for environmental relief could be identified. Since environmental relief might be entailed in all applications of nanotechnologies, there is a need for accompanying research as well as shaping of the development of future nanotechnologies.

Precautionary Principle

The Precautionary Principle is a concept which might serve as a rationale, if applied, to undertake preventive action in the case of scientific uncertainty regarding the effects of a technology. We examine the Precautionary Principle in general and how it is adapted by the European Union to derive suggestions for political action regarding the environmental and health problems of nanotechnology.

The Precautionary Principle in general is a highly debated concept and no agreed understanding on the principle as such and how it shall be implemented exists. On the one hand it is pointed out that decisions, especially regulatory decisions, should be based on sound scientific risk assessment methods to avoid arbitrary action. It is on the other hand pointed out that customary risk assessments might not be adequate against the background of the unknown and increasing complexity of environmental problems. The last interpretation therefore develops claims for adequate procedures.

The Precautionary Principle as interpreted by the communication of the European Union (COM (2000)1) firstly points out that scientific appraisal methods form the basis for a decision. But it is also highlighted, that scientific uncertainty is no reason for inaction until scientific soundness is achieved, if there might be far reaching adverse effects. If a decision to act has been made, there is still a variety of

potential actions that can be carried out. These range from a total ban to further research as well as putting forward recommendations. The question may be raised as to how to respond to nanotechnologies.

Approach "characterization of technologies"

The approach of technology assessment used in this study (characterisation of technologies) gives some first indications about potential problems of nanoparticles even before adverse effects on targets are identified. It infers potential problems from a given technology by a scrutinising the features (characteristics) of a technology. The behaviour of nanoparticles deviates from other matter at the macroscale.
The following characteristics of nanoparticles identified are (amongst others):

- *Smallness and mobility of particles:* entering the lungs and even the alveoli passing through cell membranes,
- *Changing chemical reactivity and selectivity:* Altered ratio between surface and content leads to massive changes in catalytic reactivity, unexpected toxic and ecotoxic effects are highly inferred
- *Changing and intensified catalytic effects:* Altered ratio between surface and content leads to massive changes in catalytic reactivity, unexpected toxic and ecotoxic effects are highly inferred, also photocatalytic effects in inorganic (atmosphere) and organic areas

Environmental and health effects of nanoparticles: state of knowledge

The research concerning the effects on nanoparticles is still in their infancy and therefore either no or rather preliminary and sometimes contradictory knowledge exists, especially actually no studies about dose response exists.

Effects on human health

Nevertheless especially toxicological studies give some hints concerning adverse effects of nanoparticles on human health:

- possible translocations of nanoparticles in bodies (via lungs or the olfactory nerves)
- signs for inflammations in lungs caused by nanoparticles

In general, the results point out that the behaviour of nanoparticles differs from that of macroscale materials (toxicity) of the same material class. Furthermore some other things are important: the shape, the (surface-) structure as well as new material classes. Since many features of nanoparticles influence their behaviour, no general rules can be established and the risk of each type of nanoparticle must be evaluated in its own right.

Behaviour in the environment

Furthermore, the behaviour in the environment (agglomeration etc) is widely unknown. While some indications exist suggesting that nanoparticles agglomerate and change their behaviour, the scientific foundation of this assumption is limited. Some reports point out that the introduction of nanoparticles to the environment might trigger unexpected behaviour like for example mobilization of heavy metals or the possibility of nanoparticles entering the food chain.

According to our survey of the existing research, nanoparticles might be seen in general as a new class of materials which must be evaluated in its own right. The classification of materials at the macroscale might not give hints concerning the properties of the same material at the nanoscale.

The high number of materials and their combinations and different structures make general claims problematic and there is a great need to (re)classify these materials.
General advice guidelines are currently mainly developed for the use of nanoparticles in medicine: biodegradability of the materials seems to be one approach to avoid potential health and environmental problems.

With regard to this concern we come to the conclusion, that the emission of nanoparticles should be avoided as long as there is no proof of the innocuousness of these particles.

Risks of release of nanoparticles

Proposing the avoidance of release, a need for looking at the production processes as well as the use of products containing nanoparticles arises. Are particles already being released into the environment? The survey of production processes of nanoparticles as well as the products containing nanoparticles makes evident that the risk an emission of nanoparticles might be limited as most production processes do not emit nanoparticles and nanoparticles are mostly fixed and embedded in products. In the case of handling nanoparticles (esp. at the workplace) there might be a need for precautionary action resulting in a need for regulation. Furthermore, there is a need for further research concerning the possible emission of nanoparticles over the whole life cycle of products which so far does not exist.
An initial look at the product life-cycle of different products containing nanoparticles shows that there is probably not a general problem with nanoparticles since most production processes do not use the gas phase but are in some form or the other wet processes instead. Nanoparticles contained in products are usually fixed and generally not released. This also holds true for disposal but, nevertheless, there is need for further research in this area.

Existing regulatory framework and nanoparticles

Some elements of the Precautionary Principle are present in different regulatory approaches. The regulations on chemicals, especially the upcoming REACH regulation as well as the regulations on pharmaceuticals, are examples which comprise at least elements of the precautionary approach in form of prior approval procedures. In the case of chemical regulations, these relate to new chemicals as well as new uses and, with the enactment of REACH, will also encompass "old" chemicals. Nevertheless, immense gaps exist concerning the peculiarities of nanoparticles.

The procedures of existing regulations (concerning the whole range of regulations) might be adequate to deal with potential risks of nanoparticles. A special, separate regulation of nanotechnologies might therefore not be necessary. In general, two main regulations are mentioned: chemical regulation and genetic modified organisms which might be able to handle possible adverse effects of nanoparticles.
With regard to the chemical regulation the existing framework is not adequate to handle the potential adverse effects of nanoparticles, as the difference between nanoscale and macroscale substances is not included in current regulations. Furthermore, new materials (as for example nanotubes) are not classified in a systematic way and it may be necessary to define the measurement units of nanoparticles. The current measurement unit of weight should be replaced in the case of nanoparticles by size and/or surface size.

Besides the possible problems of adapting existing regulations, our research has shown that the regulatory authorities up to now have taken no action except for horizon scanning.

In Summary
There is a need for further research:

- concerning toxicity and the behaviour of nanoparticles in the environment
- concerning the behaviour of nanoparticles in the phase of production as well along the life cycle of products containing nanoparticles.

There is also a need for:

- the adaptation of existing regulations to the particularities of nanotechnologies esp. nanoparticles
- raising awareness within regulatory bodies concerning the upcoming problem of nanoparticles.

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IÖW-Geschäftsstelle Berlin
Potsdamer Straße 105
10785 Berlin
Telefon: +49 30-884 594-0
Fax: +49 30-882 54 39
Email: *vertrieb(at)ioew.de*

i ö w INSTITUT FÜR ÖKOLOGISCHE WIRTSCHAFTSFORSCHUNG

GESCHÄFTSTELLE BERLIN
MAIN OFFICE
Potsdamer Straße 105
10785 Berlin
Telefon: + 49 – 30 – 884 594-0
Fax: + 49 – 30 – 882 54 39

BÜRO HEIDELBERG
HEIDELBERG OFFICE
Bergstraße 7
69120 Heidelberg
Telefon: + 49 – 6221 – 649 16-0
Fax: + 49 – 6221 – 270 60

mailbox@ioew.de
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